NORTHWESTERN UNIVERSITY

Classification and the Social Construction of Disease in Medical Systems: A Historical Comparison of Syphilis and HIV/AIDS in the United States

A DISSERTATION

SUBMITTED TO THE GRADUATE SCHOOL
IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

for the degree

DOCTOR OF PHILOSOPHY

Field of Sociology

By

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EVANSTON, ILLINOIS

December 2008

ABSTRACT

Classification and the Social Construction of Disease in Medical Systems:
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Classifying patients to diagnose and treat disease, ensure access to medical care, adhere to standards of quality, contain costs, and fulfill contractual obligations is critical to the delivery of healthcare. While classification is a fundamental standardizing process in healthcare, as a social process it is the product of negotiations, organizational processes, and moral conflict often hidden in bureaucratic and professional modus operandi. By comparing the early twentieth century case of syphilis to the contemporary case of HIV/AIDS, the dissertation shows how symptomological, etiological, and financial classification have been developed and deployed in the context of a transforming twentieth century American medical system; how those deployments have been sustained, modified, and/or undermined over time; and, ultimately, how classifications influence the social construction of disease through the creation of social problems and their solutions. The layering of classifications over time can facilitate the unintended and obscured persistence of categories and criteria, impacting the day-to-day practice of sorting patients, treatments, and experts. The aim of the dissertation is to study the social process of classification in its everyday operation in the interplay between discourse and practice to understand what healthcare providers actually do with the classifications they are handed, including the adaptation of classifications to local situations that, ultimately shape the way syphilis and HIV/AIDS are integrated into medical practice itself. As a result of looking at classification this way, I show how symptoms, diseases, patients, treatments, and medical care providers are dynamic objects of classification that contribute to collective definitions of disease and influence how medicine and public health organize activity in changing technological, administrative, and moral contexts.

ACKNOWLEDGMENTS

Interview and ethnographic data for this dissertation was collected as part of the project "Clinic-Level Law: The Legalization of Medicine in AIDS Research and Treatment" (Carol Heimer, Principal Investigator; JuLeigh Petty, research assistant; J. Lynn Gazley, research assistant) with support from the American Bar Foundation, the Russell Sage Foundation, and the National Science Foundation (NSF SES-0319560). Special thanks go study participants who gave generously of their time making the collection of data possible and effective. A Graduate Research Grant from Northwestern University financed the collection of archival materials from the University of Pittsburgh, Archive Center and the National Administration of Records and Archives Southeast Region. The American Association of University Women supported a year of full-time writing with a Dissertation Fellowship.

Thank you to Wendy Espeland and Arthur Stinchcombe for serving on my committee and providing valuable feedback. I could not have asked for a better advisor and dissertation committee chair than my friend Carol Heimer who I had the pleasure of working with for several years. Thank you to JuLeigh Petty for reading earlier drafts and scholarly collaboration on "From Dirty Work to Skilled Expertise: The Professionalization of HIV/AIDS Care in the U.S." presented in 2007 at the American Sociological Association annual meeting. Special thanks goes to the Southeast AIDS Training and Education Center (SEATEC) and Fulton County Government's Ryan White Part A Program, particularly Laura Donnelly, Ira Schwartz, Felicia Guest, Jeff Cheek, and Kathy Whyte. Thank you to Victoria Grochocinksi who kindly volunteered to copy-edit this dissertation in its final stages. My friend Amy Ware was a faithful comrade in armes. Thank you to my brothers, Michael and Matthew Culyba, and my parents, Michael and Joyce Culyba, for their encouragement, especially to my mom who provided countless hours of thoughtful support. Most of all, thank you to Cody, Lily, and Mark Clifton for their unending love and patience. I am especially grateful to my husband Mark, who always brings me down to earth when I need it and holds faith in me that humbles and inspires me.

LIST OF ABBREVIATIONS

ACT UP	AIDS Coalition to Unleash Power
ADAP	AIDS Drug Assistance Program
AIDS	Acquired Immune Deficiency Syndrome
AMA	American Medical Association
AZT	Azidothymidine, more commonly known as Zidovudine, also abbreviated ZDV
CARE Act	Ryan White Comprehensive AIDS Resources Emergency (CARE) Act
CCG	Clinical Cooperative Group
CCMC	Committee on the Cost of Medical Care
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
CRS	Committee on Research in Syphilis
DHHS	Department of Health and Human Services
DRG	Diagnostic Related Group
ELISA	Enzyme-Linked Immunosorbent Assay
FDA	Food and Drug Administration
GRID	Gay-Related Immunodeficiency Disease
HAART	Highly Active Antiretroviral Therapy
HIPAA	Health Information Portability and Accountability Act
HIV	Human Immunodeficiency Virus
IAS-USA	International AIDS Society USA
ICD-9-CM	International Classification of Disease, Ninth Revision, Clinical Modification
IND	Investigational New Drug
IOM	Institute of Medicine
KS	Kaposi’s sarcoma
KSOI	Kaposi’s sarcoma and Opportunistic Infections
MMWR	Morbidity and Mortality Weekly Report
MSM	Men who have sex with men
NCI	National Cancer Institute
NIH	National Institutes of Health
PAP	Patient Assistance Program
PCP	Pneumocystis carinii pneumonia
PI	Protease Inhibitor
RCT	Randomized controlled trial
RWJF	Robert Wood Johnson Foundation
STD	Sexually Transmitted Disease
USPHS	United States Public Health Service
VD	Venereal Disease
WHO	World Health Organization

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CHAPTER 1

INTRODUCTION

On June 5, 1981, public glimpses of the condition we now know as HIV/AIDS first appeared on the second page of the *MMWR*. The report, "Pnuemocystis Pneumonia – Los Angeles," described the first cases of a rare pneumonia that appeared in five young, homosexual men. Since pneumocystis carinii pneumonia (PCP) was an existing, albeit uncommon, medical condition, diagnosis was confirmed with a lung biopsy. Each man also had a confirmed case of current or previous infection from cytomegalovirus and candidal mucosal infections (CDC 1981c). Initial investigations into the distribution of pentamidine prompted this report. The CDC has been responsible for distributing rare drugs and vaccines since 1966. In 1981, it was the only source of pentamidine in the country. Soon after, a CDC-led outbreak investigation was deployed with a focus on grouping and categorizing these cases in order to identify the condition in part by ruling out those already known. Treating the cases of PCP and exploring their common cause was possible because organized medicine and public heath share a paradigm in which illness comes to be known empirically through a set of scientific and technical understandings (e.g., bacteriology, epidemiology) and practices (e.g., laboratory testing, chemotherapy).

The term syphilis first emerged in 1530 in an Italian poem about an Hispaniola shepherd who insulted Apollo and was punished with a disease of the genitals, where syphilitic lesions appear after infection. At this time, theories about how the human body functioned and illness were highly unsettled with some authorized experts believing that illness was caused by an imbalance of vital elements and others believing that illness was due to chemical imbalances sparked by the will of organs. Treatments for the condition focused on restoring balance with

bleeding, sweating, and spitting as well as the use of chemicals such as mercury, sulfar, and salt. Thus, symptoms of syphilis were grouped and treated in reference to multiple and overlapping views, which confounded collective understandings of the disease. For example, we know today that mercury poisoning commonly manifests itself with excessive phlegm, but at that time this may have been confused as successful therapy. Even by the 19th century, syphilis came to be understood as "The Great Imitator" because it mimicked symptoms from other disease that had come to be known. Not until the advent of a shared paradigm about the functioning of the human body, scientific rationality, and laboratory technology could causal agents such as bacteria be identified and targeted by medicine and public health.

With both syphilis and HIV/AIDS, however, medical and public health discourses existed alongside evaluations of people in terms of race, nationality, gender, and sexuality. Thus, syphilis was first blamed on enemies of war (e.g., Neopolitan disease, French Pox, Turkish disease) and later linked to moral evaluations of racial attributes. Similarly, HIV/AIDS was initially thought to be caused, at least in part, by homosexuality (e.g., Gay-related immune disease) and later understood by behavior attributed to racial and gender groups (e.g., Black men who have sex with men). Moreover, as collective sets of knowledge and practice become more settled, how to allocate resources and payment for scientific investigations, the development of treatments, and the allocation of care for those afflicted with the diseases must also be worked out. Consequently, syphilis and HIV/AIDS have come to be understood in the interplay between scientific, moral, and administrative discourse which can be observed in the practice of authorized experts designated to contribute to the collective understanding and solving of these social problems.

Aim and Scope

This dissertation compares how the classifications in syphilis and HIV/AIDS have been developed and deployed in the context of a transforming twentieth century American medical system; how those deployments have been sustained, modified, and/or undermined over time; and, ultimately, how classifications influence the social construction of disease through the creation of social problems and their solutions. By comparing the classifications and their effects on the social construction of syphilis and HIV/AIDS, I argue that, despite the growing salience of classification aimed at standardizing the quality and cost of treatments, the layering of classifications over time can facilitate the unintended and subterranean persistence of moral and administrative categories brought into being during the early twentieth century. The unacknowledged impact of this layering can be observed in the day-to-day practice of providers who deal with multiple systems of classifications to sort patients, their own activity, and sources of payment for their services.

The goal of this dissertation is to study the social process of classification in its everyday operation by going beyond discourse to understand how healthcare providers actually employ these classifications, how local adaptations to classifications continue to shape the way syphilis and HIV/AIDS are defined, and how these definitions are integrated into medical practice itself. By looking at classification this way, we understand that diseases, patients, treatments, and expertise are dynamic objects of categorization that contribute to collective definitions of disease impacting how medicine and public health organize activity in changing technological, administrative, and moral contexts.

The unsettled relationship between medicine and public health is at the heart of my dissertation, and I consider it by examining the ways professional authority sustains the social

construction of disease by comparing the development and implementation of classification systems specific to syphilis in the early twentieth century and with HIV/AIDS in the United States today. For syphilis and HIV/AIDS to become the objects of specific and legitimate medical and public health practice, justifying independent sites for care, research agendas, and specialized care providers, these diseases had to be seen as having unique characteristics that differentiate them from other medical problems. Only when syphilis and HIV/AIDS were established as diseases in their own right could programs designed to eradicate and manage them be designed and implemented. The establishment of each disease was shaped by the particularities of medical practice at the time of its inception. This dissertation illustrates how the classification of symptoms, causes, patients, treatments, and expertise in both syphilis and HIV/AIDS, two especially insidious sexually transmitted diseases, has had lasting impacts on the organization of medicine and public health more generally. As a result of these systems, for instance, new organizational locations and funding mechanisms for the treatment of syphilis and HIV/AIDS were established (e.g., rapid treatment clinics run by state boards of health, multidisciplinary HIV clinics), influencing how resources are allocated, the conduct of research, and specialization of care for highly stigmatized diseases.

I was drawn to study the minutia of classification in syphilis and HIV/AIDS in order to better understand how inequity in access to care persists, particularly because of the way classifications are embedded in organizational routines. The classification of HIV/AIDS contained many contradictions founded on disease classification and payment: the development of a complex case-counting system that operates outside of established surveillance for sexually transmitted disease; the incredible advancement of medical treatment (e.g., the creation of four new classes of drugs in two decades); and the disproportionate impact on racial minorities,

women, and the poor despite expansion of safety net healthcare. As one public health service officer remarked, "HIV has changed everything" (010_DC_US_032503_RC&JP).[1] However, a historical comparison with syphilis illustrates some lasting effects of the integration of American public health and medicine in the early part of the twentieth century. Known as "the Great Imitator," syphilis frustrated medical providers and a rising class of public health professionals until the early twentieth century when tests and treatments were both available. At the beginning of the twentieth century, medicine lacked the technology and infrastructure to support standardized practice by doctors, including how resources were allocated to support the care of all patients regardless of their ability to pay. As William Osler noted in 1897, "He who knows syphilis, knows medicine" (as quoted in Hayden 2003, 51).

At the beginning of the twentieth century, there was little technology and infrastructure to support treatment standards and mechanisms to allocate resources for the treatment of syphilitic patients unable to pay doctors out of their own pocket, which stymied efforts to rein the disease in even as an infrastructure of public venereal disease clinics was being built. With little funding for treatment, classification activity centered on developing local workarounds to categorize patients by ability to pay and understanding the disease by refining knowledge about the natural history of the disease (e.g., Tuskegee study), protecting "innocents" (e.g., marriage testing laws, preventing congenital syphilis), and sharpening principles of treatment (e.g., Clinical Cooperative Group, Committee on Research in Syphilis). In the case of HIV/AIDS, by contrast, case definitions were developed early in the epidemic to track outbreaks and understand the scope of the problem, but these classifications have undergone continuous modification as

[1] Interviews and fieldnotes are referenced as follows: semi-structured key informant interviews are identified by interview number, initials of the location, date beginning with the year, and interviewer initials (e.g., 010_DC_US_032503_RC&JP); ethnographic fieldnotes are identified by the date of observation beginning with the year (fieldnotes yymmdd), and informal interviews conducted at the field site are identified by the date of the interview beginning with the year (interview yymmdd). Unpublished archival materials are referenced in footnotes.

knowledge about the disease has been refined. Moreover, although the pace of science in HIV/AIDS is fast, there has been a lag between the discovery of treatment and its availability to patients and providers. To get around this, patients enrolled in clinical trials and advocated for increased access to drugs not yet approved by the Food and Drug Administration (FDA), influencing drug approval policy. For medical providers, HIV/AIDS defied systems of medical payment because diagnostic and procedure codes did not exist for the ailment and its associated tests and treatments, so medical providers used combinations of existing codes in order to be reimbursed. At the same time, the stigma associated with HIV/AIDS is such that some providers continue to use non-HIV/AIDS diagnostic codes to maintain patient confidentiality and protect patients from social and racial discrimination. This dissertation thus shows how unintentional consequences of classification can become veiled in everyday routines, influencing the way society comes to understand syphilis and HIV/AIDS as medical problems and design and implement solutions for them.

Classification is a ubiquitous and elusive social process of labeling and defining, establishing names and criteria, creating boxes in which things can be contained in order to distinguish them from other things, count and deploy them in knowledge systems. Classification is a process of objectification because, once classified, an object can be recognized and acted upon in the social world. It is a core social process for controlling and coordinating activity across time and space. Classifications are flavored with the values of those doing the classifying so are critical foundational elements to meaning-making and in the construction of social problems. Thus, classifications themselves are also the product of this social process: containers that go on to be counted and targeted by organizations and their activity. By contrast, standardization is the social process by which classifications are integrated into social and/or

organizational goals and objectives. Standards turn classifications from boxes into guideposts for action. Thus, classification is distinct from sorting, prioritizing, or standardizing because things must be classified first in order to be compared with other things or be integrated into existing systems of order or hierarchy. Not all things are classified and not all classified things are deployed in standardizing activity. Further, a single classification can be deployed for multiple purposes. For example, instances of AIDS are accumulated and counted to signal needs for interventions and resources at state and national levels, but an AIDS classification can also be a measure of disease progression (e.g., T cell count below 200),[2] signal the need for additional tests and provision of medical treatments (e.g., prophylaxis for opportunistic infections, screenings for opportunistic infection, starting antiretroviral therapy), and even secure safety-net resources by showing that a patient meets eligibility criteria (e.g., Medicaid programs typically only pay for care of patients with full blown AIDS).

The classification of objects and behavior is not new to medicine. But the sheer number and detail of classifications available and required as part of the daily work of determining the cause of a disease, diagnosing disease, treating disease, allocating resources, and designating appropriate care providers have grown astronomically in the United States over the last century with the imperative to coordinate and control the quality and cost of healthcare in an increasingly complex medical system. With sexually transmitted disease, a patient's own behavior is oftentimes the object of scrutiny, adding a layer of categorization that must be dealt with by patients, healthcare providers, and payers alike. Although classification itself is not new to medicine, in the past its value tended to be seen as the formulation of categories in which to put diseases and patients as part of medical diagnosis and decision-making by care providers. This

[2] T cells are a kind of white blood cells (lymphocytes). The immune system is made up, in part, by T cells. A T cell test measures the amount of T cells in the blood.

began to change with the emergence of public health, which posed a challenge to medicine by focusing on populations rather than individuals. For example, mass screenings of syphilis in the 1920s resulted in more cases than could be treated given limited funding and the payment structure of medicine at that time. Thus, there was little incentive for private doctors to treat patients who were unable to pay directly for their care and who were expected to have diminished ability to adhere to grueling treatment regimens. As a result, public health efforts were placed on understanding the disease (in those unable to afford treatment), its most effective treatments (in those able to afford treatment), and preventing the infection of innocents (e.g., children) through social hygiene and anti-vice campaigns.

The categories created by classification are key resources for healthcare providers when making sense of a patient's condition and for maintaining a cohesive concept of that condition. This is particularly significant for diseases such as syphilis and HIV/AIDS because they tend to manifest themselves with clinical symptoms not specific to the bacterium or virus itself. Making sense of these conditions—even after treatment is initiated by the provider—is further complicated by the patient's own behavior (e.g., adherence, compliance), the availability of resources (e.g., securing a payer source), and professional and moral obligations (i.e., abiding by standards of care, caring for the indigent, legitimizing work routines).

In today's world of healthcare, classifications ostensibly exist to assist providers, payers, patients, and other stakeholders in navigating the course of a disease and its treatment, including payment. This is the aspect of classification that I examine in particular detail: How does the provider classify the patient's condition in order to organize a course of action? How do providers make use of classification as a resource while making decisions in their daily work? Given that the classifications are constantly being maintained, negotiated, and even resisted at

this level of practice, how do providers assert their authority in these encounters? One of my objectives in this dissertation is to analyze how pre-existing classifications are mobilized and/or new classifications are developed to justify treatment and finance decisions.

Classifications are mechanisms crucial to control and coordination of organizational practices, particularly the price, funding source, and quality of their service. In the case of HIV/AIDS, although there is increased accountability in the provision of healthcare and treatment innovation is fast-paced, there remains little incentive for medical providers to take on patients with diminished ability to pay and with limited ability to adhere to grueling treatment regimens. Because those infected with sexually transmitted disease have been stigmatized as "dirty" and those who treat them as performing "dirty work," classifications have been utilized, resisted, and altogether avoided in efforts to access and finance care and to deliver the most effective care for both syphilis and HIV/AIDS. While the tediousness effects of classification may be common in many areas in medicine, stigma and governmental funding make a difference in the extent to which stakeholder practice is impacted at the ground level. Because HIV/AIDS emerged at a time when clinical treatment guidelines and standardized billing codes were being institutionalized in medicine generally, it is characteristic for administrative classifications to be influenced by current moral systems and to lag behind advancements in medical technology. This contrasts with the classification of syphilis, at that time, since administrative standards related to treatments and finance were not yet fully developed.

The development and integration of multiple sets of classifications is part of a larger push toward standardization in medicine that has taken more than a century to accomplish, but that remains unsettled. Thus, I approach the question of classification in syphilis and HIV/AIDS by focusing the analysis on the intersection of history and practice. I try to understand two issues

simultaneously: first, what is the role of classification in the social construction of syphilis and HIV/AIDS as medical problems and second, what are the specific practices of medical and public health work guided by these categories? In this sense, practices are understood as classification in action because a specific practice can cause a category to change, just as the development of a category can impact the activity of practice. To explore these two sides of classification, it is necessary to begin with the following questions: At what point were these diseases recognized as medical problems in their own right and why? What were the factors contributing to this change in perspective? Who were the actors that first made others aware of the diseases and who began to develop ways of dealing with them? Once solutions to deal with syphilis and HIV/AIDS were developed, how were they communicated to a larger group of people, and what were the conceptual, organizational, and institutional elements that helped or hindered the integration of these solutions into medical and public health practice?

The historical comparison illustrates how, during the first few decades of the twentieth century, medicine and public health systems created classifications and standards of payment and treatment as they learned about the disease and as resources allowed. Today, providers must fit themselves, their patients, the type of visit, and the procedures they perform into already existing classification systems, oftentimes requiring local adaptations in order to access resources. How are these categories employed by providers to structure and authorize their practice, and by those who regulate and pay for services to decide what care is appropriate and warrants payment? In the past, doctors developed classifications as an aid to their work. Diseases were classified, fees were often charged based on what a patient could pay, but that was about it. Today, it is not only doctors who are developing classification systems and these systems are used not only to categorize diseases but to organize payment systems. For instance, if a billing form used in an

HIV/AIDS clinic does not include a code for a procedure administered by a medical provider and justified by treatment guidelines, how does the provider account for his or her time, expertise, and the cost of the supplies? Further, how does the clinic track the provision of evidence-based medicine?

Observations focused on the interactions between discourse and practice help us understand the origins of the classifications encountered by providers and how they have impacted the ability of medical professionals to act authoritatively. Indeed, by examining both the historical development of classifications and the practical implementation of them, it is possible to look beyond the cases at hand, revealing that the social process of classification exists among stakeholders in the American medical system in general and over time. This dissertation finds that classifications tend to accumulate in layers and build upon existing classifications (e.g., case definitions include clusters of symptoms even as diagnostic tests enable the refinement of disease categories into distinct and measurable stages) and that those designed for one purpose may be used for another (e.g., non-AIDS billing codes used to bill for procedures with AIDS patients). These tendencies have some peculiar effects (e.g., doctors begin contributing to the deployment of classifications in standards in an effort to have crucial tests and procedures reimbursed by third party payers) and in some cases lasting legacy (e.g., the withholding of treatments for African-American syphilitics during Tuskegee has contributed to mistrust of public health and medical research and authority by those most affected by the disease).

As products of negotiations, organizational modi operandi, and even moral conflict, this dissertation finds that classifications have consequences both for the classifiers and the classified. Although the prevalence of classifications has increased over the last century in the organization of coordination and control in syphilis and HIV/AIDS, the composition of

stakeholders and their relative influence have changed both over time and over the course of disease. For example, in the case of syphilis, doctors ceded authority to a burgeoning class of public health professionals, eager to apply social hygiene and scientific methods to combat venereal disease, while the development of complex treatments in HIV/AIDS has sparked a growth in specialization as a way of garnering increased authority and resources. Although we know that the medical profession is a heterogeneous field that is continuously changing in terms of governance, tools of the trade, and specialty subdivisions, this dissertation shows how these subdivisions come into being, are sustained, and can be cultivated into specialties or subsumed into preexisting professional divisions as stakeholders use and develop classifications to construct a common object of practice, create boundaries around the subgroup, and garner resources for visible and legitimate practice.

Theoretical Background

The following discussion of the theoretical roots of classification will tie the dissertation to core issues in sociology to elucidate the conceptual framework to examine classification in syphilis and HIV/AIDS. This section discusses the elemental role of classification in the development of moral communities by reviewing some general characteristics of classification. First, classification is both ubiquitous and elusive because it is located in the interplay between discourse and practice. Second, classifications vary in their pliability. Thus, classifications can range from the highly durable where a quality of naturalness is acquired to the highly malleable where adaptations and resistance contribute to continuous transformation. Finally, classification can have depersonalizing effects on people and irrational effects on organizations.

Classification forms the foundation for technologies of social reproduction and organizational logic (Durkheim and Mauss 1903). Yet the labor involved in attaching things to categories as well as the ways these categories get ordered into systems of classification can be overlooked by scholars (Bowker and Star 2000). In 1903, Durkheim and Mauss argued that classification is a social rather than individual or instinctual process. They characterized classification as a "mental system" (1903, 29). For Durkheim, "To think is actually to order and to thus classify our ideas" (1912, 73). These symbolic representations produce a moral community. Importantly for Durkheim, this is a collective thought process that takes control of human sense impressions through a new way of imagining reality. Durkheim recognized that collective consciousness has material consequences. Max Weber (1978) recognized the material consequences of classification in the way that modern logic contributed to the emergence of a revolutionary social structure called bureaucracy. For Weber, bureaucracy spreads because it is the easiest form of authority for which to maintain legitimacy and ultimately eliminates existing structures of non-rational domination. Despite the coexistence of rational-legal, traditional, and charismatic forms of authority, Weber held that the trend of modern development was toward more and more complex bureaucratic systems that contain a highly codified system of rules that centralize and dehumanize the source of authority. Such rule systems rely on the collective thought process of classification.

Classifications are the product of human practice and routine and, as such, things can undermine their stability even while standardization contributes to their rigidity. First, generalizations made by classification systems are developed from a limited set of information. Consequently, classification systems are better at handling the things they were designed for rather than new things met in the process of generalization. Second, classification always has

consequences for the allocation of resources and so a variety of stakeholders have interests in how classifications are developed and used, including what information is discarded or included along the way. Third, the central technologies on which classification systems are created and exist are often taken for granted, enabling the invisibility of distinctions as well as obscuring actions of, and consequences for, stakeholders. As we will see, classifications developed out of experience with men who were infected with HIV proved inadequate when practitioners encountered HIV in women.

Classifications are fundamental to social life because they form the basis of standardization, a key mechanism for coordinating and controlling activity across time and space. Standards are critical to the production of knowledge because they are "any set of agreed-upon rules for the production of (textual or material) objects" (Bowker and Star 2000, 150). The following characteristics are central to standards: 1) they are deployed in order to facilitate the coordination of things (e.g., communication); 2) they are often enforced by legal or regulation-creating bodies (e.g., professional organizations, state); 3) technically superior standards do not necessarily win out; and 4) standards have considerable durability and can be challenging to transform (Bowker and Star 2000, 150). While standards vary from being highly formalized to being ad hoc, prevailing standards impose classification systems since they form boundaries around groups of things and actions. With formalized standards, classifications are entrenched in organizational practices. Ad hoc standards may signal opportunities for decision-making or act as a temporary storage bin for people or things.

Classifications and categorization have been associated with the purely cognitive realm of human behavior and, as such, were considered difficult to observe and analyze (Sewell 1992, DiMaggio 1997). Despite this, sociologists and other scholars have illuminated a variety of

ways to carve up the world for making decisions, coordinating activity, and social control. Several contemporary scholars have studied the relationship between consciousness and structure by focusing on schemas (Douglas 1966, Sewell 1992), cognitive schemas (DiMaggio 1998), cultural toolkits (Swidler 1986, Bruner 1990), organizational logic (Heimer 1996), structures of practice and generative schemas (Bourdieu 1987, Bourdieu 1998), genres (Bakhtin 1981), and cultural scripts and public transcripts (Scott 1985). Scholars have also conceptualized the variety of ways that classification is done, including lumping and splitting (Zerubavel 1996), narration (Czarniawska 1997), case versus biographical analysis (Heimer 2001), holistic effects on decision-making (Emerson 1983), and exemplification (Douglas 1992). In all these social processes, classifications are conceptualized as culturally available categories of thought that form the terms of debate and legitimize power, so that changes in classifications are both the means and consequences of social action.

Heimer (2001) shed light on the variability of organizational contexts in which cultural tools are actually successful in controlling thought and behavior. She found that case analysis is more easily employed in situations where social actors decide which protocol to administer to a stream of cases while biographical or narrative analysis is more useful in more chaotic situations where protocols or rules do not yet exist to manage behavior and cognition. Similarly, the use of metaphor in the production and dissemination of scientific knowledge is another alternative form of analysis that is fundamental to the social reproduction of cultural categories and therefore to classification systems (Pickering 1995, Stepan 1993). For others, classification is the basis of collective belief, not metaphor. For example, once a category is agreed upon, objects can become exemplars of the category without referring to all of its properties (Douglas 1992). All

these conceptualizations of classification illustrate how the structure of society gets projected onto nature in the process of social practice.

Espeland enables a better understanding of the consequences of classification for the material world by attending to the social process of commensuration (Espeland 1998, Espeland and Stevens 1998). Commensuration is the social process of transforming qualitative information into quantitative form by discarding information. Not every piece of information gets classified since these systems are sorting mechanisms and not designed to cover every entity (Bowker and Star 2000). Residual or "other" categories are also important to the process of classification itself, so that what is left out may be just as consequential as what is included in a classification system. To Espeland, "It is largely a process of abstracting and reducing what is known and often obscures the link between what is represented and the empirical world" (1998, 25). Consequently, relationships between people may be centered on numbers rather than by lived experience, pragmatism, or empathy. Thus, understanding something as being commensurate and included as a choice or comparison, or understanding something as incommensurate or eliminated as a choice or comparison, is a particular form of valuing and meaning-making (Espeland 1998).

In directing attention or blurring distinction, classification is a means of exerting control. At the same time, a defense of distinctiveness, of an incommensurable and intrinsic value, is a form of resistance to this control (Espeland 1998). Indeed William Sewell (1992) and Paul DiMaggio (1997) describe the mutually constitutive relationship between structure and agency, and culture and cognition respectively. Classifications are malleable and transforming under certain conditions and over time. Things are left out and made residual along various organizational paths of activity because standards must be customized to fit particular situations.

Customization endangers standardization and standards endanger customization (Bowker and Star 2000). Thus, while standards may be imposed, new categories may be developed, revitalized, or imbued with novel meaning by virtue of the absence of particular information.

The sifting of information as part of developing a classification is a crucial meaning-making component in the identification of a problem by an organization or stakeholder group. As Heimer suggests, "categorization of a situation as a problem is a deeply interactive process in which participants discuss, comment, negotiate, and threaten in order to get particular situations labeled as problems worthy of sustained attention and intervention, as situations that should be monitored, or as situations that are not problems" (1996). Indeed, the social construction of a solution suited for a particular problem is also a heavily collective process that does not necessarily follow the identification of a problem directly. Solutions may be matched to a variety of problems, some of which are unexpected, amassed for use in the future, or not provide complete resolution to the problem, thus making room for alternative solutions (Heimer 1996). As Espeland argues, "Defining procedure amounts to defining the terms of the debate, of determining what can be talked about and what cannot and, ultimately, defining how to resist" (Espeland 1998, 252).

Members of modern pluralist societies take for granted a core shared universe while accommodating the coexistence of various partial universes. Under such conditions, tolerance and co-optation have to some degree replaced explicit ideological conflict (Berger and Luckmann 1966). Thus, classifications have the potential to become durable and taken for granted in spite of their material consequence for stakeholders. In *The Order of Things*, Michel Foucault (1970) proposed that the experience of order is located between the fundamental codes of culture that serve as preliminary criteria and scientific theories that reflect order itself. In

other words, the more natural social classifications appear, the more stabilized institutions become. This natural quality increases as categories are compared to one another and deployed.

As Jack Goody (1977) noted, the "trouble with categories" is their durability. The longevity of a categorical distinction is more likely when classification systems supply stable connections between the natural and social world (Douglas 1986). Bowker and Star (1999) characterize this "convergence" as being critical to the process by which the social world and the information artifacts that undergird it mutually sustain one another. Foucault (1970) raised political and ethical questions about how the expansion of classification systems tends to camouflage the fragile ties between categorical distinctions and organizational processes, ultimately influencing relations of authority. Thus, the appearance of silence about something in discourse (i.e., the absence of a category of thought) is a powerful social process in itself because social actors often time resist these silences in practice (Foucault 1978).

One of the irrational effects of classification is that bureaucrats may not notice modifications in how difference is expressed in their own routines (Espeland 1998). Moreover, because the production of knowledge symbolizes competence and authority, inspires trust, and legitimizes decisions, the production of information by organizations is often more important for symbolic value than for practical decision-making (Feldman and March 1981, 177-78 as cited in Carruthers and Espeland 1991, 53). Indeed, there may be more economic resources spent on the creation and maintenance of standards than in producing "pure" knowledge of a scientific sort (see Latour 1987). The result can be that the standardization of classification can become the end goal itself rather than a means to organizational goals. It is precisely when the work of classification becomes obscured in routines that stakeholders are unable to resist or modify classifications and standards themselves. The distinctions of

classification reviewed above are important to understand since we will observe how moral communities develop around the development and deployment of classifications, how classification resides in both discourse and practice, how classifications seem natural and become durable over time and space, the role of technological mediation, the potential depersonalizing effects of classification on people, and the irrationality it can motivate in organizations.

Classification in Medicine

In medicine, a variety of objects get classified in the process of socially constructing the disease itself, including symptoms, treatments, drugs, patients, health care providers, and payment types. These classifications result in a range of consequences such as helping to identify an illness and treatment, forming dividing lines between occupations, determining the availability of resources, and securing sources of reimbursement for health systems. In other words, classifications help to socially construct understandings of the disease and interventions designed to deal with it (Brandt 1988a, Brown 1992). Sociologists have long been concerned with the relationship between the social construction of disease and the scope of medical jurisdiction (Parsons 1951, Pitts 1968). Thus, an analysis of classification fits well with issues important to the sociology of medicine, particularly medicalization, the social process of how a problem is defined in medicine.

With medicalization, problems that were previously defined as moral issues or as matters of deviance and criminology come to be defined as medical problems and thus amenable to medical solutions. So, with syphilis and HIV/AIDS, the diseases have become less about moral failings solved by improving character or criminality solved by prosecution or punishment, and

more as problems better solved by medical treatments, public health surveillance, and safety net healthcare. Despite this shift, moral evaluations continue to be brought to bear on classification with syphilis and HIV/AIDS. For example in medicine, doctors brought a conception that "socialized medicine" in any form would diminish their authority over a distinct category of expertise. In public health, a historical association with the social hygiene movement, where adhering to "good" behavior was thought to prevent the spread of diseases such as syphilis, has become intertwined with the imperative to collect population-level data with the advent of the science of epidemiology.

What we think of as "orthodox" medicine only gained professional dominance during the nineteenth century. Medicine grew out of a variety of forms of healing and quackery, eventually claiming superiority and authority by associating with a biomedical model and asserting a relationship with laboratory science (Jones 2004). The cultural authority enjoyed by physicians at the turn of the twentieth century was sustained by standardization and claims of expertise over a body of complex knowledge (Starr 1982). Instead of a single unilinear transition from unscientific to scientific conceptualizing medical practice, a cognitive transition from conceptualizing medical practice as an artful application of scientific knowledge into a cognitive interpretation of the scientific nature of medicine itself occurred during the post-World War II era. By the 1950s medical practice was still distant from science, but was gaining authority with a boom in biomedical research (Berg 1995). Indeed, the profession made economic gains during this fee-for-service "golden age of doctoring" (McKinlay and Marceau 2002). Skeptics at that time thought too much "scientific paraphernalia" would lead to a loss of the art of medicine embedded in physician decision making, that the uniqueness of individual symptoms and complaints might be lost, and that doctors would begin practicing "push button medicine" (Berg

1995). Resistance to medical authority began to appear in the 1970s in the form of law suits by patients and social critics (Conrad 2004, Wolpe 1985, Foucault 1973, Friedson 1970, Zola 1972), contributing to the era of scrutiny and to what Paul Starr (1982) describes as the decline of professional authority in medicine. By this time, techniques such as clinical decision analysis, clinical practice guidelines, and evidence-based medicine were emerging as standards by which to guide and evaluate the activity of physicians (Berg 1995).

Shifts in the relationship between science and medicine correspond to shifts in the relationship between medicine and public health because the rise of evidence-based medicine and the emphasis on improving the cost and quality of medical care is associated with the shift from a focus on individual pathogenesis to epidemiology in the knowledge base of medicine (Timmermans and Kolker 2004). Evidence-based medicine was born in the United Kingdom with appeals to use randomized controlled trials to study medical interventions in order to decrease the overuse of dubiously substantiated techniques (Cochrane 1972). In the U.S., attention was drawn to the need for increased scientific support of medical treatments through epidemiological mapping of geographic variation in treatment interventions (Wennberg 1999). Clinical epidemiologist David Sackett (1996) developed methods for studying medical interventions and urged physicians to apply the "current best evidence" when making treatment decisions. Other studies in the 1990s focused on the overuse, underuse, and/or misuse of medical interventions leading the way for the quality improvement movement in medicine (Bodenheimer 1999).

The rise of epidemiology is a central force in the medicalization of syphilis and HIV/AIDS because it improved the scientific legitimacy of categorization and of estimates of the seriousness of the problem (Timmermans and Kolker 2004). The infusion of population-level

classifications in medicine also represents the introduction of public health as an authorized stakeholder in medical discourse and practice more generally. Simultaneous with the rise of epidemiology, the weakening of medical authority and increased scrutiny over medical practice is also due to changes in the organization of medicine in the last thirty or more years. These changes include, most notably, the shift in health policy from a focus on access to concern with cost-control (i.e., rise of managed care), an increasingly influential role of biotechnology (e.g., pharmaceutical companies), and the new consumer orientation of patients (e.g., legislation enabling direct-to-consumer advertising by drug companies and allowing off-label use of FDA-approved drugs) (Conrad 2005).

The Cases of Syphilis and HIV/AIDS

Syphilis and HIV/AIDS are good cases for a discussion of classification because both illustrate the effort involved in developing classification in its first stages, how classifications are deployed in standardizing activities, and how these deployments can loop back to influence classification itself. By comparing the early twentieth century case of syphilis with the contemporary case of HIV/AIDS it is possible to track changes in both moral and administrative forces embedded in medicalization, including the rise of epidemiology, an emphasis on cost in policy, a consumer/activist orientation of patients, and the increased power of the biotechnology and insurance industries. As the historical analysis will show, while remarkably similar in clinical complexity, the two diseases are markedly different in the classification activity and technology available to understand its social consequences, including the management of uncertainty associated with eliminating them as medical and social problems. For example, we will observe an objective change from protecting innocents to allocating resources efficiently

evidenced by the shift from syphilis marriage laws and mass screening efforts of the 1920s designed to identify cases in order to treat them to a highly bureaucratic confidential HIV/AIDS surveillance system used to estimate prevalence for the purposes of allocating funds, targeting prevention efforts where they are most needed, and improving the accuracy of how classifications represent the epidemic.

Both syphilis and AIDS have been particularly troubling to society because of their horrifically visible symptoms and because of the sometimes unsavory link between morals and regulations. Despite these similarities, syphilis is unique since it has been an object of classification and mis-classification for more than four centuries, even before the Enlightenment and development of medicine as a legitimate organizing force in societies. AIDS, on the other hand, shocked American medicine when it first appeared in the early 1980s because medicine at that time was confident of its success in ending the era of infectious disease in the United States. Table 1.1 illustrates how syphilis and HIV/AIDS share similar elements of classification.

Table 1.1 Overview of Syphilis and HIV/AIDS Cases

	Syphilis	HIV/AIDS
Symptoms	Manifests in any organ system, visible manifestations (e.g., skin rashes, neurological symptoms), latent period	Manifests in any organ system, visible manifestations (e.g., skin lesions, neurological symptoms), latent period
Etiology	Bacterium Treponema pallidum, isolation 1905	Human Immunodeficiency Virus (HIV), isolation 1984
Patients	Behavior/risk, race, gender, sexuality, income/poverty level	Behavior/risk, race, gender, sexuality, income/poverty level
Treatments	Chemotherapies such as salvarsan, mercury rubs; patient adherence; relapse	Antiretroviral chemotherapy; patient adherence; viral mutation/drug resistance
Experts	Dermatology cedes to public VD clinics	Interdisciplinary teams supported by public funding; research funding attracts infectious disease specialists

With both syphilis and AIDS only a small number of the symptoms experienced by a patient are particular to the diseases themselves, a fact which can make diagnosis and treatment an arduous process. Both share a brief initial outbreak followed by a long period of latency (current

definitions of both diseases are summarized in Table 1.3). For example, patients who are first diagnosed with HIV because they sought treatment for an AIDS-defining opportunistic infection were probably infected with the virus ten or more years previously (Jones 1996, Ward 1999). After latency, both syphilis and AIDS manifest themselves with an extraordinary array of devastating symptoms often appearing on skin or in visible neurological disorders such as dementia. Scientists isolated etiological causes of both syphilis (a bacterium) and AIDS (a virus). Since a person infected with either disease may have a false sense of security and unknowingly infect others, once the causal agents of syphilis and AIDS were discovered, diagnostic screenings became important technologies for reducing the spread of infection by monitoring and controlling outbreaks.

Both syphilis and AIDS are transmitted sexually, but can also be transmitted from mother-to-child, from patient to healthcare worker or vice versa, through blood transfusions, and between intravenous drug users who share needles. Drug treatment for both syphilis and for HIV/AIDS requires correct dosing to control disease progression while not hurting the patient. Strict adherence to drug regimens and follow-up visits for effectiveness are crucial, but patients may find adherence difficult when they experience toxic side effects of the drugs and lack a source of payment for the expensive treatment. Modes of accessing these grueling treatments for patients and securing payment for the administration of treatment are a central difference between the two cases. Control of syphilis in the first half of the twentieth century was handled by government agencies who, when adequately funded, engaged in mass educational and testing campaigns in order to provide treatment to the infected. At the same time, though, there were few mechanisms in place to monitor and standardize care or to regulate industry across geographical areas. This contrasts with the case of AIDS where government oversight on the

pharmaceutical industry and epidemiological surveillance were in place by the time the epidemic began in the U.S. in the early 1980s. Thus, with HIV/AIDS both medicine and public health contribute to the classification of the disease through the development of definitions of expertise.

Although syphilis has a long history, I will touch on this only briefly since the analysis here is in classification processes that began in the early twentieth century. There are several important differences between syphilis and HIV/AIDS. For one, syphilis is curable while HIV/AIDS increasingly resembles a chronic disease (i.e., although the disease does not go away, medical treatment can increase life expectancy and improve quality of life). Today, chronic diseases such as cardiovascular diseases, diabetes, cancer, and others are the most serious and costly conditions facing industrialized healthcare systems. Unlike curable conditions, chronic diseases must be treated over months and years with limited knowledge about how to treat them. Patient adherence to treatment, including diet, exercise and drug regimens, is critical to success in treating a chronic disease. Thus, treating a chronic disease is indeed a management of uncertainty in terms of how to treat, how to pay for treatment, and how to control patient behavior.

However, before penicillin was discovered to cure syphilis in the years following World War II, syphilis was treated with grueling regimens including an array of mercury preparations (e.g., rubs, injections, chocolates) and chemotherapies (e.g., salvarsan, arsphenamine). Even with the availability of curative treatments, providers were often more concerned with giving enough treatment to decrease the infectiousness. Indeed, for both syphilis and HIV/AIDS preventing the transmission of congenital infection were successful first line courses of action to control their spread. Additional prevention, however, requires the identification and modification of behavior that is considered private, offensive, or even illegal. Both syphilis and HIV/AIDS captured the

attention of the media and share social stigmas associated with race, gender, class, and cultural conceptions of risk. Because of the stigma, patients often may be reluctant to be tested, providers may be reluctant to treat patients, and governments may be unwilling to pay for treatment.

Conceptual framework

In this section I present a conceptual framework for understanding how classification in medical systems can be compared across social contexts and progression of disease. This framework supports a set of nested findings about classification and the social construction of syphilis and HIV/AIDS. As we have seen, a study of classification must examine discourse (the creation of categories), practice (the use of categories), and the interaction between the two. This iterative process by which discourse and practice shape each other can be observed in the daily work of people, particularly in organizations where classification (e.g., sorting, grouping, ranking, pricing) and standardization (e.g., aligning, codifying, coding) are core aspects of everyday routines. Medical systems are particularly rich for observing classification because scientists, regulators, activists, professional associations, industry, and patients all have a stake in the products and consequences of classification activity. Moreover, these stakeholders are active participants in the tasks of forming, using, and modifying classifications. It is at this level where classification activity can be observed. With both syphilis and HIV/AIDS, I observed a complex process where categorizing and standardizing were embedded in information-gathering and decision-making activity.

By studying the social process of classification in syphilis and HIV/AIDS, organizational links between multiple stakeholders and their everyday practice are also illuminated: namely, the

development of scientific knowledge, the labeling and surveillance of behavior, the distribution of healthcare resources, the establishment of standards and cost of treatments, and the definition of professional expertise. This dissertation conceptualizes three core types of classification: symptomatological, etiological, and financial. Table 1.2 provides an overview of these forms of classifications and the elements that distinguish them from one another throughout the analysis.

Table 1.2 Typology of Classification

	Elements of Classification				
Type	**Object**	**Stakeholders**	**Discourse**	**Practice**	**Mode**
Symptomatology	Symptoms	Scientists, medical providers, patients	Clinical descriptions, case definitions	Technological innovation, diagnosis, treatment, data collection, counting	Grouping, Administrative
Etiology	Bacterium, virus	Scientists, medical providers, patients, regulators, payers	Diagnostic testing protocols, laws and reports; research protocols and findings	Technological innovation, diagnosis, treatment, data collection, counting	Causal, Grouping, Administrative, Moral
Financial	Patients	Patients, regulators, scientists, payers	Eligibility criteria, categories of risk behavior, disease nomenclature, diagnostic codes	Risk assessment, resource allocation, data collection	Grouping, Administrative, Moral
	Treatments	Scientists, industry, patients, medical providers, regulators, payers	Treatment guidelines, procedure codes	Standardization, cost, treatment decision-making; also organization, research, Evidence-Based Medicine	Grouping, Causal, Administrative
	Medical providers	Medical providers, regulators, payers, patients	Definitions of expertise in treatment guidelines, regulations/law, professional standards and credentials	Professional specialization, credentialing, Evidence-Based Medicine	Grouping, Causal, Administrative, Moral

The most important difference between these types of classification is the object of the classification. There are many different entities to be classified in medicine and I will focus on the classification of symptoms, diseases, patients, treatments, and medical providers by comparing how they become objectified as categories and used by stakeholders in the practice of coordinating and controlling syphilis and HIV/AIDS. Stakeholders encounter these classifications along the way to a variety of goals. As discussed previously, the dissertation focuses on the intersection between discourse and practice because, at heart, classification is part of a feedback loop between textual communication and social action. By focusing on this intersection, the analysis attends to how classifications impact the context and consequences of practice such as in paths of diagnosis, stigmatization, access to care, everyday medical decision-making, and definitions of expertise.

Each form of classification described in Table 1.2 was identified through a grounded theory approach where theoretical themes emerged as part of data collection, note taking, and coding rather than through the testing of a hypothesis (Glaser and Strauss 1967, Charmaz 1983). These forms of classification involve several elements: an object of classification or something that is objectified in the process of classification; stakeholders who both influence and face the consequences of classification; discourse or authorized textual elements involved; practice or examples of classification activity; and the modes of classification involved described in more detail below (i.e., grouping, classification, moral, administrative). Importantly, once something is recognized as an object during classification, it can enter the marketplace or a repertoire of action because it is recognizable (Swidler 1986). Stakeholders play an important role in developing, deploying, and resisting classifications. As discussed earlier, classification is simultaneously the act of sorting, sifting, and streamlining information. As such it involves both

discourse and practice, which come together when classifications are standardized in formal guidelines, official definitions, and in organizational protocols.

Discourse takes many forms ranging from the informal to the highly formalized. The types of discourse outlined in Table 1.2 reside on the more formal end of the continuum, particularly as they are deployed as part of regulatory activities. However, the dissertation finds that formal discourse is responded to more informally in the daily work of providing care to syphilis and HIV/AIDS patients. Clinical descriptions, or groupings of symptoms, are used by medical providers as part of differential diagnosis, the elimination of ailments in order to narrow the probable cause of an individual's symptoms. With the case of syphilis these were often written by physicians who specialized in treating syphilitic patients and are more commonly used in low-tech settings such as the early twentieth century. Case definitions, by contrast, may include groupings of symptoms, but oftentimes include the identification of a causal agent such as a bacterium or virus and require laboratory technology for a patient to be counted as a case. Case definitions are used in public health practice to track outbreaks and better understand the spread of disease in a population and are embedded in administrative data collection and management procedures.

Similarly, the discourse around diagnosis and screening for syphilis and HIV range from the highly formal discourse of state laws that require testing before marriage to recommendations made by governmental agencies that outline steps to be taken by health care workers including reporting positive cases to state surveillance systems. Likewise, publicly funded surveillance and treatment systems use codified discourse in the form of eligibility criteria and risk categories to decide how to distribute limited resources, ensure accountability, and improve understanding of how the disease is spread. Treatment guidelines are formalized directives for how to care for

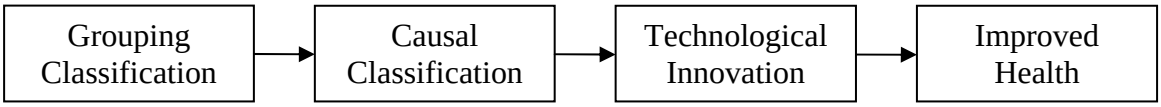
patients based on scientific evidence and professional expertise. Although physicians, scientists, and professional societies contribute to their writing, regulatory bodies such as payers and governments translate these into systems of payment. Billing codes are then developed by professional societies, third party payers of health care, and governmental agencies. They categorize diseases and their associated procedures in order for health care providers to be paid for providing patient care. Definitions of expertise are related to billing codes as they set standards for appropriate credentials of care providers. However, they too are developed by professional societies, payers, and governmental agencies alike.

Because discourse is shared among a variety of stakeholders and communities of practice, Table 1.2 is not meant to imply that these forms of classification exist in isolation from one another. For instance, a disease is often diagnosed in stages in order to signal the appropriate care and expected outcomes for each stage. Likewise some kinds of disease transmission are easier to prevent than others, for example mother-to-child transmission as compared to controlling sexual activity of people who do not know they have the disease. Pregnant women have a good likelihood to interact with the healthcare system whereas people engaging in high risk behaviors such as exchanging sex for money or a place to stay are more likely to avoid healthcare until they are actually sick.

The far right column of Table 1.2 summarizes four general modes of classification identified in this dissertation: grouping, causal, moral, and administrative classification. Grouping mode is where items are collected in order to form a category while causal mode is where an item is identified as the reason for a category. While some forms of classification observed here have been typologized as being primarily in grouping mode and others causal, some forms of classification involve both more equally. Grouping and causal types of

classification are fundamental to the construction of disease, seemingly coming first in a sequence of classification events in medical and public health science as illustrated in Figure 1.1.

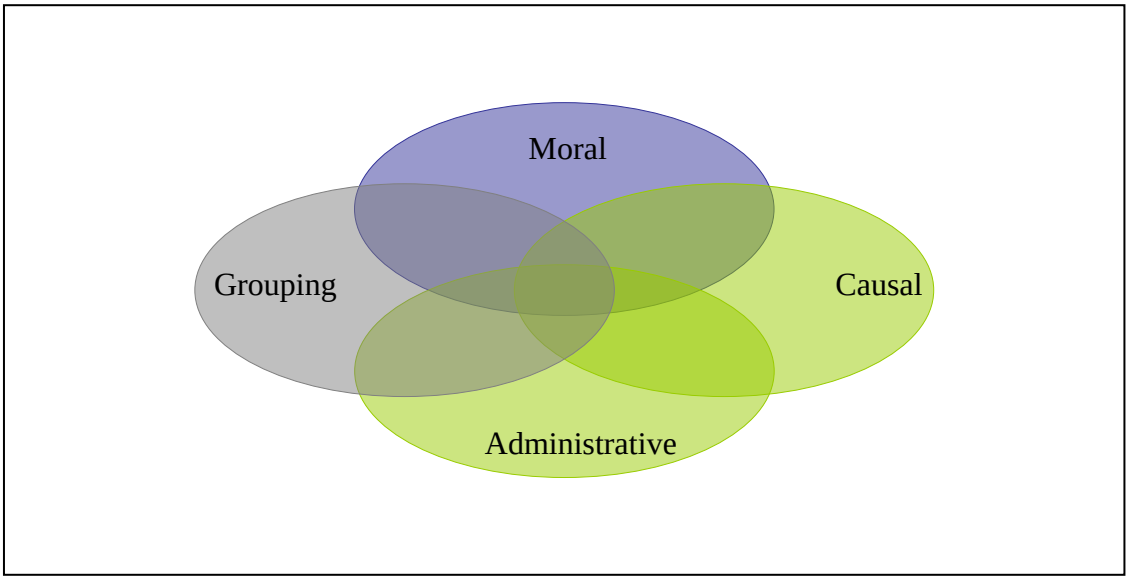
Figure 1.1 Linear Model of Classification



By classifying items into a group, analysts are asking what the thing is whereas in making causal classification analysts are asking how it is caused. Once these basic questions are addressed, it becomes possible to move onto the next two stages. Even fundamental classifications are not fully linear and static, not least because mis-classification can occur in attempts at grouping and causal modes of classification.

Indeed, grouping and causal classification often become mixed with moral and administrative modes of classification in bureaucratic and professional modus operandi. Figure 1.2 offers a visual representation to show how grouping and causal modes of classification overlap with administrative and moral modes.

Figure 1.2 Interactive Model of Classification



Each oval in Figure 1.2 represents an array of discourse and practice that contributes to the social process of classification. The center of the diagram, where these modes of classifications overlap, illustrates how the social construction of disease coalesces through the interactive process of classification. After all, social construction contains all these elements: grouping, causal, moral and administrative. It is precisely the overlap of these modes that make it possible for residues of earlier classification systems to continue to have effects. For instance, the realization that existing risk categories were not capturing the complexity of how HIV was spread, categories changed from "homosexual" to "men who have sex with men." Furthermore, sometimes one mode of classification has more influence, at other times another mode is more influential. By directing analytical attention to how grouping and causal classification fit into this convergence, this dissertation observes how the addition of administrative classifications can diminish the impact of moral classification, although not completely. Thus, when administrative classification exists alongside moral classification, the effect of moral classification may be diluted. With HIV, people are stigmatized, but are still processed as patients in a healthcare system. With syphilis, by contrast, a lack of administrative classification contributed to the resilience of moral modes of classification.

Each of the three main types of classification on which this dissertation focuses plays a role in the social construction of syphilis and HIV/AIDS as problems, the social construction of their solutions (e.g., treatments, policy), and the management of uncertainty as an organizational practice (successful or otherwise). Each type of classification studied here is also mediated by technology, bureaucratic processes, and a variety of stakeholders whose makeup and impact have changed over the course of time. The core task of classification in any organization is to standardize activity and behavior across time and space in an effort to reduce uncertainty about

how to act. When taken at face value, standardization would appear to decrease uncertainty in an organization. However, classification resides at the center of a paradox in healthcare efforts to reduce uncertainty by standardizing technological discoveries into everyday practice only to introduce fresh uncertainties. For instance, until a single code was developed for AIDS in 1994, providers used a mix of codes in order to be paid (Fasciano, et al. 1998). This happens because there is a lag between the time a new treatment or procedure is discovered and the time that innovation is classified and becomes recognizable in existing billing systems. In the interim, medical providers and other stakeholders create work-arounds in order to keep up with the science. The lack of standardized coding for a disease and its associated treatments (even if combining codes) means that there is uncertainty about the cost and reimbursement even if uncertainty is reduced about the appropriateness of the clinical decision. Even as classifications become more settled into billing systems, some providers may continue to use work-arounds in order to maintain confidentiality about a patient's HIV status. So, even stigma has an effect at this level and type of classification.

The first chapters of the dissertation examine the development of symptomatological and etiological classification that is fundamental in the construction of diseases as discrete problems. Rows 1 and 2 of Table 1.2 summarize these forms of classification. First, illnesses can be defined by their symptoms (symptomatology). The assemblage of these symptoms into clinical descriptions is a grouping type of classification that becomes more systematic as medical systems develop into complex information sharing organizations. Medical problems can also be defined by their cause (etiology). This second type of classification is causal in nature because the definition of syphilis and AIDS as medical problems is linked to the existence of a germ or a virus in the human body. Table 1.3 illustrates how both grouping and causal classifications

contribute to the definition of syphilis and HIV/AIDS as having distinct stages warranting their own treatments.

Table 1.3 Classifications of Syphilis and HIV/AIDS[3]

Staging of Disease	Grouping Classification	Causal Classification
Syphilis		
Primary Syphilis	Symptomatic • Characterized by lesion, chancre at site of infection • Lasts several weeks and heals without treatment	Bacteria present and active
Secondary Syphilis	Symptomatic • Characterized by rash that appears after chancre appears • Lasts several weeks and heals without treatment	Bacteria present and active
Latent Syphilis	Asymptomatic • Can last up to 10 years • Some relapse to secondary stage	Bacteria present, not active
Tertiary Syphilis	Symptomatic • Characterized by complications such as large sores, damage to the cardiovascular system and lining of the brain • Can occur as early as 1 year after infection and at any time thereafter • Some never reach this stage	Bacteria present and active
HIV/AIDS		
Acute HIV Infection/Primary	Symptomatic • Characterized by flu-like symptoms • Lasts up to several weeks after exposure	Virus present • Highest amount of virus in course of disease, no HIV antibodies (i.e., HIV antibody test will be negative until seroconversion)
Secondary Asymptomatic HIV Disease	Asymptomatic • Lasts average of 10 years	Virus present • Active replication of HIV virus (not true latency), HIV antibodies present • CD4 count >350
Early-Medium Stage HIV Disease	Symptomatic • Opportunistic Infections • Takes an average of 5-7 years to mild symptoms	Virus present • Active HIV causing diminished immune response; HIV antibodies present • CD4 >200
Advanced HIV Disease	Symptomatic • Opportunistic Infections	Virus present • Active HIV • CD4<200

[3] Adapted from San Francisco AIDS Foundation 2008 and CDC 2008.

One of the great differences between the causal classifications of syphilis and HIV/AIDS is that with syphilis the causal classification is qualitative – is the bacterium there or not – and the quantity of bacteria does not impact treatment; with HIV/AIDS the quantities of virus and of T cells help to determine the stage of disease as well as to track disease progression and treatment effects.

Chapters 2 and 3 illustrate how classifications of disease, whether by grouping cases or identifying like causal agents, are foundational elements in constructing medical problems. Both syphilis and AIDS became causes célèbres of medical research and public health practice in their own rights, particularly during periods of intense information gathering associated with diagnostic and treatment innovations. How the American medical systems arrived at these definitions of disease and how it uses these definitions of disease to allocate resources, identify standards of treatment and cost, and define expertise and health outcomes differ greatly because of the rise of epidemiology, federal public health treatment and research programs, the politics of sexuality, and diversification of funding sources that finance the American health system. In other words the arrival of definitions of disease is done through a combination and convergence of grouping, causal, moral, and administrative classifications. These classifications impact and are impacted by technological innovation, stakeholders, and organizational routines.

Chapters 2 and 3 describe how the unintended consequences of syphilis screening efforts improbably influenced the path that AIDS has taken in contemporary American medicine. Ultimately, the discovery of a disease etiology led to more transparent diagnosis, mass screening efforts, and treatment. However, the availability of treatments or preventive measures impacted the foundational questions about transmission and cause of disease. Furthermore, classifications overlap with one another, resulting in a retrospective view of disease origins and constructions of

risk that can perpetuate labels and stigmas associated with syphilis and HIV/AIDS specifically and sexually transmitted disease generally. Chapters 2 and 3 also give an overview of the history of the cases of syphilis and HIV/AIDS themselves. We will see how even in its developmental phase, classification is a social process. Therefore, moral conflict, scientific and medical theories, technology, resource allocation, law, and politics can each influence the way that these fundamental classifications first take shape. This is especially the case when the classification of objects is later used to classify humans through a variety of organizational routes.

As the dissertation will show, patients, treatments, and medical providers are objects of financial classification (see rows 3, 4, and 5 of Table 1.2). Chapter 4 attends to how diagnostic categories of syphilis and HIV/AIDS serve to sort patients for purposes of case counting and eligibility in relation to government safety net resources. Chapter 5 examines how treatments of syphilis and HIV/AIDS have been categorized according to their efficacy and price tag. Finally, chapter 6 attends to the way that medical care providers, particularly physicians, group themselves in reference to these medical problems. With syphilis and HIV/AIDS, classification is accompanied by moral categorizations that have historically influenced the social construction of the disease as well as our sense of the allocation of resources to prevent, study, and treat them. In chapters 4, 5, and 6, we will see how moral categorizations intersect with administrative classification systems while patients, treatments, and providers become objects of financial classification as part of case processing, organizational fiscal operations, and professional specialization. For instance, patients are grouped both by their ability to pay and the severity of their disease in order to become a case in the clinic system and to receive appropriate treatments. Patients must also provide documentation that the virus is causing their disease with proof of an

HIV confirmatory test in order to become a patient in the clinic and providers are required to report positive cases to the state.

We will see in chapters 4 through 6 that grouping and causal classifications intersect and adjust with moral and administrative classification as they are deployed and resisted when sorting patients diagnosed with the medical problem, developing standards of treatment that address both quality and cost, and establishing parameters of expertise. As the American medical system has become increasingly evidence-based and standard-heavy, administrative and fiscal classifications have become increasingly important to everyday operations. Whether used to identify cases of a disease, create standards of treatment, or grant authority to experts, these classifications are part of social processes that overlap, conflict, and have unintended consequences crucial to the social construction of diseases themselves. At the same time, classifying patients, treatments, and experts in order to diagnose and treat disease, ensure access to medical care, adhere to standards of quality, contain costs, and fulfill contractual obligations is critical to the delivery of healthcare at all stages of technological innovation.

Data and Methodology

This study employs a unique research design which incorporates archival, ethnographic, and interview data. Data were collected from 2003 to 2005 and were analyzed using a grounded theory approach. Data for this dissertation comes from observations of classification activity written in letters and reports and laws, described in interviews, and in observed interactions between clinic staff and patients. These qualitative data illustrate the activity of public health officials, scientists and researchers, medical care providers, administrators and bureaucrats, patients, activists, politicians, as well as representatives of government, industry, and science. Social scientists know that people often say one thing and do another and so an examination of

discourse of classification in syphilis and HIV/AIDS is not enough. In addition to content analysis of classifications themselves, observational and archival data allow my analysis to speak to the details of classification in action.

Primary sources for the syphilis case include correspondence, reports, and other documents collected from the collection of Thomas Parran papers at the University of Pittsburgh archives located in Pittsburgh, Pennsylvania and the National Archives and Records Administration collection of the Tuskegee Study of Untreated Syphilis located in Jonesboro, Georgia. Thomas Parran was a major player in developing structures of and research about the treatment of venereal disease as part of the institutionalization of public health in the early twentieth century. Key to this was the development of classifications as well as dealing with a lack thereof. Correspondence, reports, and forms from Parran's archives shed light on how classification took place in this context and how syphilis was constructed as a public health rather than a medical problem. Another major player in the development of classification was Raymond Vondherler, the primary force behind the Tuskegee study of untreated syphilis in Negro men in Macon, Alabama. Correspondence related to the Tuskegee study reveal how classification, albeit highly unstandardized, was used to legitimize transformation of the study from a testing-treatment initiative to an observational study of the disease's life course in a vulnerable and uninformed population of research subjects. I made several visits to both archives and collected over 300 letters, reports, and forms.

Primary sources for the case of HIV/AIDS include interviews with experts in the fields of HIV/AIDS public health and medicine and field observations and informal interviews that I conducted at an anonymous public HIV/AIDS clinic in the Southeastern United States as part of the project "Clinic-Level Law: The 'Legalization' of Medicine in AIDS Treatment and

Research," (Carol Heimer, Principal Investigator). Participant observations were conducted at this site during a twelve-month period in 2004 and 2005 with a variety of staff shadowed and informally interviewed including administrators, registered nurses (acting as clinicians, managers, researchers, and case managers), midlevel clinicians (e.g., nurse practitioners, physician assistants, and other advanced practice nurses), health educators, data managers and technicians, and others. I shadowed 21 staff members, conducted 30 informal interviews, attended 38 regularly scheduled meetings, and made observations on 11 other occasions (including observations of staff in two workrooms, two interdisciplinary discharge planning meetings at the hospital, a quality assurance meeting, a data monitoring debriefing in the research unit, a community advisory board meeting, a staff forum with the health system Chief Operating Executive, a pharmacological training session, and an annual memorial service). Notes were taken during observations and interviews and extensive fieldnotes were written after the field visit was complete. In addition to creating fieldnotes, I also gathered forms, manuals, memos, and other documents that were used in practice at the clinic. Interview transcripts and fieldnotes were analyzed using HyperResearch, a qualitative data analysis software, to identify themes that were ultimately coded as the five broad forms of classification described below. Letters and reports collected from the archives were coded by hand. Semi-structured key informant interviews conducted by the research team in the United States from 2003-2005 supplement and clarify the regulatory aspects of formalized classifications observed in the field site.

The clinic was comprised of roughly 170 staff members with a caseload of approximately 4,000 primarily uninsured or under-insured HIV-infected patients. Most staff and services at the clinic are funded through the provision of a Ryan White grant. Thus, to be eligible for care,

patients must meet both clinical and financial eligibility criteria under provisions of the Ryan White CARE Act first passed in 1990. The clinic was an ancillary of a larger public health system that housed a teaching hospital and clinical research. During the period in which I conducted my observations, the health system was dealing with a fiscal crisis on the order of tens of millions of dollars. New upper-level administrators were hired to rein in the massive debt and a series of cost-containing tactics were administered at all levels of the system.

Conclusion

By studying classification, the dissertation continues the sociological exploration of the relationship between consciousness and structure where classification is a fundamental social process because it is a mechanism of social construction. As a social process, classification does not reside purely in the realm of cognition, but rather is attached to the material world through the objectification of action, behavior, technology, and people. In medicine, classification allows us to recognize a disease, identify those who have the disease, and connect them to resources and treatment. However, technological and bureaucratic practices can obscure the connection between classification, the humans that developed it, and the people who are classified, creating an atmosphere of depersonalization. This depersonalization may help to sustain some categorical distinctions by giving them a natural, taken-for-granted quality. Because classification is a human achievement, however, the stability of classifications can also be challenged by stakeholders through the development, modification, and resistance to the standardization of these categories.

Classification in medicine is similar to classification in other parts of the social world such as science because both contribute to the construction of social problems through the

identification of causal relationships, assertion of expert authority, and technological innovation. In science, the connection between classification activity and the social world is often obscured by valuing the production of knowledge for its own sake. And although classifications make their way into standards that govern scientific work, in medicine standardization of classification is increasingly developed and deployed by non-medical social actors to govern the daily work of doctors and other healthcare providers.

As is the case in other organizational fields, classification systems are essential tools in medicine. Without classifications, healthcare professionals and patients would lack mechanisms for recognizing diseases, their treatment, and paths to payment. This dissertation will show how, as the business of healthcare has grown, organizational and bureaucratic layers of classification have become increasingly salient to the distribution of resources and to the daily work of health care providers. Classifying patients according to authorized disease case definitions, definitions of risk, and even billing codes is necessary to ensure access to care for patients, to receive reimbursements from third party payers, and to guide and legitimize treatment decisions made by health care providers. While physicians caring for syphilis patients lacked classifications and standards to guide the provision of care and its price, clinicians providing care to HIV patients are often faced with layers of classifications for sorting patients in order to secure payment as well as to make diagnostic and treatment decisions. With both, the social process of classification often veils the relationship between medical practice and the complex and overlapping discourse embedded in bureaucracies that sustain a health care organization's multiple institutional obligations.

A comparison between syphilis and HIV/AIDS illustrates general tendencies about classification in medicine, for instance how innovations in treatment influence diagnosis.

However, the comparison also highlights important shifts in American medicine since the 1920s, particularly the pace of innovation. By examining both cases, we will learn how the deployment of classifications in standards is simultaneously vital to the functioning of medicine yet impinging on the authority of medicine itself. We will observe how medicine responds by taking an active role in developing classifications. Most importantly, this dissertation observes how stakeholders in the field of medicine develop work-arounds to the lack of standardized classifications with syphilis and the overabundance of classifications with HIV/AIDS.

Epidemic illness can have a devastating impact on a society, burdening core institutions such as families, economies, militaries, and schools with decreased labor, increased financial costs, and a host of uncertainties about the future. The comparison of syphilis and AIDS is instructive because both diseases were challenging to define both symptomatologically and etiologically. With syphilis, it was the discovery of the bacterium spirochete palladium in the early twentieth century that came to shape the way the disease was handled by medical systems. Prior to the discovery of the spirochete, syphilis was identified with a series of clinical markers whose connections to syphilis were unsettled. As we will see, the discovery of the bacterial agent causing syphilis was made possible by advances in laboratory technology and germ theory. These scientific and technical innovations played an important role in the development of public health as a discipline and as a regulatory arm of the state.

By contrast, the original case definition of AIDS and its subsequent etiology were developed in a context where the way we understand diseases and disease outbreaks had become highly technical and bureaucratically structured by the institutionalization of medical research and epidemiology. Thus, other diseases, such as cancer and Hepatitis B were used as cognitive and scientific models during the process of developing classifications for the new syndrome.

Finally, although syphilis became the face of premarital and prenatal screening for sexually transmitted disease, as well as the object around which the first community health clinics were developed and cooperative medical research was first conducted, syphilitics experienced a great deal of stigmatization.

Behavior must be classified in order to understand how the causal agent of the illness and the effectiveness of the cures depend on patient behavior, such as being tested, taking the medicine, and understanding the instructions. This process is key both to the construction of the public health problem and to its solution. Improvements in public sanitation, the development of a vaccine, or targeted prevention education for the public are all solutions aimed at curbing the spread of illness and controlling disease outbreaks with administrative rather than moral classifications. However, moral conceptions continue to be attached to definitions of disease. This is especially true in the case of syphilis and HIV/AIDS where some of the infected people are labeled as innocents while others are blamed for having unprotected or homosexual sex that puts them at risk.

Over the course of the last century, the classifications involved with standardizing care and its cost have increased substantially and developed into a highly complex system that some call a medical-industrial complex (Relman 1980). Although with evidence-based medicine the lines between routines to ensure quality care and to control cost are often muddied, it is clear that the coordination of administrative and financial systems are crucial to the integration of technological innovations, specialized skills and knowledge, and individual disease progression. The comparison between the cases and time periods will illustrate some key similarities and differences that help both to lend specificity to how syphilis and HIV/AIDS have become objects of medicine and public health systems in the United States, and to conceptualize some general

notions about how classifications influence and are influenced by decision-making in organizations.

First, the dissertation observes the legacy of the classification of syphilis in HIV/AIDS practice and discourse. For instance, salvarsan, the main drug treatment prescribed to syphilitics prior to the end of the Second World War, was an early form of chemotherapy, a type of treatment with which we are familiar today in both the treatment of cancer and HIV (Jones 1993). A second finding of the dissertation is that while medical costs were a concern in the early decades of the twentieth century, in today's world it is through mechanisms of cost containment and quality control that classification saturates healthcare. Yet there is a lack of coordination between the two and this results in medical error (Kohn, et al. 2000), unsatisfactory quality (Committee on Quality of Health Care in America 2001), increased medical costs (Geyman 2003), and work-arounds by stakeholders interested in improving the efficiency and quality of healthcare at the local level.

Third, when people are objects of classification, they may not fit existing classifications. For instance, HIV-infected individuals may not consider their behavior homosexual or may not disclose their homosexual behavior during case interviews with public health workers and so the box for homosexual transmission of HIV/AIDS may be left unchecked. Thus, classifications while durable are susceptible to the influence of stakeholders. Lastly, some classifications impinge on all the rest because they are deployed with more authority. The question remains, then, under what circumstances are classifications more or less susceptible to change? For instance, the classification of patients as eligible for care either by clinical or financial criteria is something that not only takes up an inordinate amount of labor in public health, but influences the practice of providers and payers alike.

Classification and the social construction of disease are in an evolving relationship. At times, diseases are defined more by moral classification than by grouping classifications. With sexually transmitted diseases, individual behavior is grouped and those identified as cases of the disease are sorted according to that behavior. Infected adults are recognized both as having the disease and perhaps as having violated moral or legal conventions. Infected children and others whose own behavior is not implicated are recognized as innocents, thereby placing additional blame on those who engaged in the so-called "risky" behavior. The process of recognizing medical problems is further mediated by technological innovation, organizational infrastructure, as well as the actions and perceptions of stakeholders. At other times diseases are defined more by administrative classification (e.g., billing codes) than causal classification. By comparing the social aspects of how syphilis and AIDS first came to be classified as medical problems, we are better able to understand how the discovery of biological cause of medical problems does not necessarily absolve individual behavior. This comparison also reveals how categories of medical problems themselves become objects around which scientific innovation, organizational routines, and collective action are organized. The resulting picture of this social interaction is a web of classification activity that strongly contributes to the social construction of disease.

Despite the abundance of classifications for distinct diseases, modes of transmission, standard treatments, and providers, a "veil of secrecy" still obscures how hospitals are paid (Reinhardt 2006) and how treatment efficacy is measured. Stakeholders continue to ask why this lack of coordination exists and call for overhauls of systems for financing care and measuring its quality. We need to know more about how this lack of coordination arose before new classifications confound an already burdened system of coordination and control in public health. This analysis of classification is a first step in illuminating the distinctive roles of classifications,

their mediators, and stakeholders in a healthcare world where patients, providers, and payers are all saddled with multiple systems of classification.

CHAPTER 2

THE SYMPTOMS ARE WHAT?
FROM CLINICAL DESCRIPTIONS TO CASE DEFINITIONS

The classification of a medical problem by its symptoms is so basic that over time its invention can become obscured in the functioning of medical systems. For the sick and their caregivers, assessments of the type and severity of these symptoms may be the first step toward a diagnosis and treatment in a medical system. Little thought is given to the process of classification before classifications are agreed upon. The grouping classification of both syphilis and AIDS by their symptoms has been particularly important because unlike many medical problems, these conditions manifest themselves in arrays of symptoms that are not necessarily particular to the disease itself. In contemporary medical terms, these diseases are often referred to as multi-systemic and highly disseminating, meaning that they affect multiple organ systems. Because of this, both syphilis and HIV disease mimic an array of other diseases. Once a cluster of symptoms becomes recognized as a unique medical problem, then individuals may be sorted as cases of the condition and continue to be processed in a medical system.

In retrospect we know that syphilis first presented itself as a problem in Europe over four hundred years ago. However, its differentiation from other diseases was stymied both by the fact that it was only one of several epidemic diseases playing havoc in society and because modern medicine's "empirical-therapeutic" paradigm had not yet beat out "ethical-mystical" views of illness (Fleck 1979, 5). By the time unusual groupings of symptoms came to be classified as AIDS in 1982, a component feature of the American medical system was the development of a case definition as a standardized practice of public health outbreak investigations. As we will see, four hundred years of standardization in medical systems does not mean that the process of classifying diseases is uniform or settled among stakeholders or diseases.

From Great Pox to Great Imitator: Classification of Syphilis by Grouping Symptoms

> He first wore buboes dreadful to the sight
> First felt strange pains and sleepless passed the night
> From him malady received its name
> - Fracastoro, *Syphilus Sive Morbus Galligus*[1]

By most accounts, the first Old World syphilis epidemic occurred in the late fifteenth century. In Europe, syphilis began to be understood as a medical problem separate from other medical problems rather quickly, although its ability to be transmitted sexually was not grasped until later. Table 2.1 provides an overview of classifications of syphilis since its earliest recognition.

Table 2.1 – Historical Classifications of Syphilis

Era	Name(s)	Classified by	Theories and practices
15th century	Pox, Great Pox, Neapolitan sickness, Morbus Gallicus, French Pox, Italian Pox, Turkish disease, Grandgore	Grouping of symptoms (Genital lesions, rashes, rapid death), association with race/nationality	Galenic, Paracelsus, blaming enemies of war
16th – 17th century	Syphilis, carnal scourge	Grouping of symptoms, association with genitals	Astrology, Renaissance
18th century	Syphilis	Grouping of symptoms, association with moral depravity, focus on children	Enlightenment, Scientific Reasoning
19th century	Syphilis, "The Great Imitator"	Grouping of symptoms (Three stages: primary, secondary, tertiary), association with cause ("virus")	Modern, Germ theory, Unicists, Physiological, New Doctrine/dualist
20th century	Syphilis	Grouping of symptoms (latency and congenital infection defined), Etiological (causal agent identified as *spirochete palladium*), association with race	Technological innovation in medicine and science (microscope, bacteriology), eugenics
21st century	Syphilis	Grouping of symptoms, etiological	Disease prevention and treatment (Public health screenings and surveillance)

[1] As quoted in Hayden 2003, 22

In the 15th century, theories about illness and the functioning of the human body were conspicuously unsettled. Indeed, some experts of the time upheld the traditional Galenic theory of humors that considered all medical problems, including syphilis, the result of an imbalance among vital elements in the body that must be restored to balance by such methods as bleeding, sweating, and spitting (Gould 2000). Others pointed to the Paracelsus theory that considered all diseases to be chemical in nature resulting from the individual wills of organs. The ill will of organs was relieved and chemical balance restored to the body using the three principals of mercury, sulfur, and salt (Clancy 1999). The first recorded use of mercury to treat syphilis occurred in 1496 and remained a common treatment for the disease even into the 20th century. In fact, mercury became so closely linked to syphilis that "quacksalvers used mercury as an operational definition for syphilis; if mercury provided a cure, the patient was syphilitic" (Magner 1992, 179). Mercury was administered in a myriad of forms, from mercury salve rubbed directly on the patient's skin to ingesting mercury powder in flavored capsules or mercury-laced chocolates designed to provide treatment to unsuspecting wives infected with the disease (Hayden 2003, 47-49). In the 17th century, patients sat in a tub of hot water in a closed room where they were rubbed with mercury several times a day (Magner 1992, 179).

Mercury is nearly as deadly to the patient as syphilis however, and so experts also looked to herbal preparations. Ironically, the use of mercury appealed to the Galenics because it produced more phlegm, which they considered an important byproduct of treating syphilis. In modern times, we know that abundant saliva is a classic indication of mercury poisoning (Clancy 1999). Even the toxic effects of treatment itself confounded the grouping classification of the disease. Early monikers for the disease reveal associations of blame and risk with particular races of people. Racial and ethnic classifications have their own sort of durability and influence

on disease classification because moral classification overlapped with the symptomological classification of syphilis.

The symptomological classification of syphilis was further confounded in the 16th century because syphilis was just one of several epidemic diseases running rampant in war-ravaged Europe. Astrology, rather than modern medicine, was the dominant force in how these scourges were understood. The term "syphilis" entered our lexicon in 1530 with the publication of a long poem by an Italian physician named Girolamo Fracastoro (Gould 2000, Parran 1937, Clancy 1999). In the poem, Syphilus was a fictional shepherd who acquired the disease after insulting Apollo (Gould 2000, Parran 1937). Fracastoro upheld the traditional Galenic theory of humors that considered all disease, including syphilis, the result of an imbalance among vital elements in the body that must be restored to balance by the aforementioned purging methods (Gould 2000). At the same time, the sign of Scorpio was perceived as ruling over the genitals, the region of the body where lesions often appear as the first sign of syphilis. Thus, astrology contributed to the designation of syphilis as the carnal scourge, differentiating it from other epidemic diseases and helping to establish a connection between syphilis and sexual contact (Fleck 1979).

In his foundational work *Genesis and the Development of a Scientific Fact*, Ludwig Fleck posited that two perspectives on syphilis developed alongside one another at this time. He referred to these as "ethical-mystical" and "empirical-therapeutic" characterizations (Fleck 1979). Fleck argues that these two perspectives were often at odds with each because the first had its roots in astrology and the second had its roots in the use of mercury as the natural treatment for the disease (Fleck 1979). He illustrates how scientific concepts and theories are culturally conditioned, manufactured objects. Thus, how particular definitions become

established as fact is a social process with grouping classification as its basis. Indeed, until the 19th century, venereal diseases such as gonorrhea were included in the definition of syphilis (Fleck 1979).

Once the venereal origin of the disease was recognized then there was a perception that those who became infected deserved their affliction for violating religious and moral law. Moreover, they deserved punishment and treatment for syphilis was commonly done in prison-like settings (Clancy 1999). Even after the causal agent for the disease was discovered, syphilitics continued to be feared and loathed. According to Daniel Wolfe,

> Syphilis, for centuries so feared that it was known as the "great" (as opposed to small) pox, has been distinguished as much by the desire to blame it on others as for its power to destroy. Medieval cities banished syphilitics outside their gates or "cured" them with mercury ointments that made their bodies shake and their teeth fall out before they died. In the U.S., well into the 20th century, syphilitics were subject to toxic treatments both physical and moral: expensive, ineffective drugs as well as public condemnation as "plague spots" and infectors of "innocent victims." (2000, 1)

Thus, the moral view of stakeholders played an important role in prioritizing punishment over prevention in collective attempts to control the disease and those infected both before and after the crystallization of the scientific facts about syphilis.

The 18th century was an era where differentiation through taxonomy was a key activity for the discipline of science. Indeed, differentiation through the development of classification systems was what distinguished science from alchemy, astrology, natural histories, and religion (Foucault 1970). At the same time, differentiation between sexes and races was a concurrent process of classification. As with race, "Sex and age could function as parallel—or, perhaps, conjoined—variables in assessing the manifestation, and the impact, of common illnesses" (Churchill 2005, 11). At this time, the weaving of myths into definitions of disease served a policing function by reinforcing existing prejudices about certain groups and behaviors

(McAllister 2000). The Enlightenment was an era of acute historical change in the science of sexuality and sexual disposition. The previous Aristotelian 'one-sex' model where women were thought to be less perfect versions of men became the 'two-sex' model of biological dichotomy (Schiebinger 1993, 37). Indeed, "an anatomy and physiology of incommensurability replaced a metaphysics of hierarchy in the representation of women in relation to men" (Laqueur 1997, 220). However, the woman's unique role in reproduction was analyzed by scientists until the feminine body became, as Michel Foucault wrote, "thoroughly saturated with sexuality":

> …it was integrated into the sphere of medical practices, by reason of a pathology intrinsic to it; whereby, finally, it was placed in organic communication with the social body (whose regulated fecundity it was supposed to ensure), the family space (of which it had to be a substantial and functional element), and the life of children (which it produced and had to guarantee, by virtue of a biologico-moral responsibility lasting through the entire period of the children's education)…(1978, 104).

It is the communication of this sexual pathology to the social body that ensured the significance of the figure of the mother, embodied in feminine appearance, virtue, and dependence.

For enlightened Europe, scientific fascination with sex differences exemplified the sensibility that the laws of nature prescribe the laws of society and the notion that healthy children lead to a healthy state. By the 18th century, congenital syphilis had unfortunately become a major killer of children. In 1780, the Vaugivard Hospital opened in Paris. It was the first institution dedicated to the treatment of congenital syphilis, but was not judged to be effective and was closed (Clancy 1999). Because no one knew how to prevent these children from contracting syphilis or dying as a result of congenital syphilis, failed attempts only threatened the hope of a healthy state and contributed to the influence of moral classification about innocents in the grouping of symptoms for syphilis.

As we see in Table 2.1, systematic attempts to differentiate venereal diseases from one another began in earnest during the 19th century. This was a period of great confusion and

discord among those who studied venereal disease, however. The unicists, who subscribed to the "theory of unity," thought that gonorrhea was an initial stage in syphilis rather than a distinctive disease entity (Fleck 1979, Dracobly 2004). They held that syphilis was caused by a material thing, a "virus," and they categorized its symptoms into "local" or "primary symptoms and "secondary" or "consecutive" symptoms. Unicists believed that all these symptoms were highly irregular and so it was not the clustering of symptoms that gave the disease its unity, but rather its cause. They continued to employ mercury treatment targeted to that cause (Dracobly 2004). Apart from the unicists, there were some who denied that syphilis was caused by a particular thing. "Physiologists," on the other hand, held that syphilis could be caused by irritation, including from excess coitus. In their view, the virus described by the unicists did not exist but was a "product of reason" and they rejected the wholesale use of mercury to treat the disease (Dracobly 2004).

By mid-nineteenth century, Phillipe Ricord defined syphilis by grouping symptoms into three stages of pathology: primary, secondary, and tertiary. The primary stage of syphilis is characterized by lesions local to the site of infection, usually a genital chancre.[2] The disease then disseminates throughout the body and can lodge in any organ system, diminishing the obvious association of symptoms with sex. The secondary stage manifests itself in a rash often developing like warts on the hands and feet. When syphilis has spread through the body, an array of symptoms may be present, including: fever less than 101 degrees, sore throat, general feeling of weakness and dull pain, weight loss, patchy hair loss (especially eyebrows, eyelashes and scalp), swollen lymph nodes, and nervous system symptoms such as headaches, irritability, paralysis, and imbalanced reflexes and pupils. Without treatment these symptoms disappear and

[2] Ricord maintained for many years that the primary stage of syphilis was the only infectious stage. In 1863 he admitted that secondary syphilis was also infectious (Harsin 1989, 78).

the latent stage of syphilis begins. The disease stays in the body, however, and throughout the tertiary stage damages internal organs, including the brain, nerves, eyes, heart, blood vessels, liver, bones, and joints. Signs of this damage may not manifest until many years later as difficulty coordinating muscle movements, paralysis, numbness, gradual blindness, dementia, and gummata (large sores inside the body or on the skin). Cardiovascular, neurosyphilitic, and other damage may be serious enough to cause death (CDC 2008).

Syphilis can mimic many diseases, which led Ricord to write that the more syphilis infiltrates the body, the more it resembles other serious ailments (Dracobly 2004). In 1879, Jonathon Hutchinson delivered the speech, "Syphilis as Imitator," to the British Medical Association. He listed various disease states that have a syphilitic counterpart as well as outlining a general law of imitation for the disease. He did this by cataloguing the many ailments that syphilis imitates using case histories (Hayden 2003). Hutchinson's speech served as a guide for diagnosing syphilis based on clusters of symptoms. Although the causal agent of syphilis was identified in the early part of the twentieth century and the catalogue of its associated symptoms has been scrutinized since this early differentiation, these three stages of syphilis have remained largely intact until today. (See Table 1.3 for a summary of Syphilis and HIV/AIDS classifications).

The grouping classification of syphilis allowed clinicians to diagnose cases of syphilis prior to a laboratory test being available in the twentieth century. It also allowed the stage of disease to be diagnosed and enabled the identification of congenital syphilis. This classification played an important role in constructing syphilis as a medical problem in its own right in the 19th century. The grouping classification is less important today, since clinicians rarely see late stages of syphilis. Screening tests allow diagnosis of syphilis before symptoms occur or when

the disease is its latent stage. As we will see with the case of AIDS, the grouping classification for syphilis also differs from contemporary grouping classifications for sexually transmitted disease primarily because the organization of public health was still in its infancy and routines of developing and using grouping classifications for investigating outbreaks of disease or reporting instances of sexually transmitted diseases were not yet established.

From KSOI to GRID: The Classification of AIDS by Case Definition

> Greetings, Prophet! The great work begins! The Messenger has arrived!
> - The Angel, *Angels in America*[3]

By the time AIDS emerged in the early 1980s, public health routines of developing case definitions, mass screening, case reporting, contact tracing, and immunization programs were well established. These routines were mostly established by the Centers for Disease Control and Prevention (CDC) and its predecessors. At the same time, biomedical research was also in its heyday, particularly at the National Institutes of Health (NIH). Both public health activity and biomedical research can trace their accomplishments to an influx of resources in the post World War II era. Prior to the emergence of AIDS, many regarded these public health practices and innovations in medical science as so successful that they had conquered infectious disease altogether.[4] Since the grouping classification for HIV/AIDS was developed in this context, a

[3] Kushner 1993, 117

[4] In retrospect we know that while public health and medical research activity focused on chronic disease, AIDS was quietly spreading. Chronic disease continues to pose major problems for American medicine. However, a variety of infectious diseases have regained their status as medical, public health, and even security problems for the United States (Hirschberg, et al. 2004). Furthermore, while tobacco-related disease and heart disease continue to cause the bulk of health problems worldwide, a recent study projected that HIV/AIDS would be among the top three leading causes of burden of disease by 2030 (Mathers and Loncar 2006). For tropical developing countries, however, infections and parasitic diseases remain the biggest killers with HIV/AIDS accounting for most of the burden followed by diarrheal disease, malaria, tuberculosis, measles and other STDs (Hotez, et al. 2004). Not only do symptoms from these diseases resemble symptoms of AIDS, infection with any of them increases one's likelihood of contracting HIV and vice-versa.

brief history of American disease reporting and biomedical research will provide useful background for the analysis.

Until the late 19th century, U.S. public health authorities relied on death registrations to identify outbreaks of disease. Our current system of disease reporting has its roots in the 19th century when the U.S. Marine Hospital, predecessor of the U.S. Public Health Service (USPHS), was authorized by Congress to collect information about cholera, yellow fever, smallpox and plague overseas in order to prevent their spread into the United States. Domestic reporting began in 1893, but became quicker and more uniform in the early 20th century under the direction of the USPHS (Koo and Wetterhall 1996). The Communicable Disease Center or CDC was established in 1946 as a branch of the PHS (Etheridge 1992). In 1961 CDC took over the National Notifiable Diseases Surveillance System (NNDSS) along with the mechanism that disseminated results of the reports, the *Morbidity and Mortality Weekly Report (MMWR).*[5]

The National Institutes of Health (NIH) also traces its roots to the nineteenth century U.S Marine Hospital when a one-room laboratory was set up in 1887. By the early twentieth century, the lab, known as the Hygienic Laboratory, moved from New York to Washington, DC and had an expanded role in public health sanitation efforts. Routine federal appropriations began at this time and contributed to the Hygienic Lab becoming a center of federally-funded research. Its name was changed in 1930 to the National Institute of Health with the passing of the Ransdell Act (Hardin n.d.). Although federal support at that time reflected the harsh economic reality of

[5] Importantly, the method and mechanisms of reporting as part of NNDSS varies by state and by disease. The National Electronic Telecommunications System for Surveillance (NETSS) standardizes the communication aspects of NNDSS somewhat by accepting a standard record format from a variety of computer software packages. Unlike syphilis and other communicable diseases, HIV/AIDS reporting is not integrated into NETSS, but rather is handled exclusively by the Division of HIV/AIDS Prevention --- Surveillance and Epidemiology in the National Center for HIV, STD, and TB Prevention (NCHSTP) (Jajosky, et al. 2006; Koo and Wetterhall 1996). NETSS has been supplemented somewhat by CDC's National Electronic Disease Surveillance System (NEDSS) initiative to provide further standardization. However, only 10 states were using NEDSS as of March 2005 (Jajosky, et al. 2006).

the Great Depression, medical research gained prominence and federal resources in the post-Word War Two era (Berg 1995; Heimer, et al. 2005). Thus, between 1946 and 1949, Congress created institutes for research on mental health, dental diseases, and heart disease. The 1948 National Heart Act changed the name of the umbrella organization to the plural: National Institutes of Health (Hardin n.d.).

By the 1970s, both CDC and NIH expanded their roles significantly away from infectious disease. In 1970 the Communicable Disease Center was renamed the Center for Disease Control to reflect a broader preventive health mission.[6] Over the next several years, the agency absorbed the National Institute for Occupational Safety and Health (NIOSH), which focuses on protecting Americans from on-the-job hazards, and opened an expanded, maximum-containment laboratory to handle viruses too dangerous to handle in an ordinary laboratory. This intense reorganization of CDC during the 1970s was due to its expansion from infectious disease and a general reorientation towards lifestyle and environmental issues (Etheridge 1992). This era was thought to mark the end of infectious disease and plagues (Fee and Fox 1992). Exemplary of this shift is CDC's work on a Hepatitis B vaccine during the 1970s, where the division of Sexually Transmitted Disease formed ties with the gay community (Etheridge 1992).

Similarly, NIH's role was expanded in the 1940s with the addition of the National Cancer Institute (NCI). However, it wasn't until 1971 that President Nixon injected $1.6 million into the NCI as part of the "War on Cancer." Truly a colossal sum, this money helped the NCI gain independence from the NIH as well as fuel the search for viruses that cause cancers. The recent discovery of reverse transcriptase and retroviruses also fueled this quest. NCI's budget continued to grow at a rapid rate during the 1970s, from $377 million in 1972 to $815 million in

[6] The name was changed again in 1992 to the Centers for Disease Control and Prevention (CDC 1992a).

1976. However, the cancer-virus project was seen as a failure and many of the associated labs were being shut down by the times AIDS emerged (Crewdson 2002).

On June 5, 1981, public glimpses of the condition we now know as HIV/AIDS first appeared on the second page of the *MMWR*. The report, "Pnuemocystis Pneumonia – Los Angeles," described the first cases of a rare pneumonia that appeared in five young, homosexual men. For each, diagnosis was confirmed with a lung biopsy. Each man also had a confirmed case of current or previous infection from cytomegalovirus and candidal mucosal infections (CDC 1981c). This report was sparked by a physician's request for pentamidine, the drug used to treat pneumocystis carinii pneumonia (PCP). The CDC has distributed rare drugs and vaccines since 1966. In 1981, it was the only source of pentamidine in the country. The method of accessing these drugs was separate from the disease reporting mechanism.

Standardized disease reporting or surveillance has been historically, and continues to be, one of the most challenging aspects of public health practice. The CDC provides guidelines for reporting, but lacks the authority to mandate standard reporting practices across states and territories (Roush, et al. 1999). CDC relies on state-level mandates that require health care professionals and laboratories to report cases of notifiable disease to local or state health departments who then report cases to the CDC. The notion that infectious diseases were no longer a threat to public health increased complacency and decreased vigilance when it came to reporting (Berkelman, et al. 1994). Thus, after private discussions with physicians revealed that more cases were being treated than reported to CDC, pentadimine records were investigated and they showed one similar case before 1980, nine from June to December 1980, and an increase in requests for pentadimine starting in February 1981 (Etheridge 1992).

In some of the PCP cases, CDC officers reported Kaposi's sarcoma (KS), a rare cancer only seen among elderly men of Mediterranean or Jewish heritage, organ transplant patients, or young adult African men. Subsequently, a second report of about 26 cases of KS resulting in 8 deaths was published in *MMWR*. KS was grouped together with PCP and other "opportunistic infections" such as toxoplasmosis, severe recurrent herpes simplex, pervasive candidiasis, cryptococcal meningitis, and cytomegalovirus (CMV). Although the cause of these infections was unclear at this time, the report identified all 26 cases as being in homosexual men, thus linking the grouping of symptoms to sexual behavior. In fact, the reference to homosexual men moved from the text in the June 1981 MMWR to the headline in July 1981 (CDC 1981b). By August 1981, immunosuppression was reported to be the cause of this cluster of infections, although the cause of the immunosuppression was not yet known (CDC 1981a). According to the first report, that each of the five cases was in a homosexually active man "suggests an association between some aspect of a homosexual lifestyle or disease acquired through sexual contact" (CDC 1981b, 305).

By midsummer 1981, CDC had set up a KSOI (Kaposi's Sarcoma and Opportunistic Infections) task force to investigate the outbreak. Under the old organization, the Bureau of Epidemiology and Bureau of Laboratories would have been in charge of investigation. In the new structure, the investigation began in the STD Division with surveillance (Etheridge 1992). The first working definition was "a biopsy-proved case of Kaposi's sarcoma or other life threatening or fatal opportunistic infection in persons under sixty years of age without an underlying reason for immunosuppressive disease" (Etheridge 1992, 324). Investigators solicited cases by telephone and asked health departments to report any new cases. Investigators used a long questionnaire to ask ill men in San Francisco, New York, and Los Angeles about

their medical history, travel, occupation, use of drugs, and sexual practices. They conducted thirty 2- to 3-hour interviews. Epidemiologists from the STD Division were assigned to work solely on AIDS, dropping other medical problems such as penicillin-resistant gonorrhea (Etheridge 1992, 324-325).

There were budgetary problems at CDC, however. There was an order for a reduction in force, which came out of the Omnibus Budget Reconciliation Act (OBRA) of 1981. Orders were to reduce staff by 15 percent. Harold Jaffe was recruited into the Epidemic Intelligence Service class of 1981 just so he could remain on the staff of the KSOI team (Etheridge 1992, 325). The first major job of the KSOI Task Force was a case control study. The controls were healthy gay men. Many of the patients reported using "poppers" (amyl nitrates), but investigators on the team did not think that the disease was toxicological. Members of the task force and STD division had close ties with the gay community, particularly because of work CDC did on Hepatitis B (Etheridge 1992, 326). Before a causal virus for AIDS was located, epidemiologists at CDC and elsewhere locked into a 'lifestyle' analogy and later a model based on Hepatitis B to define the new syndrome.

In 1981, CDC began to conduct surveillance of cases of KSOI by requiring cases be reported to them (CDC 1981a). The first case of a woman with KSOI was reported in August 1981 (CDC 1981a). By May 1982, the task force received reports of 355 cases of KSOI, 4 percent of whom were women and 12 percent of whom were heterosexual men (CDC 1982f). Because of a shortage of funds, the results of the case-control study were not tabulated immediately (these were later published in August 1983, nearly 2 years after blood samples and interview data were collected (Jaffe, et al. 1983; Etheridge 1992; Hughes 1997). Dr. William Darrow, a sociologist, was sent out to southern California to study KSOI and the sociological

aspects of the disease. He linked 40 people in 10 cities by sexual contact and is credited with identifying the so-called “patient zero” (Etheridge 1992; Auerbach, et al. 1984; Shilts 1987).

As Table 2.2 below indicates, the disease we currently know as AIDS did not have an official name at first. Indeed, different groups referred to it in different ways. The CDC generally referred to it by reference to observed symptoms, for example lymphadenopathy (swollen glands) (CDC 1982a, CDC 1982b). It was sometimes referred to as KSOI, the name given to the CDC task force assigned to investigate the outbreak. Some still linked the disease to its initial occurrence in gay men, with a letter to the editor in *The Lancet* referring to it as "gay compromise syndrome" (Brennan and Durack 1981). Other scholars and writers referred to the syndrome as GRID (gay-related immune deficiency), AID (acquired immunodeficiency disease), "gay cancer" or "community-acquired immune dysfunction," and even early staging attempts with “AIDS-related complex” and “pre-AIDS” (Kanabus and Fredrickson 2006, Shilts 2004).

Table 2.2 – Definitions of AIDS and HIV infection, 1981-1993

Year(s)	Name(s)	Author(s)	Use
1981	Kaposi’s sarcoma and Opportunistic Infections (KSOI), lymphadenopathy, gay compromise syndrome, gay-related immune disease (GRID), AIDS-related Complex (ARC), Acquired Immune Deficiency (AID), pre-AIDS	CDC, Scholars, Media	Diagnosis, outbreak investigation
1982	Acquired Immune Deficiency Syndrome (AIDS), ARC	CDC	Diagnosis, outbreak investigation
1985	AIDS, ARC	CDC	Diagnosis, surveillance
1986	HTLV-III/LAV infection, AIDS, ARC	CDC	Diagnosis, surveillance
1987	AIDS, ARC, HIV Infection	CDC	Diagnosis, surveillance
1993	HIV disease (asymptomatic HIV infection, ARC, AIDS)	CDC	Surveillance only

According to Etheridge, “In quickly defining the epidemic in terms of lifestyle and linking it to homosexuals, the task force laid the groundwork for an extended debate on the

nature of the disease" (1992, 329). The CDC model encouraged others and CDC to define the disease in terms of "promiscuous" behavior, a term with heavy moral weight. Newspaper headlines featured phrases such as "homosexual disorder" and "gay cancer" (Altman 1982). The so-called "patient zero" was first identified by William Darrow, a sociologist and member of CDC's outbreak investigative team. Darrow identified a complex transmission scenario based on interviews about sexual networks with suffers. Patient zero, who by his own account had 250 partners a year, was identified as a gay Canadian flight attendant named Gaetan Dugas in the book *And the Band Played On* by Randy Shilts (Henry 1987, Shilts 1987). Darrow, now a professor of public health, has stated that his study's conclusions were misrepresented in Shilts' book and that it is a myth that Dugas was the first person to get the disease (Avert 2008). In fact, patient zero had been designated by Darrow as patient "O" for "Out of California." According to Darrow,

> There's a conventional wisdom that he started the whole epidemic, but that's not true…Nobody said he was the first case. You had a few people in L.A. who had AIDS. They didn't have sex together, but they had sex with this guy, so he was important. He linked it. That was the whole idea of social networks, which I happened to know about then and is now a big thing in disease control. (as quoted in Olson 2006)

Although we now know that HIV was spreading long before Dugas began to travel, he was nevertheless maligned as a 'mass spreader' of HIV and the original source of the epidemic among gay men until his death from AIDS in 1984 (Avert 2008).

Anthony Fauci of the NIH published the first public disclosure that KSOI would spread to other parts of the population (Fauci 1982). By 1982 there were reports of hemophiliacs, Haitians, intravenous drug users and women infected with the mysterious disease (CDC 1982a, CDC 1982b, CDC 1982c, CDC 1982d, CDC 1982e DCD 1982g, CDC 1982h). CDC described four risk factors for getting the disease: male homosexuality, intravenous drug use, Haitian

origin, and hemophilia A (CDC 1982g). Meanwhile, the first hemophiliac patients with *Pneumocystis carinii* pneumonia began to appear in south Florida (Etheridge 1992, 330). The reporting physician quickly linked these cases to Factor VIII, medication used to temporarily prevent or control bleeding episodes in patients with hemophilia. Factor VIII is made by combining plasma from multiple donors. CDC's expert on hemophilia notified the FDA, but did not think it was possible for Factor VIII to be spreading the disease (Etheridge 1992, 331).

Curran, who led the task force, organized a meeting where the FDA, the Gay Task Force, the Hemophilia Foundation, other governmental agencies, representatives from the pharmaceutical industry, and blood banks were present. The KSOI Task Force wanted to discourage possible carriers from donating blood. Hemophiliacs did not want to return to the primitive methods of testing pre-Factor VIII, blood banks feared a loss of good donors, and the FDA, the agency with authority to enforce regulations, was skeptical that the disease even existed. At this meeting in July 1982, the acronym AIDS, for Acquired Immunodeficiency Syndrome, was suggested as the official moniker for the ailment that had spread beyond the gay community (Etheridge 1992, Kanabus and Fredrickson 2006, Kher 2003). Once it was realized to be a blood-borne agent, members of the task force met with blood banks and tried to exclude high-risk donors. This was in constant tension with the always-low blood supply, however. In the end, plasma companies introduced screening for HIV before blood banks because blood banks were more concerned with maintaining ties with "good" donors while plasma companies were concerned about those who used their product (Healy 2006).

By August, the name AIDS was being used in newspapers and scientific journals, although it received its first official designation by the CDC in September (CDC 1982f). The name was more inclusive than KSOI and sexually neutral compared to GRID, which allowed it

to encompass reports of infections transmitted to women through heterosexual sex with men (CDC 1983). Despite this, no one outside of CDC wanted to hear about AIDS unless it was appearing in homosexuals, Haitians, hemophiliacs, and IV drug users (Etheridge 1992, 332). The task force, meanwhile, felt that the focus on these groups allowed non-CDC officials to ignore the problem. However, the task force's projection that children would begin to become infected came to fruition when the first child appeared with the disease in 1982. The epidemiological trends identified by the CDC task force were insufficient to support FDA recommendations that could stand up in court (the FDA's recommendations must stand up in court). At this time, the CDC was still dealing with increased scrutiny by the press over its weaknesses following the 1976 swine flu debacle. CDC staff were overly cautious, so all documents on AIDS were reviewed a number of times before publication and statements to the press were avoided (Etheridge 1992, 333-335).

In March 1983, the FDA, NIH, and CDC published guidelines to prevent the transmission of AIDS. By that time 1,200 cases had been reported from 34 states, District of Columbia, and 15 countries; 450 people had died. These commonsense guidelines were based on experience with Hepatitis B (CDC 1983a). Despite all this, the term AIDS was not mentioned in public by President Reagan until 1985. That same year, CDC discontinued its AIDS education programs because the administration felt this work was tantamount to giving lessons on anal intercourse (Bronner 2003). By then, at least one case of HIV/AIDS had been reported from each region of the world. There was growing public concern, political activism, and controversy surrounding the emerging epidemic.

Today, medical personnel commonly refer to "HIV infection" as "HIV disease." While having HIV disease does not necessarily mean a person has AIDS, everyone who meets the

definition of having AIDS necessarily has HIV disease and is infected with the HIV virus. AIDS is technically a syndrome, which is defined as a complex of symptoms that indicate an underlying abnormality or disease. A disease, on the other hand, is defined as, "a pathological condition of a body part, an organ, or a system resulting from various causes, such as infection, genetic defect, or environmental stress, and characterized by an identifiable group of signs or symptoms" (Houghton Mifflin 2002).

There have been two approaches to defining HIV infection: the epidemiological and the laboratory (Oppenheimer 1988, Oppenheimer 1992). The first prioritizes a grouping classification while the second frames the disease in terms of causal classification. Both approaches have been integrated into the U.S. government official definitions of the disease since its inception. Before laboratory tests were widely available, the 1987 definition identified cases in two ways: with a confirmatory lab test of HIV or, when a lab test was not possible, by symptoms alone. Further differentiation occurred in 1993 when T-cell count lab tests became commonly available. At that time, the case definition was revised to include three sub-classifications of the disease according to T-cell count: asymptomatic HIV infection with T-cells above 500, symptoms with a T-cell 200-499, or symptoms with T-cells below 200 (CDC 1992b).[7] The second sub-classification was widely known as AIDS-Related Complex (ARC). The use of the term ARC has dwindled since the availability of triple-drug therapy in the mid-1990s reduced the number of opportunistic infections. Although the epidemiological definition of AIDS has been the object of political activism, particularly by gay men who were stigmatized

[7] This differs from developing countries where the technology of such lab tests and treatments are not as commonly available. Thus the World Health Organization (WHO) case definition of the disease includes both causal and grouping classifications in a four stage classification (WHO 2006b). Laboratory tests also do not have as much primacy in definitions of HIV/AIDS in industrial countries such as Canada where only some opportunistic infections require a confirmatory HIV antibody test to count as a case of AIDS (Health Canada 2000).

by the disease at its outset, laboratory definitions of the disease have not been immune to political and social resistance.

The Centers for Disease Control and Prevention use US Census data to estimate prevalence rates for HIV and AIDS (CDC 2000). However, to count as an AIDS (without a positive serology) case one must have one of the opportunistic infections listed in the CDC case definition. Prior to the 1993 revision, studies showed that women diagnosed with AIDS die faster than men, not because they are more susceptible, but because they discover that they are HIV-infected later in the progression of the disease.[8] Gynecological manifestations of HIV/AIDS, such as severe pelvic inflammatory disease (PID) and vulvovaginal candidiasis, were excluded from the case definition, resulting not only in undercounts, but also in late or missed diagnosis (Levine and Stein 1991, Stoll 1992).

Part of the controversy in the early days of AIDS revolved around procedures for designating who counted as a case. The fact that women did not have equal access to all the resources for managing the disease was not because women known to have HIV were ignored; instead, the original paradigm through which policymakers, researchers, educators, and the media first understood the AIDS epidemic was grounded in a gendered conception of AIDS that led to an undercount of women with HIV (Patton 1990, 1994). Today we know that women are more susceptible to becoming infected with HIV during intercourse, are more likely to take care of loved ones and children infected because of social gender roles and norms, and have clinical manifestations and treatment requirements that differ from men. HIV is more easily transmitted from men to women than from women to men during heterosexual sex. Women also tend to carry the burden of child and elder care in families, are more economically dependent, and

[8] ACT UP asserted in ads and flyers, “Women don’t get AIDS. They just die from it” (Carter 1992).

experience more domestic violence and sexual coercion than men. Thus, women are more likely to exchange sex for money, less likely to negotiate safe sex, and have difficulty leaving abusive relationships (Farmer, et al. 2007; Gupta 2000). Finally, HIV/AIDS has clinical differences in women and men. Women tend to have lower viral loads and higher CD4 counts at similar stages of the disease, but experience faster progression to advanced HIV disease than men (HIV/AIDS Bureau 2005, Eaton 2005).

Women tend to have different clinical markers and opportunistic infections than men, experience more severe and different side effects to treatment, and have the added risk of transmitting HIV/AIDS to children during pregnancy, birth, and with breastfeeding. In fact, 80 percent of women with AIDS are of childbearing age (HIV/AIDS Bureau 2005). For these reasons, the primary care needs of women with HIV/AIDS are unique. They are also understudied since clinical trials often have difficulty recruiting female participants (Gupta 2000). Since HIV/AIDS cases were first defined by a series of conditions found in men, the unique ways that women were impacted was overlooked in the early years, causing late or missed diagnoses. Thus, women are currently highlighted as a category for policymakers, researchers, and the like at high profile conferences and research centers (Anderson 2004, National Institute of Allergy and Infectious Disease 2006).

Although previously case definitions were presumed to be diagnostic tools, in 1993 the CDC case definition explicitly stated that it is designed for surveillance purposes only and should not be used for diagnosis or as a standard of care (CDC 1992b). Despite this, the case definition is used for a number of auxiliary purposes including by the Social Security Administration (SSA) for determining disability and distributing benefits such as Medicare, Medicaid, Supplementary Security Income (SSI), and Social Security Disability Income (SSDI) (Levine and Stein 1991).

SSA has the authority to come up with its own definition of AIDS. The agency admits, however, that they adopted the CDC case definition for convenience (Levine and Stein 1991, Stoll 1992). In 1990, eleven plaintiffs who represented women, drug users, and poor people filed a class action lawsuit against Health and Human Services Secretary Louis Sullivan. They argued that they were denied SSI benefits even though they suffer from HIV-related illnesses. The AMA joined the case as *amicus curiae* on behalf of the plaintiffs.

Conclusion

As we have seen with the symptomotology of syphilis and AIDS, grouping classification can contribute to the counting of cases and to distinction of one disease from another. However, moral classifications of those deemed "innocent" influenced the grouping of symptoms in both the symptomological classification of syphilis and HIV/AIDS. With the symptomotology of syphilis and HIV/AIDS, we see that grouping classification is susceptible to moral classification because disease classifications bear the imprint of the group in which they are first identified, thus creating a path dependence for the evolution of further definitions, diagnostic and treatment technologies, etc. So, with HIV/AIDS, attention to gay men diminished attention to female-specific manifestations. Similarly, the grouping of differences in disease progression and dosing of antiretroviral medicines between pediatric and adult cases continues to be classified and misunderstood.

The comparison between syphilis and HIV/AIDS illustrates how grouping classification is greatly influenced by the social location in which a disease is first identified. Thus, we see how the availability of technology influenced the time that the symptomotology remained unsettled for syphilis, whereas with HIV/AIDS there was a heightened but compressed period where the symptomatology was unsettled (about 10 years compared to hundreds of years). This

is partly because of basic advances in science and technology (e.g., bacteriology, laboratory testing). However, a central difference between the symptomotology of syphilis and HIV/AIDS is that in the early days of syphilis, public health was not yet authorized to investigate and track outbreaks of disease. With syphilis, doctors were concerned with educating other doctors on diagnosing syphilis based on their own clinical experience in an era where the dissemination of information happened at a slow pace. By contrast, with HIV/AIDS a team of public health officers (including a sociologist) were deployed to collect and report groupings of symptoms in order to understand what was happening in a timely fashion. Importantly, these groupings were associated with particular groups of people (gay men, Haitians, etc.) so that some symptoms and some groups were both left out of early symptomotology. Grouping classification is closely related to causal classification since both types serve as starting points for social action, such as resource allocation and treatment. The following chapter discusses the development of etiological classifications for syphilis and AIDS, which also become taken for granted in the functioning of medical systems.

CHAPTER 3

THE CAUSE IS (IN) WHO?
FROM MASS SCREENINGS TO ROUTINE TESTING

Advances in laboratory technology and biomedical science enable the classification of diseases according to the presence or absence of a discrete causal agent even when a patient exhibits no symptoms. This type of classification creates a set of intellectual tools that facilitates the search for other causal links, sometimes aptly and sometimes incongruously. This chapter will attend to this etiological type of classification, which links a disease to causal agents such as a bacterium, a virus, a genetic defect, old age, an injury, exposure to a toxin, or something yet unknown. (For a summary of etiological classification, see row 2 of Table 1.2). Etiological classification is a foundational element to the social construction of medical problems because it forms the basis of diagnostic protocols, mass screening programs, and epidemiological surveillance and risk assessments. Like symptomotology, etiology is so basic that it can be obscured in the functioning of medical systems. Unlike symptomotology, as we will see, etiological classification is tied more closely to administrative forms of classification such as regulations about getting tested or reporting cases of a disease.

This chapter will illustrate how etiological classification became embedded in administrative systems as part of the institutionalization of public health activities such as epidemiology and mass testing programs. As we will see, moral classification plays an important role in how etiological classification is ultimately deployed in medical systems because in addition to the case itself, demographic and behavioral information is also collected, counted, and sorted in the creation of cases. Moreover, identification of etiological agents may be of little value if there are no treatments available to stop the disease from progressing in the

patient or at least rendering the patient noninfectious. Thus, this chapter will touch on the role that treatment technology plays in the extent to which etiological classification is deployed in counting and case-finding efforts in public health. Even more important, diagnostic tests designed to identify etiological agents may be difficult to implement, expensive, or inaccurate. Thus, symptomological classification remains important in medical practice even after etiological agents are classified. And although the grouping of symptoms is sometimes used in case definitions deployed by public health, symptomological classification alone was not sufficient to facilitate the rise of public health as a professional discipline in the twentieth century.

Although some trace the history of epidemiology back to Hippocrates, the nineteenth century discovery of the link between cholera and water in London is often cited as the beginning of public health as a profession and as a regulatory system (Brookmeyer 1996, Etheridge 1992). At that time, statistical methods coupled with a system to register sickness and death enabled William Farr and John Snow to link the cholera epidemic to water contamination, ultimately revealing the illegal operation of the East London Waterworks Company (Eyler 1979). This is an early example of the "epidemiological imagination," a particular way of working and thinking about disease and illness characterized by a concentration on human populations, quantitative analysis of gathered information, a strong applied purpose, and interdisciplinarity (Ashton 1994). As we will see, this way of thinking and working is distinct and sometimes in conflict with early twentieth century medical practice, which focused more on experience to make diagnostic and treatment decisions. Today, public health professionals are trained to use the epidemiological imagination with a multitude of technologies to identify public

health problems, assess risk, analyze cost and benefit, and design policies around etiological classification.

Etiological classification is crucial to conceptualizing syphilis and HIV/AIDS epidemiologically because both are communicable diseases with periods of latency when a patient experiences no symptoms and both involve chemotherapeutic treatments administered to some extent by patients themselves. Thus, identifying the disease without the presence of symptoms and tracking the effects of treatments are important to medical systems, both for controlling the unintentional spread of communicable diseases and for improving individual patient health. With syphilis and HIV/AIDS, these efforts evolved over time from identifying infected individuals through mass screening programs to tracing contacts to developing regulations and rules about case reporting and disease surveillance. Moral evaluations and the availability of technology contribute to the context of the classification activity and influence the way in which asymptomatic cases are identified, both in terms of what groups of people are targeted for screening and in refining knowledge about a disease's natural history. With syphilis testing, "dragnets" reinforced notions about the sexual promiscuity of African Americans in the rural South, while laws requiring syphilis tests before marriage focused on protecting "innocents" (e.g., wives, children). With AIDS, once HIV was discovered, investigations into the sexual networks of infected homosexuals overshadowed some of the other ways that HIV was being spread and the groups being affected (e.g., women, African Americans).

The origins of a particular disease cannot be investigated without its classification both in terms of the grouping of symptoms and in terms of identifying causal agents. It was challenging for medicine and public health to construct the correct causal story for syphilis because, like HIV, syphilis manifests in an astonishing variety of symptoms, making it difficult to trace a

causal agent. Even after bacteriology was mostly settled in medicine, syphilis patients were easily confused with those infected by gonorrhea and other venereal diseases. While the causal story for AIDS was constructed in just a few years, the "discovery" of HIV was influenced by the social construction of other diseases (e.g., cancer, Hepatitis B) in which the government and industry had invested in studying after the Second World War. A greater variety of stakeholders influenced how etiological classifications were deployed with AIDS than with syphilis because more scrutiny, mistrust, and hope surrounded science and medicine itself by patients awaiting a cure and payers awaiting the price tag. Moreover, homosexuality, although present during the syphilis case, was less culturally available as an administrative category to classify people for science and advocacy work as with the case of AIDS. With both cases, however, demographic categories such as race and gender played an important role in how the diseases have come to be constructed as medical problems.

Even after an etiological agent is identified, classifications derived from earlier symptomological accounts can become difficult to modify. For instance, it took several years after the discovery of HIV to include female-specific opportunistic infections to the CDC's case definition for AIDS. With syphilis, by contrast, there was little funding available to treat syphilitics with no ability to pay and so those patients were vulnerable to less costly investigations focused more on symptomotology or the natural history of the disease when untreated. In spite of this, the classification activity with syphilis helped to establish case reporting standards and a network of venereal disease clinics over the next several decades, enabling HIV/AIDS counting and case reporting to be created in contrast to established public health practice around sexually transmitted disease.

From pus to bacteria in syphilis: Determining cause and counting cases

As we saw in chapter two, syphilis was regarded as the "Great Imitator" and was the moniker under which many other ailments were mis-classified for hundreds of years. Even after nineteenth century germ theory, bacteriology, and technological improvements on the microscope enabled modern medicine to emerge (Foucault 1973, Reiser 1978), tracing a causal story for syphilis continued to be difficult. It wasn't until 1838 that Ricord conclusively differentiated syphilis from gonorrhea by demonstrating that the pus from syphilis chancres alone contained and transmitted syphilis (Clancy 1999). Ricord proved this "new doctrine" of venereal disease with a technique known as "autoinoculation" in which he took pus from a syphilitic chancre and introduced the microorganism to the same patient somewhere else on the body. A positive result was one that resulted in the reproduction of the same chancre, while a negative result produced nothing but perhaps a scar from the procedure. Although this method had been used previously, it had never been performed so systematically or on such a large scale (Ricord claimed to have performed around 2,500 experimental autoinoculations). He proved the unicists and physiologists wrong since he "materialized" the cause of syphilis and formed the "theory of duality," where syphilis and gonorrhea were shown to be distinct since pus from syphilitic chancres produced positive results and gonorrheal pus always produced negative results (Fleck 1979, Dracobly 2004). Despite this, many doctors continued to think that syphilis and gonorrhea were the same disease until Hutchinson's "Syphilis as Imitator" speech of 1879 (Hayden 2003, 33).

Before the availability of diagnostic tests to detect the presence of an etiological agent, syphilis cases were classified according to symptomotology alone. In the U.S., the first case of syphilis was recorded in 1646 (Parran 1937). During the Civil War, syphilis was estimated to

have an infection rate of 8.8 percent (Parran 1937). Although the sexual transmission of syphilis was understood by then, no etiological agent had been discovered and so only those with symptoms could be counted. Moreover, there were simply not many advances in treating syphilis until the introduction of iodide and potassium in 1834 (Parran 1937). Thus, efforts by medicine and public health focused on groups who, by treatment or education, were able to reduce infection rates in other groups important to the state such as the military or laborers.

As early as 1874, a speech delivered to the American Medical Association (AMA) advocated the medical inspection of prostitutes as well as treatment for those infected with syphilis and syphilis prevention education for the public (Parran 1937). In 1876, one physician proposed that syphilis control be the responsibility of already existing state boards of health, which had gained authority during national efforts to control the spread of contagious diseases such as smallpox, cholera, and yellow fever (Parran 1937). This suggestion was not taken seriously until the AMA created a Committee on Prophylaxis of Venereal Disease in 1903. The committee reported that "While other contagious diseases were controlled or combated by boards of health with great vigor and excellent results, venereal diseases are ignored by our sanitary authorities, and the morbidity therefrom is consequently not a matter of record; *officially, there are no venereal diseases in the United States*…" (Parran 1937, 79). Parran contended that not only was there a longstanding *fear of talking* about syphilis because of its association with deviance, but there was also a *fear of counting* syphilis itself (1937, 53). Of course, there are difficulties with counting when symptomological classification systems are unsettled and etiological classification is absent. As Parran notes, the duration of a case was not obvious at that time because "there is no sharply defined end point representing assured cure" (1937, 53).

The breakthrough for the etiological classification of syphilis came in 1905 when two German microbiologists, Eric Hoffman and Fritz Schaudinn, isolated the bacterium that causes syphilis, which they called *Spirochaeta pallida* (Jones 1993, Parran 1937).[1] Then, in 1907, the Wasserman test was developed, enabling physicians to diagnose clinically obscure and latent cases of syphilis as well as to track how well treatment diminished the presence of the causal agent itself (Jones 1993, Parran 1937). That same year, Paul Erlich discovered the first effective treatment for syphilis, an arsenic compound called Salvarsan. Erlich's discovery introduced chemotherapy as a new paradigm in medicine and won him a Nobel Prize (Strebhardt and Ullrich 2008). (See chapter 4 for an analysis of how treatments become objects of financial classification through standardization.) However, Erlich's "magic bullet" for treating syphilis disappointed many when it was found to cause considerable side effects including fatal arsenic poisoning (Brandt 1985, Morabia and Zhang 2004, Parran 1937). During this time, about 5.6 percent of soldiers in the army showed symptomatic evidence of some kind of venereal disease upon enlistment, but most of the rank and file were never diagnosed because, although the serological test was available, side effects of treatment would have jeopardized the army's functioning (Morabia and Zhang 2004).

[1] Although debated until just recently, the dominant account of the origin of syphilis suggests that the first Old World syphilis epidemic occurred in the late 15th century Europe after being brought back from the Americas by Christopher Columbus and his crew (Gould 2000, Rose 1997). An alternative account contends that syphilis existed in Europe for centuries and happened to mutate into a dangerous form just as ships were arriving back from the New World (Poirier 1995). Such a mutation would have had to occur in one of two ways according to this theory: either syphilis existed in Europe for centuries but was confused with other diseases until urbanization, social turmoil, and promiscuity created the conditions for a more virulent form of syphilis to emerge or syphilis evolved into a sexually transmitted disease from another related disease, such as yaws, in order to survive in a nontropical climate (Clancy 1999). The New World origin position gained prominence with the completion of the genome sequencing for syphilis in 1998 (Fraser, et al. 1998). It was further confirmed with the discovery of syphilitic bones on the island of Hispanola where Columbus and his men stayed (Rothschild, et al. 2000). The only skeletal evidence of pre-Columbian syphilis in Europe is more likely to be from yaws, a disease whose bacterial cause is also spirochetal in shape (Rose 1997, Hayden 2003). Recent evidence suggests that an original treponemal disease spread from Africa through Asia, entering North America and mutating into syphilis approximately 8 millennia later (Rothschild 2005).

The Wasserman test used to serodiagnose syphilis was not a simple procedure. It is based on "fixation of complement," a biologic reaction discovered separately from syphilis in 1901. The test required five elements to perform: non-syphilitic human or animal serum, the patient's serum to be tested, and extract of beef heart, rabbit serum, and sheep serum. Even after the original Wasserman test had been improved upon and used in practice for over twenty years, it was described as "the bane of medical students" because of its complexity (Parran 1937, 9). It took two hours to administer and involved taking a sample of blood or cerebrospinal fluid and introducing the antigen, usually a bovine muscle or heart extract containing cardiolipin (Time Magazine 1962).[2] A positive reaction included an increase in anti-cardiolipid antibodies, the intensity of which was rated on a severity scale of one to four. Anti-cardiolipin antibodies can also increase in a variety of other conditions, including malaria and tuberculosis, so the test is not specific. The technically complex Wasserman test had other shortcomings in specificity, including false positive results and false negative results, with nearly one-third of patients with positive spinal fluid having negative blood tests (Parran 1937, 18). Moreover, although it was often used to track the progress of treatment, the test sometimes only became positive after mercurial treatment (Osborne 1921, 344). Despite these shortcomings, the Wasserman test was heralded as a major advance in the detection of syphilis and was deployed as part of mass screenings efforts beginning in the 1910s (CDC 1999a).

During the early twentieth century there was a decline in government attention to venereal disease and renewed focus on moral uplift rather than medical means to prevent

[2] Cardiolipin is a diphosphatidyl glycerol that is found in the membrane of Treponema pallidum. It is the antigen, or the protein molecule that can induce an immune response, detected by the Wasserman test for syphilis (Center for Cancer Education 2007). Today, cardiolipin antibody is measured to help determine the cause of recurrent miscarriage or infertility, frequent blood clots, and to determine risk complications from blood clotting in lupus patients (Harris, et al. 1987). The test has also been used alongside differential diagnosis of symptoms, including arterial and venous thrombosis, neuropsychiatric disorders, thrombocytopenia, and fetal wastage to diagnose cardiolipin syndrome in HIV-positive patients (Cone, et al. 1996).

transmission (Brandt 1985). Once the syphilis test was refined and treatments were more available in the 1930s, screenings for syphilis began en masse. Such mass screenings were known as "Wasserman dragnets" (Parran 1937, 163), modeled after mass screenings performed in Denmark, and were executed by the U.S. Public Health Service (USPHS) in cooperation with local governmental agencies and philanthropic organizations. In 1929, the Surgeon General asked the Rosenwald Fund to financially support a Wasserman dragnet targeting poor, rural blacks in the Southeastern United States. With a history of philanthropic work with African Americans dating back to its support of Booker T. Washington at the turn of the century, the Rosenwald Fund agreed to help the USPHS develop health programs for Southern African Americans in six counties beginning in 1930. Of these, Macon County, Alabama was described by Parran as "the most primitive of the counties studied and the most poverty ridden" (1937, 164). As we will see, the project was intertwined with a moral evaluation of those black Southerners.

In *Shadow on the Land*, Parran describes the project as a "study of syphilis and a demonstration of treatment among the Negroes" in a chapter titled, "White Man's Burden" (1937, 160-181). Parran described syphilis as "the white man's disease" both because it was whites who brought the disease to non-whites and because whites were best positioned economically and had gained the trust of the affected by controlling typhoid fever, malaria, and pellagra (1937, 160-166). Public health officials chose not to teach the patients the correct medical term for the disease and chose to refer to syphilis as "bad blood" instead. While "bad blood" was a familiar term to blacks in the rural South, it meant different things to different people and more often than not was a generic phrase that referred to an array of ailments (Jones 1993, 71). Despite hiring as many African American professionals to work for the states' local

health departments while USPHS provided coordinators, the project depended on support from the influential white community (Jones 1993). It was promoted as such at meetings with white plantation owners and community leaders, one of whom responded, "Tell those niggers the health doctor will be at the Possom Hollow school tonight. He's got some medicine to cure the blood disease" (as quoted in Parran 1937, 166). Moreover, Parran understood that "the Negro instinctively trusts the white man," particularly the "government health doctor" as well as local African American leaders such as preachers, school teachers, and "the occasional doctor" (1937, 165). However, blacks in Macon County at this time were so poor that they suffered from a variety of illnesses. Since they attributed "bad blood" to many of these, they thought they were being tested and treated for whatever ailed them (Jones 1993, 73). Given the lack of specificity of the test itself, false positives and negatives only sustained the local definition of "bad blood" as a catchall for many illnesses.

Under the Rosenwald demonstration project, treatment for positives was designed to render infectious patients noninfectious since curative treatment was too costly (Jones 1993, 57). The treatment goal for patients in one arm of the study was twenty-five injections of arsphenamine (an arsenic compound also known as salvarsan or 606) and about 200 skin rubs with mercury ointments which necessitated at least thirty-four weeks or nearly eight months of treatment (Parran 1937; Jones 1993, 57). Arsphenamine, a yellow powder, was administered to patients either intraspinally or intravenously, but was prepared (as with the Wasserman test) using the patient's own serum. According to Oliver Osborne, author of *Principles of Therapeutics*,

> It has been considered best to give arsphenarninized serum intraspinally. This is prepared from the blood of the patient as follows: the arsphenamine is given as usual, intravenously; an hour later 40 mils of the blood is withdrawn from a vein; this blood is allowed to clot and is placed on ice for twenty-four hours; the serum exuded from the clot

> is then centrifuged, and 12 mils of this upper centrifuged serum is added to 18 mils of sterile physiologic salt solution; this diluted serum is then heated to body temperature, and, after an equal amount of spinal fluid is withdrawn, is injected intraspinally; the patient is then placed in the Trendelenberg position,[3] to allow the fluid to gravitate toward the brain. (1921, 348)

Treatments such as these produced severe side effects such as fever over 100 degrees, vomiting, dizziness, edema, cyanosis, circulatory depression, inflammation of the auditory and optic nerves, inflammation of the peripheral nervous system (neuritis), albumin in the urine (a sign of kidney problems), and chronic arsenic poisoning (Osborne 1921, 348). Before patients were allowed to leave the clinic, their spinal fluid was tested for the presence of syphilis as a precaution against later nervous complications (Parran 1937, 234). Arsphenamine also had a strong acid reaction in water that if injected into a patient could endanger his or her life. Thus, care had to be taken to ensure proper preparation, including insurance that "an alkaline solution, fifteen per cent sodium hydroxide, is to be on hand for the doctor's use" (Goodman 1919, 200).

Mercury could be administered to patients through intramuscular injections alongside arsphenamine treatment. One expert at the time advised five or six intravenous injections of arsphenamine about once a week and twenty to thirty intramuscular injections of soluble mercury either daily or every other day. After this course, the patient would rest for six weeks and then repeat the course regardless of a negative Wasserman test (Osborne 1921, 345). Mercury shots were extremely painful and not well tolerated by patients, however. Thus, many doctors preferred the "old" mercury treatment in the form of ointment rubbed on the skin daily or every other day. Since the ill effects of mercury were widely known, doctors instructed syphilitic patients to rub mercury on one another, realizing that no fee could compensate for the harmful effects mercury might have on themselves (Magner 1992, 179). Because of this danger,

[3] A person in the Trendelenberg position lies supine with their head slightly lower than their feet.

the Rosenwald Wasserman dragnet had to figure out the best method of administering mercury to those testing positive.

Parran recounted that intramuscular injections in the buttocks were ruled out as a treatment because they caused painful lumps at the site of injection, which "the Negro particularly dislikes" (1937, 168). Since "rural Negroes wear no shoes," ointment in the sock was also ruled out. Parran noted that in the past, sailors rubbed mercury on one another while sitting in a circle and the project considered modeling this with the Rosenwald demonstration as follows:

> Get them together in church, sitting in a circle, have the pastor lead them in a spiritual, keeping time to the up-and-down and round-and-round rubbing of mercury ointment into the backs. This was tried, but with indifferent success; partly, someone said, because the pastor thought he didn't get rubbed hard enough. (1937, 168)

Ultimately, the method selected was for the doctor to instruct patients on how to self-administer mercury ointment on a rubber and canvas belt as follows: "Take this package of salve, cut it into six pieces. Every morning, smear one piece on the belt; like this. Tie the belt tightly around your waist; on the seventh day, wash yourself thoroughly and meet me here" (Parran 1937, 168). Since the doctors were not be able to oversee the application of the ointment, Parran noted that the belts were "endowed by the doctor, it is true, with all the white magic of health and strength-giving qualities his tongue could contrive" (1937, 168).

On average, 8.4 intravenous injections of arsphenamine and 72.6 mercury rubs were administered per patient as part of the demonstration project, which was less than forty percent of the treatment goal. Despite this, Parran wrote, "This is as good a record as one sees in the average public health clinic or hospital dispensary. It is not good enough, but even so, many infectious cases were eliminated and many person-to-person epidemics stopped" (Parran 1937, 172). The cost of these demonstration projects, including testing for positives, was $8.60 per

case (or roughly $93.72 in 2005 dollars).[4] However, the Rosenwald Fund policy required states to pay at least part of the salary of key personnel. With rates of infection ranging from 8.9 percent in Virginia to nearly 40 percent in the deep south of Macon County (1937, 169-170), treating all the cases was an expensive endeavor. Parran argued that syphilis if left untreated doubled the number of unemployed. He wrote, "If the Government were to take one fifty-second of the annual average wage, one week's pay, and spend it in finding and treating syphilis, the results would more than pay for the cost in better labor efficiency" (Parran 1937).[5] However, the cure rate with treatment was found to be less than 30 percent since the regimen was lengthy and had side effects so toxic they could be fatal (CDC 2005c). Ultimately, the Rosenwald demonstration was determined to be not viable and the high prevalence of syphilis, coupled with the economic depression which began with the Wall Street crash in 1929, made treating all cases too costly and the Rosenwald Fund discontinued its funding for the demonstrations in 1931.

The following year, Dr. Raymond Vondelehr pursued a follow-up study of men in Macon County, Alabama, one of the original demonstration sites (CDC 2005c). The study began as a limited continuation of the demonstration, with Vondelehr and Assistant Surgeon General Taliaferro Clark garnering resources from the USPHS and clinics local to Macon County, most notably from Tuskegee Institute Hospital. In a letter to Clark, O.C. Wenger notified him of Tuskegee's support for the demonstration,

> Doctor Dibble stated that he would be very glad to have his interns and nurses give these treatments under Doctor Vondelehr's supervision. Doctor Dibble further proposes to offer Doctor Vondelehr an office and examination room in his outpatient clinic for these examinations. I might say that these examination rooms are ideally located and equipped for this work. Doctor Dibble suggested that his operating room be used for the spinal punctures where they could be done under operating room technique to avoid any possible spinal infections. Just across the hall from the operating room is a male ward

[4] Calculation based on formula provide by http://www.waynesthisandthat.com/cost.htm and http://www.dollartimes.com/calculators/inflation.htm

[5] Parallel cost-benefit analyses have been done for HIV/AIDS. See, for example, Holtgrave 2004b.

> where the patients could rest if necessary or even remain over night if the reaction is very severe.[6]

The letter further offers x-ray equipment, technicians, a roentgenologist (i.e., radiologist), and even some free neoarsphenamine[7] if finances permit. The letter also discusses the need to examine patients' eyes to detect neurosyphilis. While a subsequent letter to Clark from Wenger outlines an emergency requisition for drugs to treat syphilitic patients in Macon County, he offered cost-saving treatment ideas such as substituting calomel tablets[8] in place of mercury pills.[9]

By the close of 1932, mentions of treating syphilitic patients wane in correspondence among Clark, Vondelehr, and others. In its place is discussion of which categories of cases to include in the special studies of untreated syphilis.[10] Vondelehr became particularly excited about seeing pathology attributable to syphilis. About one case of syphilitic involvement of the cardiovascular system, he wrote to Clark, "I call this my prize case but unfortunately Doctor Meyer was in the field and [did] not see it."[11] The uncovering of so much pathology encouraged

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[6] Wenger, O.C. Letter to Taliaferro Clark dated September 16, 1932. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[7] Neoarsphenamine, also known as "new arsphenamine" or 914 was a modification of arsphenamine available in 1912. Neoarsphenamine was more easily tolerated by patients and was easier to prepare than "old arsphenamine." However, dosing was different for neoarsphenamine and care had to be taken to avoid warm or hot water when preparing the compound for injection (Goodman 1919).

[8] Calomel, or mercurous chloride, was used in medicine since the early sixteenth century. It was sometimes administered like mercury in the treatment of syphilis.

[9] Wenger, O.C. Letter to Taliaferro Clark dated September 29, 1932. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[10] Clark, Taliferro. Letter to R. Vonderlehr dated November 30, 1932 and Vonderlehr, R. Letter to Taliferro dated December 5, 1932. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[11] Vonderlehr, R. Letter to Taliferro Clark dated December 8, 1932. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

the belief both that the cardiovascular system was a particular vulnerability for blacks[12] and that the observations of untreated syphilis would "attract world wide attention."[13] Thus, the researchers were eager to attract the attention of syphiologists by contributing to the definition of syphilis. However, they were just as eager to avoid the attention of others, particularly the community to which the untreated men belonged. At the start of 1933, the cost of spinal punctures (where serum was collected in order to detect neurosyphilis) and hospitalizations began to be felt. The offering of treatment to patients needed to continue, as Clark noted to Vondelehr, "in order to minimize the amount of attention that will be given to this activity by the people of the community."[14] The activity in question was identifying black men with syphilis who had not been treated as part of the demonstration project begun just a few years earlier. Indeed, Clark later wrote to Vondelehr, "I find your report of March 6th quite interesting but regret the necessity for Wassermanning and treating such a large number of individuals in order to uncover this relatively limited number of untreated cases."[15] Both diagnosis and treatment of syphilis required the collection of serum and serum was collected throughout the study, sometimes at a an average rate of 909 Wasserman tests per month for the purpose of case finding

[12] Clark, Taliferro. Letter to J. E. Moore dated December 20, 1932. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).
[13] Clark, Taliferro. Letter to H. H. Davis. dated October 29, 1932. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).
[14] Clark, Taliferro. Letter to R. Vonderlehr dated January 16, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).
[15] Clark, Taliferro. Letter to R. Vonderlehr dated March 9, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

only. In Macon County alone,[16] despite only 11 percent of those identified as cases for Vondelehr's study of untreated syphilis, 4 percent of these defaulted from the study.[17]

The collection of human serum as part of diagnosis and study examination continued to reveal high rates of cardiovascular syphilis to Vonderlehr. Clark became concerned that this was perhaps due to some bias in case selection,[18] but was improbably reassured by the assumption that the cases in question were Negroes and so "the incidence of cardiovascular syphilis under any circumstances is several times that in whites."[19] Meanwhile, a classification system was proposed for identifying syphilitic aortitis in prospective cases and by the summer of 1933 continuation of the observational study was being pursued by Vondelehr.

It is at this point that the Tuskegee study took its "fateful turn" toward a long-term study that hired a full time nurse, distributed placebo treatments, recruited controls, and offered burial benefits in exchange for autopsies. Vondelehr became convinced that the study's aim should be to follow cases into post-mortem examination, which would require long-term staffing and

[16] A "Macon County Study" report specifies that 1,423 total individuals were given a primary Wasserman in October and November 1932, 512 in December 1932, 993 in January 1933, and 659 in February 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[17] A "Macon County Study" report specifies that 412 of the 3,587 primary Wassermans were "cases uncovered for untreated syphilis study between October 1932 and February 1933. Of these, 18 defaulted from the study. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[18] Clark, Taliferro. Letter to J. E. Moore dated April 19, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[19] Moore, J.E. Letter to Taliferro Clark dated April 21, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

coordination with the USPHS and state and local health departments.[20] Because the USPHS was understaffed he suggested two alternatives:

> As I see it, we have no further interest in these patients until they die. To secure the post-mortems two plans present themselves. When these patients die, some of the dozen or more physicians in Macon County must sign a death certificate, which goes to the County Health Office, Doctor Murray Smith. Doctor Smith could then notify Doctor Dibble who could make arrangements for the post-mortem. Or, thru the cooperation of Doctor Dibble, we could arrange with the doctors in Macon County to turn over to Doctor Dibble any of our demonstration cases applying to them for treatment…There is one danger in the latter plan and that is if the colored population become aware that accepting free hospital care means a post-mortem, every darkey will leave Macon County and it will hurt Dibble's hospital. This can be prevented, however, if the doctors of Macon County are brought into our confidence and requested to be very careful not to let the objective of the plan be known.[21]

And so it was that Vondelehr began contacting local physicians asking for their cooperation in reporting deaths to the study as well as offering placebos as treatments and garnering burial incentives, all the while keeping secret the intention to bring patients to autopsy.[22]

At first glance it appears that enthusiasm for defining cardiovascular syphilis was a driving force behind continuation of the study despite it being conducted in an atmosphere of few resources and with little attention to either research ethics or research design. Although the treatment program was gradually transformed into an observational study as funds for treatment dried up, the deception and focus on race are clues that those involved understood their study not to be ethically acceptable. Moreover, Vondelehr contacted the cardiovascular experts at the American Heart Association (AHA) in order to get their opinion on "the feasibility of more

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[20] Vonderlehr, R. Letter to E.H. Dibble dated July 18, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[21] Wenger, O.C. Letter to R. Vonderlehr dated July 21, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[22] Vonderlehr, R. Letter to M. Smith dated July 27, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

accurately classifying the cardiovascular disease in these cases along etiologic lines."[23] Here is the "arbitrary" classification used by Vondelehr to separate normal from abnormal findings about patients' hearts and aortas in the study:

(1) A heart which was enlarged, as ascertained by methods of percussion and palpitation, more than 10 cm. to the left of the mid-sternal line was considered abnormal; a measurement of 10 cm. or less was considered normal. The extension of the cardiac area of dullness or the cardiac impulse to the sixth interspace was considered as an evidence of abnormality.

(2) The borderline of abnormality in determining the retro-manubrial dullness between the two intercostals spaces was placed at 5 cm.; a difference of .5 cm. has been accepted as being definitely positive.

(3) The aortic second sound, even though only slightly accentuated, has been considered abnormal.

(4) The greatest problem lies in the interpretation of the relationship of hypertension as an etiologic factor in these cases. The normal for systolic pressure has been taken as 120 (or less) plus the age of the patient; this, naturally, in a number of instances exceeds the 140 mm. of mercury for systolic pressure as recorded in the "Criteria for the Classification of and Diagnosis of Heart Diseases". Such an allowance has been made because it is felt that, for example, a systolic pressure in a 38 year old patient should be considered normal even of it exceeds 140; according to our scale any figure less than 159 mm. of mercury would be considered normal for the individual.

(5) In patients under 45 years of age there are a number who have slight or moderate sclerosis of the temporal and brachial arteries. Should positive findings in cases of this type be assigned to syphilis or is the hypertensive factor of primary importance?[24]

Responding as to whether such a classification is proper, H. M. Marvin from the AHA responded, "If you will allow me to express a purely personal opinion, I will say quite frankly that conclusions based upon the observations indicated in your letter would be regarded by me as of very little if any value."[25] He critiqued each of the five in turn as follows:

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[23] Vonderlehr, R. Letter to H.S. Cumming dated July 29, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[24] Vonderlehr, R. Letter to S. R. Roberts dated July 29, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[25] Marvin, H.M. Letter to R. Vonderlehr dated August 2, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

(1) Percussion is notoriously unsatisfactory in determining the size of the heart; moreover, it is surely unsafe to adopt an arbitrary figure of 10 cm. as the upper limit if normal, in view of the known fact that normal hearts vary within wide limits in relation to the stature of the individual.
(2) I seriously doubt if 5 cm. represents the upper limit of normal with respect to the width of the supracardiac vessels, and I am positive that I would never accept an increase of 0.5 cm. in this measurement as indicating abnormality, even if shown by seven foot x-ray films. If this measurement is made by percussion, I believe it to be utterly worthless.
(3) The detection of changes in the aortic second sound involve a very large personal equation, and slight accentuation by itself could scarcely be accepted as evidence of luetic aortitis.
(4) Unless the blood pressure is taken repeatedly and with the subject at rest for some time, moderate variations from the accepted normal limits can scarcely be regarded as important.
(5) I believe it to the consensus of opinion among the most competent observers that syphilis has little or no relationship to arteriosclerosis of the peripheral vessels.[26]

Despite all these "personal objections" to Vondelehr's classifications of cardiovascular syphilis, Marvin assured him that his request would be sent to different men and at least one standing committee at AHA. In a letter of reply to Dr. Marvin, Vondelehr wrote, "I have no doubt that a considerable percentage of the individuals included in this study have some form of cardiovascular disease. As I see it, the difficulty, however, lies in the etiological classification of this form of involvement and, while I realize that the entire subject is open to discussion, I would like to have the most accurate information obtainable. This is my reason for asking the views of the American Heart Association."[27]

Vondelehr also contacted experts in syphilology and cardiology to get their opinion on his findings that syphilitic involvement of the cardiovascular system is the most common among

[26] Marvin, H.M. Letter to R. Vonderlehr dated August 2, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).
[27] Vonderlehr, R. Letter to H.M. Marvin dated August 5, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

the Macon County population.[28] In a memo summarizing a conference with one Dr. R. W. Scott, Vondelehr wrote,

> He agreed that the teleroentgenolographic (x-ray) evidence and clinical manifestations of syphilitic aortitis could not be correlated in the study of untreated syphilis among Negroes because of the great multiplicity of findings in cases of early cardiovascular syphilis…Although hypertension or arteriosclerosis may to some degree be due to the syphilitic process, this disease is by no means productive of all hypertension and arteriosclerosis and it would be erroneous to assume that this is the case even when every individual in the study is known to have a positive serological test for syphilis.[29]

Other experts agreed that correlating clinical manifestations with x-ray evidence was difficult and perhaps impossible especially in its early stages.[30] Vondelehr found a variety of evidence for syphilitic involvement of the cardiovascular system, including aneurisms, aortitis, and aortic regurgitation. The total cases in the study were 407 syphilis patients, of which 148 had to be eliminated because of hypertension or peripheral arteriosclerosis, 145 showed "some evidence" of uncomplicated syphilitic aortitis, and 29 had definite evidence of cardiovascular syphilitic pathology. Five of these had "certain" aneurisms evidenced by both x-ray and clinical manifestations, while those classified as "probable" or "possible" aneurisms were categorized as uncertain.[31]

In November of 1933, Vondelehr received a report from the Reference Committee to the Executive Committee of the AHA responding to his request for assessing the accuracy of his classification of cardiovascular syphilis along etiological lines. The AHA concurred with

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[28] Vonderlehr, R. Letters to P. O'Leary dated August 15, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[29] Vonderlehr, R. Memo dated September 21, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[30] Vonderlehr, R. Memo dated September 21, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[31] Vonderlehr, R. Letter to J. J. Peters dated September 22, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

Marvin and even elaborated some of his objections, stating in the report: "It was the consensus of opinion of the majority of the Committee that syphilis has little or no relationship to arteriosclerosis of the peripheral vessels."[32] In reply Vondelehr wrote to thank Dr. Marvin and members of the Committee and informed them that a control group was being studied in identical fashion to the group studied the previous winter: "This control group is presumably, at least so far as is possible to determine by clinical means, nonsyphilitic and it is hoped that a proper comparison will be permitted which will eliminate the nonsyphilitic processes in our study."[33] The number of controls needed and how to recruit them was also a subject of various correspondence between Vondelehr and others during this time. Despite Vonderlehr's insistence that the high incidence of cardiovascular disease he observed was due to syphilis, published accounts avoided stating this specifically (Vonderlehr, et al. 1936). Rather, assuming that blacks were syphilitic, they inferred that the cardiac pathology they observed must be syphilitic in nature. In reality there was no correlation between the clinical and pathological diagnoses of aortitis and syphilis (Roy 1995).

Tuskegee subjects were considered the most syphilitic patients in the U.S. According to Roy (1995), the Tuskegee study did not attend to any questions of basic science or pathogenesis of syphilis, but instead used the subjects as a natural resource of disease in order to maintain the United States dominance in the biotechnology industry. At this time, syphilis could not be manufactured in serum either in the lab or in animals. Furthermore, the market for syphilis serodiagnosis was considerable since it was the cornerstone of syphilis control programs around

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[32] American Heart Association. "Report of the Reference Committee to the Executive Committee of the American Heart Association" dated October 10, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

[33] Vonderlehr, R. Letter to H.M. Marvin dated November 18, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

the world. Syphilis testing rose worldwide from 2 million tests per year in 1936 to 28 million tests worldwide in 1943 and stabilized at 12 million tests per year worldwide into the 1960s. The domestic market alone could be counted on with the passing of laws requiring testing prior to marriage, for newborns, military recruits, hospital admission, and industry physical exams (Roy 1995, 313). For instance, in 1943, Alabama passed a unique law mandating that every citizen between the ages of 14 and 50 take a Wasserman-like test, but mass testing did not begin until 1945 (Time Magazine 1945). Tuskegee sera were used to help develop standards and regulating laboratories for such nonresearch purposes. To camouflage the true purpose of the project, Roy argues that the USPHS made a distinction between direct clinical studies and indirect studies of tissue and body fluids. According to Roy (1995), from 1932 until the 1970s, the Tuskegee study made it possible for the U.S. to overtake Germany in syphilis technological innovation, which contributed to economic domination in the biotechnology industry as well international dominance with superior positioning in the World Health Organization (WHO).

Tuskegee was crucial in developing standards for diagnosing syphilis and regulating the labs that processed the tests because alongside the misguided investigation of cardiac manifestations of syphilis, the study collected sera from patients that were used to improve diagnostic technology for use in future screening efforts (Roy 1995, Washington 2007). The Venereal Disease Branch of USPHS itself acknowledged that the sera of the infected Tuskegee subjects was used to develop more reliable tests for syphilis, including the Venereal Disease Research Laboratory (VDRL) test invented in 1946 (Harris, et al. 1946) and the fluorescent treponemal antibody absorbed (FTA-ABS) test first used in 1957 (Bos 2008). In 1970, Dr. James B. Lucas, of the PHS Venereal Disease branch, admitted, "Probably the greatest contribution that the Tuskegee Study has made and can continue to provide has been documented

sera for study in our laboratory ... In a great measure the development and our endorsement of the FTA-ABS test rested on Tuskegee sera" (as quoted in Washington 2007, 177-178). Thus, as a complex causal system was being worked out, people focused on that causal agent as the basis of all sorts of other activity. Indeed, mass screening enabled refinement of diagnostic testing itself because a lot of human sera was needed to test the efficacy of new technology. In 1962, the Rapid Plasma Reagin (RPR) became available, and other tests based on monoclonal antibodies and immunofluorescence are used in place of the Wassermann test today because they are simpler, faster, and more specific.

The deployment of these tests and the collection of sera during Tuskegee is linked to the moral evaluation of people through a racial lens. Officers in the Venereal Disease (VD) unit at the USPHS unit had strong ties to the eugenics movement, including those involved with the Tuskegee Syphilis Study in the 1930s (Lombardo and Dorr 2006). Indeed, Clark first established a working relationship with the Rosenwald Fund, which supported the demonstration projects preceding the study, by conducting a eugenic survey in Indiana in 1916. Here he conducted anthropomorphic measurements of children linking them to race and ethnic background (Lombardo and Dorr 2006, 311). Subsequently he was involved in the enforcement of eugenic immigration policy and eugenic theory about venereal disease among blacks. Clark directed the VD branch of the USPHS beginning in 1930 and was a crucial force in establishing the Tuskegee study and in selecting Vonderlehr to be involved. It was Vonderlehr who stressed the increased prevalence of cardiovascular syphilis among blacks despite doubt from independent cardiologists (Lombardo and Dorr 2006, 312). Indeed, during the study, Clark wrote in a letter to Moore,

> We have not yet commenced the spinal punctures. This operation will be deferred to the last in order not to unduly disturb our field work by any adverse reports by patients subjected to spinal puncture because of some disagreeable sensations following this

> procedure. These negroes are very ignorant and easily influenced by things that would be of minor significance in a more intelligent group.[34]

The collection of diseased sera reinforced the notion that blacks were saturated with syphilis due to diminished intelligence and moral standards.

Prostitutes were also seen as carriers of the disease who, by infecting soldiers (at that time, primarily white), caused the infection of the soldiers' innocent wives and children. In May 1940, a formal agreement was made by the War and Navy Departments, Federal Security Agency, and State Health Departments for controlling venereal disease in areas where armed forces and national defense employees are concentrated. With the persistence of the American Social Hygiene Association (ASHA), this agreement was formalized into the July 1940 Act passed by Congress which made prostitution a federal offense in those areas in which it was invoked. However, in their 1941 report, "Plain Words About Venereal Disease," Parran and Vonderlehr criticized the Army for not invoking the procedures set forth by the War Department to repress commercial prostitution in cooperation with state and local health agencies (Armfield 1963).

Unlike the Rosenwald demonstration project and the Alabama mass testing law, mandatory testing before marriage did not capture as many syphilis cases as first predicted (Brandt 1988a). Other scholarship illustrates that marriage screening laws and anti-vice regulationswhich focused on protecting innocent whites were intimately connected to the formation of racial distinctions (Donovan 2003, Polsky 2002). Thus, grouping, causal, administrative, and moral modes of classification helped to construct a definition of syphilis as an unhygienic ailment caused by ignorance, inferiority, and deviance that was explicitly linked to

[34] Clark, T. Letter to Moore dated March 25, 1933. Tuskegee Syphilis Study Administrative Records, 1929 – 1972; Records of the Centers for Disease Control and Prevention, 1921 – 2002, Record Group 442 (RG 442); National Archives and Records Administration--Southeast Region (Atlanta).

race. Ultimately, this social construction helped to bolster U.S. industrial interests and public health practices developed by the venereal disease branch of the USPHS itself. As diagnostic technology advanced and administrative modes of classification were institutionalized, public health was preoccupied with counting and tallying in order to predict how outbreaks might occur. Thus it was in this context that HIV/AIDS emerged. As we will see in the next section, medical problems continue to be socially constructed through the lens of morality and race in the U.S. and sustained through public health initiatives that group those with HIV/AIDS according to risk.

From cancer to virus: Determining risk and counting cases

As we have seen, the institutionalization of public health practice in the U.S. begam through law at the beginning of the twentieth century and, at first, much of the work was aimed at moral reform and the establishment of public health as an authorized actor in the field of medicine, particularly through the early development of administrative routines associated with disease surveillance and mass testing. (Chapter 4 will discuss how organizational fields of safety net care are linked to these efforts, specifically through the financial classification of patients.) However, the links between moral and administrative modes of classification persist as socially and economically marginalized persons continue to be plagued with sexually transmitted disease. Thus, as with syphilis, the definition of HIV/AIDS converges with administrative, moral, causal and grouping classifications. With HIV/AIDS, early case reporting included the collection of demographic (e.g., race, ethnicity, gender) and risk information (e.g., sexual practice, use of injection drugs, receipt of blood transfusion) used to group positive cases as part of the outbreak investigation. As we saw with syphilis, mass screening efforts focused on particular groupings

of race and moral evaluation (e.g., innocents). However, with both syphilis and HIV/AIDS, mass testing or outbreak investigations target populations saturated with disease, resulting in the reinforcement of notions of grouping people by race, for example. The identification of the causal agent for AIDS has been especially important since those afflicted by the disease are at increased risk for otherwise very rare conditions that can mimic other diseases, whether or not associated with the etiological cause (Eaton 2005). Moreover, the refinement of administrative categories attached to etiology is associated with efforts by public health to decrease stigma.

The discovery of the etiological cause of AIDS was shaped in part by the intensely aggressive research atmosphere at the National Cancer Institute (NCI) as well as the epidemiological work (i.e., counting) institutionalized at the CDC. Of course, once the viral cause of AIDS was discovered, diagnosis was simplified somewhat. However, as with syphilis, the collection of demographic and behavioral information influenced the lens through which AIDS was evaluated. By this time, risk information was also being collected systematically, further influencing the way HIV/AIDS was defined and dealt with. In 1983, HIV, the virus that causes AIDS, was isolated by Luc Montagnier at the Pasteur Institute in France. Despite this knowledge, in April 1984, U.S. Health and Human Services Secretary Heckler announced the discovery of the virus by Robert Gallo, who headed one of the few remaining cancer-virus labs at the NCI in the 1970s (Crewdson 2002).[35] This set off an international dispute that was not

[35] The origins of AIDS are not as well understood as syphilis and have baffled scientists and caused debate since the disease first emerged in the United States in the early 1980s. Although scientists have long believed that HIV was a virus that somehow leapt species from chimpanzees to humans, it is now widely accepted that HIV descended from Simian Immunodeficiency Virus (SIV) because certain types bear a close resemblance to HIV. However, there are two types of HIV, HIV-1 and HIV-2. HIV-1 is the more virulent strain and its origins are less well understood than HIV-2's. HIV was found in a 1959 human male blood specimen collected as part of research in the Belgian Congo. At one time, it was suggested that this specimen spread HIV in Africa because it contaminated the polio vaccine. Today, the most widely accepted theory of HIV's origin is the 'hunter' theory which posits that the SIV virus jumped species (from monkey to human) as a result of humans eating monkey infected with SIV and/or monkey blood getting into cuts or sores in human skin. More recently, the origins of HIV were traced back to an infection

settled until three years later when an international panel gave dual credit to the Pasteur Institute and NCI and changed the nomenclature to HIV. President Reagan and President Chirac signed the settlement in a White House ceremony (Etheridge 1992, Crewdson 2002). In 2008, however, the French virologists, Barré-Sinoussi and Montagnier, shared the Nobel Prize in Medicine in recognition of discovering HIV as the virus that causes AIDS, with no mention of Gallo (Altman 2008b).

The development of diagnostic technology to identify HIV in the human body has been crucial to the CDC's testing and screening recommendations to count cases as well as to the use of these counts in regulations about how funding is allocated to thwart the epidemic. Table A.1 provides a timeline of selected CDC and USPHS HIV/AIDS surveillance and testing recommendations, FDA approved diagnostic and treatment technology, and funding policy and recommendations from 1981 to 2006. When the ELISA (enzyme-linked immunosorbent assay) test for HIV was approved by the FDA in April 1985, it was a boon to the blood industry which quickly institutionalized testing of blood supplies at blood banks. For blood banks and plasma companies, the introduction of the test created a new uncertainty about whether they were obligated to report cases of HIV; this concern was eliminated by Congressional legislation passed the following year, which required the testing of blood and blood products for HIV. Because of this, they also worried about the loss of donated blood due to false positive test results.

CDC's HIV/AIDS disease surveillance recommendations include the following suggestions on standards: case definitions; testing, counseling and referral procedures; and privacy protections. The CDC published these recommendations in their *Morbidity and*

1930 that took place in West Africa through the tracing of genetic mutations of the virus in the form of an HIV family tree (Altman 2000, Avert 2008).

Mortality Weekly Report (MMWR). Although the CDC lacks the explicit authority to mandate the reporting of cases or that cases be tallied in a specific way, they offer technical assistance and provide funding to states to support their state HIV/AIDS surveillance activities. Since the advent of HIV testing technology in 1985, HIV reporting has been more controversial than AIDS reporting:

> AIDS surveillance was, and still is, broadly accepted among the community of persons living with HIV infection and AIDS. The relatively short period of patients' survival, as well as the need for health and human services, was thought to offset the social risks of surveillance. In contrast, HIV case reporting has generated bitter political controversy and impassioned community resistance. The first requirement of HIV reporting, in Colorado, and the early public health proposals for HIV surveillance in the mid-1980s ignited a firestorm of community protest. Civil libertarians and gay organizations opposed HIV case reporting because they did not trust the government to maintain sensitive registries and they were concerned about political retribution, potential invasions of personal privacy, and discrimination in employment, housing, and insurance. (Gostin, et al. 1997, 1162)

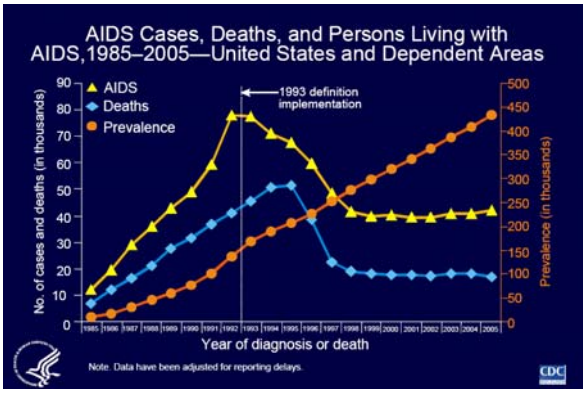
Today, only two states and territories have code-based reporting systems for HIV (Kaiser Family Foundation 2007a). Moreover, although AIDS surveillance began in most states during the 1980s, some states began HIV testing as recently as December 2003 (Kaiser Family Foundation 2007a). However, it is state legislatures that develop laws around requirements of reporting such as confidentiality, whether the system is name-based or code-based, and the inclusion of pre- or post-test counseling. State health departments receive technical and financial support from the CDC in order to implement their state-mandated reporting system, but are required to provide anonymous testing and counseling services in order to receive this assistance (CDC 1999b, 16). As we will see in chapter 4, when patients are objects of financial classification, variations in implementation of the CDC’s recommendations influence how resources are allocated for treatments.

When HIV diagnostic technology first came on the scene and screening policies were first developed, individuals were unlikely to benefit from getting an HIV test. As with syphilis, treatments for AIDS were not fully formed and there were social risks associated with getting tested for HIV (Gostin 2006). For instance, gay rights groups feared that the test could be used by insurers, employers, educators, and others to discriminate and enact violence against HIV-positive individuals (Siplon 2002). In many cases, this fear was realized. Given the lack of treatment and clear stigma, laws around HIV screening were organized around safeguarding personal autonomy and privacy (Gostin 2006). Indeed, studies showed that people would be unlikely to seek a test for HIV if it resulted in name reporting or partner notification (CDC 1999b), both of which are standard elements in public health practice for diseases such as syphilis and tuberculosis. Some argue that civil rights were taken so seriously at the start of the AIDS epidemic that it trumped traditional public health tools in the form of "AIDS exceptionalism" (Bolan 1999, Burr 1997). As an example, since 1987, CDC has recommended that counseling be provided as part of HIV testing practice and many states implemented laws requiring this (Gostin 2006, National HIV/AIDS Clinical Consultation Center 2008, see also Table A.1 in the Appendix). However, there is a great deal of variation in the extent to which states have legalized CDC's testing recommendations over the years (National HIV/AIDS Clinical Consultation Center 2008). Today, 48 states offer anonymous and confidential testing, while 11 states offer confidential testing only (Kaiser Family Foundation 2007b) and 27 states require pre-test counseling as part of HIV testing (Kaiser Family Foundation 2007c).

In 1986, a more specific HIV antibody test called the Western Blot was approved by FDA. Until recently, the "conventional" ELISA test was the most commonly used blood test performed for initial HIV testing, while the Western Blot was used as a confirmatory test. Rapid

finger-stick and oral tests were introduced in 2002 and 2004 respectively. Rapid tests continue to require a confirmatory laboratory test with Western Blot or immunoflourescent assay before a final diagnosis is made (Howerton, et al. 2006). As shown in Figure 3.1 below, as treatments have improved since 1985, the numbers of AIDS cases and deaths from AIDS have decreased in the United States.

Figure 3.1 AIDS Cases, Deaths, and Persons Living with AIDS, 1985-2005[36]



Thus, we can see that the availability of diagnostic and treatment technology influences the incentive for testing and reporting. Despite advances here, the prevalence of HIV has continued to increase.

Thus, in 2006, the CDC released *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*, overhauling its previous approach to AIDS policy by encouraging routine opt-out testing (as opposed to voluntary testing) for HIV in healthcare settings such as primary care centers and emergency departments (Gostin 2006). The recommendations also de-emphasize the importance of counseling despite more than half of state laws requiring pre-test counseling as part of HIV testing (Kaiser Family Foundation 2007c). Although testing has increased as diagnostic and treatment technologies have improved, the false positive rate associated with early implementation of universal opt-out HIV testing using oral

[36] CDC 2007

rapid tests has caused some to re-focus on how to target screening more effectively in low prevalence areas or to groups at higher risk (CDC 2008). Low prevalence areas could potentially be identified by states and CDC through the publishing of surveillance data, including the classification of risk groups, and its associated trends. So, although standardization can follow a clear cause and way of making a diagnosis, particularly when advancement in treatment provide incentives for individuals to be tested, testing for HIV could begin to look more like syphilis in the 1930s where certain groups are targeted because of their likelihood to be saturated with disease. As we will see below, this evaluation is done through the collection of demographic and risk data recommended by CDC.

Since 1999 CDC has recommended that all private and public HIV testing and care centers, including laboratories that process serums, report positive cases to state surveillance programs. State-collected data is forwarded to the CDC using their HIV/AIDS Reporting System (HARS), however it must meet certain data requirements to be counted by CDC and thus become official. Unlike with syphilis in the 1930s, states report cases of HIV or AIDS to CDC using CDC's Adult HIV/AIDS Confidential Case Report form (See Figure A.1 in the Appendix). For a case to become officially tied to a state, the case report must include the following information: patient identifier, earliest date of diagnosis of HIV infection, earliest date of diagnosis of an AIDS-defining condition, demographic information (e.g., date of birth, race/ethnicity, and sex) and residence (i.e., city and state) at diagnosis of HIV infection and of AIDS, HIV risk exposure, facility of diagnosis, and, if applicable, the date of death and state of residence at death. According to the CDC,

> To provide accurate and timely data for monitoring HIV/AIDS trends and ensuring a reliable measure of the number of persons in need of HIV-related prevention and care services, state and local HIV/AIDS surveillance systems should use reporting methods that provide case reporting that is complete (greater than or equal to 85%) and timely

> (greater than or equal to 66% of cases reported within 6 months of diagnosis). In addition, evaluation studies should demonstrate that the approach used to conduct surveillance (i.e., name or coded identifier) must result in accurate case counts (less than or equal to 5% duplicate case reports and less than or equal to 5% incorrectly matched case reports). Finally, at least 85% of reported cases or a representative sample should have information regarding risk for HIV infection after epidemiologic follow-up is completed. All HIV/AIDS surveillance systems should collect the recommended standard data in a reliable and valid manner, allow matching to other public health databases (e.g., death registries) to benefit specific public health goals, and allow identification and follow-up of individual cases of public health importance. (CDC 1999b, 13)

States develop their own methods in order to meet these data completeness and timeliness standards. Many states opt to use CDC's own case report form or a modified version of the form to collect the required elements. States' capacities to meet these performance criteria vary widely. Private physicians, while often mandated by state law to report cases, contribute to under-reporting and incomplete reporting in an effort to protect their patient's privacy (Anderson 1994). CDC also compared the ability of confidential name-based and anonymous code-based systems in meeting their case reporting performance requirements and concluded that confidential name-based reporting was more likely to meet their performance criteria (CDC 1999b).

Importantly, data elements, including demographic and behavioral data, are collected using the CDC case report form. Thus, individual HIV cases are attached to a race, a gender, and deviant behaviors such as injection drug use and homosexual or bisexual activity. Not only are these data often self-reported, but they may come from multiple sources and not necessarily during face-to-face interviews. These types of data can be a challenge to collect since it is a process of putting people into established boxes, but they are also a challenge to analyze and use for planning since assessments of risk are made by grouping infected people together by racial and gender categories who engage in similar behavior. Thus, even when grouping classification seemingly comes after etiological classification, moral classification is intertwined with the

causal and administrative classification resulting in the maintenance of certain moral assumptions (e.g., gay white men are promiscuous) and the development of new moral categories (e.g., black men who have sex with men also have sex with women). Thus, those people judged as high risk are more likely to be offered an HIV test.

Transmission risk is a highly unsettled aspect of HIV surveillance because the social construction of risk overlaps with moral classifications of behavior and its association with race and gender categorization. Risk data are also the most challenging items of information to collect using the Patient History section V of the CDC's case report form (see Figure A.1 in the Appendix). The patient is asked if prior to finding out their HIV status and after 1977, did they do any of the following: have sex with a male; have sex with a female; inject non-prescription drugs; receive clotting factor for specified hemophilia/coagulation disorder; have heterosexual relations with any of the following: intravenous drug user, person with hemophilia/coagulation disorder, transfusion or transplant recipient with HIV, person with HIV/AIDS with unspecified risk; receive blood transfusion other than clotting factor, worked in health care or laboratory setting.

Unlike other sexually transmitted diseases, once collected, the answers are tabulated and collapsed into the following hierarchy of risk first adopted in by CDC in 1986: 1) men who have sex with men (MSM), 2) injecting drug use (IDU), 3) men who have sex with men and inject drugs (MSM/IDU), 4) heterosexual contact with a person known to have HIV infection or with a person at high risk for HIV infections (i.e., high risk heterosexual), and 5) others (McDavid and Mckenna 2006, 287). In other words, while many risks may be selected, some items are weighted more heavily than others in the hierarchy. For instance, men who select both male-to-male sex and intravenous drug use are categorized separately as one risk. Male-to-male sexual

contact includes men who selected both sex with men alone and sex with both women and men (see Technical Notes in CDC 2005a).

This way of classifying risk was developed in order to be sensitive to political and moral controversy as well as the need to accurately represent the spread of the disease because the notion is that the more scientific or administrative a category becomes the less moralistic and stigmatizing it is. During the first outbreak, case interviewers asked if patients engaged in homosexual sex and found that the available categories were not able to capture the way the disease was transmitted to them. As one interviewee in our study noted:

> Well, are- and some of that stuff did bug, me 'cause, you know, I was talking about our first AIDS patient in Oregon. He'd been there before, but they never filled out a form. So I filled out the form. Well, he clearly did not identify as gay, but had the risk factor. And you know, they called me back, they said no, no, we've got to put that category in the gay or bisexual category. And I was like, the sexual orientation is what he says. He says he's not gay. He does say...he had sex with men, you know. So in many ways, you know, that- they couldn't deal with that…Till later. I mean, that was the late Eighties before they began to conceptualize that it's the risk- it's the behavior, it's not- you know, your sexual identity is what you say it is. I mean, there's no other way, you know. It's yours, you…view it. It's this completely self-identified categorization. And but, I mean, that just was impossible here. 'Cause oh no, we have to change that. I said, well, you know, he's clearly marked here - and I took this information from him personally and sat there with him, and I'm comfortable this is what he means... from what he says. Well, no, it shows up then as, you know, non-gay category. And you know, you're analyzing this stuff the wrong way. But it- it's going to cause so many problems, go ahead and change it. (006_AT_US_030306_RC)

Early on, African Americans males, in particular, did not identify as gay so their male-to-male sexual behavior was not being captured in these data and was resulting in an undercount of this type of transmission. Women asserted that silence about men in the black community having sex with men behind women's backs was causing increases in prevalence rates among women (Millet, et al. 2005).

By transforming identity into behavior over the years, CDC has attempted to diminish the stigma associated with the public health practice of counting, a highly administrative function.

Although CDC has had difficulty capturing how a person may have been infected with HIV since the early days of the epidemic (Lee, et al. 2003), the number of HIV/AIDS cases reported to CDC without an identified risk has only increased since 1993 (McDavid and Kajese 2005). In 2004, 35 percent of cases reported to CDC lacked a risk factor altogether making "no identified risk" (NIR) increasingly prevalent (McDavid and McKenna 2006). In response to these charges, the classification has changed over time and a variety of prevention education programs and materials have grown up around the new category, Men Who Have Sex with Men (MSM). MSM emerged in order to capture those not identifying as gay but who engage in homosexual sex. In the CDC risk hierarchy, MSM is ranked first both because of the efficiency of transmission associated with the behavior as well as the probability of exposure in the population group. The MSM category includes all men who self-report sexual contact with a man since 1977 regardless of how they identify or whether they also have had sex with women (Schmidt and Mokotoff 2003). Prevention activities aimed at this risk population often refer to these men in the African American community as being on the "down low" (DL) (Malebranche, et al. 2007, Montgomery, et al. 2003). Some argue that MSM further fuels the marginalization of African American men who engage in bisexual behavior because the term MSM was developed in order to capture the same behavior, but one defined differently by African Americans (Ford, et al. 2006, Young and Meyer 2005), underscoring the way that administrative classification overlaps with moral classification.

In addition, women's risk has been increasingly unidentifiable by the hierarchy because "high risk heterosexual" is only assigned to a case if a person answers questions about their sexual partners being injection drug users, HIV positive, bisexual, etc. (Schmidt and Mokotoff 2003, see also item V in Figure A.1 in the Appendix). Before 2003, women were also

undercounted in general because female-specific manifestations of the disease were not included in the case definition (Lorber 1997, Patton 1994). In an effort to pinpoint how women were becoming infected by men, the CDC changed how they collected this information. Thus, today in order for a case to be classified with heterosexual risk, a sex partner with HIV infection or another risk factor for HIV must be noted on the case report form (McDavid and McKenna 2006). In general, women and African Americans have been shown to be more likely than men and whites to report either multiple risk factors or no risk at all (Schmidt and Mokotoff 2003). Evaluations of risk factor data have consistently shown that heterosexual sex as a mode of transmission is underestimated for both women and men (McDavid, et al. 2006). While some argue that standardized terminology and training of health care providers on how to document risk will help improve risk surveillance (McDavid and McKenna 2006), others argue that the risk hierarchy itself is inadequate in describing transmission among women, who are increasingly impacted by the epidemic (Schmidt and Mokotoff 2003). Indeed, some suggested modifying CDC's risk hierarchy to include a dual IDU and heterosexual category and a "presumed heterosexual" category in order to more accurately reflect the acquisition of HIV by women (Schmidt and Mokotoff 2003).

As these transmission or risk categories have been modified over the last twenty-five years, race, gender, sexuality, and morality were conflated in the construction of AIDS as a medical problem. Aggregate information about who engages in what behavior must be morally and politically palatable in order to be deployed in public health programs. Thus, categories have evolved in order for a diversity of perceptions of risk to be integrated with tallies of disease. Even today, the system remains unsettled because as with other diseases, the reliability of these risk data is questioned because it is self-reported, medical providers may be uncomfortable

asking patients about it, and data elements of case reports may come from a variety of sources (Weinhardt, et al 1998).

The availability of accurate and effective diagnostic and treatment technology influence the degree to which mass screening efforts are implemented successfully. Moreover, the association of cases with demographic and behavioral data enable moral classification to influence administrative classification during administrative processes of counting and analyzing epidemiological data for trends. As we have seen with HIV/AIDS, the quality of race and behavioral data associated with the tallying of cases is arguable. In addition, a recent study conducted by CDC found that 56,300 people became newly infected with HIV in 2006, a 40 percent increase over the 40,000 figure the agency has published as the recent annual incidence of the disease (Altman 2008a). Yet as we will see in the next chapter, these rates are linked explicitly to how patients are classified in order for resources to be allocated for treatment.

Conclusion

Unexpected agendas can follow from etiological classification in classification systems. While the development of diagnostic testing itself is not surprising, the feedback between diagnostic testing and technological improvement means that the more testing that is done, the more we can find out about the disease itself and the more refined diagnostic testing can become. After all, diagnostic tests with both syphilis and AIDS are not only useful in identifying case, but are also used to track the effects of treatment both pre- and post-testing. Importantly, people are grouped according to their proclivity to have the causal agent inside of them. Thus, moral and administrative classifications influence how etiology is deployed and modified. The population-level information collected about both syphilis and HIV/AIDS has helped identify a variety of

risk groups. However, because both syphilis and HIV are transmitted primarily through sexual behavior, classification plays a contradictory role, both resisting and maintaining stereotypes about race, gender, and sexuality.

Furthermore, there is little incentive for screening asymptomatic people when the only known treatments were nearly as toxic as the disease itself. Although symptomological classifications of disease adjust with the introduction of etiological definitions, they do not disappear completely. After all, the utility of etiological classifications of disease depend on the accuracy of diagnostic technology and the efficacy of treatment technology. With both syphilis and AIDS, treatments and diagnostic tests eliminated many of the more gory clinical manifestations that helped to bring attention to the disease in the first place. Once a cure was available for syphilis in the mid-1940s, clinicians had less and less clinical experience with the disease and its trajectory from infection to death. Similarly, the advent of HAART in 1996 has prevented many of the opportunistic infections such as Kaposi's sarcoma and Pneumocystis carinii pneumonia (PCP) that were emblematic of the disease in the early 1980s.

Over the last century, the creation of categories of the infected has changed from moral categories of the social hygiene movement in the early twentieth century to the highly bureaucratic risk assessment of behavior and demographics today. This chapter illustrated how despite the increased codification of etiological classifications in mass screening and routine testing initiatives, definitions of disease remain unsettled because administrative and moral classifications continue to influence the social construction of disease. Those having syphilis or HIV/AIDS are most often classified as a case during diagnosis. Etiological forms of classification were undeveloped with the case of syphilis, being both disjointed and directly tied to the formation of racial and sexual distinctions by targeting specific groups assumed to be

saturated with disease. With HIV/AIDS, on the other hand, the classification of cases as part of disease surveillance and program eligibility converge as part of the social construction of the disease itself in such a way that highlights a new politics of risk where the administrative practice of counting had a formative role in racial, gender and sexual distinctions.

For example, HIV/AIDS emerged not long after the Stonewall protests of the 1970s, where what we now think of as gay culture became more openly recognized by society at large (D'Emilio 1997). Thus, engaging in behavior classified as homosexual became associated with the etiology of the disease itself. Indeed, when AIDS first emerged it was named such things as "gay compromise syndrome" or "gay related infectious disease" (Brennan and Durack 1981, Shilts 1987). This classification of AIDS was contested by an activist gay and ally community. However, not all men who practice homosexual behavior identify their behavior as such. Thus, the surveillance of risk behavior by those counted as a case of HIV/AIDS was compromised because some men told the surveyors that they did not practice homosexual behavior. CDC's answer has been to create new boxes for HIV/AIDS, including MSM. In this way rational, bureaucratic procedures distort the symbolic significance of morally charged "precious" categories by excluding certain information and also by giving this information a particular form.

Importantly, unlike in some countries (e.g., France), race has been a legal category in the United States and has been important to counting efforts from the earliest census to public health surveillance efforts today (Fullilove 2008). Because the formation of racial categories and hierarchies includes reflection impressions about sexual deviance and innocence (Donovan 2003), moral evaluations of the cause of syphilis were influenced by conceptions about racial difference, the social hygiene movement, and the aspiration of public health to count, categorize and standardize in order to gain authority over medical problems such as syphilis. The way that

syphilis is constructed through the lens of race is both uniquely American (Fullilove 2008, Omi and Howard 1994) and can be wrought with data quality problems when there is a lack of agreement about its classification. Indeed, in morbidity and mortality statistics race may be a surrogate for other factors such as geography (Fullilove 2008; Levine, et al. 2001, 482).

One important difference between how race and moral evaluation played out in the evolution of screening and testing for syphilis and AIDS, is the extent to which demographics and behavior were settled as administrative categories in the discourse of screening. With syphilis, screening was targeted in racial groups predicted to be saturated with the disease because of assumptions about the link between race and sexual behavior and intelligence. Thus, screening targeted existing groups and the Rosenwald demonstration project found high prevalence among rural black Southerners. With AIDS, on the other hand, testing has been mostly done on a voluntary basis with increased protections for privacy because the effects of stigma were so profound in the early days. However, as epidemiology has become institutionalized, so categories of race and moral evaluation of behavior have become embedded in administrative classification schemes. Thus, race, gender, and the engagement in certain behaviors have been collected alongside the counting of HIV and AIDS cases in the United States, and groups are formed as part of the analysis of these data.

Although President Clinton apologized for the Tuskegee syphilis study on behalf of the nation in 1997, the continuation of sera collection in the Tuskegee study of untreated syphilis inspired fear and mistrust in African Americans of medicine and public health that continues to be felt today with AIDS. For example, researchers from the RAND Corporation and Oregon State University conducted a telephone survey of 500 African Americans ages 15 to 44, asking their opinion on a series of questions about HIV/AIDS "myths." Almost half of respondents said

they believe that HIV is manmade, with approximately 12 percent of respondents saying they believe HIV was created and spread by the CIA (Fears 2005). Thus, fear of counting has transformed into a fear of being counted as the administration of etiological classification has evolved from the 1930s until today.

With syphilis, a mass tally of a disease by etiology included only those who are convenient to count (e.g., soldiers, prisoners, the poor, the sick) and generally excluded those without symptoms. With HIV/AIDS, a tally of disease by evidence of an etiological agent includes only those who are tested (e.g., voluntarily, by law, as part of other medical care, coercion) as well as false positives. In addition, before an etiological agent was discovered, the "cause" of syphilis was conceived in terms of one's behavior (e.g., sex with prostitutes) and/or nature (e.g., strengthened libido, lack of intelligence). In this way, tallies of disease are influenced by moral and administrative classification since the groups assumed to be depraved are also convenient to test. Thus, even etiological definitions of disease are not fixed. As these travel from labs and outbreak investigations to screening efforts, individual diagnosis, and paths of treatment, they are further shaped by the pace of technological innovation (are treatments of high enough quality to warrant mass screening?), the development of medical system infrastructure (do the tools and resources available for treatment favor testing?), and moral and political perceptions (who is at risk and who is innocent?).

This is particularly the case with HIV/AIDS, which remains incurable with current treatment technology. As we saw with syphilis, the diagnostic test came before successful curative treatment. Thus, mass screenings of military recruits by the U.S. was deemed impractical during the First World War. Subsequently, increased attention was brought to the disease between the World Wars with the Rosenwald Fund demonstration projects, laws

mandating testing before marriage, and routine testing as part of hospital admission and pre-employment procedures. Ironically, once curative treatment was available for syphilis, mass screening came to be seen as no longer cost effective. Thus, only the highest risk groups were targeted for screening to control the spread of the disease.

The aspiration to isolate and count causes of disease involves stakeholders from the patient who is sick on up to the state whose economy or security may be threatened as a result of populations of sick people. In between the patient and the state, we have medical professionals attempting to care for patients in the clinic, scientists attempting to make new discoveries in the lab, and public health workers piecing together epidemiological tales of transmission in the field. A lot is at stake in this race including money, prestige, quality of life, and knowledge. As we will see, the classification of diseases does not necessarily begin in the lab. Until Schmudinn and Hoffman saw the bacteria under the microscope in 1905, the cause of syphilis was unknown. However, syphilis could still be diagnosed clinically by medical professions prior to this. And syphilis was still understood to be transmitted sexually due to germ theory and advances in public health during the nineteenth century.

Public health programs must balance public benefits and private rights and interests in the development of public health regulation. General justifications for public health regulation include risk to others (the "harm principle"), protection of incompetent persons ("best interests"), and risk to self (Gostin 2000, 88). This notion of risk is rooted in the erosion of determinism in the nineteenth century. The rise of statistical laws is associated with the establishment of technologies of classification and enumeration as well as new bureaucracies with the authority to use these technologies (Hacking 1990). These technologies of classification allow people to be counted and for statistical facts about these people to be presented by bureaucracies whose role it

is to have some relationship with them for the social good. Indeed, one of the core functions of the public health system is to "gather information and deploy those data for the welfare of the community" (Gostin 2000, 113). Information about risk factors for, and the patterns, trends, and causes of injury and disease are the basis for public health decision-making. This is why biostatistics and epidemiology are the foundational sciences of public health.

By the time AIDS emerged in the early 1980s, there were plenty of resources supporting the search for viruses that cause cancer as well as for identifying and classifying the mechanisms of DNA and RNA by scientists, especially in the U.S. Although the symptoms being reported fit already-existing disease classifications when AIDS emerged, the configuration and frequency of the conditions physicians were seeing in otherwise healthy young men were enough to call into question those classifications. The classifications were not fitting with the patients they were seeing and public health was authorized to investigate. By this time, epidemiologists were also more skilled in understanding how diseases are transmitted and how to prevent those transmissions, especially with vaccines. Key to this process is collecting reports of unusual cases of disease, disseminating reports of unusual cases of illness, and the development of case definitions for use by health departments and medical professionals. Epidemiologists develop case definitions for use on the clinic level so that an understanding of the larger social threat of particular diseases can be better understood and the spread of disease can be controlled. Symptoms that are grouped into a case may provide clues to clinicians about when to test for HIV.

Scientists, public health workers, and medical professionals all play a role in how diseases are classified. Technology and finance mediate all of their classifying practices. Scientific innovations in the lab, such as microscopes, have played a key role in how scientists

classify. As we have seen, however, technology does not make classification any less social in its practice or in its consequences (Haraway 1997, Haraway 1991, Latour 1987, Star 1985, Pickering 1995, Gilbert 1984). Once a bacterial or viral cause is isolated, diagnostic technology can be used to complement or supersede clinical diagnosis, impacting the practice of classification itself. Newly defined disease entities and their diagnostic technology must be integrated into medical and public health practice in order to categorize a patient's illness.

As we have seen, the spheres of science, medicine, and regulation do not operate in isolation. Indeed, advances in public health and in science have impinged upon the work of physicians in medical practice with diagnostic and treatment technology, outcomes research, evidence-based medicine, and a host of new knowledge and protocols (Berg 1995, Berg 1997, Tannenbaum 1994, Hofoss 1986, Wailoo 2004). The influx of knowledge from the laboratory and from the field has impacted medicine and public health profoundly over the last century or more. Categories and names are created through political, scientific, and other organizational processes that have material consequences for people. As we will see in the next chapter, the counting of cases classified by etiology is linked to how patients are objects of classification for resource allocation.

CHAPTER 4

THE CLASSIFICATION OF PATIENTS: CASE PROCESSING AND RESOURCE ALLOCATION

Regulations and protocols that mandate the provision of treatment for those infected with syphilis and HIV/AIDS rely on the financial classification of patients on both population and individual levels. First, patients are processed as cases and turned into rates through epidemiological surveillance practices; rates are then evaluated in order to allocate funds to areas with the biggest problems. Second, patients are classified by their ability to pay for treatment and the severity of their disease through individual case processing; cases are then evaluated in order to treat the most disadvantaged patients. This financial type of classification relies on both symptomological and etiological types of classification because groupings of symptoms and epidemiological tallies of disease create a set of criteria by which patients are classified. Using examples from archival documents, fieldnotes, interviews, regulations and protocols, this chapter will demonstrate how individuals represented in rates become patients in public safety net programs through the allocation of funds and intake procedures. We will also see how safety net programs continue to gather demographic and behavioral information in an effort to account for whether treatment activities correspond to the needs identified by epidemiological evaluations detailed in chapter 3.

The financial classification of patients is an important element to the social construction of medical problems because influences the way that healthcare systems are organized, including forming the basis of patient eligibility criteria. (For a summary of the financial classification of patients, see row 3 of Table 1.2). Although financial classification is heavily administrative (e.g., patients must provide documentation of their income in order to become a case in the system), moral classification plays an important role in how these patients are ultimately

provided scarce resources (e.g., assessments of need and compliance). This is especially important with highly stigmatizing diseases that not all healthcare providers are willing to treat. Chapter 6 will illustrate the importance of the financial classification of expertise in how syphilis and HIV/AIDS have come to be understood in medicine and public health. Moreover, the identification of eligible patients may be of little value if there are no treatments or preventive methods available to stop the disease from progressing and spreading. Even more important, diagnosis and treatments may be difficult to implement, expensive, or inaccurate. Thus, both symptomological and etiological classification adjust in practice even after patients are classified.

Syphilis in the early part of the twentieth century and HIV disease today are exemplary of how patients are objects of classification because they are costly to treat, require patients to adhere to treatment and visits, and were part of the establishment of new organizational fields of medical care. With syphilis, the Rosenwald demonstration projects begun in 1929 formed the groundwork of the government funded rapid venereal disease treatment centers for established in 1938. With AIDS, the Robert Wood Johnson Foundation (RWJF) AIDS Health Service Programs served as the basis for the treatment centers now funded through federal Ryan White legislation. A comparison between syphilis and HIV/AIDS illustrates a crucial difference between how the financial classification of patients operates in different medical systems. With syphilis, the authority of public health was newly established and unsettled and the medical establishment relied on patients or philanthropic organizations to pay for treatments directly. By contrast, with AIDS, public health has established authority both to count and to treat infectious and sexually transmitted disease while the medical established relied on a variety of payers to reimburse the treatment of patients, particularly insurers and government payers. This chapter

will demonstrate how safety net healthcare in the U.S. has been influenced by the operationalization of classifications of syphilis and AIDS. Table 4.1 provides a summary timeline of important legislation, funding allocations, and philanthropic projects that influenced the financial classification of patients over the last several decades. (See also Table A.1 in the Appendix.)

Table 4.1 Summary Timeline of Regulations and Protocols Impacting Financial Classification of HIV Patients, 1918-2006

Year	Law/Demonstration/Allocation	Details
1918	Chamberlain-Kahn Act	Established Division of Venereal Disease in USPHS
1927-1932	Committee on the Cost of Medical Care	Philanthropic funding from Milbank Memorial Fund to evaluate cost of medical care
1929-1931	Rosenwald study of syphilis and a demonstration of treatment among the Negroes	Philanthropic funding of Wasserman dragnet and treatment in 6 rural Southeastern counties, targeting African Americans; requirement of states to fund staff in health departments
1938	National Venereal Disease Control Act	Provided funding for venereal disease research and control efforts
1943	Lanham Act	Provided funds for rapid treatment centers through Federal Works Agency and Federal Security Agency
1944	Public Health Service Act	Broadened authority of USPHS
1965	Social Security Act	Established Medicare and Medicaid
1986-1990	Robert Wood Johnson Foundation AIDS Health Services Program	Philanthropic funding for 9 treatment centers in 11 cities based on the San Francisco community-based model of care
1987	Budget allocation	Congress approves emergency funding of $30 million to pay for AZT
1990	Ryan White Comprehensive AIDS Resources Emergency (CARE) Act	Provided federal funds for community-based care and treatment services in Eligible Metropolitan Areas (EMAs), formula used estimated living CDC certified AIDS cases for last 10 years; once an EMA always an EMA; services modeled on RWJF AIDS Health Services Program; provided funds to states for AIDS Drug Assistance Program (ADAP)
1996	Ryan White CARE Act reauthorized	Provisions added for women, infants, children; added dental reimbursement services; training of AIDS care providers; and research on special projects of national significance (SPNS)
1999	Minority AIDS Initiative (MAI)	Congressional Black Caucus began the Minority AIDS Initiative (MAI); congress responded by allocating $156 million to fund MAI efforts using CARE Act formula

Year	Law/Demonstration/Allocation	Details
2000	Ryan White CARE Act reauthorized with amendments	Required quality management programs to ensure adherence to USPHS treatment standards; required Institute of Medicine (IOM) to evaluate State HIV surveillance systems were sufficiently accurate for purposes of awarding formula-based grants
2006	Ryan White HIV/AIDS Treatment Modernization Act	Created transitional grant areas (TGAs) in addition to EMAs; status is based on most recent calendar year living HIV/AIDS cases certified by CDC; to maintain EMA or TGA status, must maintain initial AIDS cases and minimum living AIDS cases; 75% of funds must be used for core services; codifies MAI funding with competitive application

With both syphilis and AIDS, payers such as philanthropic organizations or governments want to ensure that funds are allocated equitably and with the most impact on national health overall. Treatment centers must ensure that they comply with regulations and protocols, including by establishing protocols for distributing limited resources to patients at the local level. Population-level information is collected in an effort to inform the distribution of such resources while individual-level information is collected in order for an infected person to access those resources. This chapter will attend to the financial classification of patients, which transforms cases into rates as patients are processed into systems of care. Thus, understanding patients as both rates and cases of with syphilis and HIV/AIDS is central to the administrative and financial processes that contribute to the social construction of these diseases. As we see in Table 4.1, over the years, resources have been allocated specifically to syphilis and HIV/AIDS because regulations and protocols were developed that mandate the provision of safety net healthcare under the purview of public health (e.g., National Venereal Disease Control Act with syphilis, the Ryan White CARE Act with AIDS). As we will see, the financial classification of patients is a critical first step on a path to treatment because before treatment can begin the labor and

materials used in medical care must be made available. (See chapter 5 for details on how treatments themselves are objects of financial classification.)

While patients are objects of financial classification, they are also objects of moral classification because evaluations are made about which groups of patients should be targeted as the demographic and behavioral "face" of the disease come to be understood. For instance, with syphilis, blacks in the South were determined to be saturated with syphilis and private doctors eschewed caring for them; with AIDS, homosexuals were determined to be saturated with AIDS and private doctors avoided caring for them. With both, protocols were designed to demonstrate how treatments could be provided to highly stigmatizing medical problems outside existing medical infrastructure, both in terms of controlling the disease and in terms of cost creating new organizational fields for medical problems to be evaluated and disease to be socially constructed. Thus, definitions of both syphilis and AIDS converge with the financial classification of patients as they correspond with assessments of need, symptomotology, and etiology.

Syphilis: Developing infrastructure through the financial classification of patients

In the U.S. at the turn of the twentieth century, public health was a matter of social reform, bolstered by the work of voluntary organizations with ties to the social hygiene movement. At this time, public health was becoming increasingly disciplined and specialized as a profession. However, it was defined more in terms of its aspirations and goals, to ease the burden of disease and uphold society's health, rather than by a particular body of knowledge or set of skills. Indeed, the refinement of the "epidemiological imagination" in public health required an array of skills that existed in other professions including medical diagnosis, environmental engineering, epidemiology, statistics, nursing, inspection, and administration (Fee 1994). Thus when bacteriological discoveries by Pasteur, Koch and others were made, germ

theory and the bacteriological lab became the new and principal symbol for public health (Fee 1994). This shifting emphasis on etiological classification of disease had an important impact on the increase in public health training and authority of those trained in its science. The authority of public health began to expand beyond sanitation into the medical domain. As we saw in the previous chapter, it was precisely at this period that syphilis as a disease became better understood and linked to a causal bacterium. This section will illustrate how new authority of public health became integrated more intimately with the functioning of states through the financial classification of syphilitic patients at the population and clinic levels.

Early twentieth century federal law and philanthropy created systems in which syphilitic patients were objects of financial classification by newly established authorities in public health. Alongside the rise of testing and counting initiatives discussed in the last chapter, regulations created through federal legislation and protocols developed as part of philanthropic projects contribute to the development of authoritative public health infrastructure through the creation of treatment programs. Although public health had a strong role at the national level in guiding program standards for venereal disease, local and state boards of health ultimately authorized the criteria by which patients were classified financially as they became cases in public clinics.

In 1912, the federal government made its first tangible commitment to building public health infrastructure by transforming the Marine Hospital Service into the United States Public Health Service (USPHS). In addition to its military responsbilities, the USPHS was responsible for the medical examinations of all immigrants arriving to Ellis Island. Along with its alignment with bacteriology in the lab, public health was aligned with the eugenics movement in the United States (Fee 1994, Lombardo and Dorr 2006). After all, central to the USPHS was to protect the good and clean American stock (e.g., non-immigrants, whites) from the bad and dirty stock (e.g.,

immigrants, blacks). The rise of bacteriology coupled with increased governmental support heightened public health's ability and authority to apply moral evaluations of those with diseases. Preserving the national stock was tied both to good science and good economics, especially as new immigrants poured into the country (Fee 1994) and blacks migrated and participated in institutions such as schools, churches, and the economy.

By 1915, the USPHS, U.S. Army and the Rockefeller Foundation were the major agencies of public health whose work was financially supported by state and local health departments (Fee 1994). As USPHS's role expanded, there was increasing demand for full-time public health workers who were not distracted by private medical practice. In 1916, funding from the Rockefeller Foundation provided the academic base for epidemiology with the founding of the Johns Hopkins School of Public Health (Etheridge 1992, Fee 1994). Although new schools of public health had a preference for physicians, non-physicians studying biomedicine were also admitted.

After physical exams of World War I military recruits revealed a high rate of venereal disease, Congress passed the Chamberlain Kahn Act of 1918, establishing the interdepartmental social hygiene board (ISHB) made up of the Secretaries of War, Navy, and the Treasury. Most importantly, the law created a generously funded the Division of Venereal Disease in USPHS as well as adding one million dollars to assist states with organizing prophylaxis and treatment as part of their social hygiene efforts. By 1919 forty-four states had established bureaus for the control of venereal disease. Although these agencies concentrated much of their efforts on treating the poor, treatment was often only available in urban areas (Jones 1993). Moreover, support for venereal disease control depended largely on a "Win the War" psychology that focused on treating soldiers, so the nation's commitment to treating venereal disease declined

with the end of World War I and the Division of Venereal Diseases budget dwindled from $4 million in 1920 to less than $60,000 in 1926 (Brandt 1985). Thus, by 1926 the federal government eliminated financial support to states for their work controlling venereal disease. Funding for venereal disease control would decrease even more with the arrival of the Great Depression. During that time, the Division of Venereal Disease survived major cuts in its budget by focusing on education and abandoning its guidance in the creation of treatment facilities across the U.S. (Jones 1993). In the end, more than 2 million people in the U.S. died as a result of syphilis between the two World Wars (Jones 1996).

States had to deal with the consequences of this shifting support of venereal disease control by the federal government. Although treatment was seen as a key component of war-related efforts that targeted the spread of syphilis, states often did not really know the magnitude of the problem. Prior to the U.S. entering the First World War in 1917, only nine states required cases of venereal disease to be reported (Jones 1993). Funding for venereal disease control at this time was not explicitly tied to tallies of the disease. The Rosenwald demonstration project started in 1929, the same year as the Wall Street Crash, identified large-scale prevalence of the disease as well as illustrated the lack of money to treat all the cases. Moreover, although the Wasserman test was "frequently available without cost"[1] in 1932, the "almost universal charge" was $5.[2] As the Great Depression took hold, the Rosenwald demonstration was terminated and employers cut back on their health benefits including "company doctors." New Deal and Social Security measures helped make social welfare, including public health, the responsibility of the

[1] Parran, T. (1932). Handwritten comment on Bromberg, L., Davis, M.M. (1932). Page 5 of draft report, "The Cost of Treating Syphilis." Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[2] Bromberg, L., Davis, M.M. (1932). Page 5 of draft report, "The Cost of Treating Syphilis." Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

federal government (Starr 1982, 200). However, the American Medical Association (AMA) opposed any third party intermediary between physicians and patients because, they argued, private enterprise would turn physician services into commodities enabling non-physicians to earn profit from physician labor and knowledge (Starr 1982, 217). Since public health was being established as an interdisciplinary profession in the public sector, physicians resisted the idea of public health as "socialized medicine" as well as a corporate system of medicine because they wanted to maintain their autonomy and fee-for-service payment structure while also continuing to use hospitals and laboratories (Starr 1982; 200, 220-221). According to Starr, "Prepayment itself was an adaptation to uncertainty in the incidence of the disease and the costs of treatment; if anything, the profession's opposition to contract practice (and later to health insurance, medical cooperatives, and other prepaid health plans) increased the burden of uncertainty that patients had to bear" (1982, 26). The financial classification of patients may have reduced the uncertainty about how to get medical treatment for a portion of patients, but not for states implementing the programs since the criteria used to classify patients financially must adjust as science, law, and resources change.

There is little known about how patients were classified financially either by private physicians, boards of health, or charity clinics before the 1920s. However, the cost of medical care was increasingly a concern as both medicine and public health gained professional legitimacy. In fact, between 1927 and 1932, the Milbank Memorial Fund, created the Committee on the Cost of Medical Care (CCMC) in order to study medical expenditures and the distribution of medical care in the U.S.[3] The CCMC is a landmark in the development of American health policy because it provided the first evidence for the maldistribution of healthcare expenditures.

[3] Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

For example, the study concluded that 3.5 percent of families had the largest medical bills paying for a third of the total cost of medical care nationally at that time (Starr 1982, 261-262). While medicine was already criticized for being too unorganized, the CCMC sought their support and engaged the AMA as well as the Metropolitan Life Insurance Company in their work in an effort to shield public health proponents against criticism of being too socialistic (Starr 1982, 261). In the end, the committee recommended group practice and payment for medical care funded by voluntary insurance and taxation, but not mandatory health insurance. To them, "This is not to preclude the continuation of medical service provided on an individual fee basis for those who prefer the present method" (New York State Department of Health 1932). Not surprisingly, the major dissenters to such recommendations were private physicians who saw even voluntary insurance as destructively competitive (Starr 1982). As proponents of national public health policy, Parran and some members of CCMC with ties to the VD division went on to advocate for national health insurance (Clark 1999). Ultimately, the report was denounced by the AMA and others as a promotion of socialized "red medicine," a derogatory characterization that would follow Parran into his retirement. At the same time as it recommended a reorganization of medicine around hospitals and group practice, CCMC found that there was increased need for medical care and that physicians as a legitimate professional group should be authorized to form the standards for treatment. Chapter 5 will attend to how treatments are objects of financial classification as medicine and payers influence the development of standards of care. Importantly, CCMC failed to bring about agreement or restructuring of how medical care was organized and paid for (Starr 1982, 266).

However, the origins state and federal funding for medical services for the impoverished began "inadvertently and inconspicuously" during the Depression (Starr 1982, 270).

Furthermore, despite the AMA's opposition to cumpulsory health insurance, by the mid-thirties they began to set terms on which voluntary health insurance was acceptable to the medical profession (Starr 1982, 273). The push for health insurance gained new ground in the late 1930s during the Roosevelt presidency. His administartion set up the Interdepartmental Committee to Coordinate Health and Welfare Activities, which created the Technical Committee on Medical Care in 1937. The Technical Committee produced a report that recommended expansion of public health services, hospital facilities, increased aid for those unable to afford health care or who have lost wages due to health problems, and an investigation of a tax-supported medical care program (Starr 1982, 276). Roosevelt made portions of the report public and called a National Health Conference, which brought together representatives from labor, farmers, and health professions. The AMA felt the conference was another coordinated attempt to undermine physician autonomy (Starr 1982, 276). Despite public support, Roosevelt decided not to challenge the AMA or State Medical Societies about national health insurance (Starr 1982, 279). Thus, private health insurance plans grew silently during the 1920s and 1930s. Eventually the development of private health insurance helped to integrate physicians and hospitals (Starr 1982, 295). This compromise institutionalized a delicate balance between medical and public health authority where physicians were not subordinated to public health. Chapter six will attend more directly to the professional conflict and contest over domains of practice between medicine and public health.

Syphilis played an important role in the quiet origins of these safety net programs. As part of the Rosenwald demonstration project, state and federal welfare programs began to pay for medical services for the poor, which disturbed the AMA (Starr 1982, 271). However, during the Rosenwald demonstration project, private charities and private physicians could no longer afford

to meet the demand for free services. Thus, when federal funds disappeared states were forced to prioritize resources. For example, by 1930 Alabama categorized syphilitic patients into three groups: 1) patients who could afford care on fee-for-service basis with a private physician, 2) patients who could afford partial payment, and 3) patients who were medically indigent or who could not afford to pay for any treatment at all. The first group was not seen as a public health problem aside from their need for sex education. For the second, Alabama created a system of cooperative clinics staffed by private physicians selected by each county's medical society. These physicians volunteered a few hours each week to a clinic and were to charge patients no more than two dollars per visit while the state supplied the drugs and other necessary equipment. Free clinics for the medically indigent posed the biggest logistical problem for the state since clinics mainly existed in urban areas and indigent patients resided mostly in rural areas. Alabama, a mostly rural state, requested that private physicians outside cities treat indigent patients. In this way, doctors acted as gatekeepers because they classified patients by ability to pay and charged them accordingly. However, physicians created their own fee scales and so there was little standardization about the criteria by which patients were classified.

The fact that physicians were granted the authority to determine which patients were indigent and which had the ability to pay resulted in some physicians modifying their fees to meet the patient's economic status in an effort to receive some payment for their services. Even the two dollars charged at the cooperative clinics was prohibitive to patients accessing care since, as we have seen, treatment required nearly one year of visits for intravenous medications as well as years of follow up for testing and observation. To make matters worse, some physicians charged fees for their "in-kind" services even when they received medications from the state (Parran 1937, Jones 1993). Despite this, other cities and states followed this model whereby the

indigent were treated in free clinics and those who could pay were asked to pay for services on a sliding scale (i.e., pay clinics). Until large-scale anti-syphilis campaigns that began in the late 1930s, information about the number of treatment centers, cases, and fees charged for services was just beginning to be studied and, as such, was far from being standardized across jurisdictions (Parran 1937). As the Rosenwald demonstration project came to an end, however, the Rosenwald Fund began to study the ability of patients to pay for syphilis treatment finding that "for over 80 per cent [sic.] of the population, the minimum cost of treatment of syphilis at minimum private rates would take over ten per cent [sic.] of their incomes" while in "pay clinics" treatment of syphilis would cost less than ten percent of the income for 50 percent of people.[4] By looking at the cost of treatment proportional to income, these early studies focused attention on classifying patients by their ability to pay.

Although a national health system did not take hold, the government began purchasing public health care for the treatment of syphilis in 1938 with the passing of the National Venereal Disease Control Act under the direction of Surgeon General Parran, former director of the VD division of USPHS (Grassley, et al. 2005). The Act provided federal funding to state health boards for venereal disease control measures. In order to receive these grants, the legislation required states to submit to a summary of current activities and plans for improving these services on state and local levels to Parran. Money was then allocated for diagnostic and treatment centers, staff training, and research. The original bill provided over $271 million over thirteen years, "a national blitz against the disease," but was revised to $15 million over three years (Brandt 1985, 144). The Act also adopted VD control measures promoted by Parran, such as "contact epidemiology," the practice of notifying an infected persons' sexual partners.

[4] Davis, M. M. (1932). Draft report, "The Ability of Patients to Pay for the Treatment of Syphilis." Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

Contact tracing has expanded and is widely known today as “partner notification” which includes a range of services from counseling to medical treatment provided under the authority of public health rather than medicine (Gostin 2000, 121).

All in all, the number of clinics providing these services tripled from 1,122 in 1938 to 3,088 in 1941. Many of these were designated “rapid treatment centers” where syphilitic patients received a twenty-one day course of arsenic-based treatment on an outpatient basis (Green, et al. 2001). Private doctors continued to play a gatekeeping role referring patients to the clinics. However, as more information was being collected about poor patients, little was known about patients receiving treatment by private physicians. In 1940, an African American doctor wrote to the Surgeon General, "So long as the private practitioners are the arbiters of who shall be permitted to go to the clinics, it will never be determined whether the whites are actually being given adequate treatment or not, or, in fact, whether their infections are even being detected” (as quoted in White 2005, 574). Because of racial segregation, the categorization of race was embedded early on in the operational criteria used to classify patients in public clinics.

Under the provisions of the Lanham Act of 1943, funds were made available for the establishment of the centers in administered by the Federal Works Agency in two administrative categories: either operated by state health departments or where the interstate spread of venereal disease was deemed a serious problem, certain centers were operated directly by the USPHS (Pearce 1943). Thus, when the U.S. entered World War II in 1941, a nationwide network of clinics was established and able to deal with the anticipated wartime epidemic. Although patients could be referred by private doctors, patients were admitted and released at the discretion of the state public health officer in charge on a voluntary and involuntary basis (Pearce 1943). In 1944 the Public Health Service Act was passed. The act covered a broad spectrum of

health concerns, including the regulation of biological products and the control of communicable diseases. This act expanded the role and authority of USPHS to the following directives: coordinate with the States to set and implement national health policy and pursue effective intergovernmental relations; generate and uphold cooperative international health-related agreements, policies, and programs; conduct medical and biomedical research; sponsor and administer programs for the development of health resources, prevention and control of diseases, and alcohol and drug abuse; provide resources and expertise to the States and other public and private institutions in the planning, direction, and delivery of physical and mental health care services; and enforce laws to assure the safety and efficacy of drugs and protection against impure and unsafe foods, cosmetics, medical devices, and radiation-producing projects (Department of Health and Human Services 2005).

In 1945, penicillin became the drug of choice to treat syphilis and Congress gave USPHS authority to allocate funding to expand the rapid treatment centers as part of the national veneral disease control program (Heller 1946). In practice, however, only cases of early-stage syphilis were treated because pubic health officers incorrectly thought that late cases were non-infectious and harmful only to the infected (White 2000, White 2005). Yet men in the Tuskegee study were not offered even this. Further, while the rapid treatment centers admitted 185,000 patients nationwide in 1943, these were mostly military service personnel returning from overseas (Nakashima, et al. 1996). In Alabama, however, the clinic service was primarily for blacks who tested positive after the implementation of Alabama's 1943 mass testing law. Thus, the availability of treatment technology and a lack of standard criteria for assessing patients' ability to pay influenced who classified patients and how they were classified.

The Rosenwald demonstration contributed to the silent growth of government purchased health care during the Depression by showing the feasibility of testing and treating blacks in the South, when states paid for local staff implementing the program. The National Venereal Disease Control Act provided money for research on venereal disease and funded state venereal disease control efforts based in part on the Rosenwald demonstration. The Public Health Service Act consolidated and revised existing public health law substantially broadening the authority of USPHS to financially support state programs. Thus, states established protocols for how to classify patients in order to allocate treatments in a new organizational field of care. However, the issue of expanding health insurance coverage reemerged over the years.

Post-World War II policies created a large structure of medical schools, teaching hospitals, and related institutions that acted as a counterweight to privately practicing physicians. Constiuents from the academic side of medicine perceived their role as helping to solve society's problems. Thus, new educational programs were based on an ideology favoring increased access to healthcare. Moreover, after almost ten years of political wrangling, the Social Security Act of 1965 established Medicare and Medicaid. The legislation laid out three parts: Part A was a plan for mandatory heath insurance under Social Security; Part B was government-subsidized voluntary insurance to cover physicians' bills; and Medicaid was increased assistance to states to pay for the medical care of the poor. Some doctors claimed they would boycott, but Medicare turned out to satisfy both sides of medicine: it was a treasure trove for private physicians and use of medical care by the poor increased (Starr 1982). In the Medicare structure, the federal government gave up direct control over the program and its costs by allowing "fiscal intermediaries" to provide reimbursements, consulting and auditing services as well as assigning regional "carriers," primarily Blue Shield, to serve those functions geographically. Moreover,

the law adopted the Blue Cross practice of paying hospitals their costs rather than negotiating rates. Thus, the administration of Medicare was based on insurance systems that fit the interests of providers while the government simply paid the bill (Starr 1982, 375). Despite a continued gap in healthcare for the uninsured, Medicare and Medicaid established a system where the federal government plays a role in standardizing minimum criteria used by states to assess patients' financial and disease status.

HIV/AIDS: Challenging existing infrastructure through the financial classification of patients

By 1987, nearly 50,000 adult cases of HIV had been diagnosed and 13,468 deaths were attributed to the disease (CDC 1990). Hospitals recoiled at the possibility of dealing with all the impending cases. Third party payers also cringed at paying hospital costs upward of $600-$800 per day (Heagerty 1987). Estimates of the cost of these first AIDS cases varied widely from $50,000 to $150,000 from diagnosis to death and from an annual cost per case of $20,000 to $60,000 (Institute of Medicine 1986). Even the average costs for nursing home and home care were far less expensive, starting as low as $100 per day (Hellinger 1994, New York Times 1987). Many may have over-estimated the actual cost of AIDS (see Scitovsky, et al. 1986 and Seage, et al. 1986); nevertheless, the perception that AIDS would financially burden the medical system was widespread and influenced the organization of AIDS treatment, especially in terms of utilization of inpatient hospital services. Beyond the costs of hospitalization, patient activists and public health officials also worried about how stigma affected access to hospital care. There were reports of "patient dumping" with some hospitals refusing to admit patients with HIV even after the Federal Emergency Medical Treatment and Active Labor Act (EMTALA, also known as the Patient Anti-Dumping Law) was passed in 1986 (McCormick 1993) and private hospitals referring patients to public and charity hospitals (Jonsen and Stryker 1993, 66).

The San Francisco model of care, with its use of volunteer buddy systems, offered a cheaper and less discriminatory alternative to hospitalization. The San Francisco model consisted of community and home-based outpatient care using not only healthcare providers but volunteers and social service agencies. The model was developed in collaboration by local government and community based groups in the Bay Area and was credited with reducing the length of AIDS-related hospital stays in San Francisco; the average hospital stay was 11.7 days in San Francisco compared with 25.4 days in New York City, where outpatient community-based care did not exist (Bronner 2003). Since home-based care was provided by volunteers for AIDS social service agencies, friends, partners and family members, those costs were not reimbursed by third party payers nor were they absorbed by hospitals (London 2001). The first comprehensive AIDS care clinic was created in 1984 followed by the incorporation of the community-based, collaborative model of care in 1985 (Volberding 1985, Institute of Medicine 1986, Bronner 2003). AIDS activists and clinicians worked together to provide care; for example, volunteers from the San Francisco AIDS Foundation set up hotlines to refer cases to the clinic. In this way, the formative years of AIDS care established the community as gatekeepers for care rather than private doctors.

This was necessary since the initial creation of the San Francisco model was a response to widespread stigma and government inattention. The Reagan administration treated AIDS as a problem for state and local boards of health, largely ignoring the problem and making little to no public comment on the epidemic until 1985, the same year that CDC stopped funding AIDS education programs because the administration thought this work was equivalent to teaching people how to have anal intercourse (Bronner 2003). In 1987, the Helms Amendment banned the use of federal funds for programs that encouraged or promoted homosexual activities either

implicitly or explicitly (Bronner 2003). This political atmosphere of silence fueled the stigma of HIV/AIDS in the medical community and diminished the authority of public health to educate the public. Many private physicians refused to see patients in the early days and likely underestimated the number of their patients at risk for HIV. In fact, only 40 percent of surveyed AMA physicians reported that they obtain at least a brief drug use and/or sexual history on all their patients (Bresolin, et al. 1990). Furthermore, 56 percent of these reported a fear of getting infected from their patients with AIDS; 83 percent reported that physicians in general were fearful of getting infected (Bresolin, et al. 1990).

Amid this atmosphere of fear and stigma, the Robert Wood Johnson Foundation's (RWJF) AIDS Health Services Program began funding AIDS specialty clinics in hard hit U.S. cities in 1986 (Institute of Medicine 1993). This was an unusual decision for RWJF, when founded in 1972 explicitly decided against funding disease-specific projects (Bronner 2003). However, by the early 1980s urban hospitals, also oftentimes serving as teaching hospitals for medical students, were swamped with inpatients devastated by the crack epidemic (Levenson 2004). According to Drew Altman, then vice-president of RWJF, the San Francisco model might save teaching hospitals around the country which were struggling to make ends meet and unprepared for a stream of patients with AIDS (Bronner 2003). RWJF funded 11 demonstration projects to test the San Francisco Model of care. The projects were funded with the expectation that, if successful, another party would match the grants and take over the programs (Bozzette, et al. 2001).

According to a nurse practitioner who helped to establish an AIDS clinic with Robert Wood Johnson funding,

> I came to the health system in December '85 because they had like five patients in the hospital who, now we know retrospectively, they probably had MAC [Mycobacterium

> avium complex][5], but we didn't know what MAC was in '85 or '86. So, they had diarrhea and fevers, and they were always coming in for fluids, blood transfusions. Then you had the folks who were diagnosed with Cryptococcal Meningitis, and the only drug we had back then was Amputerasin, and you had to get an IV every day. So, health system's big dilemma, even though there weren't many patients, was we gotta get somebody who can set up an outpatient clinic program that's gonna be able to treat people in an acute setting without keeping them in the hospital until they died…And, so, that was my charge. Figure out a way to get these five or six patients out of the hospital, give the blood transfusions, and I guess just the scope of stepping into something new. (interview 050216)

However, as these patients approached death there was not a nursing home in the state that would take them (interview 050216). Even after death few funeral homes would deal with the bodies (Levenson 2004).

Four years after RWJF awarded the first grants, the federal government allocated emergency funds to continue the programs with the passing of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in 1990 (Bronner 2003). Similar to the National Venereal Disease Control Act of 1938, the Ryan White CARE Act (CARE Act) provided grants to states to implement partner notification services, including medical treatment. Unlike the 1938 Act, however, the CARE Act provided grants to Eligible Metropolitan Areas (EMAs), cities and surrounding counties with the highest number of living AIDS cases, to provide medical treatment modeled on the RWJF clinics. Most notably, the CARE Act built upon infrastructure built around syphilis and continued to grant authority to state and local jurisdictions about the best way for programs to be organized. Since the inception of the Ryan White program, funding has been allocated using both mathematical formulas (formula award) and the expert review of qualitative and quantitative data proposed by applicants to justify

[5] Mycobacterium avium complex (MAC) is an opportunistic infection caused by bacterium commonly found in the environment. Mycobacterium can enter the body through the respiratory or gastrointestinal tracts and manifest as multisystem infections with nonspecific symptoms and signs such as fever, sweats, weight loss, abdominal pain, fatigue, chronic diarrhea, and anemia and even central nervous system disorders (AIDS Education & Training Centers National Resource Center 2008).

budgets (supplemental award) to different geographic areas under three main medical service provision titles: Part A (formerly Title I) for metropolitan areas, Part B (Title II) for states and local health districts, and Part C (formerly Title III) for rural areas. The CARE Act was first reauthorized in 1996 and extended services to women and children through the creation of Part D funding (formerly Title IV) (Kaiser Family Foundation 2006a). The majority of funds go to states and metropolitan areas with 70 percent of all Ryan White program funds allocated to Part A and B programs in fiscal year 2001 (Institute of Medicine 2004, 87).

At the time of the CARE Act, there were very few but costly treatment options available and AIDS clinics originally funded by RWJF witnessed a great deal of death. One nurse practitioner and clinic manager who was originally hired to start a clinic with RWJF funds recounted,

> …by 1990, all I remember is every day we turned around there were men coming off that elevator literally almost dying on the floor. And it stayed that way until we maxed out. By 1992 we had five to seven hundred deaths a year in our clinic…We had basically turned a conference room into a MASH unit. We had sheets with paper clips…we would do hydration with IV fluids, and blood transfusions, and sometimes antibiotics…And you know, we got a lot more physicians, that's when I got mid-levels [physician assistants, nurse practitioners, and other advanced practice nurses], got more physicians, I mean a lot got laid down in the early years. I tell people, if you had to set up a program any time after 1994 in the United States, we could have never done what we've been able to accomplish in terms of multi-disciplined, what I call really full-scale medical and ancillary healthcare because healthcare has just become so layered and so expensive. (interview 050216)

Thus, by the time funds approved by the CARE Act were allocated in 1991, clinics such as this one had established an interdisciplinary outpatient clinic organized around acute and palliative care. When, in 1995, the first protease inhibitor (PI), Saquinivir was approved in record time by the Food and Drug Administration (FDA), patients, clinicians, and payers were optimistic. As treatments improved, however, clinics such as this would have to adjust to providing patients long-term care.

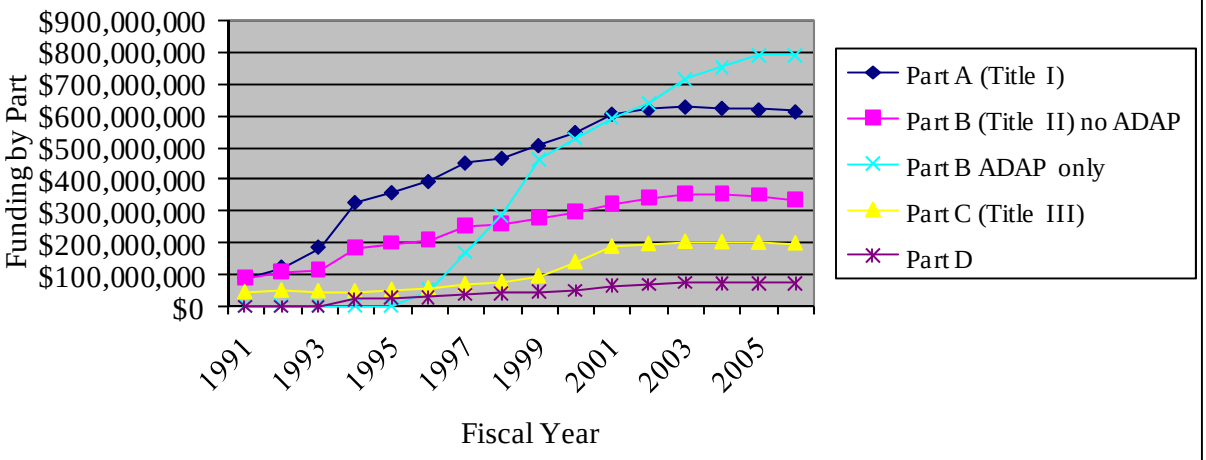
In 1996, two additional protease inhibitors became available, ushering in the era of Highly Active Antiretroviral Therapy (HAART) and the demise of single drug treatment (monotherapy), revolutionizing the care and management of HIV-infected patients (Smart 1996; Hirschhorn, et al. 2005). HAART entails the use of at least three drugs from at least two of the four classes of HIV drugs: nucleoside transcriptase inhibitors, non-nucleoside transcriptase inhibitors, protease inhibitors and fusion inhibitors (Department of Health and Human Services [DHHS], 2006). HAART was a key turning point in HIV/AIDS care. A second landmark in treatment innovation occurred in1996 with the advent of HIV viral load testing, which measures the amount of virus on the blood, thereby measuring the effectiveness of HAART. Chapter 5 provides a fuller discussion of how HAART became the object of financial classification through the development of standards of care. Thus, in 1996 the CARE Act was reauthorized to provide funds for states to provide medications through the AIDS Drug Assistance Program (ADAP) awarded through Part B (HIV/AIDS Bureau, Health Resources and Services Administration 2008).

As illustrated in Figure 4.1,[6] with the exception of ADAP, Ryan White program funding patterns increased from 1991 until 2001, but have remained flat or decreased since then. With the advent of HAART, deaths from AIDS and AIDS cases themselves declined as diagnostic and treatment technologies enabled the identification of asymptomatic HIV infection and extended the lives of those living with AIDS (see also Figure 3.1 AIDS Cases, Deaths, and Persons Living with AIDS, 1985-2005). Since its inception, Ryan White legislation increasingly favors funding direct medical services and drugs over the original San Francisco Model adopted in 1990, which favored the inclusion of support services such as “buddies” who helped AIDS patients with

[6] Adapted from historical appropriation data available for download from http://hab.hrsa.gov/reports/funding.htm.

cleaning and cooking at their home since patients often lacked other family support during their death. Indeed, beginning with the Ryan White HIV/AIDS Treatment Modernization

Figure 4.1 Selected Ryan White Program Funding, 1991-2006



Act passed in 2006, 75 percent of program funds must be spent on "core" services (e.g., ambulatory care, oral health, pharmaceutical assistance, substance abuse services, hospice, treatment adherence, medical case management) (Kaiser Family Foundation 2006a).

Advances in testing and surveillance have also impacted the allocation of Ryan White funding over the years. In 1990 when the CARE Act was first passed, data used for the formula had to be certified by the CDC to designate Eligible Metropolitan Areas (EMAs) who were eligible for Part A grants. At that time, once an area was designated an EMA they remained an EMA and were eligible for continued funding. Ten years later, there was concern that living AIDS cases underestimated HIV disease in emerging areas (Institute of Medicine 2004). As we saw in the last chapter, HIV reporting was controversial, igniting a "firestorm of community protest" (Gostin, et al. 1997). Thus, when the Ryan White CARE Act was reauthorized in 2000, the legislation required the Institute of Medicine (IOM) to evaluate whether state HIV surveillance systems provide adequate and reliable information on the number and demographic

characteristics of HIV cases and sufficiently accurate for purposes of awarding formula-based grants. The IOM report concluded that AIDS cases should continue to be used to allocate limited Ryan White funds until HIV case reporting is more reliable and comparable across states and jurisdictions (2004).

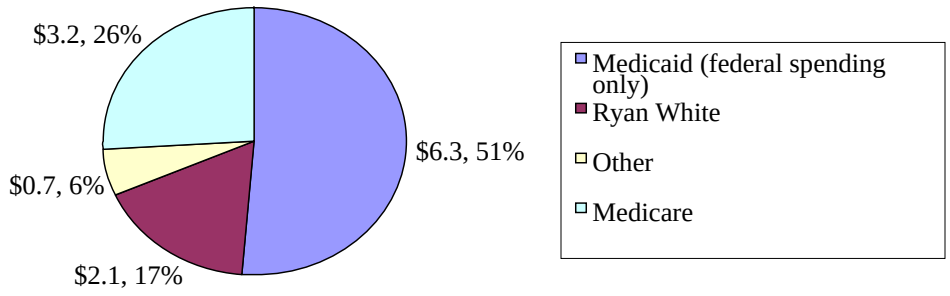
Despite this, the 2006 Ryan White HIV/AIDS Treatment Modernization Act allocates formula awards according to an algorithm using previous calendar year living HIV and AIDS cases certified by CDC with a preference for name-based reporting (HIV/AIDS Bureau 2002, Kaiser Family Foundation 2006a). Moreover, while formula-based awards may be appear simpler and more objective than competitive allocations, "this appearance may be deceptive and mask underlying values or priorities that shape the selection of formula data sources or calculation methods" (Buehler and Holtgrave 2007). As we have seen, there is variation between states HIV/AIDS surveillance practices (e.g., name-based versus code-based, year of implementation) and the provision of safety net healthcare for the uninsured and under-insured (e.g., city and state public health programs). The most recent states to institute HIV case reporting, such as Georgia who implemented HIV reporting at the end of 2004, did so only when CARE Act funding for treatment programs became tied to the ability to de-duplicate cases as part of reporting (Glynn, et al. 2007; Institute of Medicine 2004). During a phone conversation on August 29, 2008, Jeff Cheek, Director of the Fulton County Ryan White Part A Program, explained that rather than using the grantee's own qualitative and quantitative justifying their budget, the Atlanta EMA's 2007 formula funding was based on the CDC's mid-point of the estimate for HIV in Georgia because CDC had not yet certified the state's HIV surveillance data. This estimate may represents an undercount of HIV cases, but was used because the state's

reporting system was considered immature by CDC since it had not been operating for five years.

The 2006 legislation also created transitional grant areas (TGAs) in addition to EMAs. While both TGAs and EMAs are eligible for federal funds, eligibility is based on the most recent calendar year living HIV/AIDS. Thus in order to maintain EMA or TGA status, initial AIDS cases and minimum living AIDS cases must remain fixed. Since these formula-based funds are awarded annually, EMAs and TGAs have increased uncertainty about whether an expansion of health services will be possible from year to year (Roussel 2008). Some grantees have elected to spend funding on equipment and temporary personnel rather than develop new services (Roussel 2008). Jeff Cheek also reported during a telephone conversation that renewed attention is being paid to improving the process and quality of counting HIV cases.

By law Ryan White programs are the "payer of last resort." According to a 2007 policy update sent to Ryan White grantees, funds must be used to "supplement" rather than "supplant" existing funds from local, State, and Federal healthcare programs. Thus, grantees must be able to provide related documentation, such as back bills to Medicaid for services provided to Medicaid eligible patient (HIV/AIDS Bureau 2007). While Medicaid coverage varies widely from state to state, as Figure 4.2 below illustrates, to date, Medicaid is the largest payer of HIV care in the U.S. in the billions of dollars (Kaiser Family Foundation 2006c). Medicaid pays for comprehensive health care as well as prescription drugs. However, Medicaid requires that an individual meets both income and categorical eligibility to receive these benefits. With the exception of demonstration projects, state Medicaid programs are mandated to provide services only to those with full blown AIDS (027_DC_US_050323_RC). Thus, Medicaid presents a

Figure 4.2 Federal Spending on HIV/AIDS Care by Program, Fiscal Year 2006[1]



"Catch 22" since it often doesn't pay for an HIV-infected person's care until they are quite sick and are categorized as being disabled, despite the existence of treatments that can prevent them from becoming disabled (Kaiser Family Foundation 2006c). According to Centers for Medicare and Medicaid (CMS) staff, Medicaid is built on clinical/reactive model, so pays for when people are sick rather than preventing people from getting sick (027_DC_US_050323_RC).[7] The Ryan White Program fills the gap of this Catch 22 by covering the cost of care for HIV-infected individuals who are not eligible for Medicaid. HIV-infected individuals who do not have Medicare, Medicaid, or private insurance and meet income requirements may qualify for various Ryan White programs, including ADAP. Since Ryan White program grantees may be subject to federal audits to look for documentation that other payer source options were used first. However, just as state surveillance systems vary, so too do coverage of HIV/AIDS care by state Medicaid programs. Thus, individual cases that enter safety net treatment programs must be

[7] The provision of antiretrovirals in urgent cases ultimately costs hospitals less by preventing patients from getting a lot sicker. This is complicated by the fact that the state's Medicaid program paid only for care once a patient had full blown AIDS. While there is growing evidence that starting anti-HIV therapy before the onset of AIDS can postpone a patient's disability, many low-income people infected with HIV aren't eligible for benefits until they are disabled. A Medicaid demonstration project in Maine was designed to provide early treatment for HIV. Maine's demonstration and waiver project is based on a budget that neutralizes the cost of hospitalization by starting ARVs before disability sets in. A component of the plan also relied on discounts from drug manufacturers on top of those given to Medicaid already, so in its early stages the project was embroiled in legal conflict over drug pricing with the pharmaceutical industry itself (027_DC_US_050323_RC, Laurence 2001).

categorized on an individual basis, in order to first assess eligibility by documenting potential payer sources such as Medicaid.

I observed the process by which individuals come to be classified financially and become patients in an HIV clinic funded through the provision of a Ryan White funding. Thus, to be eligible for care, patients must meet both clinical and financial eligibility criteria under federal and local provisions of Ryan White funding. In this particular state, those 300 percent above the federal poverty limit (FPL) are eligible to receive care as of June 2001 (Institute of Medicine 2004). This clinic was funded to serve primarily AIDS patients and so patients were referred from other Ryan White funded clinic in the EMA. Thus, eligibility criteria also include a CD4 count less than 200 or an AIDS-defining condition such as Kaposi 's sarcoma (fieldnotes 031226, fieldnotes 040123). Thus classification begins, as with many safety net programs aimed at the poorest and sickest, in a new patient's first encounter at the facility by meeting with a financial counselor. During this meeting, potential patients provide documentation of their income or lack thereof and any payer sources they may have for care, including Medicaid and Veterans benefits.

Once financial eligibility was determined for Ryan White or another payer source, then patients were screened for tuberculosis (TB) and given a CD4 test. As a recipient of Ryan White dollars, however, the clinic was required to collect demographic and risk information and report it in aggregate to HRSA each year so that Congress can assess whether the funding is reaching targeted populations identified through HIV/AIDS surveillance. Thus, when patients returned three days later to have the TB skin test read by a nurse and set up their first medical appointment, they also met with an HIV educator who continued to classify the patient using an intake form (fieldnotes 040123). With this form (see Figure A.2 in the Appendix), the HIV

educator collected information such as gender, race, housing status, disease-stage, as well as when and how the patient was first diagnosed. These HIV educators also ask patients about how they think they got HIV by asking "Which one of these HIV/AIDS transmission categories applies to you?: Men who have sex with men, Injection drug use, Men who have sex with men and injection drug use, hemophilia/coagulation disorder, heterosexual contact, transfusion of blood, perinatal (mother-to-child), other HIV exposure, unknown/undetermined" (fieldnotes 040123). I observed two educators who used this question to talk with patients about how HIV is transmitted and thus how to prevent someone from getting it from them. They also educate the clients about infections they are susceptible to because of their HIV infection and how they can prevent them and also answer any questions that the clients may have about their HIV infection. One client asked whether he needed to wash his hands around their nieces and nephews because of his HIV infection.

According to HRSA, in 2002, at least one of every two Ryan White clients lived below the Federal Poverty Level (FPL), fewer than 10 percent had any private health insurance, and only 27.9 percent were enrolled in Medicaid. This program data also revealed that 67.6 percent of these clients were male, while 31.3 percent were female. Forty-six percent of patients were African American, 35.4 percent were white, and the rest were other minorities or unknown. HRSA concluded that the clients served by Ryan White "were served in roughly equal proportion to their representation among people living with AIDS" (HIV/AIDS Bureau, Health Resources and Services Administration 2005). While client data collected by the Ryan White program are compared with epidemiological data, they are not unduplicated at the national level. Beginning in 2009, recipients of Ryan White funds will be required to submit client-level data that can be unduplicated at a national level (HIV/AIDS Bureau 2008). However, data elements

will continue to be captured in highly variable ways since it is clinics who design forms such as the intake form described above.

Despite the institutionalization of formula-based awards and the collection of program data in administrative classification systems, such systems are not as value-free and transparent as they may appear. Thus, they are susceptible to debate and controversy. For example, those who do not believe that the HIV virus causes AIDS, Peter Duesberg and other "AIDS dissenters," argue that AIDS is a "category" formed through grouping classification rather than a disease classified causally with the identification of a specific etiological agent. The myriad of illness included in the CDC definition, they argue, are not new to us. Rather than HIV causing AIDS, they argue, AIDS is brought on by other factors that cause immunodeficiency including malnutrition, poverty, crowded living conditions, chemotherapy including AZT and other anti-HIV drugs, poppers, illegal drugs such as methamphetamines, crack, and heroin. The list goes on to include such things as infection with other STDs, anxiety and depression. That the AIDS case definition includes a positive test for HIV codifies the relationship between the virus and the disease. This is problematic for AIDS dissenters because even if the clinical diagnosis and symptoms were the same for an HIV positive person and negative person with pneumonia the clinical outcomes would not be the same. In 1993, the case definition was expanded to categorize individuals who tested positive for HIV and have T cells lower than 200 as AIDS cases even if they are not "sick." AIDS dissenters argue that over half of the new AIDS cases since then are not sick and have no clinical symptoms of disease (Alive & Well Alternatives 2005, Root-Bernstein).[8] Some dissenters argue that the case definition was expanded in order to

[8] The U.S. uses different criteria for defining AIDS than Canada and the world Health Organization. Canadian and European definitions of AIDS are based on the CDC definition, but exclude a T cell count <200.

expand access to healthcare rather than to refine the etiology of the disease itself in order to improve the science of diagnosis (Root-Bernstein n.d.).

Conclusion

As ways of counting and assessing need have become more standardized they have become more directly tied to funding and contribute to the convergence of definitions of disease between grouping, causal, administrative, and moral modes of classification. In this chapter we observed the transformation of public health from relatively new with syphilis to increasingly legitimate in the era of HIV/AIDS as quantification across social, behavioral, and medical sciences has increased. According to Porter (1995), the credibility of quantification is a moral and social problem. In this sense, expert knowledge is a product of the relationship between professionals, here medicine and public health, rather than truth of a scientific sort. Indeed, official statistical categories are often contested terrain. Despite being the creation of humans, these categories become attached to humans and often resist change during the process of social construction of disease. As Porter asserts,

> Legions of statistical employees collect and process numbers on the presumption that the categories are valid. Newspapers and public official wanting to discuss the numerical characteristics of a population have very limited ability to rework the numbers into different ones. They thus become black boxes, scarcely vulnerable to challenge except in a limited way by insiders. Having become official, then, they become increasingly real. (1995, 42)

Since the symptomological and etiological classification of cases of syphilis and HIV/AIDS are so intimately intertwined with the financial classification of patients in order to for organizational fields of care to exist for populations and for individuals to become patients at the clinic level, we can see how constructions of the disease themselves are reinforced and adjusted for through administrative classification. As we have seen, a shared understanding of disease

converges and become “real” when individuals are transformed from rates into cases when becoming patients in a publicly funded clinic.

The comparison between syphilis and AIDS is instructive because although syphilis case processing suggests that those cases identified as part of dragnets were more likely to be impoverished Southern Blacks who couldn’t afford treatment themselves and were infecting one another at alarming rates. While these cases were used to justify philanthropic and state funded public health programs, private doctors acted as gatekeepers in the financial classification of patients. Moreover, because ways of counting were not fully formed nor standardized, funding of rapid treatment centers were based on expert review of program plans. By contrast, with HIV/AIDS case counting is more developed yet remains unstandardized with state reporting laws and surveillance systems. Official case rates inform the allocation of state resources to support treatment programs, but these cases only become official on a population level once the required amount of supplemental information about the individual is collected. Thus, even when ways of counting are institutionalized as seemingly objective allocation processes, moral classification continues to influence how diseases are understood because public health officials and funders act as gatekeepers by valuing certain forms of counting and categorizing over others. As testing campaigns and treatment technologies improve the ability to identify cases earlier and delay the progression of disease, the financial classification of patients adjusts impacting both the way care is organized as well as how people with disease become patients.

Seemingly static administrative solutions to public health problems, such as funding algorithms and criteria used to determine client eligibility, can be morally and politically charged when there are not enough resources available to fund treatment for all the infected. This was exacerbated in the case of syphilis and AIDS, since both were marginalized from existing

medical infrastructures both because of stigma and because of a lack of effective treatments. Indeed, probability and conceptions of risk are based on the systematic collection of information about deviants (Hacking 1990). In addition, organizations often collect vast amounts of information more for symbolic value rather than for practical decision-making. Thus, the production of knowledge symbolizes competence, authority, inspires trust, and legitimates decisions (Feldman and March 1981). Even when the allocation of resources becomes more systematic and quantitative, moral classifications remain. Moreover, as strategic bids for legitimacy become habitual, organizations can forget that they ever intended them. As Espeland (1998) emphasizes, the symbolic significance of our most precious categories transcends the capacity to measure their empirical impact. In the end, difference can be expressed or erased as part of the institutionalization of bureaucratic routines which have the added effect of making such operations appear to be at worst veiled in secrecy and at best immune to political visibility.

The deployment of etiological classification of syphilis and AIDS converge in the overlap between grouping, causal, moral, and administrative classifications that are involved in the feedback loop between diagnosis, how cases are tallied and resources are allocated, how patients receiving treatment are counted, ultimately influencing the counting of cases itself. As we have seen, the classification of patients by severity of disease and ability to pay is a financial type of classification that is embedded in administrative classifications at the individual patient level. As patients are evaluated in order to become patients in a clinic, rates are transformed into cases at the clinic level. Etiological definitions and moral evaluations of those infected with syphilis and HIV/AIDS are operationalized through the implementation of law at the clinic level of practice as protocols and regulations designed to allocate limited healthcare funding to the neediest patients are implemented. As we will see in chapters 5 and 6 respectively, this process of

classifying the patient as eligible for services operates concurrently with the financial classifications of both treatment and expertise.

CHAPTER 5

CLASSIFYING TREATMENT: UNCERTAINTY AND THE STANDARDIZATION OF CARE

This chapter examines how the financial classification of treatments (e.g., procedures, visits, prescription drugs) for syphilis and HIV/AIDS are developed through standards of research and practice and then dealt with at the clinic level. Treatments become objects of financial classification during decision-making about the best available treatments and facilitation of their purchase. Row 4 of Table 1.2 summarizes this type of classification. As we will see, medical providers use existing classifications and develop local workarounds to existing classifications in order to ensure payment for providing the best available treatment to patients. In the early twentieth century, a lack of codified, "official" standards outlining the most effective treatment and its price resulted in a repertoire of services and fee scales authorized by medical providers, based primarily on their own previous experience, best judgment, and individual finances. Thus, organized medicine and public health collected information about how providers themselves treated patients and the fees for those treatments. By contrast, treatments for HIV/AIDS were integrated into existing structures of evidence-based medicine and fiscal classification systems, resulting in the development of local workarounds by providers to ensure that the best treatments are provided to patients in a context of fiscal constraint. The development of standards of treatment is closely linked to determining the cost of treatment. With both syphilis and HIV/AIDS, then, providers balance population-based discourse with individual-level practice when classifying treatments as fiscal objects. Thus, multiple stakeholders influence and are influenced by the financial classification of treatments.

Similar to the financial classification of patients, increased attention to venereal disease by public health (e.g., funding of rapid treatment centers) coupled with the rise of third party

payment structures (e.g., health insurance, Medicare, Medicaid) helped trigger a drive toward official standardization targeting both the effectiveness and cost of treatment that continues today. The financial classification of treatment serves as a mechanism of social construction for syphilis and HIV/AIDS because providers' ability to treat the diseases effectively is a process of managing uncertainty about what treatment to select for a patient based on its likelihood to be effective, any associated side effects, the ability of the patient to adhere to it, and its cost. Scientific medicine is a symbolic system of coping with medical uncertainties (Fox 1974), and medical science and technological advances reveal the ignorance and mistakes of medicine (Fox 1980; Gerrity, et al. 1992). As we will see, when stakeholders improve their precision, the uncertainty of medicine becomes more obvious and potentially more morally charged. Treatments for syphilis and HIV/AIDS are not curative, cause severe side effects, require patients to take them for extended periods, are expensive, are increasingly regulated, and enter the marketplace at an increasingly faster pace. Fox notes an "uncertainty-about-uncertainty" flavor to this process that may signal a larger cultural disorientation when it comes to the constant re-examination of which treatments are best (Fox 1980, 44). Pressures to thwart increased costs of these treatments intensify the predicament (Gerrity, et al. 1029). Thus, treatments may be affordable and effective under some circumstances and cost-prohibitive and ineffective in others, resulting in increased attention to uncertainty in low-tech and fiscally constrained clinical settings.

Since the Second World War, standards for how drugs are developed, studied, and marketed have become more settled and regulated. Treatment technology is classified and ranked according to efficacy based on types of evidence demonstrating efficacy (Petty 2008). At the same time, standardization of and regulation over treatment technology increased the

availability of novel treatments for patients simultaneous to their study. Despite this, there is often a lag between the availability of treatment and the recognition of treatments as purchasable objects by payers of healthcare. Consequently, stakeholders can influence the legitimization of treatments, particularly how these treatments become recognized in fiscal systems through discourse and practice of standards of care. Although technological innovations of treatments appear to decrease uncertainty with syphilis and HIV/AIDS, fresh uncertainties are introduced with efforts to standardize treatments into everyday practice. After all, there has been excitement and optimism with the advent of new treatments (e.g., Erlich's "magic bullet" for syphilis, HAART for HIV/AIDS) only to be met with unintended consequences (e.g., arsenic poisoning with salvarsan, viral mutation with HAART).

In order for these new uncertainties to be resolved, providers must select the most appropriate treatment for their while remaining cognizant of how much it will cost and who will pay. The manner by which these uncertainties become settled differs over time as well as over the life course of a disease. In this way, uncertainty can be resolved in part by science or resolved primarily by developing workarounds to administrative classifications. Other forms of uncertainty, such as the variation of individual patient adherence and health, are more difficult to manage through either science or administrative tools. Moreover, the relationship between technology and health is not linear. For instance, treatments that target symptoms may be available before treatments that target the cause of those symptoms. Moreover, treatments themselves cause unintended problems resolved by another treatment, adjustments in treatment regimens, and/or the use of tests to track the intended and unintended effects of treatment. As Gerrity, et al. argue, "expectations have grown as the number of serious diseases cured has increased and knowledge expanded; this resulting a more painful uncertainty when medicine's

limits and doubts are confronted" (1992, 1023). Thus, the resolution of one form of uncertainty impacts the occurrence of others and the character of the uncertainty itself.

Importantly, symptomological and etiological classifications adjust in the lag between technological innovation of treatments and their integration into administrative systems, which influences collective understandings of diseases. Although the cost of healthcare has long been a concern of medicine and public health, attention to innovation and organizational workarounds are foci during the classification of treatment more for some disease than others. Both syphilis and HIV/AIDS are reputed as complicated and expensive diseases to treat, not least because success depends partly on patient behavior. Even after syphilis became a curable disease, patient adherence remains a strong component of how we understand it since patients are blamed for contracting it in the first place. As we saw in the last chapter, an array of administrative classifications was developed since the early twentieth century in an effort to downplay these moral evaluations. Today providers deal with these uncertainties by responding to existing systems of classification such as evidence-based medicine and financial coding schemes.

When financial classifications have not caught up with standards of care, however, providers use existing classification in new ways. Likewise, when financial classification lags behind science itself, professional associations deliberately codify standards in treatment guidelines to influence their purchase. Thus, the practice of evidence-based medicine and the multiplicity of payer sources continue to provide momentum for increased standardization and fine-tuning of classification at the level of the clinic where providers interact with both patients and organizations. However, when there is not enough treatment to go around because of a lack of resources or technology, treatments are selected based both on their classification as effective as well as on the likelihood of patients to comply with treatment and tolerate its side effects.

Thus, with both syphilis and HIV/AIDS the moral evaluation of patients overlaps with the classification of treatment.

In the early decades of the twentieth century, there was little information to guide providers about how to treat syphilis and how much treatment should cost. Medicine was interested in improving individual patient health and being appropriately compensated for their individual time and skills. By contrast, public health was interested in the effects of treatment on society, such as its ability to control epidemics and to finance these efforts aimed at the public good. Although many books and papers were published in the early decades of the twentieth century, these described physicians' preferences for treating syphilis based on individual clinical experience with patients rather than describing evidence from systematic or comparative studies. In the 1920s, Thomas Parran and others in public heath organized cooperative efforts to collect and disseminate information about which treatments work best. These efforts were also based on the grouping of individual practices rather than a Randomized Controlled Trial (RCT), the "gold standard" of clinical research today.

For example, in *Shadow of the Land*, Parran outlines specific ways for treating syphilis based on the Rosenwald demonstration project. These treatments were aimed more at stopping the spread of disease rather than improving the health of a particular patient. In the lower tech setting of syphilis, a focus on prevention by public health authorities was warranted, particularly when there was great variability across clinics in terms of being properly equipped to track the efficacy of treatment. Indeed, Parran recounted that the chief of a syphilis clinic had not been given permission to purchase the equipment necessary to fully diagnose syphilis until it became known that he was coming for a visit:

> Much as I regret this implication of characteristic tactlessness on my part, I have wondered since then if it might not help the good cause to cultivate my reputation for

> speaking rudely about poor equipment and service and make more, and more widely-heralded visits to syphilis clinics the country over. Yet in spite of this single circumstance to uphold the theory, I can't help thinking that if the patient had a clearer idea of what good service is, and if reasonable support for their clinic services were available from public funds, the voluntary hospitals could level up their standards rather promptly without the need for swashbuckling supervision. (Parran 1937, 149)

Early public health logic, then, envisioned the government as a purchaser of treatment, including supporting and enforcing the technology and equipment necessary for treatment at the clinic level.

Since then, the practice of evidence-based medicine has become a core mode of practice for medicine as a professional discipline. Evidence-based medicine is defined as "the conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients" (Sackett 1998, 1085). Its practice involves incorporating individual clinical expertise with the best available evidence from external systematic research, from the basic sciences of medicine, and from patient-centered clinical research on the efficacy and safety of treatments as well as the accuracy of diagnostic tests and symptomological markers associated with the disease and its treatment. Such research invalidates previously accepted treatments and replaces them with new and more powerful, more accurate, more efficacious, and safer treatments (Sackett 1998, 1085). Treatment guidelines rank available research and expert findings about which treatments work best and offer a recipe of sorts for providers to follow when deciding how to treat a particular patient's condition (see Petty 2008).

Today, providers practice evidence-based medicine at the clinic level by adhering to "standards of care" codified in treatment guidelines. The extent to which a care provider deviates from a guideline depends upon how settled treatments are for that disease entity as well as the resources available to pay for treatment. Thus, curable conditions may have an algorithmic or otherwise formulaic guideline limited to a discrete set of procedures and drugs,

while chronic diseases may require an evolving and continual set of procedures and drugs because long-term treatment is complicated by obesity, old age, and other infections. As Table 5.1 shows, numerous guidelines exist for preventing and treating opportunistic infections in HIV patients, using viral load and resistance testing as part of treatment, as well as guidelines for particular types of patients (e.g., pediatric patients and pregnant women).

Table 5.1 HIV/AIDS Treatment Guidelines, Authors, Years, and Frequency of Updates[1]

Author(s)	Title	Year of First Publication	Number of versions
National Institute of Allergy and Infectious Diseases (NIAID)	Antiretroviral Therapy For Adult HIV-Infected Patients: Recommendations From a State-of-the-Art Conference	1993	1
USPHS, Infectious Disease Society of America (IDSA)	Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents	1995	9
International AIDS Society-USA (IAS-USA)	Interim Guidelines for the Use of Plasma HIV RNA Assays for Patient Management	1996	1
	Recommendations for the Use of Antiretroviral Therapy	1996	7
	Recommendations for CMV Treatment	1998	1
	Recommendations for the Use of HIV Resistance Testing	1998	2
	Use of the Ganciclovir Implant for the Treatment of Cytomegalovirus Retinitis in the Era of Potent Antiretroviral Therapy	1999	1
	Management of Metabolic Complications Associated With Antiretroviral Therapy for HIV-1 Infection: Recommendations of an International AIDS Society–USA Panel	2002	1
DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, A Working Group of the Office of AIDS Research Advisory Council (OARAC)	Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents	1998	18
Public Health Service Task Force	Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States	1998	20
National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), HIV Medicine Association of the Infectious Diseases Society of America (HIVMA/IDSA)	Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection	1998	15

[1] Compiled from current and archived guidelines available at www.aidsinfo.gov and www.iasusa.org.

As technological advances are made and as payers fund treatments, guidelines are adjusted and updated. Taken together, these guidelines codify the standard of care for HIV-infected patients in the U.S.

As illustrated in Table 5.1, the guidelines for HIV/AIDS are authored and updated by a variety of groups, including medical professional associations (e.g., IAS-USA, IDSA), public health agencies (e.g., CDC, DHHS), and scientists and providers represented on expert panels and by the National Institutes of Health (NIH). As an example, the *Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents*, published in 1995, were the first national-level guidelines and were authored jointly by USPHS and the Infectious Disease Society of America (IDSA). IDSA is a professional organization representing physicians, scientists, and other healthcare professionals specializing in infectious disease (IDSA 2008). These have been updated nine times in thirteen years. Since 1998, DHHS supports a panel of experts to develop and update the *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents.* These guidelines have been updated 17 times, an average of nearly two guidelines issued per year for ten years. Three updates were released in 1998 and again in 2001. The International AIDS Society-USA (IAS-USA) was the first to develop guidelines around antiretroviral treatment in 1996 and has published a total of thirteen guidelines since then. IAS-USA is a nonprofit professional organization founded in 1992 (IAS-USA 2008). The number of updates in the guidelines tells us that a great deal of new evidence and experience has been integrated into the standard of care for HIV/AIDS over the years.

Stakeholders develop guidelines for different purposes with varying consequences. For instance, DHHS guidelines can be updated more quickly than IAS-USA guidelines because they are not published in academic journals (019_SF_US_030602_RC). Moreover, guidelines must

also be tailored to local settings and to particular kinds of care providers. According to a nurse trainer at a federally funded AIDS Education and Training Center, their local guidelines were shared during the early 1990s when clinicians from less urban areas called to seek guidance about a treatment decision (017_AT_US_030416_RC). In 1993 these guidelines were formalized into a guidebook entitled "Clinical Management of the HIV-Infected Adult: A Manual for Midlevel Clinicians" with funding from the Health Resources and Services Administration (HRSA). The March 2003 revision is a product of collaboration between the Southeast AIDS Training and Education Center (SEATEC) at the Department of Family and Preventative Medicine at Emory University School of Medicine, Grady Memorial Infectious Disease Program, the Midwest AIDS Training and Education Center at the University of Illinois at Chicago, and the Department of Health and Human Services. In addition, clinics create local guidelines in addition to using IAS-USA and DHHS guidelines and manuals such as this (016_CH_US_030410_JP&CH).

Such formalized discourse authorized by medicine and public health authorities simply did not exist during the 1920s and 30s. Instead, treatment demonstrations focused more on reducing infectiousness rather than improving the health of individual patients. While the *Guidelines for the Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health* include a strong focus on preventing perinatal transmission during pregnancy and birth, adult and pediatric HIV/AIDS antiretroviral guidelines and guidelines to prevent and treat opportunistic infection focus more on improving individual health rather than rendering a patient noninfectious. Consequently, when Swiss researchers recently concluded that HIV may not be transmitted from patients who have undetectable viral loads for at least six months and who are strictly adherent to an antiretroviral regimen, debate and controversy ensued. AIDS advocacy

groups and scientists felt this tantamount to condoning unprotected sex among certain couples affected by HIV (Bjorn 2008). Since a reduction of HIV in blood does not mean that the virus is eradicated from other parts of the body, Australian researchers predict that HIV incidence would quadruple if condom use declines (Ballantyne 2008).

As we will see, however, the categories that providers use to financially classify the procedures, tests, and drugs needed to treat a patient are also complex and must catch up to the most recent research so that treatments are available in a provider's repertoire or "toolkit" (see Swidler 1986). In the early twentieth century, providers were paid on a fee-for-service basis by charities and patients, while today providers are generally paid by a third party such as a health insurance company, managed care entity, or public safety net programs such as the Ryan White CARE Act, Medicare or Medicaid. With syphilis, public health focused on gathering information about the variety and costs of treatments prescribed by providers to support the need for clinical studies and national systems to pay for healthcare. When AIDS emerged, a variety of classification systems existed for processing payments of treatment and provider services. In 1992, Congress began regulating the standardization of these nomenclatures with the passing of the Health Insurance Portability and Accountability Act (HIPAA). I will touch only lightly on HIPAA in order to provide background for observations of how two of these nomenclatures were used and adjusted in clinic-level practice. With HIV/AIDS, I observed that providers develop local classifications to support treatment decisions in an atmosphere of fiscal constraint. With both, fiscal systems influence the way that etiological and symptomological classifications of disease converge with administrative and moral classifications that sustain collective understanding of disease.

Syphilis: Observing and influencing standards of treatment, costs, and drug advertising

As detailed in chapter 3, the so-called "magic bullet" for syphilis was invented in 1910. This injectable arsenic-based treatment was initially reported to cure syphilis after only one dose. Optimism declined after about a year when it became clear that severe side effects, including death and relapse, were common (Brandt 1985, Jones 1993). By 1913, twenty to forty injections of salvarsan over one year were thought necessary for a patient to be cured of syphilis, but this was costly. Moreover, during World War I German-made salvarsan was cut off from the United States and prices soared to $100 or more per dose. Thus, in 1916 the state of Massachusetts passed a law authorizing its Board of Health to manufacture the drug despite German patents. The Germans purposely falsified manufacturing methods, causing delays in domestic production of salvarsan. However, it was eventually manufactured under the name of arsphenamine in the U.S. (Parran 1937). This wrangling over patents is ironic given how today's pharmaceutical companies resist the violation of patents by other countries during public health emergencies such as AIDS (Médecins Sans Frontières 2008; Holmer, et al. 2000).

During the early twentieth century, specialists wrote books to aid general physicians in diagnosing and treating syphilis such as *Syphilis* (Hutchinson 1909), *Modern Clinical Syphilology* (Stokes 1926), and others (Morton 1918, Kolmer 1926). However, there was a lack of information about how less specialized private physicians actually treated syphilis and the price they charged for treatments provided to patients. Indeed, the shift from individual-level pathophysiology to population-based epidemiology in medical knowledge would not take hold for several more decades (Timmermans and Kolker 2004). This is due in part to the large role that the social hygiene movement played in the development of public health as a regulated authority in the U.S. Exemplary of the social hygiene movement's perspective is the American

Social Hygiene Association (ASHA), which, founded in 1914, focused attention on the education of soldiers about venereal disease in order to win the war as well as protect families from contracting venereal disease upon the soldiers' return home (American Social Health Association 2008). Public health worked with the social hygiene movement to develop the groundwork for this shift by focusing effort on the education of general physicians about the most advanced treatments and development of mechanisms to ensure these treatments were funded in cases where patients or charities could not afford to pay.

Founded in 1928, the Committee on Research in Syphilis (CRS) brought together distinguished scholars on the disease with support from the USPHS and ASHA (Brandt 1985). In addition, the Clinical Cooperative Group (CCG) began research focused on syphilis under the auspices of the League of Nations in 1928, around the same time as the Rosenwald demonstration project. Together the CCG and CRS supported the Cooperative Clinical Studies of Syphilis which combined information from 75,000 cases of treated syphilis during the late 1920s and early 1930s from five academic-based clinics led by public health-minded physicians: Johns Hopkins University Clinic in Maryland headed by Moore, the Mayo Clinic in Minnesota headed by O'Leary, the University of Michigan headed by Wile, the University of Pennsylvania headed by Stokes, and the Western Reserve University Clinic in Ohio headed by Cole (Vonderlehr 1935). These physicians were specialists in syphiology and had an orientation to public health.[2] Many were involved to some extent in the Tuskegee study of untreated syphilis.

While the goal of the Rosenwald demonstration project was to render patients noninfectious (Parran 1937), the purpose of the Cooperative Clinical Studies of Syphilis was to "utilize the results of this composite experience to simplify and standardize methods and practice

[2] Bromberg, L. and Davis, M. (1932). "The Cost of Treating Syphilis." Draft manuscript, page 3. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

in the treatment of syphilis for the information of the specialist and the guidance of the doctor in general practice" (Vonderlehr 1935, 133-134). The study synthesized information from medical records collected with a standardized form, reflecting the "opinion and experience of the participating clinicians" (Vonderlehr 1935, 134). The form used to collect this information was large, collecting patient-oriented information in eleven sections outlined in Table 5.2 below.

Table 5.2 Committee on Research of Syphilis Case Record Card[3]

Section	Section Title	Data Elements
I	Identification data	Clinic name, history number, date of last visit, race, sex, age, marital status, height and weight
II	History	History of syphilis infection, including dates of onset of primary, secondary and latent stages of disease; pregnancy information; number of children, both alive and deceased; and information on the partner or parent
III	Admission examination	Patient's complaint on admission, symptoms and their possible cause
IV	History of previous treatment	None, No data, Yes; If yes "started on basis of"
V	Diagnosis on admission	Diagnosis code (if available), duration, if no code then write-in
VI	Examination and treatment	Courses and intervals of treatment, date spans of these intervals, blood and spinal fluid tests and results, listing of specific drugs used as treatment (arsphemines, bismuth preparations, mercury preparations, and other), and notes on complications and clinical progress and/or relapse
VII	Status of last examination	Whether periodic exams were carried out, the date of the last periodic exam, x-ray results, whether there is evidence of progress, and status of other diseases
VIII	Marriage and pregnancies during treatment	Marital status, syphilis status of partner, pregnancy details and birth outcome
IX	Summary of results	Whether the case was "cured" (in quotes) or arrested; whether the patient was re-infected or probation;[4] whether the case is still under treatment or relapsed; if treatment lapsed, why (e.g., death); and open ended space for autopsy results
X	Duration of observation	Date range or amount of time that lapsed between the date of infection and last clinic date, first to last attendance at clinic, and time after suspension of treatment
XI	Supplemental data	Eight questions recording information about those cases of cardiovascular syphilis with aortic regurgitation, aneurism, or coronary thrombosis

[3] Committee on Research in Syphilis Cooperating with the League of Nations Health Organization. Case record card. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[4] Probation in this context refers to the temporary suspension of treatment with monitoring by a doctor (Drake and Thomson 1932).

During this time, medical record keeping was shifting from physician or hospital unit case record books to patient-centered case files (Timmermans and Berg 2003). This shift gained momentum more from attempts by the medical profession to gain control over hospitals' individual doctors than from humanistic desires to put patients first (Timmermans and Berg 2003, 40). Moreover, the new recordkeeping system facilitated clinical research by organizing information around the unit of the patient rather than the unit of the hospital or physician (Timmermans and Berg 2003, 37). Thus, the patient-centered record used by the CRS was designed with both science and oversight in mind.

In addition to the case record card described in Table 5.2, the League of Nations administered a supplemental survey to Directors of Clinics about "the principles governing the treatment during the entire period covered by the case record cards contributed to the present enquiry".[5] The questionnaire contained thirty-four semi-structured questions asking for opinions about and experiences with treating syphilis with pure salvarsan and salvarsan in conjunction with bismuth and/or mercury. It also asked physicians to comment on the methods of diagnosis, criteria for judging results, and how they decided the best treatment based on serological test results. Of 16 archival case records sampled by convenience, 94 percent of cases were white males with an average age of 52 years. Since funds did not exist to study the treatment of poor Southern blacks considered to the most syphilitic, early standards on the best way to treat the disease were based primarily on white male patients in the Northern U.S. who were able to pay for treatments.

Data from the Cooperative Clinical Studies of Syphilis were analyzed and disseminated to the medical profession in journal articles on topics ranging from treatment of early syphilis,

[5] League of Nations. "Health Organisation Enquiry into Syphilis Treatment, General Questionnaire." September 15, 1930. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

the problem of mucosal and cutaneous relapse, the treatment of latent syphilis, the effects of syphilis in pregnancy, and reactions of the human body to the arsenical compounds administered in the treatment, treatment of early syphilis, and treatment of syphilis of the cardiovascular and central nervous systems (Vonderlehr 1935). Private and generalist physicians were the primary gatekeepers for selecting and recording treatments at this time. However, the results were "also of inestimable value to the health officer because they place in his hands informative material for physicians regarding the most modern and authoritative procedures in syphilis therapy" (Vonderlehr 1935, 135). Ended in 1935, the project suffered from a lack of resources and heavy demands on the senior investigators' time. Investigators did not agree on standard protocols and methods to collect the data and failed to consider the syphilis treatments in common use among general practitioners since these specialists prejudged these to be ineffective. Thus, the study produced a lot of data but very little new knowledge (Meldrum 2000). Although the CRS disbanded after the stock market crash, the CCG set the stage for the current convention of the cooperative clinical trial through the development and use of patient-centered data collection instruments (Brandt 1985, 130).

At this time, medicine was consolidating the training of physicians as well as dissemination of information about technological advances in treatments, particularly from commercial entities (see Starr 1982, 119-134). Although the FDA had some legal jurisdiction over therapeutic claims (e.g., misbranding patent medicines), most of its energy was aimed at food, cosmetic, and device safety rather than medicines. The medical profession had previously organized efforts against direct-to-consumer advertising of patent medicines by forming the Council on Pharmacy and Chemistry in 1905. The Council was charged with setting standards for drugs and then evaluating them with the goal of steering patients away from ineffective

patent medicines toward pharmaceuticals prescribed by a physician (Donohue 2006). Thus, oversight over the manufacturing and advertising of new drug products was informal, initiated by physician specialists, and taken up by public health officials and the AMA under the guise of research until the Food, Drug, and Cosmetic Act passed in 1938. The Act passed only after more than one hundred children died after taking an untested sulfa product, Elixir Sulfanilamide, manufactured by a Tennessee drug company. The solvent used in the pediatric product turned out to be antifreeze (Swann 1998). The question of false advertising for syphilis medications had been taken up by the CRS as early as 1929. In August of that year, John Stokes, a physician and professor of syphiology and dermatology, contacted Parran, then Assistant Surgeon General and chairman of the CRS, complaining about an advertising packet and article he received from a drug manufacturer. Stokes was a prominent specialist in the diagnosis and treatment of syphilis as well as a proponent of public health. He participated in the CRS Cooperative Clinical Study of Syphilis and wrote for lay as well as techinical audiences, including *The Third Great Plague: A Discussion of Syphilis for Everyday People* (Stokes 1918) and the first illustrated book of diagnostically challenging case studies of the disease (Stokes 1926). Dr. Herman Hille, president of Hille Laboratories, Inc., sent Stokes a reprint of the article, "Colloidal Mercury Sulphide-Hille: A Preliminary Report of Clinical Findings," which asked why the medical community was looking for a new drug when,

> Mercury always has been and still is the most reliable drug in the treatment of syphilis. Arsenic, bismuth and various other agents push their way to the foreground from time to time, but always, sooner or later, mercury again steps to the front as THE dependable drug for this disease. (DuBois 1929)

Hille wrote to Stokes, "If you wish to be one of the few who report on the clinical results obtained with so promising a product, which has a thorough scientific foundation, I shall be

pleased to supply you with the necessary quantity, if you will be good enough to indicate the number of cases in which you wish to use it."[6]

Stokes complained to Parran,

> The original article on colloidal mercury sulphide appeared from some other pen than Hille's in the Archives of Dermatology and Syphilology and this propaganda has grown at a great rate and with a distinctively Prussian flavor since the appearance of that article. Perhaps the preparation is all right, but this is a typical example of newsprint publicity in advance of substantial clinical support. It is hardly to be imagined that Hille has got out these reprints, based on four or five cases treated by a urologist, with intent to circulate them only among the men who are to test his product therapeutically in man before it is offered to the profession at large. Again, as I say, I don't mean to imply that colloidal mercury sulphide is no good or Hille a rascal, but I think he is adopting a hurry-up method of cashing in on the work, which is a bad example to everybody involved.[7]

Only 10 days later Stokes again became upset by a postcard he received advertising Loeser Laboratories' new preparation of intravenous bismuth to treat syphilis. This second example of "improper advertising" was forwarded to Parran by Stokes who wrote, "Perhaps you won't agree with me, but this method of substituting bismuth for arsphenamine, delaying the treatment of the patient with an increased risk of non-cure, appears to me to be particularly bad propaganda."[8]

For his part, Dr. David Loeser, Director of Loeser Laboratories, inquired to Mr. McCoy, the Director of Hygienic Laboratories in the USPHS, whether offering their product to specialists violated any regulations or "desires" of the venereal disease branch.[9] He also replied to Stokes, wondering, "whether your objections are based on our method of offering our solution to specialists for clinical trial, or whether your objections are based on the method of administration

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[6]Hille, H. Letter to John H. Stokes dated August 8, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[7]Stokes, J. H. Letter to T. Parran dated August 13, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[8]Stokes, J. H. Letter to T. Parran dated August 23, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[9]Loeser, D. Letter to G. W. McCoy dated August 24, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

of bismuth."[10] "Clinical trial" here does not mean a formal study with randomization of patients to test different treatments, but rather suggests a limited group of specialists trying out the drug on their patients prior to its general use by less specialized doctors. McCoy forwarded the letter from Loeser directly to Parran.[11] In the meantime, Stokes further elucidated his disapproval to Parran,

> With reference to the matter of Loeser and the intravenous bismuth – my objection to this approach is that it is uncontrolled, depending merely on the judgment of an individual doctor in an individual case; that it is an effort to substitute bismuth for an arsphenamuine at the very time in the individual patient's case when bismuth should be a minor consideration; and that it is a deliberate sacrifice of the welfare of our human patient in each and every case in which it is tried out. It is really an attempt on Loeser's part to induce members of the American Dermatological and Urological Association to conduct a wholesale uncontrolled and logically improper experiment upon human beings. While I can conceive that it might be permissible to try the spirocheticidal effect of this drug on patients, it should certainly not be done in any such fashion as Loeser is attempting to do it with his postal card campaign.[12]

Stokes further conjectured that if the Council on Pharmacy and Chemistry of the AMA authorized this individual "try-out" of the product then there would be need for further discussion with the council and AMA. Stokes's protest, then, was not so much about the potential of intravenous bismuth as a treatment for syphilis, but the manner in which the manufacturer was attempting to test its efficacy. Stokes envisioned "controlled" studies overseen by physician specialists rather than the inclusion of a "control" or placebo arm as with RCTs today, as a more legitimate approach than testing its efficacy with general practitioners. In other words, Loeser's "uncontrolled" approach undermined medical authority by engaging less specialized physicians rather than having physician specialists consolidate and systematize the

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[10]Loeser, D. Letter to G. W. McCoy dated August 24, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[11]G. W. McCoy Letter to T. Parran dated August 29, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[12]Stokes, J. H. Letter to T. Parran dated September 11, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

clinical trial itself. All this bewilderment over the best way to test Loeser's treatment speaks to the unsettled process by which treatments were deemed effective, the role of manufacturers in research, and the role of the government in regulating manufacturers.

Parran, signing as the scientific chairman of the CRS, arranged to speak with Mr. Loeser who subsequently revised advertising materials to read more conservatively, especially where they implied that bismuth should be used in place of arsphenamine.[13] Parran wrote to Stokes, "It appears that we have succeeded in influencing to a considerable extent his method of advertising this drug."[14] However, Parran communicated to Loeser his concern that the interpretation of a particular study was misplaced and that the article presenting its results did not support the statement that "bismuth tartrate intravenously is 'bismuth at its best.'"[15] Parran then wrote to Cole, a participating investigator in the Cooperative Clinical Studies of Syphilis, to inform him that Loeser's advertising packet "states that one of your articles corroborates his attitude on the intravenous administration of bismuth" and to ask for his comments on Loeser's interpretation of Cole's results. [16] Importantly, Parran wrote,

> I may explain to you further that my discussions with the Loeser Laboratory in connection with this matter are based on the statement agreed upon at the conference of clinicians here in Washington last January, in an effort to see what practical results can be secured by bringing voluntary pressure on pharmaceutical houses which make statements concerning their products which do not appear to be supported by clinical facts.[17]

Thus, marketing techniques could provide the impetus for a drug to be considered illegitimate by organized medicine.

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[13]Loeser, D. Letter to T. Parran dated September 13, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[14]T. Parran Letter to J. H. Stokes dated September 16, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[15]T. Parran Letter to D. Loeser dated September 17, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[16]T. Parran Letter to H. N. Cole dated September 17, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[17]T. Parran Letter to H. N. Cole dated September 17, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

In a letter to Parran, Cole remarked that Loeser Laboratories picked a sentence here and there from his article in order to satisfy their own "a priori reasoning."[18] According to him,

> To be sure, Loeser can manufacture and ladle out to physicians a dose of bismuth that can be used intravenously. The dose, however, therapeutically, will be of very little value. If they attempt to use a dose that will be of the proper size it would be too close to the toxic dose of the drug to be employed by this route.[19]

Even as a physician himself, Loeser was operating outside the orientation of the medical profession. In order for Loeser's claims to be taken seriously, Cole suggested that he apply for permission to conduct such a trial to AMA's Council on Pharmacy and Chemistry.[20] As it turned out, Loeser felt that the Council was prejudiced against him since they previously criticized his marketing techniques.[21] Loeser attempted to assure Parran and Stokes of his company's good faith and honesty. He also criticized their techniques of standardization, writing

> It is amusing to witness the twisting logic of these men whom you term authorities and on whose sole evidence you would apparently decide a question in therapeutics. As an instance, notice on page 1416, the latter part of the first paragraph in which he [Cole] states, "AS FAR AS THE DIURETIC ACTION IS CONCERNED, THE EXCRETORY RESULTS WOULD FAVOR THE USE OF BISMUTH SODIUM TARTRATE RATHER THAN THE INSOLUBLE OR OIL SUSTAINING COMPOUNDS; BUT, AS FAR AS USE IN THE TREATMENT OF SYPHILIS IS CONCERNED, THIS MAY OR MAY NOT BE THE CASE." The two articles of Cole et al and Hanzlik et al merely confirm what the general practitioner learned of what you term empirical experience that soluble bismuth salts were more effective than insoluble. One author concludes that the improved effect in syphilis is due to the more rapid absorption. On the other hand, the other authority acknowledging more rapid absorption from soluble compounds and attributing the diuretic effect to the increased amount entering into the circulation, appears to deny that the improved clinical effect is due to the same increase in concentration of bismuth in the circulation. This you will agree is a curious situation

[18]Cole, H. N Letter to T. Parran dated September 20, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[19]Cole, H. N Letter to T. Parran dated September 20, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[20]Cole, H. N Letter to T. Parran dated September 20, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[21]Stokes, J. H. Letter to T. Parran dated September 11, 1929; T. Parran Letter to J. H. Stokes dated September 16, 1929 Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

> representing in my mind indications of a rabid prejudice and unwillingness to agree to or to try out a logical conclusion of their own work.[22]

As with the Clinical Cooperative Study for Syphilis, the approach taken by the CRS with drug advertising was oriented toward eliminating quackery and consolidating the authority of organized medicine through specialization. Chapter 6 will examine the role of medical specialization in the financial classification of providers. However, Loeser's frustration with organized medicine was apt, since the ad hoc pressure from Parran and the CRS was highly informal, unstandardized, and based on select clinical experience.

Estimates of the costs of syphilis treatment were based on "standard treatment" in an article published by USPHS in 1929, "Management of Syphilis in General Practice" (Moore, et al. 1929). [23] Indeed, "standard treatment" used for estimating cost was based on findings from the CRS study described above. Information about the cost of treatment was collected in the same manner as the treatments themselves: "Opinions have also been obtained from several syphiologists who are in touch with physicians in general practice and with young men they have trained to work especially in the field of syphilis."[24] Estimated charges for a physical exam ranged from $3 to $25 or more depending on the reputation of the physician and economic group of the patient. The usual cost of intravenous injections provided by a general practitioner was estimated to be around $5, although some younger physicians charged as little as $2.50 and rural physicians charged upwards of $7.50. [25] Specialists and public health did not disparage these

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[22]Loeser, D. Letter to T. Parran dated September 24, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[23] Bromberg, L. and Davis, M. (1932). "The Cost of Treating Syphilis." Draft manuscript,. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[24] Bromberg, L. and Davis, M. (1932). "The Cost of Treating Syphilis." Draft manuscript, page 5. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[25] Bromberg, L. and Davis, M. (1932). "The Cost of Treating Syphilis." Draft manuscript, page 5. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

charges as exorbitant. Indeed, they argued that rates should be "commensurate with his skill and the large investment of time and money during long years of training."[26]

What we now think of as the "gold standard" in medical research, the Randomized Clinical Trial (RCT), did not exist until after the Second World War. Moreover, before the Nuremberg Trials of 1945-1949, regulations concerning the ethics of research either focused on the corrupting influence of drug advertising or were aimed at protecting physicians (see also Heimer, et al. 2005). Although there was some debate about whether to inform patients that they were participating in an experiment, such "benevolent deception" was easily forgiven before World War II (Lederer 1995). By the 1930s, drug manufacturers felt attacked by physicians at the same time that the medical community was interested in scientific reform, or "rational therapeutics," that would enable practitioners to understand the benefits and limitations of particular treatments while allowing them to appreciate the benefits and limitations of their own practice (Marks 1997).

Scientific evidence is only one type of evidence used to guide medical decision-making. In contemporary treatment guidelines, RCT data is found at the top of the evidentiary hierarchy as practitioners become more removed from the complexities of clinical care (Petty 2008). Prior to World War II, however, many felt that the increasing use of statistics in medicine would help the medical community garner credibility and authority. Thus, although Stokes felt that while "a man intent on selling something can work up an argument for his point of view from almost any point of the compass," he also noted that "Personally I am interested in the question of eligible bismuth medication by the intravenous route, for I am coming to the conclusion that from the

[26] Bromberg, L. and Davis, M. (1932). "The Cost of Treating Syphilis." Draft manuscript, pages 5-6. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

standpoint of the patient alone, intravenous therapy has something to commend it."[27] Stokes' clinical experience propelled an interest in newer and better therapeutics, while Loeser, as it turned out, engaged in the "war of words"[28] with Parran so "that you would be sufficiently impressed that you would lend your influence to stimulate a clinical study."[29] Ironically, then, Loeser advocated wide-scale research, while Stokes considered his own clinical experience when considering the truth of Loeser's claims.

By 1939, the "standard" treatment for syphilis, which included bisumuth or mercury supplements to arsphenamine for 60 weeks to reach a cure, was based on observational studies rather than systematic controlled studies (Jones 1993). Doctors and public health officials were troubled that few patients completed the desired amount of treatment because early symptoms subsided quickly and patients stopped coming for treatments, patients' inability to pay for such long courses of treatment, and the intolerability of side effects (Parran 1937, Brandt 1985). Physicians eventually resigned themselves to the fact that curing syphilis was not an easy matter, although they retained their optimism that the disease would be eradicated in their lifetime (Jones 1993).

Penicillin was discovered in 1928 by Alexander Fleming, but the United States Department of Agriculture did not grow large quantities of penicillin until 1941 for use on the battlefront of World War II to prevent and cure infections of wounded American troops. In 1943 it was announced at an American Public Health Association (APHA) meeting that four cases of human syphilis were cured with the drug. Without standards for testing this efficacy against a

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[27]Stokes, J. H. Letter to T. Parran dated September 27, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[28]Stokes, J. H. Letter to T. Parran dated September 27, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.
[29]Loeser, D. Letter to T. Parran dated September 30, 1929. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

control arm, the announcement made penicillin the "New Magic Bullet" (Time Magazine 1943). Since the military also reversed its World War I policy and provided condoms to soldiers, the military was fully armed against syphilis (Brandt 1988b). By 1945 penicillin was accepted as the treatment of choice for syphilis. That same year the Penicllin Amendment was passed by Congress requiring testing and certification of safety and effectiveness of all penicillin products by the FDA. In 1947, rates of syphilis peaked in the U.S. at 106,000 cases. Although penicillin cut the syphilis rate in the U.S. from 234.7. cases per 100,000 in 1948 to 68.5. per 100,000 by 1958, rates of syphilis began to rise by 1959 after a decrease in funding for venereal disease control (Time Magazine 1960, Brandt 1988b). Thus, even this "magic bullet" did not eradicate syphilis, since the disease stimulates social conflict about the risks of sexual behavior, the role of the state in promoting public health, the doctor-patient relationship, and the social responsibility of medicine (Brandt 1988a, Brandt 1988b).

During the 1950s and 1960s medicine was in its "Gold Years," as its professional power became even more closely linked to scientific innovation (Berg 1995, 446). As 'scientific' became a vague but positive label to be applied to medical practice, problems were uncovered within medical practice such as specific communication problems among physicians and between physicians and researchers. Organized medicine focused on improving the precision of clinical recordkeeping so that clinical observations made by physicians, thought of as 'irreplaceable scientific data,' could be integrated into clinical research (Berg 1995, 477). During this time, standards were created for medical record keeping and in 1961 the AMA took over responsibility for updating the Standard Classification for the Nomenclature of Disease

(American Medical Association 2005a).[30] Prevailing wisdom held that physicians, researchers, planners, governmental agencies, epidemiologists, and others would benefit from catalogued patient files and uniform diagnostic categories, including medical practice itself because a variety of stakeholders would understand hospital records, communication would be improved, and diagnostic error and observer variation would decrease as a result (Berg, 1995 448). Although not born out of the need to standardize pricing per se, this nomenclature ultimately contributed to contemporary pricing systems and was developed at a time when health care costs were of concern to government and insurers.

Parran (1937) envisioned that the rationalization of medicine would help patients better understand the treatments they receive and become better consumers of medical care. However, it was not until the late 1960s and early 1970s that medical action became structured more like scientific action, with defining, clarifying, separating, recording and auditing as core activities (Berg 1995, 449-450). During that time, some continued to argue for increased standardization of the medical file itself as a way to improve medical practice (Feinstein 1967, Weed 1971). As with earlier decades, organized medicine felt that such standardization would benefit administrators, insurers, and government agencies to the detriment of the professional autonomy of physicians (Berg 1995, 451). While contemporary patients are consumer-oriented, this is due to a combination of increased science, continued mistrust of medical providers, and the advent of direct-to-consumer advertising (Conrad 2005).

[30] Until the first volume of the Standard Nomenclature of Disease was written by the National Conference on Nomenclature of Disease in 1933, hospitals, health organizations and insurance companies used their own local disease classifications. Some were based on the anatomical location of a disease, while others were based on etiology (Chaddock 1933). Prior to this, only physicians would be able to decipher the patient's diagnosis and the procedures used to treat it recorded in the medical record. As with the standardization proposed with national health insurance, physicians were wary of this proposed nomenclature and how it might diminish their professional autonomy. By contrast, statisticians hoped that such a classification would help to produce trust between doctors by putting medicine on a more scientific ground (King 1931). However, physicians wanted to have control over the classification. Thus, the AMA published the nomenclature beginning with the first edition.

By the the time Medicare was passed, levels of syphilis began to level off. CDC prepared educational materials for physicians and the public in an attempt to separate medicine from morals. Despite finding cheap and effective methods of treatment and testing, the CDC's 1968 "Syphilis Eradication Program" was not sufficiently funded to carry out its goal. This was partly because physicians needed to be convinced that reporting every case of syphilis to public health authorities was key to eradication (Etheridge 1992, 20). In addition, organized medicine began to believe that scientific advances, such as with antibiotics, ended the era of plagues.

The scientific character of medicine contributed to medicine's increased autonomy during the 1970s and 1980s with a new individualizing discourse. This new discourse, rooted in cognitive psychology, changed the scientific status of medical practice into a feature of the physician's mind (Berg 1995, 452). In this discourse, physicians are imagined as testing hypotheses when engaged in clinical problem solving and decision-making. Thus, in this era, diagnosis was likened to an "exercise in statistics" (Berg 1995, 455), where the doctor calculates the probability that a patient has a certain disease given the symptoms. By the 1980s, medical work was characterized as an individual, cognitive process (Berg 1995, 457). Individualized knowledge is a special form of cognition because it is mediated by technologies of written culture (Goody 1977). The development of record keeping and treatment standards synthesized with this new way of imagining medicine, resulting in population-level problems being intertwined with individual-level decision making (Berg 1995, 465), increased scrutiny, and decreased confidence in the medical profession (Starr 1982, 379). Thus, when AIDS emerged, medical and epidemiological imaginations set the stage for a seemingly settled process by which treatments enter into provider repertoires. However, the deployment of treatments for AIDS resulted in unintended consequences that undermined the tenacity of standards themselves.

HIV/AIDS: Regulating and resisting standards of research, cost, and patient access

By the 1980s, federal policy was established to support both physician autonomy and the research industry allowing the pace of treatment innovation to increase rapidly. However, it still typically took eight years for a drug to go from its first clinical trial to FDA approval. Unlike salvarsan to treat syphilis, when AZT was under development for treating AIDS, FDA required phase I, II, and III trials for approval, which enables a new drug to enter the marketplace legally.[31] As detailed in chapter 4, the cost of hospital care for AIDS patients was exorbitant. Moreover, in the early days of AIDS, gaps existed in private insurance coverage of experimental therapy and community-based services (such as home-based care) (Institute of Medicine 1986). This dearth of financial standards was brought about both by an absence of established treatments settled into systems of payment as well as stigma associated with the disease. Twelve years before treatment guidelines were published, the FDA, NIH, and CDC published guidelines on the prevention of the transmission of AIDS (CDC 1983a). By that time 1,200 cases were reported and 450 people died from 34 states, the District of Columbia, and 15 other countries. CDC became concerned that their supply of pentamidine, distributed free of charge for "compassionate use" by physicians treating patients with PCP, would be depleted (Siplon 2002). Patients, providers, and payers were desperate to speed up the pipeline for new and effective AIDS treatments.

In 1983, Congress passed the Orphan Drug Act which enabled the FDA to promote the research and marketing of drugs needed to treat rare diseases by giving "orphan drug" status to promising treatments. In 1984, a small pharmaceutical company named Lymphomed applied for

[31] Phase I trials include the first introduction of the new drug in humans, usually 50 to 80 participants, to detect how it works in the body metabolically and pharmacologically, including side effects and early evidence of efficacy. Phase II trials focus on the collection of preliminary efficacy data as well determining common side effects and risks using a couple hundred participants. Phase III trials focus use several hundred to thousands of participants to collect sufficient information about safety and efficacy to include on drug labels (FDA 1998).

orphan drug status for an injectable form of pentamidine, becoming the first drug for AIDS approved under the legislation. The injectable form was highly toxic, however, and did not penetrate the patient's lungs, the focal point of the pneumonia. Some doctors quickly made an aerolized version of pentamidine available to their patients. Although FDA did not formally approve this measure, these physicians exercised "off-label use" provisions provided by the Kefauver-Harris Drug Amendments passed by Congress in 1962 (Shapiro 1979, Siplon 2002). Off-label prescribing remains quite common among physicians today, especially when treatments fail or do not exist (Klein and Tabarrok 2004). Off-label prescribing also tends to happen when developments in medical knowledge are produced at a faster rate than FDA can accommodate under its regulatory process. A 1993 survey found that 81 percent of patients received at least one drug for off-label use, and 40 percent reported all their drug use was off-label (Brosgart, et al. 1996). Pediatric and cancer patients are also more likely than others to be prescribed drugs for off-label use (Tabarrok 2000).

Today pharmaceutical companies often cite the great expense of research and development when defending the high cost of prescription drugs. Even in the 1980s many companies employed the quickest and cheapest way to find a "new" drug, which is by rediscovering properties in an already existing compound approved for another condition. Tests were run on various compounds with live HIV virus to see if any antiviral activity took place. Since pharmaceutical labs were not equipped for conducting research with a virus as infectious as HIV, Burroughs Wellcome and other manufacturers shipped compounds to the most safe and secure labs for testing (e.g., Duke University, FDA, NCI) (Siplon 2002, 22).

As a result of the slow pace of movement from scientific innovation to FDA approval, AIDS activists advocated for increased access to experimental therapy, even as part of clinical

trials. Thus, heretofore uncontested epidemiological and biomedical methodology was challenged by activists who argued that participating in a clinical trial was therapy (Epstein 1996). Since proponents of evidence-based medicine envisioned progression from early research through clinical trials to codification in treatment guidelines, this blurring of boundaries was unsettling and had implications for how treatment was classified. For instance, some studies did not allow subjects to take aerosolized pentamidine to ward off PCP (Epstein 1996, 214-215). This meant that the line between research subject and patient became blurred, with some individuals feeling like "sacrificial lambs" and others who undermined studies by accessing drugs in a treatment underground (Epstein 1996, 216).

Phase I trials began for AZT on July 3, 1985 with 19 subjects. The trial ran for six weeks with ambiguous results. Phase II trials for AZT began in February 1986 with 282 subjects. Only 24 participants, less than ten percent, completed the study described as double-blind and placebo-controlled in line with the gold standard of the RCT. In fact, treatment groups unblinded themselves early by having their pills chemically analyzed and pooled and shared their pills to increase the chances they might get the drug instead of the placebo. AZT also had such extreme effects on the subjects' blood profiles that researchers knew who was on the drug. Twenty-four weeks into the study, 19 control group subjects died compared to one in the AZT arm; the trial was stopped and placebo subjects were offered the drug (Epstein 1996, Siplon 2002). At first, AIDS activists argued that placebo-controlled, double-blind trials were cruel, out of touch with the reality of patients, and impossible to keep double-blind. Researchers continued to argue that RCT is the "cleanest" kind of study design (Siplon 2002, 23). Later, when clinical trials proved that some AIDS drugs were ineffective or had severe side effects, activists agreed that more caution was needed. In the midst of the battle between scientists and activists for

authority over AIDS treatment research in the early days, FDA waived the Phase III requirement for AZT, allowing its manufacturer to focus on its new drug application instead.

What was the role of activists in changing FDA policy? In 1987 the AIDS Coalition to Unleash Power (ACT UP) was established in New York to protest FDA's slow drug approval process. After a 1987 demonstration, the FDA announced a two-year shortening in the drug approval process with the creation of a new class of experimental drugs, treatment Investigational New Drugs (INDs) (Boffey 1987, Schoofs 1997). A treatment IND is the procedure for moving promising drugs that are in the process of being tested to treat severe or life-threatening illness through the FDA pipeline at an accelerated pace. Drugs considered for distribution through this program must have completed Phase I testing, show some evidence of efficacy, and show no extreme toxicities (Roy 1989). Prior to its Phase I trial, AZT was already released in a modified treatment investigational new drug program at the FDA, so the 1987 announcement was a formalization of existing procedure. To date, FDA has approved eleven treatment IND protocols for AIDS-related products (FDA 2008).

AZT was approved in March 1987, making it the first anti-HIV drug approved by the FDA. FDA's review and approval of the new drug application for AZT took less than four months under the agency's 1-AA priority review designation for AIDS drugs which they heralded as "one of the shortest approval actions on record" (FDA 1987). The recommended dose was one 100mg capsule every four hours around the clock or six times each day. Burroughs Wellcome began marketing the drug immediately (Siplon 2002, 23). AZT was called a miracle drug by some, while to others it was poorly tested, toxic, and more useful for producing profit than as a medical therapy (Siplon 2002, 21). ACT UP also protested the high the cost of AZT, which at $10,000 a year was the most expensive prescription drug on the

market. That same year, U.S. Congress approved a one-time $30 million in emergency appropriation for states to pay for AZT for AIDS patients (see Table 4.1). After two years of protests, Burroughs Wellcome lowered the price of AZT to about $6,500 per year (Hilts 1989). Stakeholders were befuddled with members of Congress later taking issue with the price of AZT while activists questioned the government's acceptance of AZT's medical efficacy (Siplon 2002, 21).

Subsequent studies of AZT expanded its market. For example, a study conducted by the AIDS Clinical Trial Group (ACTG 019) found that AZT therapy could benefit those infected with HIV but who had not yet progressed to AIDS, which increased the potential market tenfold (Siplon 2002, 24). Since treatment for PCP was available, the life of AIDS patients and, by extension, their use of AZT increased (Siplon 2002, 24). AZT is just one example of one of the several changes in FDA regulatory policy simultaneous to AIDS contributing to the increased pace of treatment innovations, and, thus, uncertainty about efficacy of treatments for AIDS as well as their cost. Other changes included the liberalization of the interpretation of import regulations, subpart E regulations to expedite the approval process, and the parallel track proposed in 1989 to allow drug access earlier in clinical trials.

Thus, AIDS and HIV drug therapies can be approved in a matter of months and have been made available to thousands of patients outside of clinical trials through expanded access "parallel track" protocols and accelerated approval of "breakthrough" drugs (FDA 2008). The purpose of FDA's parallel track is to ensure that promising experimental drugs are accessible to patients who cannot participate in controlled clinical trials and for whom approved treatments are ineffective. In 1992, stavudine or d4T was the first parallel track approved by the FDA, making the drug available to about 12,000 patients (FDA 2008). Bristol-Myers Squibb, the manufacturer

of d4T, implemented the program and provided the drug "free of charge" to patients through physicians. Physicians whose patients are approved to participate were added to the list of registered investigators and were required to submit follow-up and adverse event forms to the manufacturer (FDA 1992). FDA considers drugs "breakthrough" based on "surrogate endpoints" that predict a drug's clinical efficacy. The AIDS drug Videx or ddI was approved in six months using such surrogate endpoints (FDA 2008).

These new FDA policies resemble the approach taken by David Loeser in the 1920s, where private physicians were offered free drugs in exchange for collecting information about it for the manufacturer. Thus these new FDA regulations made strange bedfellows of the Reagan-Bush administration, the increasingly profitable and influential pharmaceutical industry, medical providers, and AIDS activists, all of whom favored deregulation of the drug approval process in the early days. In this way, the AIDS epidemic muddied the distinction between treatment and research, changed the FDA from a focus on consumer protection to technology promotion, and put patients at risk of harm from useless drugs (Annas 1990, 186). These FDA policies were passed at the height of death and dying for many AIDS patients.

The development and approval of AZT, along with public outcries over the desperation of AIDS patients, cleared the path for codification of policies and procedures for speeding up the drug development and licensure process. However, Siegel and Roberts (1991) argue that these changes were not the product of fundamental reform, but primarily the codification of preexisting, informal procedures for expanding access to unapproved drugs. Although FDA long accommodated itself to the contradictory demands of science and industry, in the 1980s FDA was faced with an antiregulatory administration as well as criminal activity within the agency itself (Hilts 2004, 236). Thus, AIDS activists did not so much shape FDA policy, as FDA

foresaw the extraordinary politics of AIDS and rushed to get treatments approved, paving the way for other disease-specific lobbies (Hilts 2004, Carpenter 2004). As Carpenter argues, "there is considerable evidence—from anecdote, from factual inspection of the FDA's behavior, and from statistical analyses of drug review times—that the political organization and newsworthiness of patients is negatively associated with drug review times (that is, it causes these review times to get shorter)" (2004, 59). Thus, AIDS activists did influence the process, but more in terms of legitimizing the disease-specific lobby.

There were unintended consequences and costs with off-label prescribing and FDA's new fast track policies, however. Off-label prescribing practices are not available to all patients because in order for these services to be included in a provider's repertoire, the physician must be aware of off-label use, and its cost must be absorbed by someone (e.g., patient, doctor, hospital, safety net). Aerolized pentamidine, for instance, was not distributed to AIDS patients in an equitable manner because only those physicians "in the know" prescribed it in this way (Siplon 2002). By 1990, six years after the FDA approved pentamidine, Blue Cross and Blue Shield began to reimburse off-label uses of a drug as long as there was specific evidence supporting its efficacy (Nichols 1991, 55). While Blue Cross and Blue Shield did pay for aerosolized pentamidine when it was distributed under a treatment IND in 1989, other insurance plans had a mixed record on this (Nichols 1991, James 1989).

As we saw in chapter 4, in 1996, Highly Active Antiretroviral Therapy (HAART) introduced a new era in the treatment of HIV/AIDS because it helped HIV/AIDS become more like a manageable chronic disease (Smart 1996; Hirschhorn, et al. 2005; Dray-Spira 2003). Moreover, treatment guidelines were critical for creating standards of reimbursement for the specialized procedures of HIV/AIDS treatment. Although there were government-sponsored

guidelines published about AZT (Sande, et al. 1993; see also Table 5.1), by late 1995 unpublished results from two studies about the efficacy of combining two drugs to treat HIV/AIDS had been presented at conferences for about a year (Delta, ACTG 175) (019_SF_US_030602_RC, Hirsch and Yeni 1996). There were hints that three drugs might be even better. Despite this, 60 percent of patients were starting on AZT alone (Fischl, et al. 1995; 019_SF_US_030602_RC).

DHHS was unable to write guidelines for combination therapy because the relevant study results were not yet published. It was a matter of policy at that time that DHHS did not include "expert interpretation" as evidence when creating a new guideline (019_SF_US_030602_RC). Thus, the board of directors at IAS-USA felt that a guideline would help establish combination therapy as the standard of care. Standards of care are recognized by physicians, patients, and health care payers. Thus, the IAS-USA published the first set of "national" guidelines for combination drug therapy in 1996 with the intention of creating a reimbursable standard of care (Saag, et al. 1996). The guidelines also specified how to use the viral load test, which was not yet FDA-approved. At that time, there were no government HIV/AIDS treatment guidelines because government guidelines could only recommend procedures supported by clinical trials and approved by the FDA.

DHHS began producing HIV antiretroviral guidelines in 1998, altering its rules to allow recommendations based on clinical experience rather than solely on clinical trials and FDA approval. The DHHS guidelines have become the dominant set of treatment guidelines in the field of HIV and established highly active antiretroviral therapy as the standard of care and treatment, with less than two drugs as sub par. By pronouncing HAART as the standard of care, the government essentially instructed itself to purchase the cocktail for clients in their care either

via Medicaid or Ryan White funds (Siplon 2002). These guidelines also instructed private physicians on the "official" way to treat HIV infection. As of October 2006, DHHS has produced sixteen versions of the antiretroviral guidelines. As we saw earlier, private insurance companies are more likely to pay for treatment that is the standard of care rather than treatment considered "experimental" by FDA fast track policies.

Unlike previous therapies that targeted opportunistic infections resulting from AIDS, such as aerosolized pentamidine for PCP, suppression of the virus requires uninterrupted access to multiple prescription drugs. Thus, HAART is extremely costly, starting at about $10,000 annually. These drugs must be taken daily and are not available in generic form in the U.S. As observed in the last chapter, HIV/AIDS disproportionately affects minorities and the under- or uninsured. In 1998, the General Accounting Office (GAO) estimated that Medicaid covered 55 percent of all AIDS patients and 90 percent of pediatric AIDS patients, underscoring the fact that many people with HIV and AIDS are extremely poor (Siplon 2002, 37). In addition, HAART introduced unforeseen complications with significant side effects and viral mutation causing treatment to be intolerable, ineffective, and potentially strengthening to the virus itself (Rosengarten, et al. 2004). While HAART introduced a dramatic decrease in mortality from AIDS it also introduced "HIV/AIDS complacency" both in terms of societal support for mobilization around the disease and increased evidence of unsafe sexual practices (Valdiserri 2004). Some HIV-infected individuals rejected the use of antiretroviral therapy because of complacency and because of "pill fatigue" (Richardson 1998, Deeks 2006). At the same time, public health systems, already under financial distress, were forced to balance the cost and benefit of providing antiretrovirals that lacked a secured third party source of payment (Singer, et al. 2002).

Also in 1996, a study revealed that levels of viremia measured by HIV RNA could be used as a proxy for progression of HIV disease and thus a measure of treatment efficacy (Ho 1996; Mellors, et al. 1996). With this discovery, HIV viral load testing surpassed CD4 count as the best predictor for death from AIDS. Viral load tests were used for years in research to determine the efficacy of antiretroviral drugs. Indeed, FDA granted approval of protease inhibitors whose effectiveness was demonstrated with decreases in viral loads measured by HIV RNA (Baker 1996). However, the costs of viral load tests became a burden when expanded access drugs were provided "free of charge" by drug manufacturers. For instance, when Bristol-Myers Squibb provided ddI under an FDA expanded access protocol in 1989, the required lab tests cost $100 to $300 and were not reimbursed by third party payers, so either the patient or the health care system had to absorb the cost (Nichols 1991, 53). Clinicians were having an especially difficult time getting viral load tests reimbursed by health insurance companies (017_AT_US_030416_RC). One study found that from 1993 to 1997 HAART reduced utilization costs for inpatient hospital stays, but increased costs for laboratory tests (Mole, et al. 1999). According to a letter from the Healthcare Financing Administration (HCFA, now called the Centers for Medicare and Medicaid Services), "Low payments have led to complaints by labs and physicians/clinics that have had to bear the liability for the balance of costs, and, therefore, have resulted in barriers to access" (Cade 1997).

On July 3, 1996, FDA approved Roche Molecular Systems to market the Amplicor HIV-1 monitor test, the company's viral load assay (Smart 1996). FDA approved the Roche viral load test only to predict disease progression in HIV-infected individuals, but experts at IAS-USA argued that the test could be used to decide when to initiate therapy, whether current therapy is working, and whether and when to switch to antiretroviral regimens (Smart 1996). Since this

clinical laboratory test was a new technology, no billing code or combination of codes existed that could sufficiently describe it for purposes of payment. Thus, IAS-USA developed their first guidelines deliberately so that providers could be reimbursed for the cost of viral load testing, so that the test could be financially classified as a legitimate component of treatment recommendations (017_AT_US_030416_RC, 019_SF_US_030602_RC). All in all, the IAS-USA guidelines coupled with FDA approval of Roche's viral load assay increased the likelihood that insurance companies, Medicaid and other third party payers would reimburse providers for the test (Smart 1996).

In order for treatments to be available, guidelines must work in concert with billing codes. However, there are almost 100 classification systems used to track and sort health information (National Library of Medicine 2004). I will touch on CPT and ICD-9-CM coding systems in order to give background for how they adjust and are adjusted to accommodate innovations in treatments. Although by and large associated with health information privacy, the Health Insurance Portability and Accountability Act (HIPAA) was passed by Congress in 1996 in large part to simplify administration in healthcare by eliminating local and proprietary code sets and formats used for the electronic transmission of patient-identifiable health-related information. In this way, HIPAA attempted to address how the healthcare industry submits and processes claims for payment of health services by third parties. The idea was to reduce the administrative burden of the healthcare industry by inducing them to use five uniform code sets, thereby enabling health providers to submit the same financial transaction to any third party payer in the U.S and enabling information systems to communicate more easily with one another despite software having been developed to deal with specific payers' format requirements. Significantly, the codes in the system are used not only for reimbursing providers, but also for

evaluating quality, outcomes, and cost, and for identifying fraud. The code sets mandated for use by HIPAA took effect in 2002. See Table 5.2 for a summary of these code sets, including their title, authors, year of origin, and included data elements.

Table 5.2 Code Sets Adopted for Use by HIPAA[32]

Code Set	Origin Year	Full Name	Author(s)	Description
ICD-9-CM	1893	International Classification of Diseases, Revision 9, Clinical Modification	Centers for Medicare and Medicaid Services, National Center for Health Statistics, American Hospital Association, American Health Information Management Association	Nonproprietary 3-5 character code, both numeric and alphanumeric for diagnostic and inpatient hospital services
CPT-4	1966	Current Procedural Terminology	American Medical Association	Proprietary 5 character code, numeric for physician and all other services
NDC	1969	National Drug Codes	Food and Drug Administration in association with drug manufacturers	Nonproprietary 11 character code, numeric for drugs and biologics
CDT	1969	Code on Dental Procedures and Nomenclature	American Dental Association	Nonproprietary 5 character code, initial letter "D" followed by 4 numbers for dental services
HCPCS	1978, 1982, 1983	Healthcare Common Procedure Coding System	Centers for Medicaid and Medicare Services	Nonproprietary 5 character code, initial letter followed by 4 numbers for health related procedures, services, equipment, supplies, durable medical equipment

Current Procedural Terminology (CPT) codes were first developed by the AMA in 1966 and "encouraged the use of standard terms and descriptors to document procedures in the medical record; helped communicate accurate information on procedures and services to agencies concerned with insurance claims; provided the basis for a computer oriented system to evaluate operative procedures; and contributed basic information for actuarial and statistical purposes" (American Medical Association 2004). This code set is copyrighted by and available

[32] Adapted from Centers for Medicare and Medicaid Services (2002).

for purchase from the AMA. CPT codes are maintained by the CPT editorial panel which meets quarterly each year to address changes proposed by interested parties such as hospitals, medical specialty societies, physicians, and third party payers. There are three categories of CPT codes: category I describes procedures or services, category II codes are used for performance measurement, and category III codes are for emerging technology. Services and procedures included in new or revised category I codes must be approved by the FDA (American Medical Association 2004).

Although the AMA planned to add a CPT code for the viral load test, it was not expected until 1998 (Cade 1997). Meanwhile, some state Medicaid programs developed their own code, paying anywhere from $60 to $220 for tests. On April 7, 1997 the HCFA established a new code G0100 “HIV-1, viral load quantitative” to be used by Medicaid, Medicare, and private payers as appropriate (Cade 1997). Because of the wide variability of price-setting across payers, HCFA spent additional time using a “gap fill” approach to set a national limitation amount (NLA) for the test (Institute of Medicine 2000a, 93). By 2000, HCFA capped the price of viral load tests by setting the NLA for the test at $117.59 (New York State Department of Health 2000). Thus, although uncertainty about whether the test would be reimbursed was reduced, fresh uncertainty about the price of the test was introduced. The same is true with the absence of CPT codes for HIV prevention (Akers 2003) and delays in CPT codes for routine HIV testing (Kirchner 2007), thus impeding the provision of these services since physicians cannot invoice payers for reimbursement.

In contrast to CPT codes, the International Classification of Diseases is part of a series of classifications rooted in the 1850s, when the discipline and practice of statistics was developing (Hacking 1990, Porter 1995). The first edition, called the International List of Causes of Death

(ICD), was adopted by the International Statistical Institute in 1893 (World Health Organization 2008a). When the World Health Organization (WHO) was established in 1948 it became responsible for the ICD. That same year the sixth revision was published; it included causes of morbidity for the first time (World Health Organization 2006). The ninth revision was published in 1978 by WHO. The USPHS modified the ICD-9 to meet the requirements of American hospitals and renamed it the International Classification of Diseases, Ninth Revision, Clinical Modification or ICD-9-CM. By 2006 the ICD-9-CM contained three volumes, was updated annually, and was used in the U.S. to track morbidity data. Although the ICD-9-CM does not include prices, it was designed with billing and other administrative purposes in mind.

The rise of AIDS coincided with the implementation of diagnostic-related groups (DRG). DRGs assign a fixed reimbursement rate to particular diagnoses based on groupings from the ICD-CM-9. DRGs had far more impact on the delivery of healthcare than anticipated (Ruggie 1992). It was years before the DRGs were altered to fit the new diagnoses needed for AIDS patients, which was a major hindrance to data collection and cost analysis in the early days of the epidemic (Institute of Medicine 1986, 185). AIDS created a significant challenge to the DRG pricing system, which matched specific diseases and procedures to patterns of hospital reimbursement. As one official remarked, “if you try to make one DRG out of AIDS, it would be one of the worst DRGs in terms of homogeneity, in terms of length of stay within that DRG that we’ve seen” (as quoted in Berkowitz 1998, 219). Throughout those years multiple ICD-9-CM codes were used to indicate HIV infection, AIDS, or unspecified disorders of the immune system. In 1994, a single ICD-9-CM code for HIV disease was formed from previously distinct codes for AIDS and HIV infection (Fasciano, et al. 1998). The uncertainty of coding diagnoses in these days reflects the time it takes for new diagnosis codes to be implemented at the clinic

level. However, some patients and physicians continued to use unspecified codes to avoid stigma (Fasciano, et al. 1998).

To the government, guidelines are a good idea from a cost perspective since standards of care and standards of expertise are crucial to setting (and controlling) costs for Medicare and Medicaid. After all, the federal government mandated the creation of the Agency for Health Care Policy and Research to write guidelines (Heimer, et al. 2005).[33] On the other hand, adherence to the DHHS guidelines for antiretroviral care may actually increase the cost of care for HIV-infected patients (Bessesen and McCollum 1999). As we have seen, guidelines are both about getting new science out to practitioners and about creating paths of reimbursement which solidify the standard of care through the institutionalization of evidence-based medicine at the clinic level. In addition, sometimes scientific data does not exist to support off-label use of a drug, but there are other reasons that physicians choose to use a drug this way. For instance, since atazanavir was approved by FDA in 2003, many physicians prescribed it using ritonovir to boost its efficacy. While this approach was not included in the DHHS guidelines because it was not supported by any clinical trial findings, there were demonstrated advantages of boosting with other drugs in the same class, including its effects on resistant virus and the likelihood of the virus becoming resistant in the event of treatment failure (Gallant 2006).

Recently, the authors of a 2006 editorial in *Clinical Infectious Disease* worried that the rate of reimbursement has not kept pace with the increasing complexity of treatment, noting:

> HIV has become increasingly sub-specialized, necessitating a cadre of well-trained providers who understand optimal combinations of the >20 antiretrovirals now available for treatment, their side effects and the complex interactions with the many other medications patients with HIV infections receive, ranging from cholesterol-lowering drugs to antidepressants. (Mayer and Chaguturu 2006, 1011)

[33] The Agency for Health Care Policy and Research was renamed the Agency for Healthcare Research Quality. It is no longer responsible for writing new guidelines, but maintains a clearinghouse for guidelines and trains guideline writers (011_DC_US_030326_RC&JP).

This was a response to an article published in the same issue that observed that the average rate of clinic and physician reimbursement is $359 a year, approximately two percent of the total costs of HIV care (Chen, et al. 2006). It is hard to interpret this kind of data because it does not allow us to determine whether the low reimbursement rate relative to the costs of overall care is simply a byproduct of very expensive drugs. Regardless, the complexity of these classification systems influence provider behavior at the clinic-level since the discourse and practice of evidence-based medicine (i.e., treatment guidelines) is embedded with ever-changing financial classifications of treatment (i.e., billing codes).

HIV/AIDS guidelines and pricing as barriers and paths to treatment

During field research in a publicly funded outpatient HIV specialty clinic, I observed how providers dealt with the financial classification of treatment during their daily work in the clinic. As we will see, the financial classification of treatment posed a challenge to providers who were faced with increasingly complex treatments, decreased funds, and a heavy paperwork burden of 5 to 10 pieces of paper to complete following a routine visit (fieldnotes 040106). Administrators and clinicians met this challenge by creating local and routine work-arounds to ensure payer sources for drugs, developing local criteria for patients needing urgent antiretroviral treatment before a payer source could be identified, prioritizing patients for treatments in short supply, and coding services appropriately to secure maximum reimbursement. Although these new routines did not always simplify the daily work of AIDS care at the clinic, they did provide some measure of equity and stability under conditions of financial constraint.

The diffusion of HAART was rapid in the U.S., with 71 percent of patients with HIV on HAART within two years of its availability (Cunningham, et al. 2005). As a result, AIDS

related morbidity and mortality decreased dramatically (Palella, et al. 1998), with the U.S. AIDS-related death rate dropping 47 percent in 1997 alone (Henkel 1999). The impact of HAART was felt at the clinic. As one nurse practitioner recalled,

> When new therapies came out, we all really believed we were, for the first time in medical history, experiencing a phenomenal cure. And our death rate went down by 70 percent. Our treatment unit, which functioned seven days a week, twelve hours a day – mid-levels would have to go in there on Saturdays and Sundays – reduced activity by 68 percent. (interview 050216)

As deaths and hospitalizations decreased, the locus of HIV/AIDS care shifted further from hospital inpatient units, homes, and hospices to outpatient clinics such as this one. Thus, by December 1996, 77.7 percent of HIV/AIDS patients received care in specialty HIV clinics (Wilson, et al. 2005a). Chapter 6 provides a fuller discussion on how these clinics helped to shape specialized HIV care. What is important here is that innovations in treatment were disseminated rapidly and impacted routines at the clinic level.

According to the medical director of the clinic, providers practice evidence-based medicine, remarking, "DHHS guidelines are standard, but best judgment is still practiced" (interview 040106). Providers may not have the time or the inclination to devote to reading guidelines that are currently 133 pages long (DHHS 2008), so how are guidelines disseminated to providers at the clinic level? A physician who served on a DHHS guideline committee remarked that although a lot of effort goes into the language and presentation of guidelines, "it has been recognized [that] what people do is to look at the table and they may or may not read the matter." Thus, the tables become "extraordinarily important" in disseminating information from the guidelines (002_CH_US_030220_JP&CH). Indeed, the medical director of the clinic routinely issued memorandums to providers, pharmacists, nurses, and educators highlighting the tables from the new guidelines (e.g., Memo "New DHHS ARV Guidelines" dated 040323).

For patients diagnosed with AIDS because of an opportunistic infection or a CD4 count less than 200, the standard of care is to start HAART immediately. However, HAART is costly. At a clinic provider meeting early in 2004, a nurse practitioner and clinic manager running the meeting notified providers that they lacked discretionary funds to pay for HAART. She said, "If there is no payer source identified for the patient, it doesn't matter if the provider wants to start antiretroviral therapy today….we've created a deficit by putting people on medication for two or three weeks before we've identified a payer source" (fieldenotes 040204). The deficit was such that she said, "We're talking jobs" (fieldnotes 040204).

Thus, clinic administrators came up with a new routine to ensure a payer source for HAART before they started patients on drugs as well as criteria for "calamitous illness" to ensure a path to treatment for those patients unable to wait for a payer source to be secured (fieldnotes 040204). Providers were told to implement the new procedure "starting tomorrow" (fieldnotes 040204). The new routine centered on a "Pharmacy Communication Form" completed by the provider, detailing the drug regimen they would like to prescribe. Providers were to add the new form to the patient's other paperwork and instruct the patient to take the form to a Patient Assistance Analyst who would determine their eligibility for the AIDS Drug Assistance Program (ADAP) and other prescription drug assistance programs (fieldnotes 040527). ADAP is the Ryan White funded drug assistance programmed run by states while patient assistance programs (PAPs) are run by drug companies. Both require patients to be classified by severity of illness and by ability to pay, but vary widely in terms of what is covered, how long coverage lasts, and how quickly drugs can be dispensed after a patient is determined to be eligible. While ADAP generally covers antiretrovirals and other HIV medication such as

drugs to prevent opportunistic infections, ADAP formularies vary widely by state since states can choose to supplement minimum federal formulary requirements.

Once a payer source was identified, often with ADAP or PAP eligibility, the Pharmacy Communication Form was to come back to the provider detailing the payer source, when the regimen could be dispensed, or a note to discuss alternatives with pharmacy staff. This routine was added to the existing communication between pharmacy, providers, and nurse educators about whether the patient had complied with adherence counseling required as part of the clinic's local Antiretroviral Therapy Protocol. According to this protocol, the pharmacy will not fill new prescriptions for antiretrovirals without the signature of the nurse educator verifying that the patient was seen for pre-antiretroviral adherence counseling (Memo "Antiretroviral Therapy Protocol" 030926). In addition, providers were notified by pharmacy staff if their patient had not picked up their antiretrovirals in more than three months, since this was cause for removal from ADAP ("ADAP Adherence Updates" form, n.d.). Thus, by adding this on top of the other pieces of paper associated with the patient, one provider joked that they could "staple the patient to the form" to ensure that it was not lost (fieldnotes 040204).

At this time, a 30-day waiting period was common for patients eligible for ADAP (fieldnotes 040428). Thus, providers were regularly informed by the pharmacy staff of antiretrovirals available through PAPs. While some drugs were available more quickly through PAPs, local pharmaceutical representatives negotiate PAP contracts with health systems so variability in speed and availability is inflated with PAPs (fieldnotes 040428). At one provider meeting a pharmacist presented a chart summarizing PAP contracts between the health system and a variety of drug companies. He explained that Glaxo sends a check to cover two months of medicine. He said "cash, we like that." Gilead, on the other hand, sends the bottle and it is a lot

of work to get the second bottle filled. Boehringer, he said, is "streamlined," so "no delay, start today" (fieldnotes 040428). At one meeting, the medical director told everyone to look at the list from the pharmacy staff and suggested that they could prescribe Kaletra, ddI, and Nevirapine regimen and start the patient today using PAPs. Since this combination is not classified as an optimum regimen in treatment guidelines, a physician assistant asked, "why would you want to do that?" The medical director replied that if a patient really needed to start today, you can always simplify the regimen later if the patient is willing to take a very potent regimen to start (fieldnotes 040428). Since, at times, the benefits of starting treatment with HAART immediately outweighs the cost of waiting for optimum treatments, the clinic can claim to practice evidence-based medicine even when not able to afford the best treatments immediately.

All this shuffling did not exclude patients from getting urgent treatment because the clinic administration developed its own criteria for exceptional cases. According to the medical director, "urgent starts" are given antiretroviral without an assistance plan when diagnosed with four discrete illnesses: cryptomeningitis, [34] AIDS related dementia,[35] leukoencephalopathy,[36] and rapidly deteriorating renal failure. Under these circumstances the only treatment is antiretroviral therapy. There were no national or state guidelines or criteria for this, so clinic leadership developed this classification system themselves (interview 040609). In order to get

[34] Cryptococcal (crypto) meningitis is an inflammation and swelling of the brain and spinal cord tissues, caused by a fungus called Cryptococcus neoformans. This inflammation is dangerous, and leads to death in nearly all people who are not treated. The fungus is common in dirt, especially dirt containing bird droppings. Symptoms include flu-like and neurological symptoms such as confusion and dizziness. Source: http://www.thebody.com/pinf/cryptococcosis.html (last visited January 17, 2005).

[35] AIDS dementia complex (ADC) is a complicated syndrome made up of different nervous system and mental symptoms including poor concentration, forgetfulness, loss of short- or long-term memory, social withdrawal, slowed thinking, short attention span, irritability, apathy, weakness, poor coordination, impaired judgment, problems with vision and personality change. The frequency of ADC increases as CD4 cell counts decrease. Source: http://www.thebody.com/pinf/dementia.html (site last visited January 17, 2005).

[36] Progressive multifocal leucoencephalopathy (PML) is a serious viral infection of the brain. Researchers estimate that about 6% of people with AIDS develop PML. Most cases of PML show up in people with CD4cell counts below 100. The first symptoms of PML are weakness or coordination problems in an arm or leg. There may be difficulty thinking or speaking. Vision and memory problems, seizures and headaches can occur. Source: http://www.thebody.com/nmai/pml.html (site last visited January 17, 2005).

patients started on drugs within a few days, urgent starts were also allowed to bypass the local Antiretroviral Therapy Protocol's adherence counseling visits required of other patients before drugs were dispensed by pharmacy.

The medical director justified these local criteria to the health system by arguing that the payer source does not matter under these circumstances because it is an investment by the health system to keep the person from getting a lot sicker and incurring more costs with hospitalization. While that is generally true in preventive medicine, the health system was acutely aware of hospitalization costs from this clinic. For example, providers from the clinic had long admitted patients to the hospital from counties outside the two for which the hospital received funding for indigent care. Because the clinic received Ryan White Part A funding, however, they provided outpatient treatment to AIDS patients from a twenty-county Emerging Metropolitan Area (EMA) defined by HRSA. Administrators emphasized at one provider meeting that the clinic is funded to provide ambulatory care only and patients outside the two counties who need to be admitted to a hospital must be referred to hospitals in their own county for any non-ambulatory procedure (fieldnotes 040114). The medical director issued a memorandum on the matter in September 2003. Thus, as part of admission to the hospital, the patient's county of residence became a financial classification of utmost importance and could launch a quest for alternative hospitalization, sometimes increasing the likelihood of stigma and decreasing the likelihood of a high standard of care.

Even without fiscal constraints such as these, there is a great deal of complexity involved with treating patients who have failed antiretroviral regimens because of genetic mutation and viral resistance. Additionally, some patients refuse the most effective therapy because of side effects, potential side effects, pill fatigue, or other reasons. The clinic dealt with this complexity

by requiring that providers to present all their cases of patients prescribed their third or more antiretroviral regimen at clinic provider meetings or during a one-on-one discussion with the attending physician. In provider meetings, the group discussed genetic resistance as well as social and psychological barriers to care. For instance, a provider presented a patient to the group who was missing doses to a relatively easy-to-take regimen, Combivir and Efavirenz. While showing her patient's genotype results on the overhead, a physician responded, "why is she spotty? We need to address that." The provider responded, "she has a horrible life." The medical director asked if the patient has seen a mental health provider, but the answer was no. The provider explained that the issue is that the patient is taking an injectable hormone replacement because she is a transsexual. Another physician asked if there is anyone in her community that they know who might help her. The provider said that when she asked the patient about this before someone from her community had just died, but she will ask her again. The physician joked, "that's not a good person to ask" and they moved on to discussions of the provider's other patients who needed regimens changed due to resistance (fieldnotes 040609).

In the meeting described above, cost was not a central topic. However, the cost of antiretrovirals can be a barrier to care. Approved by FDA in 2003, T-20 (Fuzeon) created a crisis with the ADAP in the state where the clinic was located. The intravenous drug cost about $18,000 a year, making it the most expensive antiretroviral drug on the market at the time. It was considered "salvage" therapy or treatment for patients who have failed other antiretroviral drug combinations usually because of resistance. As with other classes of antiretrovirals, T-20 works best when combined with two other agents. In an interview, the medical director said that this clinic alone had 24 to 36 patients who need the drug, but most did not have other antiretrovirals to combine it with because they have developed pan-resistance. The state ADAP

consultant set criteria for the limited funding to allocate T-20 to five patients across the state that had at least two other drugs with which to combine and the lowest T-cell counts (interview 040609).

Providers struggled with moral evaluations of treatments and patients when prioritizing patients to refer to ADAP. During one provider meeting, providers presented patients they wanted to be considered for the five state slots. One after one, providers showed patient genotype results on the overhead and gave other medical information such as CD4 cell count and resistance history. One patient, whose viral load recently jumped, was described as having "pan-resistance" since 2001 (meaning he has few treatment options since the virus in his body has developed resistance to many antiretroviral drugs). A physician provider remarked that the patient wouldn't have a good response with Kaletra, so he would be on T-20 alone. Another physician said he is not really going to get a PI [protease inhibitor] given his genotype results. A provider finally said that the patient is not a good candidate for a T-20 ADAP slot. The patient's provider responded that the patient has had "strict adherence [to antiretroviral therapy] for 20 years." A nurse practitioner remarked that they are making an ethical decision by considering her record of adherence and that they should decide referrals based on medical criteria alone. A physician provider agreed, remarking they shouldn't be "wasting" the drug since monotherapy with T-20 is only efficacious when combined with other antiretrovirals. Another physician asked, will the patient will even be here in six months? The patient's provider and a second physician responded simultaneously, "let's not even go there!" The clinic manager, a nurse practitioner, said giving T-20 to this patient is like giving the last dose of chemotherapy to a patient in oncology. She said "that's ethical" and "we're gonna get there," but the patient's provider said, "let's not belabor this" and asked that they move on to the next patient. A nurse

said, “you either set up ethical criteria or medical criteria. You can’t do both” and left obviously upset (fieldnotes 040526).

Ultimately the clinic prioritized patients resulting in the referral of three to four patients who were eligible by ADAP criteria to receive the drug. According to the medical director, the clinic planned to submit the names of all patients who needed T-20 so that a waiting list formed for ADAP thereby shedding light on the magnitude of the problem with the hope that more funds might be allocated to ADAP. The clinic used this strategy successfully with ADAP in the past, because the state is interested in not have a waiting list (interview 040609). Indeed, waiting lists do draw attention, since in 2004, President Bush announced immediate availability of $20 million in drug therapies for ten states with ADAP waiting lists (National Association of State and Territorial AIDS Directors 2004).

Using ADAP and PAP was complicated by newly released and expensive drugs and providers pushed the boundaries of financial classifications in order to obtain the best treatments for patients. For example, while shadowing a nurse educator whose work focused on providing adherence counseling to patients before and during antiretroviral therapy, she told me that she is trying to sort out a “mess” trying to get a patient on T-20 through Roche’s PAP while also trying to “sneak” another one on the program. Roche denied eligibility for the first patient because he had ADAP. The patient’s provider, a nurse practitioner, told her about three patients who got T-20 from Roche’s PAP. The nurse educator described the fuss she had to make to get the first patient classified as eligible only for the patient to not do well on the drug. The nurse practitioner said that a provider in the pediatric unit is also getting a hard time and remarked that Roche will get paid for five by the state, questioning the strictness of the eligibility criteria for the PAP. The nurse educator wondered aloud to the nurse practitioner if the patient should just

apply for T-20 via ADAP. The nurse practitioner replied with an emphatic "no," adding that ADAP is another payer source for the drug. She went on to joke with the nurse educator, "you're stupid, you don't know [the patient is eligible for ADAP]." On her way out of the nurse educator's office, the nurse practitioner reminded her that even if she did know the patient was eligible for ADAP, the patient would not get T-20 through ADAP anyway (fieldnotes 040518).

As we have seen, providers adjusted to the PAP and ADAP systems by developing new routines and workarounds in order to get patients on drug therapy. However, identifying a payer source and coding diagnoses and procedures correctly is important for ensuring patient care, maximizing income, but also avoiding fraud. For providers who must choose particular codes as part of their encounter with patients, there are many complications. Visits with patients are typically brief and paper-heavy. Billing forms provided by health systems may be difficult to navigate. Fiscal constraint can propel increased attention to the best way of filling out forms, highlighting the need for new routines and divisions of labor. Healthcare providers must be familiar with the nomenclature both to avoid accusations of fraud and to work the system to provide optimum care for patients.

While the clinic is funded through the CARE Act, it is situated within a larger public health system. Like many public hospitals and health systems in the United States[37], this one

[37] Public hospitals are experiencing increased losses across the United States. According to a report by the National Association of Public Hospitals and Heath Systems (NAPH), 52 percent or its member public hospitals lost money in 2002 compared to 42 percent in 2001. In addition, in fiscal year 2002 NAPH member hospitals and health systems provided $5.4 billion in uncompensated hospital care, representing over 24 percent of the uncompensated hospital care in the United States. Such uncompensated care represents 21 percent of NAPH members ' costs compared to just 5.4 percent of costs for hospitals nationally. While NAPH members continue to rely heavily on government funding sources, reimbursement from these sources is not adequate to cover the costs of providing patient care. Increasingly large state and federal budget deficits will only add to cuts in government sponsored health care (Singer, et al. 2003). This is significant because public hospital closures may reduce access to care for the uninsured poor in large cities (Buchmueller, et al. 2004; Thorpe and Brecher 1987). Indeed, a study by the Urban Institute found that good performance did not increase local support for a hospital's safety net programs. They also found that state and federal funding are increasingly important in guaranteeing continued access, given limited local funding and enrollment under the new programs (Bovbjerg, et al. 2000).

faced a fiscal crisis and structural reorganization during my field observations. Since this particular clinic is an established outpatient facility primarily with many staff salaries paid by federal grant dollars, some key organizational changes in the health system did not impact the clinic directly. However, the clinic also created revenue for the health system by seeing patients who had third party payers such as Medicare and Medicaid, so fiscal constraints impacted the clinic in a variety of other critical ways.

Thus, in addition to developing routines to ensure payer sources for antiretroviral therapy, the health system began training providers on coding procedures and visits to maximize reimbursements from Medicare. During one provider meeting, a nurse auditor from the health system came to train the providers on "modifier 25," a Medicare code defined under the CPT code set mandated by HIPAA.[38] The health system already had an operational policy describing the procedure for appending billing codes with "modifier 25." When physicians write "modifier 25" next to a particular code, it indicates that they have performed a separate service or evaluation from the code indicated. This is a necessary modification to the coding scheme because only some procedure codes have multiple services included in their classification. The nurse auditor announced that the clinic had a 100 percent error rate with "modifier 25" and as a result is noncompliant. This drew laughter from the group at first, but before long there was confusion. A physician told the nurse auditor to re-read the regulations, a nurse manager crossly remarked that the auditor only got that error rate because of the particular charts she pulled, and debate ensued about whose responsibility it is to write "modifier 25" on the billing form (see Figure A.4 in Appendix). Providers felt they were being "retrained" about something that was not their first responsibility.

[38] Current Procedural Terminology (CPT) defines modifier 25 as "significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service." Modifier –25 was approved for hospital outpatient use effective June 5, 2000 (Centers for Medicare and Medicaid Services 2001).

After the nurse auditor left, the medical director said it sounds like we're doing a lot of work and not billing for it. For instance, providers at this clinic order lots of intravenous antibiotics and colposcopies, so they need to be sure that they bill correctly for them. He said some codes have saline built into them while others need saline added as an additional code. The question remaining was whose job it was going to be to document a "modifier 25". One physician said doctors should write it because, "we know what we documented." Another physician remarked that it is a bad way to run the system to ask the physicians to do it. Instead, she suggested, the discharge nurse should do it. The debate became somewhat heated when the first physician asked, how will someone else (i.e., the discharge nurse) know when to write in a "modifier 25?" The medical director calmed the discussion by reminding the group that their capacity to bill correctly for procedures affects the money that the clinic has to function (fieldnotes 040128).

Not only are clinical divisions of labor impacted by the use of the codes, but the codes may not capture all the treatments administered by the provider during a visit. Indeed, I observed a nurse practitioner drawing additional boxes on a billing form so that she could check them off (see Figure A.5 Billing form for diagnoses in the appendix). When I asked how often she needs to do this, she remarked "at every visit." She explained that since a committee at the health system is responsible for creating these forms and incorporating revisions to the ICD-9-CM, how they are revised and what gets included or taken off depends on who is on the committee in charge of revisions. Moreover, since the form is limited to one page, all diagnosis codes cannot be included. What gets included depends on the makeup of the committee. For instance, there are a lot of kidney related codes on the form whereas she needs more liver related codes. Clinic providers have little influence since they are often only given 72 hours or less

notice that the form is going to change (fieldnotes 040127). However, the provider is made responsible by a disclaimer on the top of the form that reads, "This form is a coding reference only and is not meant to suggest or in any way influence the selection of ICD-9CM and/or CPT codes, or imply that physicians or their representatives should select only the codes listed on this form" (see Figure A.4 Billing form for procedures in the Appendix).

Coding is important to public health systems such as this because safety net payers such as Medicare, Medicaid, and Ryan White do not cover all treatment costs. Thus, public health systems provide the majority of uncompensated care in the U.S. (Singer, et al. 2003). At the same time, the medical director of the clinic described the tendency of clinic providers to "code low" because they do not want to get in trouble with the government for billing fraudulently (interview 040106). Thus, in addition to internalizing treatment guidelines, providers are supposed to memorize billing codes to be sure they are coding at the correct level. If reviewers see coding too high then they may think their money is being thrown away on patients who are not that sick (interview 040106). In addition to being careful to avoid fraud, the medical director said that indeed providers do need to judge decision making by the codes because if you code a patient for pneumonia they will get only one day in the hospital, but if coded as PCP or pneumonia *and* diabetes, then the patient will be admitted to the hospital for three days. The health system monitors this through the process known as utilization review. He recounted a time when he admitted a patient to the hospital with a "newly described condition" related not to her disease, but was an outcome of her drug therapy. Since there was no code to justify her hospitalization, he kept getting calls from the health system telling him to get her out of the hospital even though she was on a ventilator (interview 040106).

Given all this, there was a broad understanding of the debt and how funds are allocated. One nurse told me that they are truly impacted now by the "realities of reimbursement" (fieldnotes 040402). In another meeting, providers discussed the fact that "rule out TB" is not an ICD-9 code, so it cannot be used to admit someone to hospital (fieldnotes 040505). They joked about their record of "soft" admissions done by writing "rule out TB" on the hospital admission form (fieldnotes 040505). Soft admission is medical provider jargon for an admission made without sufficient medical justification, such as the proper codes. These may be done more for ethical rather than medical reasons. For instance, perhaps a provider knows that a homeless patient, even if only temporarily, will have better health outcomes after a few days off the street with regular meals. Such soft admissions would likely be eliminated once a centralized admissions system was introduced as a cost-containing measure by the health system. The centralized admissions system positioned a nurse as gatekeeper to prioritize admissions based on "hard" medical reasons rather than ethical or "soft" reasons.

While healthcare providers are more and more accustomed to coding schemes and operating alongside cost-containing measures, the newness of HIV/AIDS and its character as a chronic disease influence both the development of treatment guidelines and code sets as well as their use in everyday practice. People living with AIDS depend on a mélange of pharmaceuticals to treat comorbidities, such as Hepatitis C, prevent opportunistic infections such as PCP, and combat side effects of their antiretrovirals, such as neuropathy, in addition to their daily anti-HIV regimen. Suppression of the virus requires uninterrupted, daily access to multiple prescription drugs. Long-term suppression of HIV requires near-perfect adherence to antiretrovirals. Even moderate non-adherence is associated with viral failure, viral mutations, and resistance (Paterson, et al. 2000; Manheimer, et al. 2002; Ickvicks, et al. 2002). In practice, this level of

adherence (95 percent) requires a patient on a twice-daily regimen not to miss or substantially delay more than three doses of antiretroviral medications in a month (Machtinger and Bangsber 2005). This degree of adherence is far greater than that commonly associated with other chronic diseases and is quite difficult for most patients to maintain over the course of a lifelong illness (Sackett 1979; Manheimer, et al. 2002; Howars, et al. 2002). As we have seen, then, because of new drugs and the complexity and high cost of treatments, standards of care in the management of HIV do not provide paths to treatment that are barrier-free as is the case with other diseases (Moatti and Souteyrand 2000). In this way, local classification activity and organizational routines are impacted by the national standardization of antiretroviral therapy both in terms of cost and efficacy.

Conclusion

Treatment guidelines and code sets associated with pricing are not entirely new to medicine, but their value tends to be seen as the formulation of categories in which to put diseases and patients as part of a larger effort at collecting information about and financing what providers were doing. The development and integration of multiple classifications and standards over the last century represents a larger push toward standardization in medicine that does not account for local adaptations by providers who face an assortment of pressures regarding the financial classification of treatment. The practice of evidence-based medicine alone asks providers to select treatments ranked according to how their associated research is classified (i.e., RCT, expert judgment). At the same time, fiscal systems ask providers to code their services using whittled-down versions of ICD-9-CM and CPT codes. All the while, it may be impossible to treat a patient according to the best evidence because of resource shortfalls, viral resistance,

side effects, and other exceptions. Despite practicing evidence-based medicine, then, HIV/ADS providers must select less optimal treatments frequently. Thus, the financial classification of treatment overlaps with moral and administrative classification, contributing to the social construction of HIV/AIDS as expensive, complex, and requiring more studies and novel treatments.

All this classification work has enabled new treatments to be disseminated more quickly than with syphilis. In 1937, Parran wrote, "In a world geared to hourly news flashes; where the picture of this morning's accident is in the noon edition; where the swish of a dictator's sword in Europe this afternoon flutters the headlines tomorrow morning, it is with a mixture of amusement and concern that I find that Erlich's discovery of salvarsan in 1910 is news in 1937" (Parran 1937, 133). These words exemplify the inability of medicine and public health to quickly disseminate innovations in treatment technology in the early twentieth century. Although over the course of the last century we have seen a steady rise in mechanisms of standardization, medical treatment innovations continue to create a context of uncertainty for healthcare providers. The coordination of treatment and of financing care is now immersed in a complex of standardization that draws attention to the myriad of uncertainties and creates fresh uncertainties even through the resolution of previous uncertainties (see Fox 1980). In practice, providers create workarounds to existing billing systems resulting in a reduction of local uncertainty about what treatment to select while being cognizant of fiscal constraints. However, these local work-arounds may draw attention to uncertainty in the larger system since work-arounds may resemble fraudulent behavior. For instance, the financially strapped health system likely views "rule out TB" a less legitimate reason for hospitalization than a combination of existing diagnostic codes while providers may view it in reverse.

The comparison between syphilis and HIV/AIDS reveals that the coordination of standards and pricing of care, an administrative function by all accounts, actually occurs as classification work even at the clinic level as clinicians select treatments from their evidence-based medicine toolkit. HIV/AIDS continues to elude treatment with no cure in sight, while syphilis, a quite curable condition, continues to elude eradication. This begs the question, do all of these mechanisms of standardization including the creation and dissemination of treatment guidelines, the authorization of particular coding schemes for reimbursement, and regulations about treatment innovation lead to controlled cost and improved quality of care? Recent reports from the Institute of Medicine about medical error (2000b, 2001) and other studies describing the ineffectiveness of treatment guidelines to increase quality care raise serious questions about the unintended consequences of the financial classification of treatment (Grimshaw and Russell 1993, Tannenbaum 1994, Dracup 1996, Sonnad 1998). Moreover, despite caregivers' tendency to prescribe the newest treatments in the evidence-based medicine paradigm, the newness of a treatment does not necessarily correlate with its effectiveness (Deyo and Patrick 2004). With both syphilis and AIDS, we have seen how the process of finanical classification of treatments put the status of those very treatments in question.

The classification of treatment by its efficacy and price is a core aspect of medical care in the U.S. today with HIV/AIDS and a century ago with syphilis. When providers evaluate treatments this way, treatments become objects of financial classification since the resources allocated for treatments are limited. Thus, the financial classification of treatment overlaps with the financial and moral classification of patients (e.g., prioritizing which patients to refer for limited T-20 slots). Moreover, as we will see in chapter 6, providers themselves are objects of financial classification since their level of expertise is classified by their education, experience,

and other items codified in treatment guidelines as well as professional credentialing and regulations over safety net healthcare. Thus, the financial classification of treatment overlaps with both the financial classification of patients and the financial classification of providers.

CHAPTER SIX

THE CLASSIFICATION OF EXPERTISE: MEDICALIZATION AND PROFESSIONAL AUTHORITY

Over the past century, intraprofessional processes have contributed to the intensification of medicalization in the U.S. partly through the financial classification of providers as experts. Row 5 of Table 1.2 summarizes this type of classification. Medical specialization, a continual process of occupational segmentation within the medical profession at large (Bucher and Strauss 1961), is an effort to construct boundaries around objects and styles of practice and is a key mechanism of medicalization and the social construction of disease (Halpern 1990, Conrad 1992, Baszanger 1998, Conrad 2005). In this chapter, we will see how the changing complexity of medical work with syphilis and HIV/AIDS affects jurisdictional claims in medicine, particularly how the development of tools (testing, tracking) and drugs become objects that doctors claim jurisdiction over and how the location of the work in clinics shapes these jurisdictional claims. While syphilis and HIV/AIDS have been eschewed by subgroups in medicine because of fear and stigma, they have also been claimed as highly specialized domains in medicine, contributing to how experts are defined. As work-related processes become increasingly specialized in medicine, syphilis and HIV/AIDS have become less about moral failings that can be resolved by character improvement or punishment, and more about problems that can be solved by medical experts.

In order to understand how collective understandings of both syphilis and HIV/AIDS have been impacted by medical specialization, this chapter first traces dermatology's American lineage from its ancestry with European syphiliology to its disassociation from sexually transmitted disease, its first acquaintance with AIDS, and its contributions to the multidisciplinary specialty of HIV medicine. This analysis illustrates how syphilis and venereal

disease, in general, became the domain of the U.S. Public Health Service (USPHS) with the establishment of rapid treatment centers in 1938 and later with specialty medical research following World War II. The second section of this chapter analyzes the increased formalization of definitions of expertise in HIV/AIDS in the content of treatment guidelines, peer-reviewed journal articles in the field of HIV medicine, interviews with experts, and observations in a public HIV/AIDS clinic. The analyses of medical specialization in syphilis and HIV illustrate intraprofessional processes between domains of public health and medicine generally, but are borne out in quite opposite ways. Once considered undesirable and dirty work avoided by private physicians, HIV/AIDS care is now an area of expertise subject to professional medical claims for authority. By contrast, private physicians willingly abandoned syphilis to public health. Today, standards of care and medical innovation can be operationalized to rationalize payments (e.g., reimbursements for procedures) and to bolster claims of complexity and quality. With both syphilis and HIV/AIDS, we will see how cost and technology influence these intraprofessional processes.

The subdivision of medicine into specialty professions began in early nineteenth century Europe. At this time, occupational segmentation shifted from a triangle of physicians, surgeons and apothecaries (with physicians at the top) to medical specialties organized around anatomical regions of the body (Gelfand 1976). After the Flexner report of 1910, organized medicine focused on the improvement of medical education and the weeding out of sub-par medical schools, resulting in a decreased supply of physicians. The reorganization of the medical school curriculum according to body systems rather than discipline played a role in how medical specialties claimed expertise and the proliferation of specialization in general (Starr 1982). By the 1950s, medical specialization became especially widespread in the U.S. (Baszanger 1998).

By 1976 there were more than fifty-four medical specialties, subspecialties, and other divisions of specialties (Gelfand 1976) and by 1984 there were over seventy specialties and subspecialties. Today there are thirty-six medical specialties and eighty-eight subspecialties with twenty-four medical specialty boards offering certification (American Board of Medical Specialties 2005a). The proliferation of specialization has led to a decrease in general practitioners even in areas where doctors and hospitals were plentiful (Starr 1982) with the number of primary care physicians decreasing even today (Stevens, et al. 2001; Stevens 2001; Brotherton, et al. 2005; Rosenblatt, et al. 2006).

A range of forces contribute to occupational segmentation in medicine, including technological innovation, market expansion, and the culture of the medical profession that favors the discovery of pathology (Friedson 1970). Occupational segmentation is not the only force driving medicalization, however. Indeed, forces behind medicalization have changed from professional medical authority, activities of activist groups, organizational activities, and a policy orientation toward access to managed care, the biotechnology industry, consumer-oriented patients, and policy aimed at controlling cost (Conrad 2005), contributing to the decline of authority in medicine since the 1980s (Starr 1982).

This chapter illustrates how categories of expertise are developed and evolve with the introduction of new technology and struggles over the location of care. I will argue that claims of expertise made by professional subgroups in medicine are constructed through the financial classification of medical providers in discourse about who is best qualified to provide high quality medical care (e.g., in the formation of subgroups within the medical profession, in treatment guidelines, in educational requirements, and regulations). These classifications label and signify expertise and authority, impacting the ability of providers to justify the cost of and

need for their services. Professional segments such as medical sub-specialties play an important role in the social construction of disease by defining standards of care as well as characterizing certain procedures as complex or highly technical, such as testing for genetic resistance with HIV, thus drawing boundaries around the domain of activity for specially trained personnel. As we will see, the definition of medical expertise in both syphilis and HIV/AIDS overlaps with the financial classification of patients (e.g., resource allocation) and treatments (e.g., technological innovation) in practice, which underscores the mutually constitutive relationship between moral, administrative, grouping, and causal modes of classification in medicine.

Syphilis: From dermatology to venereal disease

As illustrated in chapter two, the interpretation of clinical manifestations, especially skin lesions and rashes, was the primary way to diagnose the disease before the identification of the spirochete and introduction of accurate diagnostic tests. Thus, dermatology has a historically close association with syphilology. In Europe the specialty is still referred to as dermatovenerology (Leslie and Levell 2004). Indeed, the specialty was actually known as "dermatology and syphilology" in the U.S. until the mid-twentieth century. Because of this, dermatologists became experts not only in syphilis, but also in sexually transmitted diseases more generally. Thus, it is no surprise that dermatologists were some of the first medical specialists to deal with AIDS patients who presented with unusual skin lesions in the early 1980s.

During the late eighteenth and early nineteenth century, European dermatologists began to focus on the relationship of internal bodily processes and the treatment of skin disorders in the establishment of an academic discipline and with the establishment of specialty locations of care. Daniel Turner, called "the first English dermatologist," was one of the first physicians to suggest

internal medicines to treat syphilis. Likewise, the founder of the first specialist skin hospital was one of the first physicians to confirm that secondary syphilitic lesions were contagious and introduced potassium iodide as a treatment for syphilis (Leslie and Levell 2004). The first professor of Cutaneous and Syphiltic Diseases at the Paris Faculty of Medicine, Alfred Fournier, had an international reputation for demonstrating the syphilitic origin of tabes (progressive bodily wasting) and general paresis based on clinical observation (since no serologic tests were available for diagnosis at the time) (Tilles n.d.). Fournier was also known for cataloguing visual impairments resulting from congenital syphilis. Toward the turn of the century, Moriz Kohn Kaposi who first to describe a rare skin cancer (subsequently named for him), wrote a dissertation entitled, "Dermatologie und Syphilis" (Root-Bernstein 1990). Even Fritz Hoffman, co-discoverer of the organism Treponema palladium, chaired the dermatology department in Bonn, Germany.

At the turn of the twentieth century, syphilis had a prominent place in the specialized dermatological literature in medicine as well as in plays and novels (Tilles n.d, Haas 1998, Hayden 2003). As we saw in chapter 2, syphilis was often confused with a variety of other sexually transmitted diseases during this time. Dermatologists organized meetings around syphilis for medical professionals, such as the first International Congress of Dermatology and Syphilology held in Paris in 1889 (Wallach and Tilles 1992). The congresses were held every three years thereafter until 1911 when the International Society of Dermatology and Syphilology formed (International League of Dermatological Societies 2006). This was an era of bacteriology where new diagnostic technologies broadened the role of physicians to include classifying human bodily processes and behavior. Diseases such as syphilis were just beginning to be isolated in terms of etiology, diagnosis, and treatment, giving doctors a more formidable

role in social classification more generally (Starr 1982). Thus, dermatology played an important role in distinguishing syphilis.

In the meantime, there was a struggle over the role of syphilis and venereal disease in general for medicine. This struggle existed despite the fact that medicine's greatest contributions until the twentieth century were to public hygiene. Bacteriology, however, changed the mandate of public health from concerns over sanitation, engineering techniques, and the environment to concerns over communicable disease, medical techniques, and the individual patient. While at the end of the nineteenth century physicians supported the extension of state health department power, they struggled against public care of the sick, the reporting of infectious disease, and the establishment of public clinics. Doctors backed measures that complemented their private practice, but opposed measures that would allow others to appropriate their patients or to compete with them. This struggle became especially intense in the early twentieth century (Starr 1982).

Although Thomas Parran became one of the most influential physicians in both syphilis treatment and public health authority, he did not have his roots in dermatology. By contrast to other specialists in syphilis, Parran got his start working with the USPHS on rural health services administration, public hygiene, and the control of communicable disease. In 1926 he became Chief of the USPHS Division of Venereal Diseases, instituted during World War I, which became the "prestige unit" of USPHS (Brandt 1985, Lombardo and Dorr 2006). Officers who from this unit helped claim jurisdiction for public health as a profession by simultaneously working with private physicians, the social hygiene movement, moral reformers, and scientists to allocate resources and improve the treatment of syphilis. Although Parran and his colleagues envisioned a move away from the moralistic evaluation of syphilitics as blameworthy to a more

medicalized and scientific view of syphilis as a controllable medical problem, public health was only just beginning to gain legitimacy in opposition to medicine (Brandt and Gardner 2000).

Those interested in controlling venereal disease during the 1920s focused their attention more on sexual mores than on medical interventions, such as the civilian American Social Hygiene Association (ASHA). In 1918, Congress created the Interdepartmental Social Hygiene Board (ISHB) led by the Secretary of the Treasury, Secretary of War, and the Secretary of the Navy to protect the troops from venereal disease by focusing on prostitution as the civilian source of infection (ISHB 1920). In addition, the ISHB was charged with supporting state boards of health in diagnosing and treating venereal diseases and academic centers in the study of venereal disease and the training of students "concerning the defensive hygiene of venereal disease" (ISHB 1920, 8). Although the ISHB included a representative from the USPHS, the Division of Venereal Disease, also formed in 1918, argued that it duplicated many of its activities (see Table 4.1). Moreover, the American Medical Association (AMA) regarded the ISHB as incapable of differentiating between regulating public health and regulating public morality. Thus, both medicine and pubic health felt impinged upon by the ISHB because of conflict over who had the relevant experience to deal with venereal disease. In 1921, only three years after its inception, Congress dismantled the ISHB paving the way for public health expanded jurisdiction over venereal disease.

As public health expanded, concerns about who has the relevant experience to deal with venereal disease was intensified by fears of "state medicine" (Brandt 1985). With advances in the medicine of syphilis now classifiable by cause and by grouping of symptoms, life insurance companies and employers began mandating individual health examinations by medical doctors. The AMA endorsed such exams, even for the healthy. Public health also approved of these

preventive health examinations, helping to promote expertise of the medical profession at this time (Starr 1982). Most clinics at his time offered free services for diagnosing cases of venereal disease, but then referred patients to private physicians for treatment. However, public clinics, often funded by philanthropic groups, began to offer treatment, charging far less than private general practitioners and specialists. One study found that the cost of standard syphilis treatment was less expensive in charity clinics than in private practice and increased as providers became more specialized. For instance, a charity clinic in Chicago charged $185 for a year of syphilis treatment compared with $525 charged by private physicians. Moreover, when given by specialists the cost of treatment increased to $1,000 or more.[1] As public health devised schemes to support state boards of health to provide self-sustaining and cost-effective care for venereal disease, the medical profession accused them of unfair competitive practices. This separation between diagnosis and cure mirrored the separation between the state and private business interests (Starr 1982). The AMA's resistance to public health's expansion into medical treatment became a national issue, however.

In an attempt to bridge the divide between public health and medicine, Parran tried to influence public sentiment away from issues of morality toward a medical conception of venereal disease. As we have seen, he advocated the strengthening of health departments and the sponsorship of clinical research (Snyder 1995). However, treatment was costly and difficult, causing many patients to fail to complete it. During the 1920s some physicians refused to continue treating patients who did not pay their medical bills. Expensive treatment coupled with poor quality public clinics in short supply added to patients' unwillingness to seek care. Even more importantly, the public and pay clinics where treatment was offered were tainted with the

[1] Bromberg, L. and Davis, M. (1932). "The Cost of Treating Syphilis." Draft manuscript. Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

moral stigma of syphilis's association with prostitution and vice. Some thought that generalized clinics would do a better job of attracting syphilitic patients for care. However, venereal diseases were not covered comprehensively in medical schools leading to missed diagnoses and poor quality care. At the same time, many physicians considered venereal disease to be a low-status specialty located somewhere between dermatology and urology, depending on its clinical manifestations. As the medical profession distanced itself from the stigma of sexually transmitted disease, many of those afflicted with venereal disease looked to home remedies, patent medicines, and other unorthodox cures (Brandt 1985). With other non-sexually transmitted diseases, the medical profession worked quite hard to distance itself from such quackery at this time. With syphilis, however, it was Parran and others specialists in syphiology who formed evidence about the complexity and cost of treatment in order to carve out some authority from medicine over venereal disease in the U.S.

Thus, while medicine began to integrate population-based thinking into its socially isolated practice, public health began to integrate clinical thinking into the development of bureaucratic structures (Brandt and Gardner 2000). Medicine was torn over the syphilis problem, seeing both potential revenue and potential discredit. In an effort to raise the standards of this medical specialty in the U.S. and maintain their jurisdictional control over a disease whose prevalence had increased, potentially offering a large market share for patient care, the American Board of Dermatology and Syphilology incorporated in 1932. This board was one of the four original boards who were predecessors of today's American Board of Medical Specialties. The certifying examination covered most aspects of common syphilitic conditions. Despite this, stigma remained for physicians associated with venereal disease. In 1935, dermatologists objected to the status given to syphilis at the American Board of Dermatology

and Syphilology annual meeting. One member complained about the "prominence" of the word "syphilology" on Board certificates and refused to display it in his office. Others in the Board felt that it was important to keep the term since they had long struggled to include syphilis as a fundamental part of dermatology rather than as part of the competitive arm of public venereal disease clinics (Livingood 1982).

The reduction in personal incomes during the Great Depression caused a decrease in the use of medical services. As we saw in chapter 4, public assistance for medical care increased rather inconspicuously during this time (Starr 1982). In a 1933 Michael Davis, Director of the Rosenwald Fund, sent a confidential report to Parran describing the practical experimentation with group practices, group hospitalization, and voluntary insurance was reportedly gaining ground, especially in the Western states. Among the causes contributing to the economic burden of sickness and distribution of care included, "the system of paying physicians' fees in proportion to services rendered the sick; excessive competition among physicians in some localities; overspecialization, leading to the parceling out of the patient; insufficient means for correcting this by teamwork among specialists and general practitioners; lack of facilities whereby physicians can be kept abreast of advances in medical science and practice."[2] Davis suggested that since the final report of the Committee on the Costs of Medical Care was met with such resistance by the medical community and that President Roosevelt had shied away from the insurance issue, programs designed to tackle this issue should be done with a common understanding rather than a national committee of some kind.

There was continuing struggle at this time over where to locate care for venereal disease (i.e., public clinics, private offices) and who will pay for the care (e.g., state, patient, insurer).

[2] Davis, M. (1933). "Programs of Medical Economics." Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

As we saw in chapter 4, public health's role broadened beginning with the 1929 Rosenwald demonstration project and the establishment of venereal disease control and research efforts as part of legislation passed throughout the 1930s and 40s (see Table 4.1 for a summary timeline). Syphilis was a central to the expansion of public health's jurisdiction. For example, more than 10 percent of the $8 million given to USPHS under Title VI of the 1935 Social Security Act was directed toward syphilis. States used those funds to develop diagnostic facilities, clinics, and surveillance programs (Brandt 1985). As we saw above, treatment provided by specialists was more expensive than treatment provided by generalists. Thus, by 1936, Parran and his colleagues suggested that medical professionals needed to be educated about syphilis being treated "under medicine rather than dermatology."[3]

In 1938 the Venereal Disease Control Act made funds available for rapid treatment centers with new sulfa drugs and later with penicillin, but did not address changes in how physicians were paid. At that time, organizations such as hospitals and insurers treated physicians as independent entrepreneurs, which allowed for the profession's economic position. Medicine was interested in maintaining their autonomy and authority with patients, insurers, hospitals, and the pharmaceutical industry because it allowed them to influence pricing, policy, and garner support for professional and political activities (Starr 1988, 26-27). Venereal disease was not very profitable and was associated with moral degradation. Although some physicians worried that venereal disease control could be the opening for socialized medicine in the U.S., leading to decreased autonomy, authority, and income the medical profession as a whole focused on defeating legislation aimed at national health insurance rather than provisions in the 1938 Act (Brandt 1985). Meanwhile clinics dedicated to the treatment of venereal disease grew from

[3] Webster. (1936). Papers of Thomas Parran, 1916-1962, RG 90/F14, Archives Service Center, University of Pittsburgh.

1,750 in July 1938 to 3,000 in 1940. Over the same period, treatments with minimum therapy increased from 15 to 58 percent and Wasserman testing increased by 300 percent (Brandt 1985). Rates of syphilis peaked in the U.S. in 1947. By this time, penicillin was offered in public clinics. Thus by 1950, rates of syphilis declined and private physicians, especially dermatologists, effectively gave up their jurisdiction over syphilis and venereal disease altogether. As we saw in chapter 5, however, physicians specializing in syphilis and public health were intent on guiding general practitioners in private practice and public health authorities on standards of treatment.

Just as dermatology ceded authority of syphilis to public health, the number of physicians choosing to become certified in dermatology increased an average of 100 percent annually from 1949 to 1953. In 1955, members of the Board of Dermatology and Syphilology opted to remove the term "syphilology" from their name. Also around that time, both the American Academy of Dermatology and Syphilology and the *Archives of Dermatology and Syphilology* dropped "syphiology" from their titles (Livingood 1982). By then, syphilis was easily cured with antibiotics and biomedical science was gaining unprecedented financing in non-venereal disease arenas (Starr 1982, Berg 1995). Medical specialization increased rapidly during this era with generalists and community clinicians having the least prestige of the profession. Alongside this increased specialization and sub-specialization in the medical profession, health care itself was becoming one of the largest industries in the U.S., largely owing to the channeling of health insurance through employment which provided the health care industry with a secure income (Starr 1982).

With syphilis and venereal disease in general, then, specialization shifted from medicine to public health during an era of professional antagonism over where care should be located and

how that care should be paid. Ironically, public health gained prestige in attempts to decrease the moral evaluation of venereal diseases established by the social hygiene movement by developing infrastructure to support the public care of syphilitics while medicine distanced itself from syphilis, even eliminating the term from its specialty home of dermatology. Thus, when dermatologists began to see the first sign of AIDS manifested in Kaposi's sarcoma (KS) in young gay men in the 1980s, medicine did not respond with enthusiasm for caring for all the patients. Instead, physician specialists and non-physician clinical care providers began to carve out a specialty both borne from public health and medicine.

HIV/AIDS: Origins of a Multidisciplinary Specialization

Since the beginning of the epidemic, HIV/AIDS care has been considered a multidisciplinary area of specialty, partly because it manifested itself in an array of symptoms and also because it was avoided by health care workers because of stigma and fear of exposure (Gerbert, et al. 2001; Mayer and Chaguturu 2005). At first, experts envisioned that HIV/AIDS care would be integrated and dispersed throughout the existing healthcare system with treatment provided by primary care doctors. However, its treatment became increasingly concentrated among a small cadre of physicians practicing in HIV specialty clinics. Thus, over the past twenty-five years, the professional definition of HIV/AIDS care has shifted from dirty, uninteresting work (Bosk and Frader 1990) often ceded to nurses (Aiken and Sloane 1997) and even lay persons (e.g., San Francisco Model) to a multidisciplinary specialty. Today, there are efforts to gain formal recognition for HIV medicine as a subspecialty from the American Board of Medical Specialties.

Similar to syphilis, many physicians avoided HIV/AIDS because they feared catching the disease themselves, feared losing patients because of stigma, and were not willing to take on the

grueling and expensive work of treating the disease (Bosk and Frader 1990). As we saw in chapter 5, physicians "in the know" were able to access innovative treatments through off-label prescribing and FDA fast track policies, but ancillary costs had to be absorbed by someone. Thus, private physicians often refused to see AIDS patients and community-based clinics were developed to address both stigma and cost. Over time, however, the introduction of new treatments and the funding of multidisciplinary HIV/AIDS research and clinical care centers by the federal government resulted in a distinct field of medicine complete with its own credentialing body (American Academy of HIV Medicine), professional associations (HIV Medicine Association), and definitions of HIV expertise found in treatment guidelines and regulations. The advent of Highly Active Antiretroviral Therapy (HAART) marked a turning point in this specialization. As one specialist physician noted at that time, HIV care is now considered an activity that "requires a level of expertise that non-specialists cannot be expected to have" (Volderbing 1998). In this way, HIV/AIDS has influenced intraprofessional processes both in terms of technology and in terms of finance. Indeed, HIV care has become increasingly specialized as care providers must be able to select from over twenty antiretroviral medications and mange their side effects, interactions with other drugs, viral resistance and genetic mutation, coexistent psychosocial issues that make medication adherence a significant challenge, and comorbidities as patients live longer (Mayer and Chaguturu 2006).

As with syphilis, one of the first indications of AIDS a new disease was the appearance of Kaposi's sarcoma (KS), a rare skin cancer, which materializes in violet-colored spots on the body (Altman 1981, CDC 1981a, Friedman-Kien 1981). This prompted many AIDS patients to seek help from dermatologists who diagnosed the cancer during an in-office biopsy (American Academy of Dermatology 1997). One of the earliest organized responses to AIDS by the

medical community came in 1981 with the establishment of the Kaposi 's sarcoma Clinic in San Francisco by Marcus Conant, a privately practicing dermatologist and member of the faculty at the University of California, San Francisco. KS patients were easily recognized and the clinic encouraged private physicians to send KS patients their way. The KS clinic relied heavily on volunteered time and resources in the early days. Thus, this clinic was not intended for ongoing primary care of AIDS, but focused instead on coordinating biopsies for diagnosis, case reporting, and developing a multidisciplinary research protocol. In its first year of operation, Paul Volberding, a young oncologist, joined the clinic as co-director and an infectious disease specialist was brought on board, expanding the clinic's orientation beyond dermatology. When manifestations of AIDS fell outside the boundaries of dermatology, oncology, and infectious disease, patients were referred to relevant specialists outside the clinic. By 1982 the clinic was associated with ten different specialties: dermatology, oncology, opthamology, radiology, pathology, internal medicine, psychology, immunology, dentistry, and gastroenterology. In addition, a psychologist was brought on to provide "primary emotional care" to help both patients and staff devastated by the syndrome's destruction and stigma (Hughes 1997). Although the establishment of specialized clinic for a specific condition was not new for medical specialties such as dermatology, the establishment of a clinic that came to pave a way for multidisciplinary specialization was unprecedented until HIV/AIDS.

Manifestations from AIDS other than KS were dealt with in already existing medical facilities. A couple of years later, an AIDS clinic, a hospital ward for AIDS patients, and a pulmonary clinic to evaluate patients with PCP were started in San Francisco. As we saw in chapter 4, a new organizational form known as the "San Francisco model of care" emerged in the mid-1980s and came to dominate the organizational structure of HIV/AIDS care in the United

States. Remarkably, then, the lack of effective treatment coupled with the concentration of care in specialty clinics galvanized the organizational field of HIV/AIDS. As more people were affected by the disease, patients, care providers, scientists, philanthropists, the government and lay persons joined in a shared mission to combat the disease and its associated stigma. Thus, the struggle over who is an expert and who is not is not just an intraprofessional process in medicine, but is also a struggle between professionals and the lay community because it is about the authority to give care and be paid, but also about the obligation to give care. In this way, the initial specialization of HIV/AIDS care was a result of organizational change rather than professional claims-making (see Petty and Culyba 2007).

Since the beginning of the AIDS epidemic, organized medicine supported specialization for HIV/AIDS care while early "experts" supported universal care by general practitioners, hoping that universalized HIV/AIDS care would de-segregate patients and mitigate stigma. Initially, HIV/AIDS specialists were "self-made" experts (Gerbert, et al. 2001) who came from various areas of medicine including dermatology, general medicine, oncology, infectious disease, and public health (Amman, et al. 1984). For these HIV/AIDS care providers, a willingness to treat AIDS patients with palliative care and emotional support distinguished them from others who eschewed such dirty work. Nevertheless, jurisdiction over HIV/AIDS care was not particularly attractive even to these new experts in the 1980s. There were few tools available to treat patients, and the tools of the trade that were available were relatively low tech. Moreover, there was little formalized training or guidance for physicians about the disease at that time. Thus, much of AIDS care could be provided by non-experts or even extra-medical professionals and so specialists did not have much to offer. In fact, early AIDS activists, especially from the gay community, shifted the definition of medical and scientific expertise to include patients

(Epstein 1996). Thus, the initial movement toward specialization around HIV/AIDS arose largely because non-experts avoided HIV/AIDS patients and others felt obligated to care for them, not because anyone wanted to claim jurisdiction over them to increase their professional autonomy or authority.

In those early years of HIV/AIDS, then, self-made experts felt that HIV/AIDS should be handled by primary care providers. There were calls to train primary care physicians to manage the disease and provide emotional support prior to referring HIV-infected patients to specialists when major complications with AIDS arose (Katsufrakis and Radecki 1992). The rationale for supporting a universal approach to HIV/AIDS care included expectations that the number of patients infected with HIV/AIDS would outgrow specialized inpatient and outpatient facilities and related worries about "burnout" among HIV/AIDS care providers (IOM 1986). Still, physicians were divided on universal HIV care in the 1980s. In an AMA survey, 48 percent supported a specialist approach while 45 percent supported a universal approach (Bresolin, et al. 1990). Ironically it was HIV/AIDS "experts" who favored a universal approach. The more experience a physician had with treating AIDS patients, the more likely he or she was to support a universal approach to AIDS care with 73 percent of the physicians who had treated 10 or more patients with AIDS supporting the universal approach (Bresolin, et al. 1990).

At the same time that "expert" physicians and the public health community supported the universal approach to HIV/AIDS care, HIV/AIDS care became increasingly segregated from existing medical and public health infrastructures of care. As discussed in detail in chapter 4, in 1986 the Robert Wood Johnson Foundation's AIDS Health Services Program began funding specialty clinics to care for AIDS patients based on the San Francisco model. At that time, USPHS was not heavily involved in treating AIDS, but focused its attention on investigating the

source of the outbreak and observing patterns of its spread in order to prevent further transmissions and allocate resources equitably and effectively. Thus, by the early 1990s physicians treating HIV/AIDS patients had de facto specialization, despite having few treatment tools to claim as their own. Moreover, prior to the advent of HAART in 1996, AIDS was more costly than other diseases because of hospitalizations and expensive treatments for opportunistic infections. Since many of these patients were young and previously healthy they were not covered under Medicare or Medicaid safety net programs, public hospitals quickly felt the burden of unreimbursed services for AIDS patients. Prevention of occupational exposure through the use of gloves and other measures was also an added cost for hospitals. There were increased reports of "patient dumping" going on in the 1980s. Although it is not clear how often this happened, dumping of AIDS patients did occur (Gionis, et al. 2002). There was at least one case in New York where a nurse was sentenced for dumping an AIDS patient (Associated Press 1989).

Public hospitals, as we have seen, were trying to stay afloat financially in the 1980s. Oftentimes these public hospitals were also teaching hospitals trying to make ends meet. After Medicare and Medicaid began in the mid-1960s public hospitals began to be major providers of insured as well as uninsured care. At first there was a lot of confidence that private insurance would make the safety net of public hospitals unnecessary. As an Urban Institute report suggests, however,

> Such optimism proved unfounded. Medicaid quickly dropped its initial aspirations to fund mainstream access for all the poor, and the extent of insurance coverage has been dropping nationwide since the early 1980s, although the rate of uninsurance varies greatly by state and locality. Nationally, the number of uninsured has risen to 44 million people, about two-thirds of them poor or near poor, so demand for uncompensated safety net care has also risen. (Bovbjerg, et al. 2000)

At the same time, teaching hospitals incur more expenses than non-teaching hospitals. The costs incurred in teaching in hospitals are called Graduate Medical Expenses (GME) and are paid for by Medicare either directly or indirectly as well as by private plans. However, as competition increases private plans are less willing to pay for GME. In fact, the largest single Medicare subsidy, $6.9 billion in 2000 was for GME to support the advanced training of physicians, mainly in teaching hospitals, after they graduate from medical school. In the 1960s, 1970s, and to a decreasing extent in the 1980s, most private health plans as well as Medicare and Medicaid paid hospitals both on the basis of their charges or their costs as well as including an amount to cover the extra costs of physician specialists who do the teaching. Medicare has maintained its GME support by making higher payments to teaching hospitals than it does to non-teaching hospitals. However, as competition for enrollees among private plans has increased, teaching hospitals say the plans are no longer willing to pay more to compensate for GME costs (National Bipartisan Commission on the Future of Medicare n.d.).

The development of specialization in HIV medicine has taken place alongside medical innovations in antiretroviral treatment which have decreased AIDS mortality and increased the complexity of managing the disease. Yet, the “medical” explanation which treats specialization as a natural response to scientific change and gives specialty groups a raison d’etre (Hofoss 1986) is incomplete. The division of medical work is shaped by both internal and external forces (Abbot 1988, Hafferty and Light 1995) including professional culture, market conditions as well as scientific discovery (Halpern 1988, Halpern 1990). In other words, the new technology of HIVAIDS provided an opportunity for the organizational and occupational structure of care to transform (Petty and Culyba 2007).

In medicine, the development of occupational segments has long been recognized as a continual process that influences the definition of disease and medical practice (Bucher and Strauss 1961). Exclusion techniques and the creation of professional standards have been instrumental to establishing medical authority since the nineteenth century (Starr 1982). Specialization had its heyday in medicine during the 1950s and 60s when medical students perceived specialization to signify mastery in the management of a previously untreatable condition through a combination of knowledge and technological skills (Kendall and Selvin 1957; Baszanger 1998; Kazzi, et al. 2001). This overspecialization led to a dearth of general practitioners in the 1970s (Starr 1982). Some see the trend in specialization reversing as more medical students choose to specialize in primary care (Kazzi, et al. 2001) while others heartily disagree (Rosenblatt, et al. 2006). However, occupational segmentation remains a force behind medicalization today albeit one tempered by competing forces such as the shift in health policy from access to cost-control (i.e. rise of managed care), an increasingly influential role of biotechnology (especially pharmaceutical companies), and a new consumer-orientation of patients (e.g., legislation enabling direct-to-consumer advertising by drug companies and allowing off-label use of FDA-approved drugs) (Conrad 2005).

Mick (2004) challenges claims about a physician surplus leading to diminished physician domination over agenda-setting, oversight, hospital admissions, revenue and patient referrals. Although there has indeed been a surplus in physicians, he argues that physicians have maintained their autonomy for three reasons: first, a shortage of nurses and failure of nurses to become more professionally autonomous (with own practices); second, the decline of AMA and the concentration of expertise in specialty groups; and third, the trend of physicians going into

managerial and administrative positions in healthcare organizations. The decline in authority of the AMA coincided with the rise of specialty organizations:

> …the rise in the number of professional groups in medicine concomitantly with the decline in the proportion of physicians in the American Medical Association (AMA) is a factor neutralizing forces arrayed against medical influence. Instead of a balkanizing effect leading to a weakening in medicine's political clout, the subdivision of medicine into more and more specialty groups, including a proliferation of certification subgroups, has, I would argue, assisted in filling the gap in medical authority left by the slow decline of the AMA. This is because new avenues for professional concern and control have resulted, often very specific to the group or specialty involved. This has made for a more potent concentration of medical expertise and authority in virtually dozens of medical specialties, heightening medical influence through alternatives to the AMA. (Mick 2004, 12).

It is in this context that specialized care has taken the place of nonspecialized care in the practice of caring for HIV-infected patients.

Medical specialization is not inevitable with the emergence of a new disease. In the early 1980s AIDS was considered a "radical break" in twentieth century trends toward a world freed of epidemic disease (Fee and Fox 1992). At the same time, the uniformity of medical practice was being scrutinized in the emerging evidence-based medicine movement (Timmermans and Kolker 2004). A variety of forces impact medical specialization such as professional culture, scientific discoveries, and altered market conditions (Halpern 1988, Halpern 1990). The development of specialization in HIV medicine has taken place alongside medical innovations in antitretroviral treatment which have simultaneously diminished the more visible signs of AIDS (e.g., KS, wasting) and increased the uncertainty of managing the disease (e.g., genetic resistance, side effects, comorbidities such as diabetes). The discovery of treatment for a catastrophic illness or the financing of health care for the catastrophically sick can provide the opportunity for institutional entrepreneurs to define the meaning of the event and contribute to organizational change. For instance, with HIV/AIDS the creation of multidisciplinary clinics

specializing in the treatment of HIV-infected patients attached to teaching hospitals created a market for and training venue for specialists in the management of HIV disease. Moreover, the legal and ethical issues raised with HIV/AIDS have been debated in a more public forum than other kinds of diseases (Epstein 1996).

As discussed in chapter 3, civil rights were taken so seriously with AIDS that "HIV has changed everything" (010_DC_US_032503_RC&JP) particularly in medical research institutions (Folkers and Fauci 2001, Valdiserri 2002). As an example, U.S. government funding for biomedical research on HIV/AIDS far exceeds funding for any other infectious disease in history (Folkers and Fausti 2001). Spending on AIDS research by pharmaceutical companies, philanthropic organizations (e.g., Bill and Melinda Gates Foundation, amFAR), and other government bodies has also been significant. Many treatment innovations have been developed through this effort and the spread of HIV has been slowed successfully in many developing countries. Yet many innovations in treatment remain since there HIV/AIDS remains incurable with current technology, so hope remains for the development of a vaccine for HIV. Successes in AIDS research suggest that rapid advances can be gained in "new" and resurgent infectious diseases such as TB, malaria, hepititis C, West Nile, and dengue. Folkers and Fausti (2001) argue that HIV/AIDS research has opened up a new door for productive research on these diseases more generally. In this way, professional focus on research also contributed to this "AIDS exceptionalism" (Bayer 1991, Casarett and Lantos 1998, Bolan 1999).

Additionally the lay public, especially activists from the gay community, were involved in scientific disputes, shifting the definition of expertise to include patients (Epstein 1996). AIDS activists played a significant role in applying pressure to funding agencies for the allocation of research funds (Shilts 1987, Panem 1988, Annas 1990, Siegel and Roberts 1991,

Rothman and Edgar 1992, Epstein 1996). As discussed in chapter 5, AIDS activism and lobbying efforts aimed at the allocation of research resources and the speeding up of approval processes by FDA served as a model for other disease-specific lobbies such as Parkinson disease and breast cancer. However, disciplines and organizations are shaped by the time period in which they are created (Stinchcombe 1965, Foucault 1970). Thus, the production of HIV medicine as a distinct field of specialization is likely to bear the mark of an era of intense change including the commercialization of health services (Relman 1980), the rise of evidence-based medicine (Berg 1997, Horton 2003), the application of cost-benefit analyses to health services (Fox 1990), and the decline of professional dominance in the era of managed care (Scott, et al. 2000). Thus, an examination of specialization in HIV medicine will tell us something more general about intraprofessional processes in this contemporary arrangement of healthcare.

Refining HIV Expertise: The Rise of Infectious Disease and the Future of Credentialing

As we have seen, in the early days of AIDS clinicians who came to the field of HIV medicine were originally trained in other specialties such as dermatology (Leslie and Levell 2004). As the availability of HIV testing has increased and a seasoned infrastructure of community-based clinics established, specialists are no longer on the front-line of diagnosing AIDS. Moreover, as treatments for HIV infection have improved opportunistic infections such as Kaposi's sarcoma are seen infrequently by healthcare providers. Thus, today, HIV care is likened to the management of a chronic disease. By contrast, today clinicians can opt to specialize in the field of HIV medicine through specialization in Internal Medicine with an additional sub-specialization in Infectious Disease. The American Board of Internal Medicine first administered an exam in infectious disease in 1972 (American Board of Medical Specialties 2005a). AIDS did not exist as we know it then, yet today 20 percent of questions on the

Infectious Disease board exam have to do with HIV (O'Rourke, et al. 2001). As we will see, however, because specialization in HIV medicine has multidisciplinary roots, board certification in Infectious Disease is often only one element of HIV specialization today. Indeed, experience with patients, continuing medical education, and multidiscplinary credentialing in HIV medicine are criteria for how HIV expertise is defined in medicine and public health.

When the AIDS epidemic first began there were fewer than 2,000 infectious disease specialist physicians in the U.S. (Mayer and Chaguturu 2005). As summarized in Table 6.1, the increase of certification of infectious disease clinicians coincided with the development of HAART in the mid-1990s.

Table 6.1 – Subspecialty certificates issued in Infectious Disease, 1995-2004[4]

Year	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	10 Year Total
Number of Certificates	0	545	223	246	241	205	230	261	255	308	2,514

When AIDS emerged infectious disease physicians were typically called on for consultations and rarely treated patients at their bed-side. With HIV/AIDS infectious disease specialists reoriented themselves from disengaged consultants to primary care providers focused on long-term care (Mayer and Chaguturu 2005).

Today, chronic diseases are the most serious health problems facing industrialized countries in terms of cost, lives lost, and number of people affected. Chronic diseases require months and years of therapeutic interventions along a trajectory filled with uncertainty (e.g., no cure, patient adherence) (Baszanger 1998). While many sexually transmitted diseases are curable (e.g., syphilis, gonorrhea, Chlamydia), they continue to mystify public health practitioners who are unable to curtail their spread. There has been some success in managing

[4] Adapted from the American Board of Medical Specialties 2005b.

the uncertainty of transmission of infectious agents: for instance in preventing mother-to-child transmission of both syphilis and HIV/AIDS, assuring a safe blood supply for hemophiliacs and others requiring blood transfusions, immunization programs, and sanitation measures. To date, no one has been able to rein in the uncertainty having to do with human sexual behavior since case rates of syphilis, Chlamydia, and fluoroquinolone-resistant gonorrhea are on the rise (CDC 2005). Like syphilis before penicillin, HIV/AIDS shares qualities of both sexually transmitted and chronic diseases.

Expertise in HIV has been cited as the most important factor in getting quality care (Wood, et al. 2003; Bach, et al. 1999; Brosgart, et al. 1999; Kitahata, et al. 2000; Kitahata, et al. 1996; Markson, et al. 1998; Shapiro 1999; Stone, et al. 2001; Willard, et al. 1999). However, the way that experts regard their own expertise contributes to how expertise comes to be defined. As one study found, infectious disease specialists are more likely than internists or family practitioners to regard themselves as being confident in technical aspects of HIV/AIDS care (Gerbert, et al. 2001).[5] In a survey of physicians who attended a continuing education event on HIV/AIDS, infectious disease specialists reported more confidence than both internists and family practitioners in interpreting genotype/phenotype results and diagnosing/managing opportunistic infections. They were also more confident than family practitioners in assessing when to begin drug therapy, choosing initial treatment, and diagnosing malignancy. However, infectious disease specialists were less confident than internists and family practitioners in promoting general health through prevention messages, managing general care of patients, and assessing patient substance abuse and sexual risk behavior (Gerbert, et al. 2001).

[5] This survey used confidence to assess confidence in particular aspects of HIV/AIDS care, not to assess the quality of the care being provided by respondents.

This atmosphere has helped sustain a sense among some clinical trainers, nurses, and physician specailists that the standard of care can only be delivered by an infectious disease specialist (017_AT_US_030416_RC, 018_AT_US_030528_RC, 002_CH_US_030220_JP&CH). However, the "team approach" of incorporating nurse practitioners, physician assistants, pharmacists, nurses, social workers, mental health professionals, and others is becoming the ideal in HIV care (Gerbert, et al. 2001). A multidisciplinary approach is also used for supporting HIV/AIDS research. The NIH-funded Centers for AIDS Research are an example of this. These are modeled somewhat after NIH-funded Comprehensive Cancer Centers (018_AT_US_030528_RC). A setting where interdisciplinary methods are practical, allows for new questions about the process of specialization and expert authority to be asked.

Volberding (2003) argues that new developments in HIV/AIDS care such as viral load testing, two new classes of HIV drugs, the establishment of combination therapy as the standard of care, and knowledge about drug resistant HIV, have made specialization necessary. In 1998, Volderbing wrote,

> As importantly, all of these developments have made the continuing care of HIV-infected individuals significantly more complex -- so complex, in fact, that the optimal medical management of patients with HIV disease now requires a level of expertise that non-specialists cannot be expected to have. The time has therefore come to rescind the consensus we reached at the beginning of the decade. It is time to recognize that HIV infection is no longer a disease that practitioners with limited experience should attempt to treat. Over the past three or four years the treatment of HIV infection, particularly in its advanced stages, has become so complicated that it is now best left to those with the greatest expertise in treating the infection and its sequelae.

One study found that access to a specialty care site mattered more to improved outcomes than access to specialists physicians (Wilson, et al. 2005a). Another found that physician assistants and nurse practitioners provide care that is as good as that given by HIV physicians and superior to care given by non-expert physicians (Wilson, et al. 2005b), which indicates that the

organization of specialty clinics is perhaps more important than the availability of physicians who have specialized in HIV medicine. Access of female and minority HIV-infected patients to specialty care (Stone 2000; Cunningham, et al. 2005) and calls for more formal specialization have also been abundant in the post-HAART era (Zuger and Sharp 1997; James 1999; Gerbert, et al. 2001; O'Rourke, et al. 2001; Landon, et al. 2002; Wolfe 2003; Gerbert, et al. 2004).

By 2000, 1 percent of physicians cared for 80 percent of HIV-infected patients in the United States, underscoring the fact that some form of specialization was taking place in HIV medicine (Gerbert, et al. 2001, 328). Moreover, leadership at the International AIDS Society USA (IAS-USA) observed that HIV specialists increasingly tend to have training in Infectious Disease (019_SF_US_030602_RC). However, infectious disease specialists and other subspecialists in medicine tend not to locate in rural areas that lack research and teaching facilities. Thus, living in a rural area has also been identified as a barrier to specialty care in the U.S. (Cohen, et al. 2001; Kilbourne, et al. 2002). Just a new specialty is developing around HIV care, other countries and rural parts of the U.S. are finding ways to delegate much of this work to non-physician care-givers who receive some special training in HIV and work under the supervision of a specialist or have access to a specialist consultant. Indeed, as we saw in chapter 5, the introduction of HAART has introduced new uncertainty into the management of HIV disease (Yallop, et al. 2002; O'Brien 2003; Rosengarten, et al. 2004). Moreover, since HAART requires near perfect adherence, 95 percent for successful treatment (Paterson, et al. 2000), care providers must be cognizant of patient-level variables that impact treatment, including socieoeconomic status, gender, managed care, and referrals to specialists (James 1999; Paterson, et al. 2000; Stone 2000; DiMatteo, et al. 2002; Golin, et al. 2002; Howars, et al. 2002; Cunningham, et al. 2005).

There has been a call for the federal AIDS Education and Training Centers (AETCs) to define minimum standards of HIV care as well as provide post-residency training in HIV care (Bolan 1999). To date, the AETCs resist defining standards of expertise and HRSA discourages the AETCs from using funds to train medical residents, a job supposedly covered by academic medical centers. While the multidisciplinary "self-made" specialization of the past was informal and resulted from the location of care in specialized clinics, today's formalized definitions of expertise in HIV medicine have to do with the desire for HIV specialists to be compensated for their expertise, self-made or otherwise. Over the last few years, definitions of what constitutes an 'expert' in HIV medicine have been developed by multiple entities including professional societies, State Medicaid programs, Centers for Medicare and Medicaid Services (CMS), and the development of a credentialing process. Indeed, the DHHS guidelines for the use of antiretrovirals by adults and adolescents also now include criteria for who should be considered an expert. These definitions have been partly due to claims about the complexity of the disease as well as the consequences from integrating new medical technology such as antiretroviral therapy into existing systems of finance. Table 6.2 provides a summary of eight defintions available in 2005.

Two professional societies exist for those who practice HIV medicine: the HIV Medicine Association (HIVMA), a sub-group of the Infectious Disease Society of America, and the American Academy of HIV Medicine (AAHIVM), which currently offers the only formal credentialing of HIV specialists. As a subgroup of the Infectious Disease Society of American (IDSA), HIVMA focuses primarily on physicians as does the American Board of Internal Medicine. For instance, HIVMA publishes "Qualifications for Physicians Who Care for Patients with HIV Infection" as "guidance to public and private health care payers and institutions to

identify and recruit health care professionals with expertise in HIV disease." To them, an HIV-qualified physician is one who has cared for 20 HIV-infected patients in the last 2 years, completed 30 continuing medical education credits in diagnosing and treating HIV in the last 2 years, and is board certified or re-certified in infectious disease in the last year. AAHIVM offers its credentialing exam to physicians who did not start out in infectious disease and non-physicians. Others such as CMS, the Arizona Health Care Cost Containment System (AHCCCS), and the state of California define expertise for physicians as well as other types of clinicians.

Table 6.2 – Definitions of HIV Expertise, 1999-2004[6]

Title	Organizational Author(s)	Year of Origin	Elements of HIV Expertise				
			Patient Experience	Continuing Education	Board Certification	Licensure and Credentialing	Other
Experienced HIV Provider	Center for Health Services Research and Policy (CHRP), George Washington University (funding from CDC and HRSA)	1999	25 patients over last 24 months; in areas of high incidence (urban) this should be 50 over last 24 months	12 hours over previous 12 months	N/A	MD, NP, PA	"experienced provider" is deemed a "term of art"
Experienced HIV/AIDS Provider	Centers for Medicaid and Medicare (CMS), Department of Health and Human Resources (DHHS)	1999	25 patients over last 24 months; in areas of high incidence (urban) this should be 50 over last 24 months	12 hours over previous 12 months	N/A	MD, NP, PA	Gives CHRP as model
Experienced HIV Provider	HIV Medicine Association (HIVMA), Infectious Disease Society of America (IDSA)	2003	Provide continuous direct medical care to a minimum of 20 patients in last 24 months	30 hours of category 1 CME courses in diagnosis and treatment of HIV patients	Infectious Disease	MD	N/A

[6] Adapted from http://www.idsociety.org/Content/NavigationMenu/Resources/HIVMA/Education_and_Training1/Experienced_HIV_Providers/Default378.htm (accessed November 3, 2005); http://www.aahivm.org/definition2004.pdf (accessed November 4, 2005); http://www.ahcccs.state.az.us/Regulations/OSPpolicy/chap300/06_05Chap300.pdf (accessed November 4, 2005); http://www.hmohelp.ca.gov/library/regulations/title28/html/title28.htm (accessed November 4, 2005); http://www.gwhealthpolicy.org/newsps/HIV/hiv.pdf (accessed November 4, 2005); http://www.cms.hhs.gov/states/letters/smd10699.asp? (accessed November 4, 2004); http://www.hopkins-aids.edu/manage/case_study_4.html (accessed November 4, 2005); http://www.med.jhu.edu/IDAIDS/qmaker/ (accessed November 4, 2005); http://www.hivguidelines.org/public_html/center/clinical-guidelines/adult_hiv_guidelines/supplemental_pages/hiv_spec_pol/hiv_spec_pol.htm#qualifications (accessed November 4, 2005)

Title	Organizational Author(s)	Year of Origin	Elements of HIV Expertise				
			Patient Experience	Continuing Education	Board Certification	Licensure and Credentialing	Other
Qualified HIV/AIDS Treatment Professionals	Arizona Health Care Cost Containment System (AHCCCS)	2003	Treated at least 5 patients during last year	At least 10 hours HIV-related CME	Infectious Disease	MD	Known in community to have special interest, knowledge and experience in the tx of HIV/AIDS infected individuals; Agrees to adhere to CDC tx guidelines for HIV disease; agrees to provide primary and specialty care for AHCCCS members infected with HIV/AIDS
HIV/AIDS Specialist	State of California	2003	25 patients in previous 12 months; 20 patients in last 24 months	15 hours category 1 CME courses in HIV-related courses in past year, minimum 5 hours in ARV; 30 hours of HIV-related category 1 courses; 15 hours of HIV-related category 1 CME courses and completed AAHIVM HIV Medicine Competency Maintenance Examination	Infectious Disease	MD, AAHIVM	Board Certification in HIV Medicine when available or certificate of added qualification (CAQ) in HIV Medicine when available

Title	Organizational Author(s)	Year of Origin	Elements of HIV Expertise				
			Patient Experience	Continuing Education	Board Certification	Licensure and Credentialing	Other
HIV Specialist Status	New York State, Department of Health, AIDS Institute	2003	20 patients over last year, involving ARVs in ambulatory setting	10 CME hours including on ARVs	N/A	AAHIVM	HIVMA definition of experienced provider, provided requirements for management of ARVs fulfilled in ambulatory setting
HIV Specialist	American Association of HIV Medicine (AAHIVM)	2004	Provide direct, continuous, ongoing care to at least 20 HIV patients over the past two years	Successfully complete the AAHIVM HIV Medicine Credentialing Examination (HMCE) at time of application	N/A	MD, DO, PA, NP	N/A
Special Needs Populations Provider	Maryland Medicaid	2004	Minimum 5 or > 50 over lifetime of practice	Hopkins HIV/AIDS Specialty Quiz	N/A	TBD	Notes lack of consensus on definition and failure to define through training/specialty board. Also notes experience in treating individuals within a special needs population and have experience in interdisciplinary medical management.

The American Board of Internal Medicine's definition of HIV expertise requires only certification in Infectious Disease and is applicable only to physicians. It should be noted that some of these definitions apply only to physicians and have further qualifying remarks for advance practice nurses and physician assistants, while other definitions apply to all HIV care providers MDs, NPs, and PAs alike.[7] While not all definitions apply only to physicians, most require some set number of hours in continuing medical education. What is most striking is that all of these definitions have been created from 1999 to 2004. Ongoing patient experience and/or continuing medical education are also emphasized. California definitions anticipates further formalization of expertise with either board certification in HIV medicine or a Certificate of Added Qualification (CAQ) in HIV medicine because it mentions that both will fulfill the criteria for being recognized as an HIV Specialists, despite the fact that neither exists.

Treatment guidelines in HIV medicine and federal funding for research and treatment support a market for HIV specialists. Thus, worries about the lack of recognition of HIV expertise is related to systems of payment. Indeed, the debate around what constitutes an "HIV specialist" has emerged partly because there is variation between state Medicaid definitions which are used to determine reimbursement rates (Mayer and Chaguturu 2005). In general, primary care is reimbursed at a lower rate than specialty care (James 1999). As we saw in chapter 5, early experts in the field of HIV/AIDS created guidelines themselves in order to establish a reimbursable standard of care. In today's guidelines, experts contribute to defining

[7] Another important work-related process impacting the social construction of the disease is the division of labor between physicians, nurse practitioners, physician assistants, and registered nurses. When the work of HIV management is partitioned according to technical versus caring work, issues of gender, status, and class are likely to be involved. This is an area that warrants further research. In the clinic where I performed field observations, state law prohibits nurse practitioners from writing prescriptions. Nurse practitioners spent a great deal of time chasing after the attending physician for signatures. Moreover, these mid-level clinicians' salaries are lumped into the "facility charges" just as registered nurses are, yet the health system insisted that they should code the level of visit as physicians do.

expertise in order to take into account the added expertise and experience required to provide the standard of care. More recent DHHS guidelines include definitions of expertise and references to the use of specialists, further evidence of a push toward specialization in HIV medicine.

Experience is important in HIV medicine because there is a lot of individual level variation in patients. It was especially important in the early days because a variety of specialists (Gerbert, et al. 2001) dealt with HIV-infected patients. Technical expertise was not as important as a willingness to provide compassionate palliative care to a new disease. Thus, experience is key to defining expertise in this area of medical specialization. By giving experience such a central role, the guidelines allow room for individual clinical judgment and for incorporating technical innovations into providers' repertoires of service. We saw in the last chapter how the discourse of federal guidelines can impact reimbursement for services. Claims of additional expertise allow for higher rates of reimbursement because the care is deemed to require specialized skills some of which are only garnered through patient care itself. New York State's department of Health AIDS Institute sponsors a program which pays increased or "enhanced" fees for qualified physicians and specialists providing care to HIV-infected patients (New York State Department of Health 2007).

Until 2004, the DHHS guidelines had not defined HIV expertise and had mentioned "expertise" and "specialists" only in the context of referring especially complex cases to external experts. However, in 2004 the DHHS guidelines specified not only what tools are necessary for care but who should be providing that care:

> Multiple studies have demonstrated that better outcomes are achieved in patients cared for by a clinician with expertise. This has been shown in terms of mortality, rate of hospitalizations, compliance with guidelines, cost of care, and adherence to medications. The definition of expertise in these studies has varied, but most rely on the number of patients actively managed. Based on this observation, the Panel recommends HIV

> primary care by a clinician with at least 20 HIV-infected patients and preferably at least 50 HIV-infected patients (DHHS 2004, 3 references omitted)

While guideline authors observe that many groups have combined patient experience with continuing medical education (CME) requirements, they do not recommend any HIV training or CME. Moreover, it is hard to interpret how expertise has been linked to mortality rates and the like since the definition remains unsettled. There is some circularity in defining HIV expertise by the number of HIV patients one is treating – treating HIV is what HIV specialists do, so they are experts because they specialize. Furthermore, treatment guidelines need not necessarily support specialization. In fact, the general argument for guidelines is to establish a standard of care and distribute information in a form that can be used by the "busy physician" who does not have time to keep up with the huge amount of medical literature. Thus, treatment guidelines could have been used as a mechanism for keeping primary care providers up to date on HIV/AIDS medicine.

It is not only infectious disease physicians, then, who may benefit from the emphasis on experience in the definition of HIV expertise. Along with the reorientation of infectious disease physicians, a subset of generalists have emerged who focus on HIV comprehensive care. Moreover, other subspecialties such as Emergency Medicine are challenged by how to train AIDS primary care physicians without subspecialty training. Mayer and Chaguturu (2005) argue that a system of credentialing is needed since there no cure for AIDS has been found, the HIV epidemic continues, and disease management continues to become more complex.

Some medical specialties are recognized by credentialing alone through the passing of an exam, such as in Emergency Medicine (019_SF_US_030602_RC). This may be the way HIV care is headed. Currently, the only organization to offer credentialing in HIV medicine for non-physicians is AAHIVM while other routes to specialization entail on-the-job training and patient-

load. According to HIVMA both New York and California are beginning to use AAHIVM's credentialing process as one way to be categorized as an HIV specialist (2006). Another avenue to signal expertise is a certificate of added qualification (CAQ). HIVMA is working with the Board of Internal Medicine and other specialty boards to create a CAQ in HIV medicine. According to HIVMA's literature, "We feel this is an important step to ensure a national standard for identifying HIV/AIDS physicians, to support a well-qualified HIV workforce, and to attract physicians to the field of HIV medicine" (2006). Would a CAQ in HIV medicine impact physician payment? According to HIVMA,

> Unfortunately, we do not have data on how reimbursement levels have been affected in these areas of specialization by the creation of a CAQ. We do know that the Medicare fee schedule for Evaluation and Management procedures does not distinguish compensation by specialty status. However, we believe that in managed care settings where physicians are reimbursed under capitation arrangements, a specialty designation afforded by a CAQ could be beneficial for negotiating rates. In several state Medicaid programs, including the program in New York, enhanced capitation rates for HIV/AIDS care and/or HIV center of excellence status are granted only when care is provided by physicians with HIV expertise. (HIVMA 2006)

In addition to increasing rates of reimbursement for physicians who specialize in HIV medicine, a CAQ may increase access to experienced providers. For instance, patients in managed care programs may be unable to secure a referral from their primary care physician to see a specialist (James 1999). Some worry that a narrow a definition of HIV expertise will be a barrier to specialty care for HIV-infected patients because rural physicians do not manage enough patients to meet current definitions (Boswell, et al. 2001). Professional attempts to manage this situation are underway with AAHIVM claiming that their credentialing process will, in fact, assist rural community physicians in identifying specialists near their geographic area who can act as consultants (AAHIVM 2006).

A roundtable on the subject of HIV Expertise was convened in 2001 in the newsletter *AIDS Care*. The discussion emphasizes that experience and knowledge can be measured, but that the integration of clinical judgment and bedside manner, while important, is more difficult to measure. Potential measures may include patient satisfaction and clinical outcomes. There was disagreement about whether clinical outcomes are a good measure of expertise (O'Rourke, et al. 2001). Indeed, there is debate about using viral load as an indicator of quality since there is so much individual-level variation that has nothing to do with the provider (Hirschhorn, et al. 2005). One discussant wondered why the fuss over defining an expert, since as physicians they accept limitations of other specialty definitions in medicine. Another discussant asked why they should accept the paradigms of other medical specialties since they are carving out something entirely new (Hirschhorn, et al. 2005). Could medical specialization be another arena for AIDS exceptionalism? Some have compared HIV specialization to human genetics, another rapidly evolving field, but gentics has a rigorous definition of expertise (Hirschhorn, et al. 2005). There is acknowledgement that a flexible definition of expertise is needed as HIV is still developing into specialty discipline, perhaps most importantly, because keeping up with rapid developments in science is important in HIV care.

A commitment to continued education provides patients and payers some guarantee since newly minted physicians certified in infectious disease may be considered experts, but need some mechanism of keeping up to date with developments in treatment, genetic resistance, and the management of side effects and comorbidities. However, there is variation in quality of CME courses and what clinicians take away. Tension remains among potential specialists since HIV/AIDS is twenty years old with established provider base that consider themselves experts. While some argue that we are entering a more stable era of HIV medicine as it is a disease

increasingly treated as a chronic disease, so it is not as complicated in past, we can see that treatments enter the clinical scene frequently, involve technical skills such as interpreting genetic tests, and an awareness of psychosocial components that can affect treatment efficacy. The question is what qualifies a clinician as being capable of providing effective care under these circumstances. For some, the goal of defining expertise should be to have the largest number of experts with greatest amount of expertise without restricting access to care, a concern especially for rural settings. At the beginning of AIDS epidemic no medical specialty devoted to care of patients with chronic viral diseases existed. As Mayer and Chaguturu note, "Credentialing will become increasingly formalized as the costs and complexity of care continue to increase" (2005, 278). Less than a decade ago, however, some argued that "Physicians providing care for HIV infected patients need to have the particular skills of a specialist as well as the general skills needed for primary care since they are responsible for keeping up with medical research findings on what is a complicated disease, with therapeutic drug regimens and their associated toxicities, with new technologies such as plasma RNA assays and drug resistance testing, as well as monitor adherence, translate medical terminology, and attend to the social and psychological consequences of a devastating and stigmatizing disease (Gerbert, et al. 2001, 322)."

In medicine, jurisdictions are defined differently in different areas. Psychosocial issues are often low status, so doctors want to avoid them. However, if there are not enough objects to make up a field, or if others can easily take over the work, then doctors may claim jurisdiction over psychosocial tasks in order to make a field. For example, pediatrics absorbed social/behavioral or psychosocial aspects of pediatric medicine in order to make the specialty more challenging and interesting to pediatricians once they finished their residency. This "new pediatrics" became institutionalized in pediatric training and research via funding from the

federal government, non-profits, and universities (Halpern 1990). By contrast, in Neonatal Intensive Care Units (NICUs), core medical tasks were complex and doctors were eager to have social workers handle the messy psychosocial stuff (Heimer and Stevens 1997).

With HIV/AIDS the core of the work has changed over time from treating opportunistic infections and providing palliative care to managing the disease with an arsenal of antiretroviral drugs, attending to side effects of treatment, tracking disease progression and resistance, working out new regimens with corresponding changes in the boundaries doctors try to draw. By virtue of their control over the tools of the trade, HIV/AIDS physicians have re-claimed jurisdiction once ceded to general providers – at least in theory if not in practice. Often, physicians are arranged at the top of a hierarchy of HIV care, where they supervise mid-level clinicians trained in HIV care. Thus, physicians are similarly claiming jurisdiction back from nurses who were able to carve out some autonomy in the early years of AIDS when stigma and a lack of effective treatment hindered physician involvement. Aiken and Sloane (1997) observe that physicians once ceded much of the dirty work of AIDS care to nurses. Nurses provided much of the care for AIDS patients who required 40 percent more nursing care than non-AIDS patients (IOM 1986, Heagerty 1987).

Furthermore, the concentration of HIV care into clinics has led to creation of a group of specialist nurses, decreasing the knowledge gap between physician specialists and nurse generalists that is characteristic of hospitals. The content of nursing work has also changed from palliative care to monitoring table patients. Nurses and mid-level clinicians now have their own specialty groups for HIV disease (ANAC 2006), their own board certification process, and are included with physicians in the AAHIVM credentialing process. The role of these professionals remains unsettled. It may be that non-physician care providers will provide much of the

HIV/AIDS primary care while specialist physicians regain their detached consultant role, making decisions about antiretroviral regimens and handling complex cases. The high cost of antiretrovirals, as well as the risk of resistance, contributes to a sense that HAART should be managed by physician experts. However, non-physician HIV specialists are attractive to payers because they cost less and may be more accessible in rural areas. This is especially in poor countries and in rural parts of the U.S. where physicians are in short supply. We expect to see a continued struggle among specialists as the field of HIV medicine develops.

Physicians also claimed back turf previously shared with patients. Initially, AIDS patient groups threatened the traditional physician-patient relationship and physician autonomy by influencing the science of AIDS and FDA's drug approval process, making treatment more accessible (Annas 1990, Epstein 1996). However, AIDS activists now focus much of their energy on increasing access to antiretrovirals and as a result access to HIV experts. Thus, in their focus on access to HIV drugs, activists have largely failed to turn the same critical gaze, which characterized their early approach to AIDS science, on antiretroviral therapy itself (Rosengarten, et al. 2004). The fact that antiretroviral therapy requires near perfect (95%) adherence by patients has impacted the provider-patient relationship by increasing the importance of monitoring patient compliance (Paterson, et al. 2000). Physicians emphasize and even measure compliance by demonstrating the clinical effects of antiretroviral adherence (with viral load tests) and the extent of non-adherence (with tests that measure the level of antiretrovirals in the blood). The resurgence of the dominant physician in the patient-physician relationship implies recognition that physician experts have knowledge and skills that activist experts do not.

In recent years, once "self-made" HIV/AIDS physician experts have worked to encourage high quality HIV/AIDS care while also influencing reimbursement levels and their own professional standing by defining expertise, establishing credentialing exams, writing treatment guidelines and applying for sub-specialty recognition. The availability of new tools for the management of HIV/AIDS has been central to their jurisdictional claims. While much has been written about the social control of patients, it is tools that medical professionals especially seek to control. Issues of who gets to prescribe antiretrovirals and interpret complicated diagnostic tests are central to claims for specialization. The development of effective tools such as antiretrovirals and diagnostic tests provided an occasion for HIV/AIDS expertise to no longer be defined solely by virtue of their corner on the market of HIV patients, but also by their control over the tools of the trade. This stage of professionalization moves HIV specialists away from the circularity of being experts simply because they care for HIV patients. Now, claims for specialty status are made on the basis of their mastery of set of skills and technical knowledge.

At first glance, the rise of definitions of experienced HIV/AIDS providers may appear to be a direct result of the introduction of HAART onto the clinical landscape. However, technological innovations do not necessarily result in medical specialization. Technologies are social objects that interact with human behavior in the context of organizational fields. As DiMaggio (1991) observed in his work on the creation of the field of U.S. art museums, the institutionalization of fields is associated not just with new organizational forms but "new categories of authorized actors" (272). By the mid-1990s, the field of HIV/AIDS management came to be dominated by specialty clinics. These clinics arose as a result of stigma and fear of contagion as well as disease-specific funding that reinforced the San Francisco model of care. While HIV/AIDS experts initially eschewed specialization, these clinics concentrated HIV/AIDS

physicians in these settings and led to a set of "authorized actors" who were positioned to grasp control of the complex technology of HIV/AIDS care when it became available. Physician experts have since claimed the prescription of antiretrovirals and the associated diagnostic tests as their "authorized acts."

A study of professionalization in the organizational field of HIV/AIDS care can elucidate some general mechanisms of medical specialization in the current context of healthcare in the U.S. Stevens (1971) has argued that targeted federal health programs have buttressed the medical specialty system in the US by encouraging the employment of experts. The case of HIV/AIDS provides another example of this. However, here we see that what is especially important is the funding of disease-specific clinics – even before there was a group of experts. Thus, the institutionalization of organizational forms that concentrate work is an important mechanism for specialization. Claims of technical complexity and skill are central to professionalization (Abbott 1988), and the success of these claims is dependent upon the distribution of this knowledge in the relevant organizational field. However, new organizational forms provide opportunities for further professionalization. In order to claim specialty status, professionals must show they have skills and knowledge that others lack. Historically, these claims have been supported through the creation of professional associations, disease-specific journals, training programs, and locations for work. In addition to these strategies, HIV/AIDS professional groups have used outcomes research, which enables experts to statistically demonstrate the benefits of their skill and knowledge on cost and patient care. Outcomes research was initially conceived of as a means of reducing ineffective treatments and the costs of care but is has become a technique for specialization, but it can leave specialty groups vulnerable

to loss of jurisdiction if other groups can show statistically that their work is equal or even superior.

The future of HIV/AIDS specialization remains uncertain. Although specialization appears to be well on its way, HIV/AIDS has not yet been formally recognized as a sub-specialty. Also, there are potential threats to specialization. First, if a cure or vaccine for HIV infection is discovered, we would expect that HIV/AIDS to become rare and follow the route of syphilis where specialists give up jurisdictional control. A second threat comes from shifts in the funding of Ryan White HIV/AIDS specialty clinics – ironically, the same clinics that provided the initial opportunity for professional specialization in the U.S. Recent changes to the Ryan White CARE Act would allocate more funds to Southern and rural states to reflect the rise of HIV cases in these areas (Kaiser Family Foundation 2006a). In the new formulation, rural areas with less access to specialty care could be granted more resources, but some urban areas, especially New York and San Francisco, could lose funding. If these epidemiological and funding changes persist, we may see the rise of HIV/AIDS care provided by general providers who refer only complex cases to specialists – a situation which was initially envisioned for HIV/AIDS at the start of the epidemic, but that would undermine the process of specialization.

Conclusion

As this chapter has illustrated, medical problems such as syphilis and HIV/AIDS are objects around which the criteria of professional expertise is classified. Such classification is a strong force behind medicalization because the authority associated with being designated as the provider responsible for administering and ensuring best treatment for patients is at stake. At first glance, the passage of syphilis from dermatology to public health in the United States may appear to be a result of treatment innovation alone. Without governmental safety nets,

physicians were often unwilling to treat patients who could not pay them. Moreover, syphilis was a dirty disease and the target of moral reform, both of which deterred the involvement of dermatologists who felt they could hand off to the public health sector without losing their domain of practice. At the same time, public health was organizationally ready to make a medical, moral, and economic case for creating treatment centers, research, and treatment standards for venereal disease as a step to developing public health as a professional domain in its own right. While medicine and public health continue to share domains of practice, the passage of syphilis from dermatology to pubic health in the U.S. marks a turning point in how sexually transmitted diseases were handled in the American medical system from then on.

Thus, when AIDS emerged in the 1980s medicine was shocked and fearful while public health had been continuing to concentrate on preventing the transmission of sexually transmitted diseases such as Hepatitis B and syphilis. Public health was also more accustomed to working with marginalized groups of people such as homosexuals and the poor; however, their efforts were over overshadowed by biomedical research focused on chronic diseases such as cancer. As it turned out, medicine and public health was, as with syphilis, poised to take on the task of caring for AIDS patients outside existing locations and payment structures for care. In both cases, philanthropic groups provided the seed money, as it were, to develop new organizational forms designed to identify and treat patients suffering from these highly stigmatized diseases. Despite the existence of venereal disease infrastructures in public health, the newness, grisliness, and expense of AIDS influenced the development of an entirely new organizational approach to caring for patients.

CHAPTER 7

CONCLUSION

At a basic level the dissertation examined how the social process of classification contributes to the social construction of disease in the organizational fields of public health and medical work around syphilis in the early twentieth century and with HIV/AIDS over the last twenty-five years. A study of classification is a worthwhile enterprise since as a sorting mechanism, classification cuts across various organizational and institutional levels, allowing for comparison over time as well as allowing for analysis of organizational interactions where classifications overlap or are negotiated between stakeholders. For sociology, classification is a useful conceptual tool for understanding how the practice of medical and public health practice are negotiated and how these negotiations impact the ability of stakeholders to claim resources, autonomy, and authority. Classification is also important because it is a key component of epidemiological and record-keeping methods and other organizational attempts at standardization. As we have seen, classification is done as part of the work of biomedical research, public health, and medical practice along paths of diagnosis, treatment decision-making, risk assessment, resource allocation, and professional specialization in medicine.

At the turn of the twentieth century, Sir William Osler remarked, “He who knows syphilis, knows medicine” (as quoted in Hayden 2003, 51). This encapsulates the dissertation’s observation that classifications in medicine were not standardized enough to allow for meaningful distinctions between medical problems and treatments, making syphilis an object susceptible to individual-level moral evaluation and financial gatekeeping in medicine. More than a century later, in 2003, an interviewee remarked that “HIV changed everything” (010_DC_US_032503_RC&JP). As the dissertation has also shown, although AIDS arrived in a

context where standards of record-keeping (e.g., the patient chart), information gathering (e.g., collection of risk data), and care were seemingly settled (e.g., evidence-based medicine), cost and morals drove already sharp organizational and institutional distinctions to change and adapt. With both syphilis and HIV/AIDS, then, classification is not static. Both cases represent the impact of classification on the social construction of disease in a transforming American medical system: syphilis served as public health's entrée into medicine while HIV/AIDS charted new territory in the operation of medicine and public health altogether. Entrepreneurial experts in both cases contributed to the creation of new organizational fields for patient care, changing the social landscape for classification in medicine more generally.

Classifications dealt with by scientists, regulators, patients, medical providers and payers are influenced by and influence technological innovation, systems of finance, morality, and organizational infrastructure. As we have seen, diseases vary in how difficult and expensive they are to diagnose and to treat. Sexually transmitted diseases carry additional stigma, making the care of the infected less prestigious for non-entrepreneurial experts. By tracing policy and technological changes from syphilis in the early part of the twentieth century to HIV/AIDS today, the dissertation illustrated how medical and public health practice has changed in the interaction between discourse and practice at the ground level. By focusing on classification, we are able to look at how classifications have developed over time and how they converge during the daily work of care providers.

Each of the substantive chapters illustrated how different types of classifications have been "done" in by medicine and public health in the Unites States. As we have seen, there is no inherent way that classifications should turn out. Specific historical contexts shape the encounters in which classifications are created and used in practice. Policy and regulation

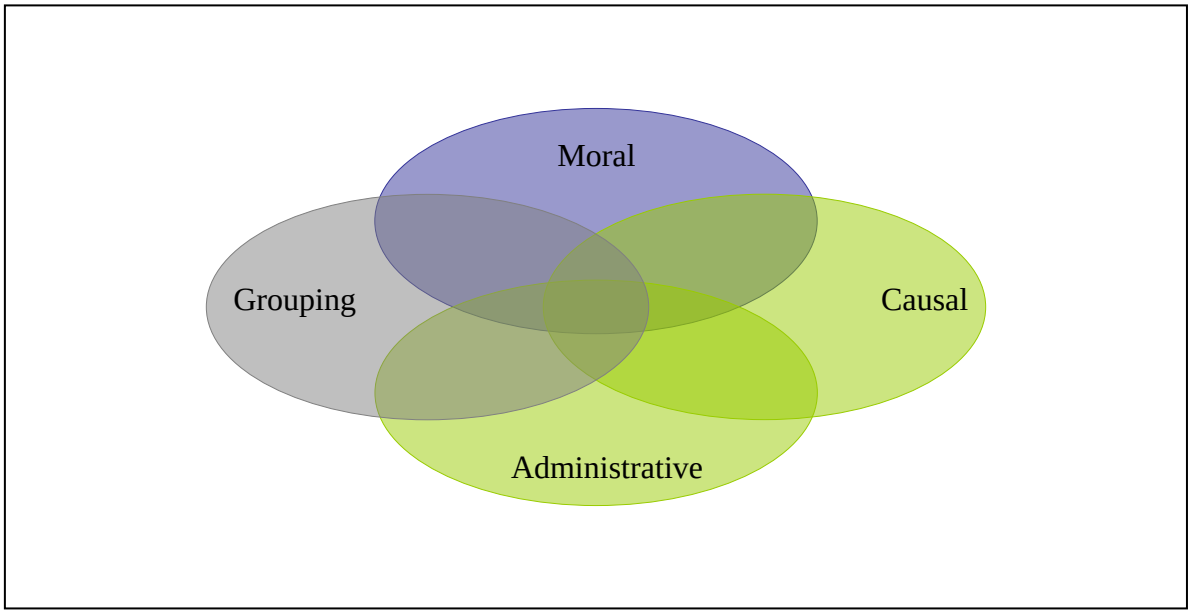
impact how scientific discoveries are made as well as how those discoveries are integrated into routines of healthcare. The expansion of public health authority, aided in part by governmental support for venereal disease control, and the advent of bacteriology, was helped along by technological discoveries, influenced the way that medical classifications evolved since the mid-twentieth century to today.

Chapter 2 illustrated how the assemblage of symptoms into clinical descriptions and case definitions became increasingly systematic as medicine and public health began sharing information. Similarly, chapter 3 illustrated how scientific innovations in technology and the epidemiological imagination enabled the isolation of causal agents for both syphilis (bacterium) and AIDS (virus) and the counting of cases. Both symptomological and etiological classifications are fundamental to understanding diseases as discrete problems. With syphilis, laboratories became important for diagnosis for the first time. Syphilis was the first venereal disease to be targeted for mass screenings, case reporting, and partner notification. By the time HIV was discovered to be the cause of AIDS, the scientific research community was wrought with competition over research funds and chances of prestige for new discoveries. The stakes were high with AIDS in the research community, but patient activists influenced how the use of AIDS' etiology was administered in practice. How stakeholders arrived at these definitions of disease and how it they use these definitions of disease to allocate resources, identify standards of treatment and cost, and define expertise and health outcomes differ greatly because of the rise of epidemiology, federal public health treatment and research programs, the politics of sexuality, and diversification of funding sources that finance the American health system. In other words the arrival of definitions of disease is done through a combination and convergence of grouping, causal, moral, and administrative classifications.

Because both syphilis and HIV/AIDS can be transmitted through sex, classification influences and is influenced by moral evaluations about how patients became infected and whose responsibility it is to care for them. Healthcare safety nets were just beginning to form in the early twentieth century. Thus, infected people simply did not seek care if they could not afford it. By the time AIDS arrived on the scene the financing of public clinics was established and patients were able to be both diagnosed and treated through public funds. However, AIDS was largely seen as gay disease, partly because the isolation of the HIV virus had to catch up to with epidemiological discoveries about the disease made primarily through symptomological classification. Moral classifications play an important role as information about race, gender, and risk become associated with cases.

As Figure 7.1 shows, the effects of classification on collective understandings of disease vary in terms of their timing and their influence on other types of classification.

Figure 7.1 Convergence of Disease through Overlapping of Classification



As we saw in chapter 4, stigma contributed to how patients infected with syphilis or HIV/AIDS were classified by their ability to pay for treatment and severity of their disease. Chapter 5 described how medical treatments were classed according to their effect on the course of a particular medical problem, either with a cure or decrease of infectiousness. With AIDS, it meant that providers were forced to develop standards and use pre-existing billing codes in order to be reimbursed. Finally, chapter six discussed how those providing care and making treatment decisions for patients become classified as experts through processes of professional specialization. The financial classification of patients, treatments, and medical providers rely on foundational elements of classification and at the same time inject them with the norms and values associated with the financing, bureaucracy, and moral evaluation of medical problems.

In this concluding chapter, I will discuss four nested findings of the analysis and their contribution to the sociological study of classification in the organizational worlds of medicine and public health. First, studying classification has allowed us to observe the relatively recent historic transformation between medicine and public health as professions and spheres of practice in the United States. In addition to a lack of scientific consensus in the 1930s, physician noncompliance with public health mechanisms for such things as birth records was prevalent. Such noncompliance was a frequent complaint during the 1930s syphilis control program (Lederer 1995, 25-26). Even after the Second World War, physician discourse was characterized by a stark separation between medical practice and science. Although doctors at this time were confident that science would benefit medical practice, the latter was not thought of as a scientific endeavor itself (Berg 1995). Public health, on the other hand, was steeped in the science of epidemiology and other statistical enterprises. Much of the work of public health professionals in these early days focused on collecting information about populations of people that could

correspond across geographic and economic space. Classification served as the technical mediator for information sharing between medicine and public health, with epidemiology entering medicine and clinical experience entering public health.

A second related finding of the dissertation is that classifications are objects of technology and communication that existence in multiple and intersecting social worlds. In this way, objects of classification are "boundary objects" because their creation and maintenance is a "key process in developing and maintaining coherence across intersecting social worlds" (Star and Griesemer 1989, 393). Boundary objects may take the form of repositories of information, ideal types, coincidented boundaries, or standardized forms of communication. Latour referred to such social objects as "immutable mobiles" (1987, 410-411) because they tend to be taken for granted in daily practice and can become hard to change because they are embedded in organizational routines. Remember the nurse practitioner who added her own billing codes to forms created by the larger health system. Here classification had a depersonalizing effect because technical and bureaucratic processes obscure the relationship between creators and objects of classification necessary to maintain collective understandings of disease. Thus, both science and finance play roles in how this depersonalization happens because as technological and bureaucratic infrastructure have increased precision, attention to uncertainty in medicine becomes more obvious and morally charged

Third, the dissertation illustrated a paradox of how classifications are used to manage uncertainty in both medicine and public health. Scientific innovation both with diagnoses and treatment manage the uncertainty of what illness an individual may have as well what type of care they should receive. Classifications of professionals and patients help to manage who is most appropriate to provide care as well as who shall receive it. This is important since there are

limited resources available for potentially life-prolonging and highly complex treatment. Managing the uncertainty of the cost and effectiveness of treatment is fundamental to the activities of medicine and public health. Much has changed in the organization of healthcare in the U.S. since the early 1900s with the advent of new governmental agencies and programs, the decline of medical authority (Starr 1982), the creation of Medicare, and the rise of evidence-based medicine (Sackett, et al. 1996; Timmermans and Kolker 2004) which have helped to standardize diagnostic and treatment procedures, mechanisms of oversight over health services and biomedical science, and systems of accessing and paying for the management of disease. By improving precision in classification, flaws in medicine and public health become more obvious. With greater attention to uncertainty comes attention to moral evaluations, adding a layer of contradiction in health policy designed to standardize the use of technological advancements (Wiendling 1993). Simultaneously, new medical technology introduces fresh uncertainty into everyday practice for healthcare providers (Webster 2002; Rosengarten, et al. 2004). Thus, although classification is integral to standardization, increased standardization has the paradoxical effect of creating fresh uncertainties in science, medicine, and morality.

Finally, classifications have material impact in world because they influence the way resources are distributed, how innovative treatments progress from scientific discovery to the marketplace, how professions and subgroups of professions carve domains of practice, and how stigma is embedded or resisted in organizational routines. Moral actors can be organizations rather than just individuals. For instance, Heimer (1999) analyzes the moral action of insurers as organizational entities. The fact that insurance is a multi-party contract, a system of nested agency relationships, means that insurance has become an increasingly accepted mode of governance (e.g., laws mandating auto insurance.). At the same time, insurers are governed by

regulatory schemes. However, Heimer concludes that risk for insurers is not just about policyholder behavior, but also about stock values. Therefore, when thinking about the extent to which insurance forms risk-sharing communities, sociologists must consider the causal role that social cohesion plays. For instance, with syphilis, Parran and his colleagues hoped that their scientific and administrative work would diminish moralistic views of those with syphilis. However, the medical profession, while happy to relinquish syphilis to public health, held firm to finance structures that supported their continued autonomy and authority among other stakeholders in medicine and public health enabling physicians to cede "dirty work" to others. With AIDS, activist and philanthropic groups as well a cadre of clinicians were instrumental in forming the organizational basis for public HIV/AIDS care in the U.S. Again, where medicine avoided a "dirty" problem, organizational entrepreneurs imagined novel ways to fill gaps in care and treatment. Unlike syphilis, however, medicine did not fully cede HIV/AIDS care to the realm of public health because with no cure in sight, a great deal of resources have been devoted to researching curative and preventive treatment.

Central to the dissertation's line of inquiry is medicalization, the process by which problems become defined and treated as medical problems (Conrad 1992). That disease is socially constructed implies that social values impact understandings of it as well as interventions designed to deal with it (Brandt 1988, Brown 1992). With a shift from medical to bureaucratic complexity, medical authority has been in a period of decline in recent decades, however. Conrad (2005) argues that the forces behind medicalization are shifting away from the authority of the medical profession, activities of social movements and interest groups, or organizational or intra professional activities to mechanisms of cost control and standards of care. The dissertation illustrates the role of classification and organizational processes to

medicalization in the myriad of classifications that medical care providers encounter in their daily work.

Categorizing and standardization are critical to the organization of modern healthcare. Yet the categories on which medical research findings are based are human creations that sort and categorize humans (Heimer 2001, Latour 2003). Thus, disease defines boundaries and reinforces stereotypes about people (Brandt 1985). Categories, definitions, or comparisons are shared across disciplines by clinicians, researchers, and activists alike. Thus, classification activity mediates, challenges, and creates a variety of forms of authority. Systems of classification can be internally contradictory and they may overlap or contradict other classification systems. It may be that patients are unable to get care because the financial classification of treatment has not kept up with medical science. At the same time, payers do not want to pay for inappropriate or fraudulent care. Thus, fitting into already established social categories can be problematic for navigating paths to diagnosis, treatment, and payment in healthcare. Nonetheless social action is organized across classifications of disease, patients, and providers.

As we have seen, the backbone of classification systems is made up of bureaucratic routines including documentary and technological practices that can obscure categorical distinctions by making them appear natural or at least taken-for-granted along a path toward accessing care, getting treatment paid for, or becoming an expert. Despite this, these systems are useful guides for action (Durkheim and Mauss 1903, 73). Indeed, treatment guidelines do not replace clinical experience (i.e., the “art” of medicine), attend to individual patient needs, or take into account the variability in clinical resources. Clinicians, for their part, have resisted the notion of “cookbook medicine” in the movement toward treatment guidelines and evidence-

based medicine (Robeznieks 2002). Yet patients, payers, and scientists would like standards that can be used to measure the adherence to standards and cost of care more effectively. Thus, clinicians must adapt and adjust to financial classifications of patients, treatments, and themselves. Pickering (1995) conceptualizes this agency under constraint and feedback as the "mangle of practice." To him, scientific practice extends scientific culture through dialectic of accommodation and resistance between human and material agency. Both human and nonhuman agents associate with one another in the actor-network that is the field of scientific practice. Extending Pickering's model, we can consider the action around classification systems to be a form of material agency involved in the legitimization of authority about how we collect evidence to support best available treatments.

The analysis takes into account the fact that the medical research findings have become increasingly critical to legal decisions, professional standards, and patient empowerment in the era of AIDS. Technologies such as treatment guidelines, standards of care, the randomized clinical trial, and surveillance tools such as case definitions and risk categories play increasingly essential roles in both professional jurisdiction and statecraft. Habermas (1970) refers to the impact of these systems of expert knowledge as the "scientization of politics" while Porter (1995) attributes it to a "culture of evidence." Essential to both is a process of simplification that is, as we have seen, mediated by documents and statistics. These techniques help politicians grapple with reality by reducing it to schematic categories. Such simplification is crucial to comparisons, description, and aggregation. The creation, enhancement, and use of these techniques may indicate an increase in state capacity (Scott 1998, 75), however because classifications are imbued with values, their utility of these techniques may be more symbolic than practical.

Organizations are decreasingly structured by technical activities. Rather, they are increasingly held together by ritualized restraints on credentials, group solidarity, and ritualized conformity with wider institutions (DiMaggio and Powell 1983). The expansion of information infrastructure and the specialization of tasks are characteristic of professional routinization and exclusion practices (Abbott 1988). Such ritualized activities as continuing medical education, the endorsement and production of treatment guidelines, the fixation on measurement, and the constant collection of information about patient outcomes and physician behavior are signals of increased specialization and professional exclusion. Indeed, a cottage industry has developed on both the provider side and the payer side for creating evidence that legitimizes expertise, knowledge, and authority for making medical decisions that impact patients in a most direct way. Thus, the production of knowledge by organizations may be more important for signaling autonomy and resources than for practical decision-making.

As we have seen, then, classifications and standards are not as durable as they may appear, even in medicine. Likewise, not everything gets classified since these systems are sorting mechanisms and not designed to cover every entity. Residual or "other" categories are also important to the process of classification itself because what is left out may be just as consequential as what is included in a classification system. Indeed, as classification systems become more complex and layered, certain categorical distinctions may become invisible despite being instrumental to ongoing organizational processes. Finally, standardized objects and processes must be customized to fit particular situations. With medical practice, classifications such as treatment guidelines are customized locally while maintaining common meaning across location (Timmermans and Kolker 2004). How classifications impact the daily work of clinicians is an empirical question that, when better understood, may help to settle debates over

to what extent the rise of evidence-based medicine has weakened or strengthened the clinical autonomy of medical professionals and how this has impacted the delivery of healthcare.

The profound changes in the financing, administration, and culture of our healthcare system since the 1920s means that a study of the minutia of evidence-based medicine and healthcare financing is overdue. There is an increased need for operations research to focus on organizational process in the delivery of antiretroviral programs (Board on Global Health and Institute of Medicine 2004). With this in mind, the dissertation examined how care providers deal with uncertainty in everyday practice. What we see in the daily practice of HIV medicine is a proliferation of overlapping classification encountered in medical practice generally. Thus, the rise of numbers in medicine and public health is more about conflict between classification systems, than scientific inference and knowledge production. Constructing syphilis as a medical and scientific problem rather then a moral one, was a way for public health to develop organizational footholds in the form of rapid treatment clinics for venereal disease and tightening relationship between epidemiology and resource allocation. Likewise, the construction of AIDS as a discrete medical problem was a strategic bid to legitimize the counting and treatment of cases. It enabled AIDS to be compared to other diseases, ultimately treated as an exception in terms of protocols, regulations, and funding. Statistical and bureaucratic techniques were crucial to this process because they helped to accomplish important boundaries around expert knowledge and allow comparisons between countries, health problems, and risk groups (gender, race/ethnicity, behavior, etc.).

A written system of communication is an organizational accomplishment that carries with it a depersonalized form of social consciousness (Smith 1984, 62). The struggle to maintain the "art" of medicine and a level of intimacy with patients when working with treatment guidelines

is evidence of such depersonalization. Clinicians who use HIV treatment guidelines report that they internalize them, referring to them less and less in practice. However, guidelines change often with the advent of new medicines and patient adherence is crucial to successful treatment. At the same time, there is a sense that treatment guidelines for HIV/AIDS are too lengthy and that physicians only read the tables leaving out important issues about adherence that should be attended to in the clinical setting. The shift from local to national guidelines itself may have had a depersonalizing effect on relations between physicians and patients. In Foucault's (1973) account of the "medical gaze," the clinic treated patients as examples of disease rather than subjects of disease. These perceptual structures coexisted for a short time. Eventually, political ideology and medical technology converged in a telling of history that privileged clinical medicine as simply the examination of the individual, which emphasized a universal sentiment rather than its relationship to a body of knowledge.

Treatment guidelines are often thought of primarily as the translation of medical research into practical guidance or the dissemination of a body of knowledge. However, they are also deployed in an effort to regulate care providers, payers, and patients. For example, hospitals are required to implement treatment guidelines in some capacity in order to maintain their accreditation from the Joint Commission on Accreditation for Healthcare Organizations (JCAHO) (004_CH_US_030303_JP&CH). The use of guidelines and definitions of expertise for the authorization of expenses undermines traditional medical authority by setting collective standards in place of physician autonomy. The use of scientific research findings to bolster such standards is one way to purify them from the bureaucracy of healthcare financing. Latour (1993) enumerates on these processes of disembedding and depersonalization by conceptualizing modernity as a system that constantly produces human and nonhuman objects, tying nature and

society together. For Latour, the term 'modern' indicates two distinct practices: 'translation' or the creation of new beings, hybrids of nature and society; and 'purification' or the creation of two distinct ontological regions, human and nonhuman (Latour 1993, 10-11). Despite the constant production of these hybrids, Latour suggests that moderns deny their existence through the mediating process of purification. By observing classification in action, the dissertation illuminates social processes typically obscured in the production and deployment of hybrid objects.

Applications

C. Wright Mills (1940) focused his sociological analysis of action on the available discourse used to explain behavior. To him, accessing and interpreting behavior with these 'vocabularies of motives' is a social action in its own right and must be historically situated. Currently, few scholars have looked at the 'vocabularies of motives' in everyday medical practice (e.g., manipulating billing codes to be paid more and access care for patients. Scholars have looked at the impact of disease classification such as the extremely dispersed coordinating mechanism known as the International Classification of Disease (Bowker and Star 1999), racial classification in public health surveillance in the United States (Hahn and Stroup 1994), and how the classification of gender and/or sexuality has impacted rates of HIV and access to services (Patton 1990, Patton 1994, Stoll 1992). Others have scrutinized the social construction of sex categories in biomedical research (Hanson 2000) and have advocated for applied research on classification in an era where such information infrastructures proliferate (Bowker 2000). Brown (1995) has advocated for a sociology of diagnosis to illustrate generalities found in the diagnostic processes. Little is known about how classifications are localized into care-giving routines in healthcare settings (Timmermans and Kolker 2004). The dissertation contributes to the

sociological and public health literature by describing how the multiplicity of classification shape local routines in the daily work of health care including in accessing care, diagnosis, in treatment, and in cost.

Research in medical sociology has established that social context affects the practice of medicine and the process of medicalization. Formal organizations such as hospitals and their ancillary clinics are central actors in contemporary society. Located between the macro-level constraints and micro-level interactions, organizations impact everyday practice in medicine. While in some ways a formal organizations reflects its social location, it also has unique structures, objectives, informal arrangements, processes, history and professional culture. The dissertation emphasizes that diseases, such as syphilis and AIDS, are socially constructed and as such have significant material consequences. Classification is a task that social actors do and take part in, and so this study examined the nitty-gritty of what people are doing when they are classifying and what people do with classifications. Discourse and practice influence one another as classifications are developed, deployed, and resisted. As healthcare costs and concerns about quality continue to increase, systems of classifications will become even more salient in the everyday practice of medicine and public health. The dissertation provides a method for observing the "doing" of classification at the ground level, such as in diagnosing and reporting disease, assessing program eligibility, practicing evidence-based medicine, and billing for services according to a variety of reimbursement schemes. With both syphilis and HIV/AIDS, scientific technology such as a diagnostic test or a new treatment must be linked organizationally with the bureaucratic technology of classification in order for public health care to be equitably distributed.

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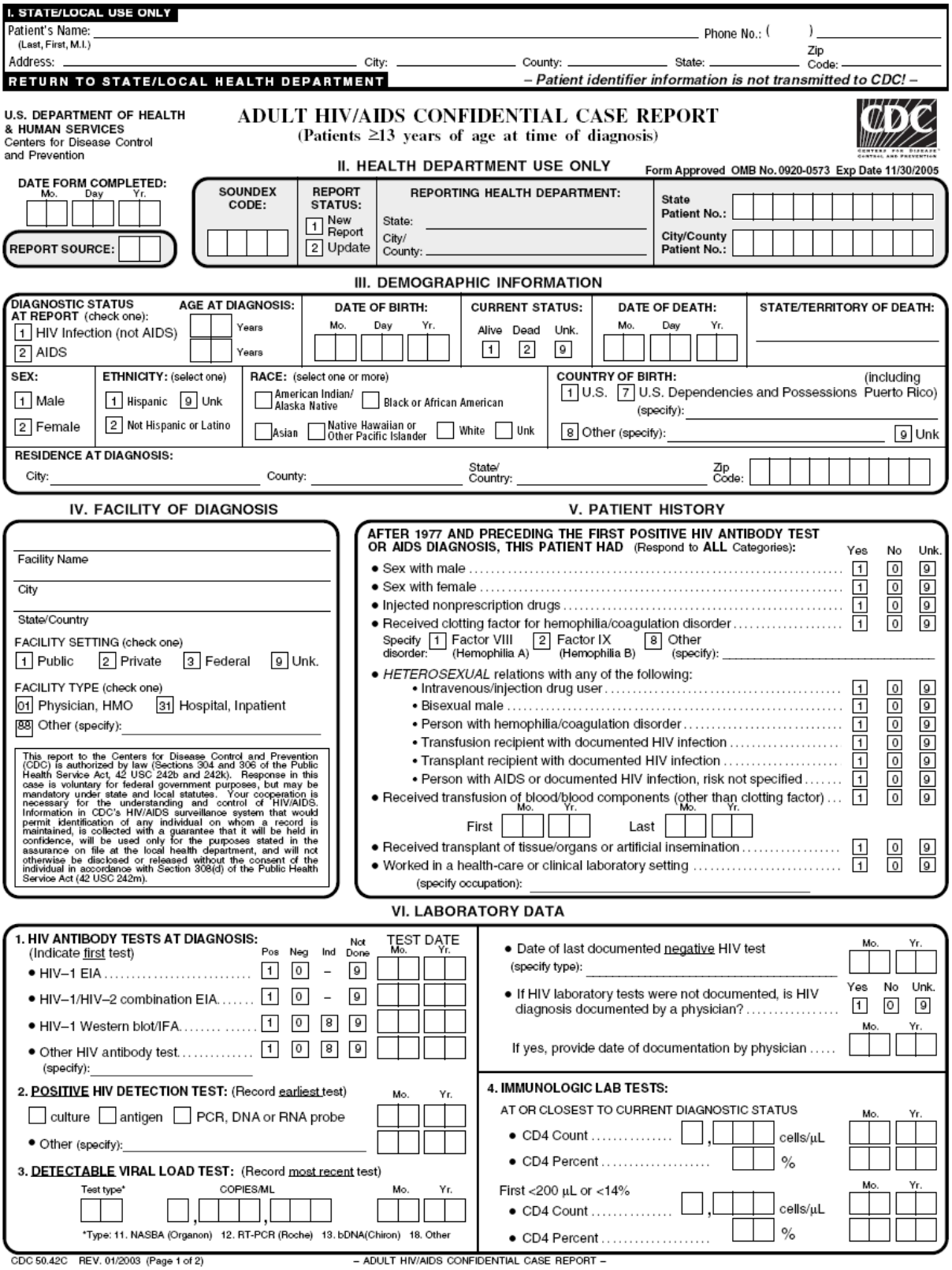
APPENDIX A

Figure A.1 CDC's Adult HIV/AIDS Confidential Case Report



I. STATE/LOCAL USE ONLY

Patient's Name: (Last, First, M.I.) _____ Phone No.: ( ) _____

Address: _____ City: _____ County: _____ State: _____ Zip Code: _____

RETURN TO STATE/LOCAL HEALTH DEPARTMENT – *Patient identifier information is not transmitted to CDC!* –

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention

ADULT HIV/AIDS CONFIDENTIAL CASE REPORT

(Patients ≥13 years of age at time of diagnosis)

CDC

II. HEALTH DEPARTMENT USE ONLY

Form Approved OMB No. 0920-0573 Exp Date 11/30/2005

DATE FORM COMPLETED: Mo. Day Yr.

REPORT SOURCE:

SOUNDEX CODE:

REPORT STATUS: [1] New Report [2] Update

REPORTING HEALTH DEPARTMENT: State: _____ City/County: _____

State Patient No.:

City/County Patient No.:

III. DEMOGRAPHIC INFORMATION

DIAGNOSTIC STATUS AT REPORT (check one): [1] HIV Infection (not AIDS) [2] AIDS

AGE AT DIAGNOSIS: _____ Years _____ Years

DATE OF BIRTH: Mo. Day Yr.

CURRENT STATUS: Alive [1] Dead [2] Unk. [9]

DATE OF DEATH: Mo. Day Yr.

STATE/TERRITORY OF DEATH:

SEX: [1] Male [2] Female

ETHNICITY: (select one) [1] Hispanic [9] Unk [2] Not Hispanic or Latino

RACE: (select one or more) [ ] American Indian/Alaska Native [ ] Black or African American [ ] Asian [ ] Native Hawaiian or Other Pacific Islander [ ] White [ ] Unk

COUNTRY OF BIRTH: [1] U.S. [7] U.S. Dependencies and Possessions (including Puerto Rico) (specify): _____ [8] Other (specify): _____ [9] Unk

RESIDENCE AT DIAGNOSIS: City: _____ County: _____ State/Country: _____ Zip Code:

IV. FACILITY OF DIAGNOSIS

Facility Name

City

State/Country

FACILITY SETTING (check one) [1] Public [2] Private [3] Federal [9] Unk.

FACILITY TYPE (check one) [01] Physician, HMO [31] Hospital, Inpatient [88] Other (specify): _____

This report to the Centers for Disease Control and Prevention (CDC) is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k). Response in this case is voluntary for federal government purposes, but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV/AIDS. Information in CDC's HIV/AIDS surveillance system that would permit identification of any individual on whom a record is maintained, is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance on file at the local health department, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).

V. PATIENT HISTORY

AFTER 1977 AND PRECEDING THE FIRST POSITIVE HIV ANTIBODY TEST OR AIDS DIAGNOSIS, THIS PATIENT HAD (Respond to **ALL** Categories):

	Yes	No	Unk.
• Sex with male	1	0	9
• Sex with female	1	0	9
• Injected nonprescription drugs	1	0	9
• Received clotting factor for hemophilia/coagulation disorder	1	0	9
Specify disorder: [1] Factor VIII (Hemophilia A) [2] Factor IX (Hemophilia B) [8] Other (specify): _____			
• *HETEROSEXUAL* relations with any of the following:			
• Intravenous/injection drug user	1	0	9
• Bisexual male	1	0	9
• Person with hemophilia/coagulation disorder	1	0	9
• Transfusion recipient with documented HIV infection	1	0	9
• Transplant recipient with documented HIV infection	1	0	9
• Person with AIDS or documented HIV infection, risk not specified	1	0	9
• Received transfusion of blood/blood components (other than clotting factor) First Mo. Yr. Last Mo. Yr.	1	0	9
• Received transplant of tissue/organs or artificial insemination	1	0	9
• Worked in a health-care or clinical laboratory setting (specify occupation): _____	1	0	9

VI. LABORATORY DATA

1. HIV ANTIBODY TESTS AT DIAGNOSIS: (Indicate first test)

	Pos	Neg	Ind	Not Done	TEST DATE Mo. Yr.
• HIV–1 EIA	1	0	–	9	
• HIV–1/HIV–2 combination EIA	1	0	–	9	
• HIV–1 Western blot/IFA	1	0	8	9	
• Other HIV antibody test (specify):	1	0	8	9	

2. POSITIVE HIV DETECTION TEST: (Record earliest test) Mo. Yr.

[ ] culture [ ] antigen [ ] PCR, DNA or RNA probe

• Other (specify): _____

3. DETECTABLE VIRAL LOAD TEST: (Record most recent test)

Test type* COPIES/ML Mo. Yr.

*Type: 11. NASBA (Organon) 12. RT-PCR (Roche) 13. bDNA(Chiron) 18. Other

• Date of last documented negative HIV test (specify type): _____ Mo. Yr.

• If HIV laboratory tests were not documented, is HIV diagnosis documented by a physician? Yes [1] No [0] Unk. [9]

If yes, provide date of documentation by physician Mo. Yr.

4. IMMUNOLOGIC LAB TESTS:

AT OR CLOSEST TO CURRENT DIAGNOSTIC STATUS Mo. Yr.

• CD4 Count _____ cells/µL

• CD4 Percent _____ %

First <200 µL or <14% Mo. Yr.

• CD4 Count _____ cells/µL

• CD4 Percent _____ %

VII. STATE/LOCAL USE ONLY

Physician's Name: (Last, First, M.I.) _____ Phone No.: ( ) _____ Medical Record No. _____

Hospital/Facility: _____ Person Completing Form: _____ Phone No.: ( ) _____

– Patient identifier information is not transmitted to CDC! –

VIII. CLINICAL STATUS

CLINICAL RECORD REVIEWED: Yes [1] No [0]

ENTER DATE PATIENT WAS DIAGNOSED AS: Asymptomatic (including acute retroviral syndrome and persistent generalized lymphadenopathy): Mo. Yr. Symptomatic (not AIDS): Mo. Yr.

AIDS INDICATOR DISEASES	Initial Diagnosis Def.	Initial Diagnosis Pres.	Initial Date Mo. Yr.
Candidiasis, bronchi, trachea, or lungs	1	NA	
Candidiasis, esophageal	1	2	
Carcinoma, invasive cervical	1	NA	
Coccidioidomycosis, disseminated or extrapulmonary	1	NA	
Cryptococcosis, extrapulmonary	1	NA	
Cryptosporidiosis, chronic intestinal (>1 mo. duration)	1	NA	
Cytomegalovirus disease (other than in liver, spleen, or nodes)	1	NA	
Cytomegalovirus retinitis (with loss of vision)	1	2	
HIV encephalopathy	1	NA	
Herpes simplex: chronic ulcer(s) (>1 mo. duration); or bronchitis, pneumonitis or esophagitis	1	NA	
Histoplasmosis, disseminated or extrapulmonary	1	NA	
Isosporiasis, chronic intestinal (>1 mo. duration)	1	NA	
Kaposi's sarcoma	1	2	

AIDS INDICATOR DISEASES	Initial Diagnosis Def.	Initial Diagnosis Pres.	Initial Date Mo. Yr.
Lymphoma, Burkitt's (or equivalent term)	1	NA	
Lymphoma, immunoblastic (or equivalent term)	1	NA	
Lymphoma, primary in brain	1	NA	
Mycobacterium avium complex or *M.kansasii*, disseminated or extrapulmonary	1	2	
M. tuberculosis, pulmonary*	1	2	
M. tuberculosis, disseminated or extrapulmonary*	1	2	
Mycobacterium, of other species or unidentified species, disseminated or extrapulmonary	1	2	
Pneumocystis carinii pneumonia	1	2	
Pneumonia, recurrent, in 12 mo. period	1	2	
Progressive multifocal leukoencephalopathy	1	NA	
Salmonella septicemia, recurrent	1	NA	
Toxoplasmosis of brain	1	2	
Wasting syndrome due to HIV	1	NA	

Def. = definitive diagnosis Pres. = presumptive diagnosis

* RVCT CASE NO.: _____

• **If HIV tests were not positive or were not done, does this patient have an immunodeficiency that would disqualify him/her from the AIDS case definition?** [1] Yes [0] No [9] Unknown

– OPTIONAL –

IX. TREATMENT/SERVICES REFERRALS

Has this patient been informed of his/her HIV infection? [1] Yes [0] No [9] Unk.

This patient's partners will be notified about their HIV exposure and counseled by:
[1] Health department [2] Physician/provider [3] Patient [9] Unknown

This patient is receiving or has been referred for:

	Yes	No	NA	Unk.
• HIV related medical services	1	0	–	9
• Substance abuse treatment services	1	0	8	9

This patient received or is receiving:

	Yes	No	Unk.
• Anti-retroviral therapy	1	0	9
• PCP prophylaxis	1	0	9

This patient has been enrolled at:

Clinical Trial	Clinic
1 NIH-sponsored	1 HRSA-sponsored
2 Other	2 Other
3 None	3 None
9 Unknown	9 Unknown

This patient's medical treatment is primarily reimbursed by:
[1] Medicaid [2] Private insurance/HMO
[3] No coverage [4] Other Public Funding
[7] Clinical trial/ government program [9] Unknown

FOR WOMEN:
- This patient is receiving or has been referred for gynecological or obstetrical services: [1] Yes [0] No [9] Unknown
- Is this patient currently pregnant? [1] Yes [0] No [9] Unknown
- Has this patient delivered live-born infants? [1] Yes (if delivered after 1977, provide birth information below for the most recent birth) [0] No [9] Unknown

CHILD'S DATE OF BIRTH: Mo. Day Yr.

Hospital of Birth: _____

City: _____ State: _____

Child's Soundex: _____

Child's State Patient No.

X. COMMENTS: _____

Table A.1 Timeline of Selected Federal HIV/AIDS Surveillance and Testing Recommendations, Approved Diagnostic and Treatment Technology, and Funding Policy and Recommendations[1]

Year	Surveillance/Testing Recommendations, Diagnostic Technology	Treatment Technology, Funding Policy and Recommendations
1981	CDC reports first cases, not yet called AIDS	
1982	CDC releases first case definition for AIDS	
1983	USPHS releases prevention guidelines through sexual contact and blood transfusions; CDC clarifies what is meant by "high risk group"	
1984	HIV isolated as cause of AIDS	
1985	ELISA test licensed by FDA; blood supply begins to be tested; USPHS releases guidelines on preventing mother-to-child transmission	
1986		RWJF creates AIDS Health Services Program
1987	Western blot test approved by FDA; CDC revises surveillance case definition for AIDS; FDA requires testing of blood supply; USPHS issued guidelines making HIV counseling and testing a priority as a prevention strategy for persons most likely to be infected or who practiced high-risk behaviors and recommended routine testing of all persons seeking treatment for STDs, regardless of health-care setting	First anti-HIV drug, AZT, approved by FDA; Congress approves emergency funding to pay for AZT
1989		FDA approves pentamidine mist for use against PCP
1990		Ryan White Comprehensive AIDS Resources Emergency (CARE) Act enacted by Congress, providing federal funds for community-based care and treatment services; FDA approves use of AZT for pediatric AIDS
1991	CDC recommends restrictions on the practice of HIV-positive health care workers and Congress enacts law requiring states to	FDA approves ddI, a nucleoside reverse transcriptase inhibitor (NRTI); 16 EMAs eligible for

[1] Adapted from CDC 2006b, http://hab.hrsa.gov/history/beforeact.htm, http://hab.hrsa.gov/history/afteract.htm, http://www.fda.gov/oashi/aids/miles.htm, http://www.cdc.gov/od/oc/media/timeline.htm, http://www.aegis.com/topics/timeline/default.asp, http://www.kff.org/hivaids/timeline/index.cfm

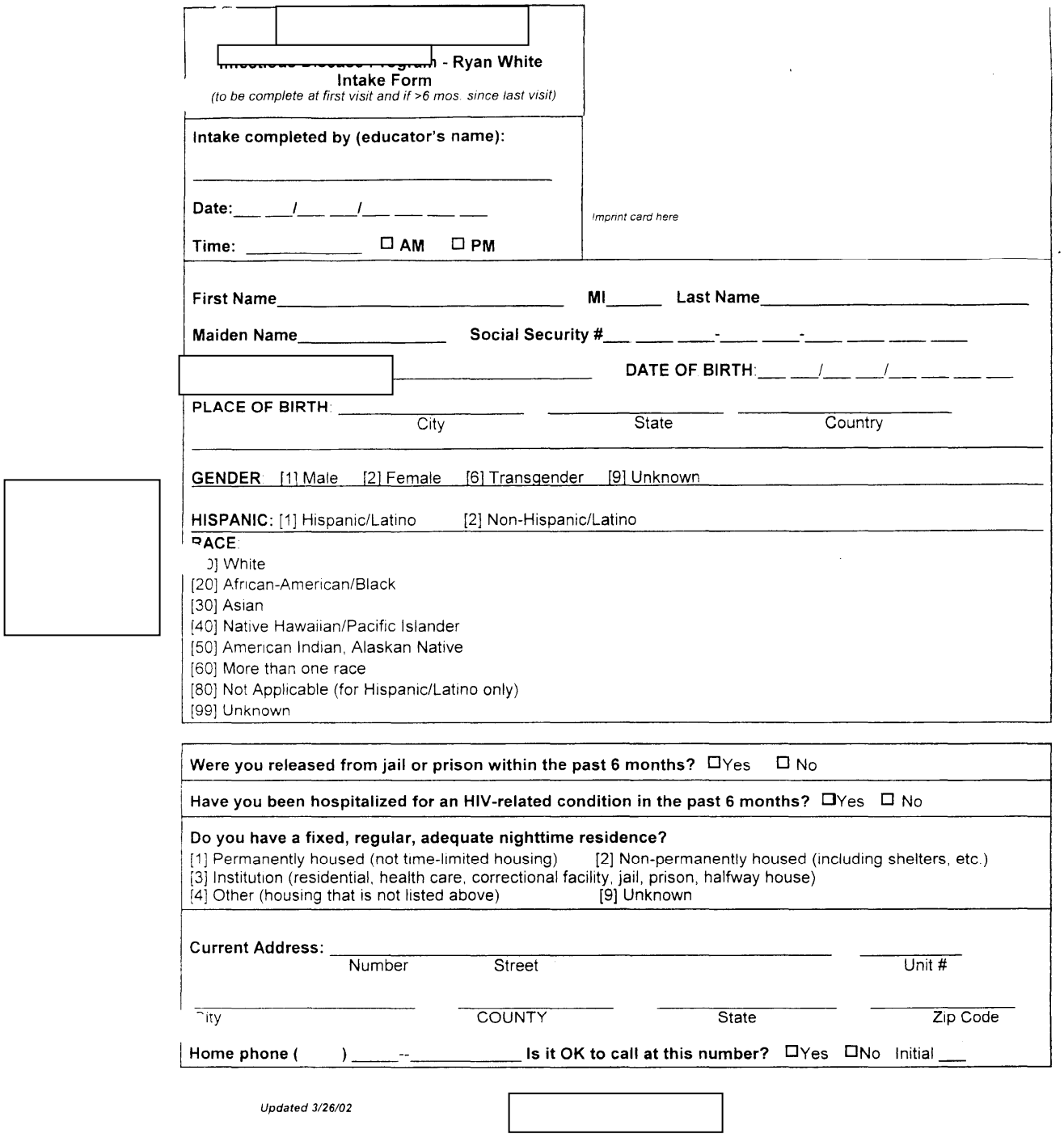
Year	Surveillance/Testing Recommendations, Diagnostic Technology	Treatment Technology, Funding Policy and Recommendations
	take similar action	RWCA Title I funds
1992	CDC adds "Prevention" to its name to reflect a broader role and vision, but retains the initials, CDC	FDA approves ddC, a nucleoside reverse transcriptase inhibitor (NRTI); Two additional EMAs added to list of eligible Title I grantees
1993	CDC expands case definition of AIDS to reflect fuller spectrum of the disease, including adding a condition specific to women and those more prevalent among injection drug users; CDC releases recommendations for voluntary HIV counseling and testing were extended to include hospitalized patients and persons obtaining health care as outpatients in acute-care hospital settings, including emergency departments	7 more EMAs become eligible for Ryan White Title I grants (total EMAs=25)
1994	CDC revises classification system for HIV infection in children; guidelines for counseling and testing persons with high-risk behaviors specified prevention counseling to develop specific prevention goals and strategies for each person (client-centered counseling); FDA approves an oral HIV test, the first non-blood based antibody test for HIV	FDA approves d4T, a nucleoside reverse transcriptase inhibitor (NRTI); USPHS recommends use of AZT by pregnant women
1995	CDC issues first guidelines for the prevention of opportunistic infections in persons infected with HIV; USPHS recommended that all pregnant women be counseled and encouraged to undergo voluntary testing for HIV; FDA recommended that blood establishments should implement donor screening for HIV-1 antigen using licensed test kits	FDA approves Saquinavir, first anti-HIV drug in the protease inhibitor (PI) class ushering in new era of highly active antiretroviral therapy (HAART); FDA approves 3TC, a nucleoside reverse transcriptase inhibitor
1996	CDC releases guidelines for HIV/AIDS Surveillance; FDA approves HIV urine test and first HIV home testing and collection kit; FDA approves viral load test, a new test that measures the level of HIV in the body	FDA approves Nevirapin, first anti-HIV drug in the class called non-nucleoside reverse transcriptase inhibitor (NNRTI); FDA approves Ritonavir and Indinavir, protease inhibitors; Congress reauthorizes the Ryan White CARE Act

Year	Surveillance/Testing Recommendations, Diagnostic Technology	Treatment Technology, Funding Policy and Recommendations
1997		FDA granted accelerated approval for nelfinavir, the first protease inhibitor labeled for use in children, as well as adults; FDA approved pediatric labeling for ritonavir; FDA granted accelerated approval for delavirdine, a non-nucleoside reverse transcriptase inhibitor (NNRTI); FDA approved Combivir, a combined form of AZT and 3TC, two previously approved antiretroviral drugs
1998	CDC updates guidelines for HIV/AIDS surveillance	HRSA brings all CARE Act programs under new HIV/AIDS Bureau; Minority AIDS Initiative created in U.S., after African American leaders declare a "state of emergency" and Congressional Black Caucus (CBC) calls on the Department of Health and Human Services to do the same; FDA approved efavirenz and abacavir
1999	CDC revises case definition for HIV infection	FDA approves amprenavir; Congressional Black Caucus began the Minority AIDS Initiative (MAI) in fiscal year 1999, cngress responded by allocating $156 million to fund MAI efforts.
1999	CDC releases guidelines for National HIV/AIDS case surveillance	
2000		FDA approved Kaletra (lopinavir and ritonavir and Trizivir (fixed-dose combination of Ziagen (abacavir/ABC), Retrovir (zidovudine/AZT), and Epivir (lamivudine/3TC); Congress reauthorizes RWCA with amendments
2001	CDC revises guidelines for HIV Counseling, Testing, and Referral; CDC modified the recommendations for pregnant	FDA approved Viread (tenofovir disoproxil fumarate)

Year	Surveillance/Testing Recommendations, Diagnostic Technology	Treatment Technology, Funding Policy and Recommendations
	women to emphasize HIV screening as a routine part of prenatal care, simplification of the testing process so pretest counseling would not pose a barrier, and flexibility of the consent process to allow multiple types of informed consent; recommendations for HIV testing in health-care settings were extended to include multiple additional clinical venues in both private and public health-care sectors, encouraging providers to make HIV counseling and testing more accessible and acknowledging their need for flexibility; recommended that HIV testing be offered routinely to all patients in high HIV-prevalence health-care settings and in low prevalence settings, in which the majority of clients are at minimal risk, targeted HIV testing on the basis of risk screening was considered more feasible for identifying limited numbers of HIV-infected persons	
2002	FDA approves OraQuick Rapid HIV-1 Antibody Test, first rapid test to use finger prick	FDA approved new dosing and labeling requirements for several previously approved antiretroviral drugs
2003	CDC introduced the initiative Advancing HIV Prevention: New Strategies for a Changing Epidemic, to make HIV testing a routine part of medical care on the same voluntary basis as other diagnostic and screening tests and reduce perinatal transmission of HIV further by universal testing of all pregnant women and by using rapid tests during labor and delivery or postpartum if the mother was not screened prenatally; In its technical guidance, CDC acknowledged that prevention counseling is desirable for all persons at risk for HIV but recognized that such counseling might not be appropriate or feasible in all settings	FDA approved FUZEON (enfuvirtide, also known as T-20); FDA approved Reyataz (atazanavir sulfate); FDA approved Emtriva (FTC, emtricitabine)
2004	FDA approves OraQuick Rapid HIV-1 Antibody Test approved for use with oral fluid	IOM report, “Measuring What Matters,” recommends continued use of AIDS data for allocating

Year	Surveillance/Testing Recommendations, Diagnostic Technology	Treatment Technology, Funding Policy and Recommendations
		CARE Act dollars until HIV surveillance systems have further evolved; FDA approved two fixed-dose combination (FDC) antiretroviral drug products for use with other antiretroviral agents for the treatment of HIV-1 infection: Epzicom (abacavir/lamivudine) and Truvada; FDA issued draft guidance for industry entitled "Role of HIV Drug Resistance Testing in antiretroviral Drug Development," addressing the role of HIV resistance testing during antiretroviral drug development and postmarketing
2005		FDA granted accelerated approval of APTIVUS (tipranavir), a protease inhibitor; Ryan White CARE Act expires
2006	CDC released Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, advising routine HIV screening of adults, adolescents, and pregnant women in health care settings in the United States; FDA approval of the APTIMA(r) HIV-1 RNA Qualitative Assay, for use in clinical laboratories and public health facilities to detect primary (early) HIV-1 infection	FDA approves Atripla, first single-pill, once-daily, triple-drug combination treatment; Prezista (darunavir), was granted accelerated approval by FDA; Congress passes Ryan White HIV/AIDS Treatment Modernization Act

Figure A.2 Intake Form



- Ryan White

Intake Form

(to be complete at first visit and if >6 mos. since last visit)

Intake completed by (educator's name):

_____

Date:___ ___/___ ___/___ ___ ___ ___

Time: _____ ☐ **AM** ☐ **PM**

Imprint card here

First Name_____ **MI**_____ **Last Name**_____

Maiden Name_____ **Social Security #**___ ___ ___-___ ___-___ ___ ___ ___

_____ **DATE OF BIRTH:**___ ___/___ ___/___ ___ ___ ___

PLACE OF BIRTH: _____ _____ _____
City State Country

GENDER: [1] Male [2] Female [6] Transgender [9] Unknown

HISPANIC: [1] Hispanic/Latino [2] Non-Hispanic/Latino

RACE:
[1] White
[20] African-American/Black
[30] Asian
[40] Native Hawaiian/Pacific Islander
[50] American Indian, Alaskan Native
[60] More than one race
[80] Not Applicable (for Hispanic/Latino only)
[99] Unknown

Were you released from jail or prison within the past 6 months? ☐Yes ☐ No

Have you been hospitalized for an HIV-related condition in the past 6 months? ☐Yes ☐ No

Do you have a fixed, regular, adequate nighttime residence?
[1] Permanently housed (not time-limited housing) [2] Non-permanently housed (including shelters, etc.)
[3] Institution (residential, health care, correctional facility, jail, prison, halfway house)
[4] Other (housing that is not listed above) [9] Unknown

Current Address: _____ _____
Number Street Unit #

_____ _____ _____ _____
City COUNTY State Zip Code

Home phone (**)** _____--_____ **Is it OK to call at this number?** ☐Yes ☐No Initial ___

Updated 3/26/02

Last school grade completed _____ **Are you currently employed?** ☐Yes ☐No

Occupation_____ **Work address:** _____

Work phone (**)** _____--_____ **Is it OK to call at this number?** ☐Yes ☐No Initial ____

Marital status: ☐Never married ☐Married ☐Live with Same-sex partner ☐Common-law marriage ☐ Separated ☐Divorced ☐Widowed

Name of Emergency Contact Person	Relationship	Address	Phone #	Aware of client's HIV status?
1.	☐Spouse ☐Partner		home: work:	☐Yes ☐No Initial:_____
2.			*home:* *work:*	☐Yes ☐No Initial _____

HIV/AIDS Status:
What is your HIV status?
[1] HIV+, not AIDS
[2] HIV+, AIDS status unknown
[3] CDC-defined AIDS
[4] HIV-negative/affected
[5] HIV-exposed infant
[9] Unknown

What is the source of information on your HIV status?
[1] HIV status reported by client/family member
[2] HIV status verified from medical record/lab report/medical professional
[8] Not applicable (client not HIV positive)

If HIV+, what year did you first test positive for HIV? *(Note: once an HIV exposed infant's serostatus is confirmed, the HIV positive year should be the birth year of the infant)*

____ ____ ____ ____

☐ [9998] Not applicable; client not known to have HIV or is HIV-exposed infant with indeterminant status
☐ [9999] Unknown/client has not been tested

Which one of these HIV/AIDS transmission categories applies to you?

[1]	Men who have sex with men	[6]	Transfusion of blood
[2]	Injection drug use	[7]	Perinatal (mother-to-child) transmission
[3]	Men who have sex with men and injection drug use	[8]	Other HIV exposure
[4]	Hemophilia/coagulation disorder	[9]	Unknown/undetermined
[5]	Heterosexual contact	[10]	Not applicable/client is not HIV positive

CD4 Count: What is the most recent CD4 count for this client, as recorded in the medical record?

CD4 count: _____ Date: ___ ___/___ ___/___ ___ ___ ___

CD4 count: _____ Date: ___ ___/___ ___/___ ___ ___ ___

CD4 count: _____ Date: ___ ___/___ ___/___ ___ ___ ___

CD4 count: _____ Date: ___ ___/___ ___/___ ___ ___ ___

[9998] Not applicable/CD4 count never done [9999] Unknown CD4 count

Viral Load: What is the most recent viral load for this client, as recorded in the medical record?

Viral load: _____ Date: ___ ___/___ ___/___ ___ ___ ___

Viral load: _____ Date: ___ ___/___ ___/___ ___ ___ ___

Viral load: _____ Date: ___ ___/___ ___/___ ___ ___ ___

Viral load: _____ Date: ___ ___/___ ___/___ ___ ___ ___

[9998] Not applicable/viral load never done [9999] Unknown viral load

----------OTHER HISTORY----------

TB/PPD History:

Did you receive a TB skin test (PPD) during the past 12 months? [1] Yes [2] No [9] Unknown

Have you received treatment due to a positive skin test during the past 12 months?

[1] Yes [2] No [9] Unknown

Date of last PPD ___ ___/___ ___/___ ___ ___ ___ (if unknown, use 01/01/1901)

History of Other Sexually-Transmitted Infections:

Syphilis: **Have you been screened/tested for syphilis ("bad blood") in the past year?**

[1] Yes [2] No [9] Unknown/unreported

If yes, were you treated? [1] Yes [2] No [9] Unknown/unreported

Chlamydia: **Have you been screened/tested for chlamydia in the past year?**

[1] Yes [2] No [9] Unknown

If yes, were you treated? [1] Yes [2] No [9] Unknown

Gonorrhea: **Have you been screened/tested for gonorrhea in the past year?**

[1] Yes [2] No [9] Unknown

If yes, were you treated? [1] Yes [2] No [9] Unknown

History of Hepatitis C:

Have you been screened/tested for Hepatitis C in the past year?

[1] Yes [2] No [9] Unknown

If yes, were you treated? [1] Yes [2] No [9] Unknown

Date of Hepatitis C treatment: ___ ___/___ ___/___ ___ ___ ___ (if unknown, use 01/01/1901)

es client have a substance abuse or dependency problem warranting treatment or that will affect the ability of the client to access care?

[1]Yes [2]No [8]Not applicable, client has no diagnosis

Does client have a known active psychiatric illness warranting treatment or that will affect the client to access care?

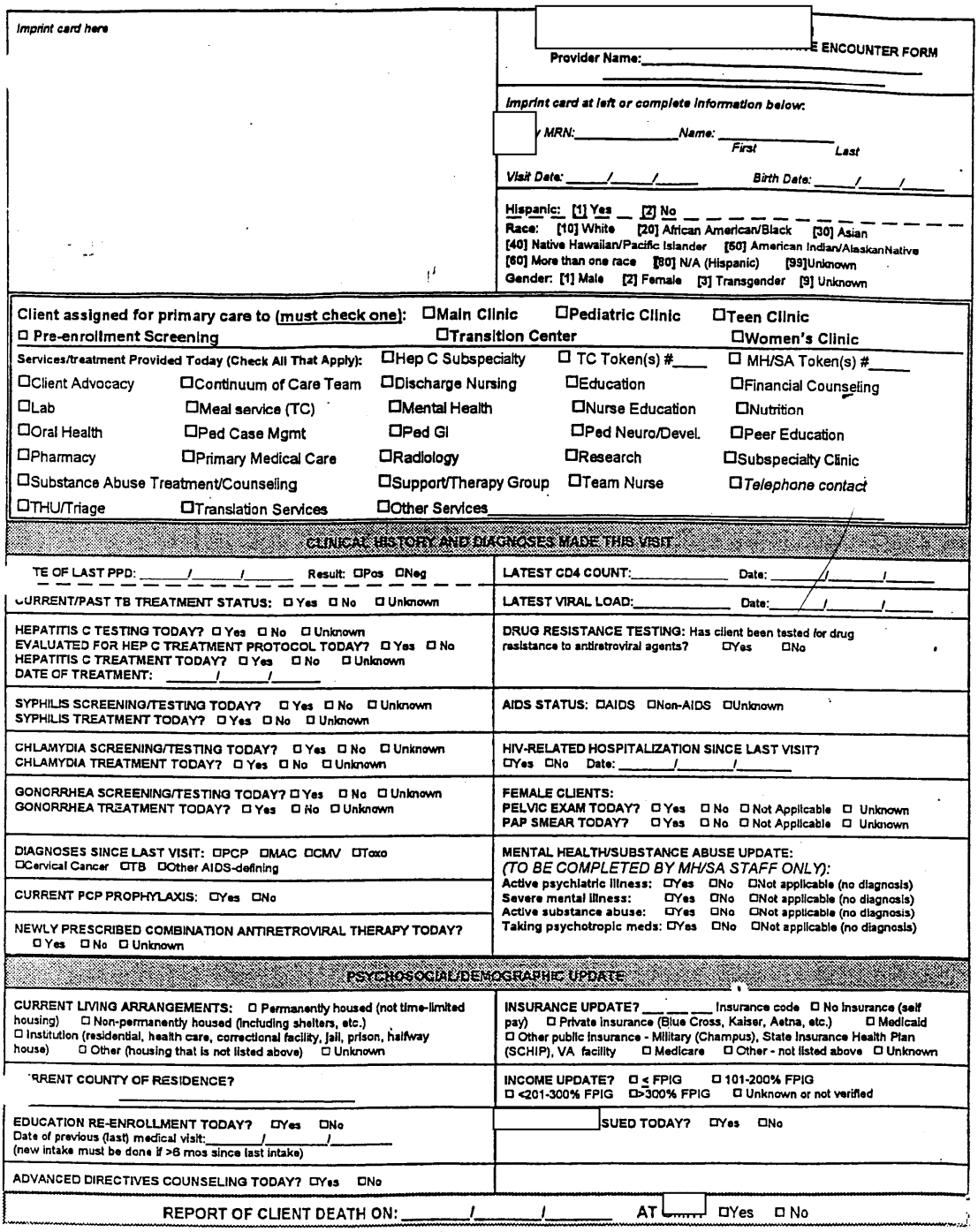
[1]Yes [2]No [8]Not applicable, client has no diagnosis

AFFIDAVIT: I hereby swear that the information I have given, is absolutely true to the best of my knowledge, and that it may be verified by an authorized representative of Grady Health Systems. I hereby consent to the release of such information necessary for this verification by any person or organization requested to give such information to the authorized representative. I further agree that as a condition of any present and future treatment at [redacted] I will take all actions necessary to pursue and obtain any third party coverage for which I may be eligible (such as Medicare and Medicaid) to pay [redacted] for services and supplies provided to me.

Signature of Patient/Patient Representative	Signature of Educator

[redacted]

Figure A.3 Encounter Form



Imprint card here

E ENCOUNTER FORM

Provider Name:_____

Imprint card at left or complete information below:

MRN:_____ Name: _____
First Last

Visit Date:____/____/____ Birth Date:____/____/____

Hispanic: [1] Yes [2] No

Race: [10] White [20] African American/Black [30] Asian
[40] Native Hawaiian/Pacific Islander [50] American Indian/AlaskanNative
[60] More than one race [80] N/A (Hispanic) [99]Unknown

Gender: [1] Male [2] Female [3] Transgender [9] Unknown

Client assigned for primary care to (must check one): ☐Main Clinic ☐Pediatric Clinic ☐Teen Clinic
☐ Pre-enrollment Screening ☐Transition Center ☐Women's Clinic

Services/treatment Provided Today (Check All That Apply): ☐Hep C Subspecialty ☐ TC Token(s) #____ ☐ MH/SA Token(s) #____

☐Client Advocacy	☐Continuum of Care Team	☐Discharge Nursing	☐Education	☐Financial Counseling
☐Lab	☐Meal service (TC)	☐Mental Health	☐Nurse Education	☐Nutrition
☐Oral Health	☐Ped Case Mgmt	☐Ped GI	☐Ped Neuro/Devel.	☐Peer Education
☐Pharmacy	☐Primary Medical Care	☐Radiology	☐Research	☐Subspecialty Clinic
☐Substance Abuse Treatment/Counseling		☐Support/Therapy Group	☐Team Nurse	☐Telephone contact
☐THU/Triage	☐Translation Services	☐Other Services_____		

CLINICAL HISTORY AND DIAGNOSES MADE THIS VISIT

TE OF LAST PPD: ____/____/____ Result: ☐Pos ☐Neg

CURRENT/PAST TB TREATMENT STATUS: ☐ Yes ☐ No ☐ Unknown

HEPATITIS C TESTING TODAY? ☐ Yes ☐ No ☐ Unknown
EVALUATED FOR HEP C TREATMENT PROTOCOL TODAY? ☐ Yes ☐ No
HEPATITIS C TREATMENT TODAY? ☐ Yes ☐ No ☐ Unknown
DATE OF TREATMENT: ____/____/____

SYPHILIS SCREENING/TESTING TODAY? ☐ Yes ☐ No ☐ Unknown
SYPHILIS TREATMENT TODAY? ☐ Yes ☐ No ☐ Unknown

CHLAMYDIA SCREENING/TESTING TODAY? ☐ Yes ☐ No ☐ Unknown
CHLAMYDIA TREATMENT TODAY? ☐ Yes ☐ No ☐ Unknown

GONORRHEA SCREENING/TESTING TODAY? ☐ Yes ☐ No ☐ Unknown
GONORRHEA TREATMENT TODAY? ☐ Yes ☐ No ☐ Unknown

DIAGNOSES SINCE LAST VISIT: ☐PCP ☐MAC ☐CMV ☐Toxo
☐Cervical Cancer ☐TB ☐Other AIDS-defining

CURRENT PCP PROPHYLAXIS: ☐Yes ☐No

NEWLY PRESCRIBED COMBINATION ANTIRETROVIRAL THERAPY TODAY?
☐ Yes ☐ No ☐ Unknown

LATEST CD4 COUNT:_____ Date: ____/____/____

LATEST VIRAL LOAD:_____ Date:____/____/____

DRUG RESISTANCE TESTING: Has client been tested for drug resistance to antiretroviral agents? ☐Yes ☐No

AIDS STATUS: ☐AIDS ☐Non-AIDS ☐Unknown

HIV-RELATED HOSPITALIZATION SINCE LAST VISIT?
☐Yes ☐No Date: ____/____/____

FEMALE CLIENTS:
PELVIC EXAM TODAY? ☐ Yes ☐ No ☐ Not Applicable ☐ Unknown
PAP SMEAR TODAY? ☐ Yes ☐ No ☐ Not Applicable ☐ Unknown

MENTAL HEALTH/SUBSTANCE ABUSE UPDATE:
(TO BE COMPLETED BY MH/SA STAFF ONLY):
Active psychiatric illness: ☐Yes ☐No ☐Not applicable (no diagnosis)
Severe mental illness: ☐Yes ☐No ☐Not applicable (no diagnosis)
Active substance abuse: ☐Yes ☐No ☐Not applicable (no diagnosis)
Taking psychotropic meds: ☐Yes ☐No ☐Not applicable (no diagnosis)

PSYCHOSOCIAL/DEMOGRAPHIC UPDATE

CURRENT LIVING ARRANGEMENTS: ☐ Permanently housed (not time-limited housing) ☐ Non-permanently housed (including shelters, etc.)
☐ Institution (residential, health care, correctional facility, jail, prison, halfway house) ☐ Other (housing that is not listed above) ☐ Unknown

RRENT COUNTY OF RESIDENCE?

EDUCATION RE-ENROLLMENT TODAY? ☐Yes ☐No
Date of previous (last) medical visit:____/____/____
(new intake must be done if >6 mos since last intake)

ADVANCED DIRECTIVES COUNSELING TODAY? ☐Yes ☐No

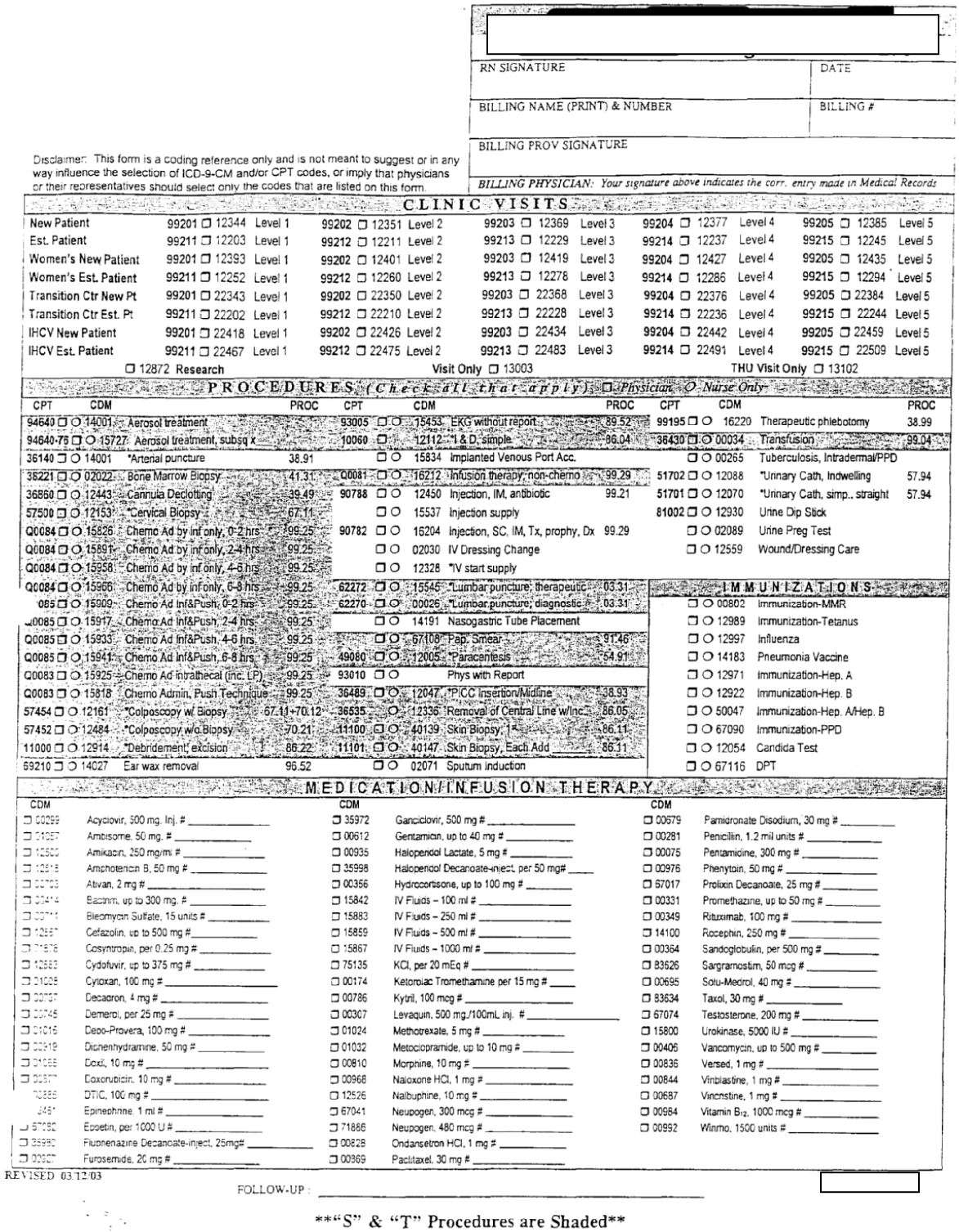
INSURANCE UPDATE? ___ ___ ___ Insurance code ☐ No insurance (self pay) ☐ Private insurance (Blue Cross, Kaiser, Aetna, etc.) ☐ Medicaid
☐ Other public insurance - Military (Champus), State Insurance Health Plan (SCHIP), VA facility ☐ Medicare ☐ Other - not listed above ☐ Unknown

INCOME UPDATE? ☐ ≤ FPIG ☐ 101-200% FPIG
☐ <201-300% FPIG ☐>300% FPIG ☐ Unknown or not verified

SUED TODAY? ☐Yes ☐No

REPORT OF CLIENT DEATH ON: ____/____/____ AT ____ ☐Yes ☐ No

Figure A.4 Billing Form (Procedures)



RN SIGNATURE | DATE

BILLING NAME (PRINT) & NUMBER | BILLING #

BILLING PROV SIGNATURE

Disclaimer: This form is a coding reference only and is not meant to suggest or in any way influence the selection of ICD-9-CM and/or CPT codes, or imply that physicians or their representatives should select only the codes that are listed on this form.

BILLING PHYSICIAN: Your signature above indicates the corr. entry made in Medical Records

CLINIC VISITS

New Patient	99201 ❒ 12344	Level 1	99202 ❒ 12351	Level 2	99203 ❒ 12369	Level 3	99204 ❒ 12377	Level 4	99205 ❒ 12385	Level 5
Est. Patient	99211 ❒ 12203	Level 1	99212 ❒ 12211	Level 2	99213 ❒ 12229	Level 3	99214 ❒ 12237	Level 4	99215 ❒ 12245	Level 5
Women's New Patient	99201 ❒ 12393	Level 1	99202 ❒ 12401	Level 2	99203 ❒ 12419	Level 3	99204 ❒ 12427	Level 4	99205 ❒ 12435	Level 5
Women's Est. Patient	99211 ❒ 12252	Level 1	99212 ❒ 12260	Level 2	99213 ❒ 12278	Level 3	99214 ❒ 12286	Level 4	99215 ❒ 12294	Level 5
Transition Ctr New Pt	99201 ❒ 22343	Level 1	99202 ❒ 22350	Level 2	99203 ❒ 22368	Level 3	99204 ❒ 22376	Level 4	99205 ❒ 22384	Level 5
Transition Ctr Est. Pt	99211 ❒ 22202	Level 1	99212 ❒ 22210	Level 2	99213 ❒ 22228	Level 3	99214 ❒ 22236	Level 4	99215 ❒ 22244	Level 5
IHCV New Patient	99201 ❒ 22418	Level 1	99202 ❒ 22426	Level 2	99203 ❒ 22434	Level 3	99204 ❒ 22442	Level 4	99205 ❒ 22459	Level 5
IHCV Est. Patient	99211 ❒ 22467	Level 1	99212 ❒ 22475	Level 2	99213 ❒ 22483	Level 3	99214 ❒ 22491	Level 4	99215 ❒ 22509	Level 5

❒ 12872 **Research** Visit Only ❒ 13003 THU Visit Only ❒ 13102

PROCEDURES (*Check all that apply*) ❒ *Physician* ○ *Nurse Only*

CPT	CDM		PROC
94640 ❒ ○	14001	Aerosol treatment	
94640-76 ❒ ○	15727	Aerosol treatment, subsq x	
36140 ❒ ○	14001	*Arterial puncture	38.91
38221 ❒ ○	02022	Bone Marrow Biopsy	41.31
36860 ❒ ○	12443	Cannula Declotting	39.49
57500 ❒ ○	12153	*Cervical Biopsy	67.11
Q0084 ❒ ○	15826	Chemo Ad by inf only, 0-2 hrs	99.25
Q0084 ❒ ○	15891	Chemo Ad by inf only, 2-4 hrs	99.25
Q0084 ❒ ○	15958	Chemo Ad by inf only, 4-6 hrs	99.25
Q0084 ❒ ○	15966	Chemo Ad by inf only, 6-8 hrs	99.25
085 ❒ ○	15909	Chemo Ad Inf&Push, 0-2 hrs	99.25
Q0085 ❒ ○	15917	Chemo Ad Inf&Push, 2-4 hrs	99.25
Q0085 ❒ ○	15933	Chemo Ad Inf&Push, 4-6 hrs	99.25
Q0085 ❒ ○	15941	Chemo Ad Inf&Push, 6-8 hrs	99.25
Q0083 ❒ ○	15925	Chemo Ad intrathecal (inc. LP)	99.25
Q0083 ❒ ○	15818	Chemo Admin, Push Technique	99.25
57454 ❒ ○	12161	*Colposcopy w/ Biopsy	67.11+70.12
57452 ❒ ○	12484	*Colposcopy w/o Biopsy	70.21
11000 ❒ ○	12914	*Debridement, excision	86.22
69210 ❒ ○	14027	Ear wax removal	96.52
93005 ❒ ○	15453	EKG without report	89.52
10060 ❒	12112	I & D, simple	86.04
❒ ○	15834	Implanted Venous Port Acc.	
Q0081 ❒ ○	16212	Infusion therapy, non-chemo	99.29
90788 ❒ ○	12450	Injection, IM, antibiotic	99.21
❒ ○	15537	Injection supply	
90782 ❒ ○	16204	Injection, SC, IM, Tx, prophy, Dx	99.29
❒ ○	02030	IV Dressing Change	
❒ ○	12328	*IV start supply	
62272 ❒ ○	15545	*Lumbar puncture, therapeutic	03.31
62270 ❒ ○	00026	*Lumbar puncture, diagnostic	03.31
❒ ○	14191	Nasogastric Tube Placement	
❒ ○	87108	Pap. Smear	91.46
49080 ❒ ○	12005	*Paracentesis	54.91
93010 ❒ ○		Phys with Report	
36489 ❒ ○	12047	*PICC Insertion/Midline	38.93
36535 ○	12336	Removal of Central Line w/Inc.	86.05
11100 ❒ ○	40139	Skin Biopsy, 1*	86.11
11101 ❒ ○	40147	Skin Biopsy, Each Add	86.11
❒ ○	02071	Sputum Induction	
99195 ❒ ○	16220	Therapeutic phlebotomy	38.99
36430 ❒ ○	00034	Transfusion	99.04
❒ ○	00265	Tuberculosis, Intradermal/PPD	
51702 ❒ ○	12088	*Urinary Cath, Indwelling	57.94
51701 ❒ ○	12070	*Urinary Cath, simp., straight	57.94
81002 ❒ ○	12930	Urine Dip Stick	
❒ ○	02089	Urine Preg Test	
❒ ○	12559	Wound/Dressing Care	

IMMUNIZATIONS

❒ ○	00802	Immunization-MMR
❒ ○	12989	Immunization-Tetanus
❒ ○	12997	Influenza
❒ ○	14183	Pneumonia Vaccine
❒ ○	12971	Immunization-Hep. A
❒ ○	12922	Immunization-Hep. B
❒ ○	50047	Immunization-Hep. A/Hep. B
❒ ○	67090	Immunization-PPD
❒ ○	12054	Candida Test
❒ ○	67116	DPT

MEDICATION/INFUSION THERAPY

CDM		CDM		CDM	
❒ 00299	Acyclovir, 500 mg. Inj. #	❒ 35972	Ganciclovir, 500 mg #	❒ 00679	Pamidronate Disodium, 30 mg #
❒ 01057	Ambisome, 50 mg. #	❒ 00612	Gentamicin, up to 40 mg #	❒ 00281	Penicillin, 1.2 mil units #
❒ 12500	Amikacin, 250 mg/ml #	❒ 00935	Haloperidol Lactate, 5 mg #	❒ 00075	Pentamidine, 300 mg #
❒ 12518	Amphotericin B, 50 mg #	❒ 35998	Haloperidol Decanoate-inject, per 50 mg#	❒ 00976	Phenytoin, 50 mg #
❒ 00703	Ativan, 2 mg #	❒ 00356	Hydrocortisone, up to 100 mg #	❒ 67017	Prolixin Decanoate, 25 mg #
❒ 00414	Bactrim, up to 300 mg. #	❒ 15842	IV Fluids – 100 ml #	❒ 00331	Promethazine, up to 50 mg #
❒ 00711	Bleomycin Sulfate, 15 units #	❒ 15883	IV Fluids – 250 ml #	❒ 00349	Rituximab, 100 mg #
❒ 12597	Cefazolin, up to 500 mg #	❒ 15859	IV Fluids – 500 ml #	❒ 14100	Rocephin, 250 mg #
❒ 01576	Cosyntropin, per 0.25 mg #	❒ 15867	IV Fluids – 1000 ml #	❒ 00364	Sandoglobulin, per 500 mg #
❒ 12583	Cydofuvir, up to 375 mg #	❒ 75135	KCl, per 20 mEq #	❒ 83626	Sargramostim, 50 mcg #
❒ 01008	Cytoxan, 100 mg #	❒ 00174	Ketorolac Tromethamine per 15 mg #	❒ 00695	Solu-Medrol, 40 mg #
❒ 00787	Decadron, 4 mg #	❒ 00786	Kytril, 100 mcg #	❒ 83634	Taxol, 30 mg #
❒ 00745	Demerol, per 25 mg #	❒ 00307	Levaquin, 500 mg./100mL inj. #	❒ 67074	Testosterone, 200 mg #
❒ 01015	Depo-Provera, 100 mg #	❒ 01024	Methotrexate, 5 mg #	❒ 15800	Urokinase, 5000 IU #
❒ 00919	Diphenhydramine, 50 mg #	❒ 01032	Metoclopramide, up to 10 mg #	❒ 00406	Vancomycin, up to 500 mg #
❒ 01055	Dexil, 10 mg #	❒ 00810	Morphine, 10 mg #	❒ 00836	Versed, 1 mg #
❒ 00877	Doxorubicin, 10 mg #	❒ 00968	Naloxone HCl, 1 mg #	❒ 00844	Vinblastine, 1 mg #
00885	DTIC, 100 mg #	❒ 12526	Nalbuphine, 10 mg #	❒ 00687	Vincristine, 1 mg #
0457	Epinephrine, 1 ml #	❒ 67041	Neupogen, 300 mcg #	❒ 00964	Vitamin B_{12}, 1000 mcg #
❒ 67082	Epoetin, per 1000 U #	❒ 71866	Neupogen, 480 mcg #	❒ 00992	Winrho, 1500 units #
❒ 35990	Fluphenazine Decanoate-inject, 25mg#	❒ 00828	Ondansetron HCl, 1 mg #		
❒ 00827	Furosemide, 20 mg #	❒ 00869	Paclitaxel, 30 mg #		

REVISED 03/12/03

FOLLOW-UP :

***"S" & "T" Procedures are Shaded**

Figure A.5 Billing Form (Diagnoses)

RN SIGNATURE | DATE

BILLING NAME (PRINT) & NUMBER | BILLING #

BILLING PROV SIGNATURE

BILLING PHYSICIAN: Your signature above indicates the corr. entry made in Medical Records

DIAGNOSIS CODES

1	2	042	HIV/AIDS	1	2	536.8	Dyspepsia NEC	1	2	715.90	Osteoarthritis/DJD
1	2	V68.0	Issue of Med. Certificate	1	2	788.1	Dysuria	1	2	380.10	Otitis, External
1	2	V58.69	High Risk Medications	1	2	782.3	Edema	1	2	382.9	Otitis, Media
1	2	V15.81	Noncompliance	1	2	492.8	Emphysema NOS	1	2	577.0	Pancreatitis—Acute
1	2	V62.3	Educational Handicap	1	2	348.3	Encephalopathy NOS	1	2	577.1	Pancreatitis—Chronic
1	2	V60.0	Lack of housing	1	2	784.7	Epistaxis	1	2	284.8	Pancytopenia NEC
1	2	V60.2	Poverty	1	2	530.10	Esophagitis NOS	1	2	533.90	Peptic/Gastro/Duo Ulcer
1	2	V62.5	Imprisionment	1	2	112.84	Esophagitis, Candida	1	2	034.0	Pharyngitis, Strep
1	2	V69.2	High-Risk Sexual Beh.	1	2	054.79	Esophagitis, Herpes NEC	1	2	461	Pharyngitis, viral
1	2	789.00	Abdominal pain NOS	1	2	780.79	Fatigue and Malaise	1	2	046.3	PML
1	2	783.21	Abnormal Weight Loss	1	2	780.6	Fever	1	2	482.9	Pneumonia, bacterial
1	2	276.2	Acidosis Lactic/Metabolic	1	2	282.2	G6PD Deficiency	1	2	481	Pneu., pneumococcal
1	2	255.4	Adrenal Insufficiency	1	2	009.0	Gastroenteritis, Inf.	1	2	136.3	Pneumonia, PCP
1	2	477.9	Allergic Rhinitis NOS	1	2	008.0	Gastroenteritis, Viral	1	2	486	Pneu., organism NOS
1	2	V15.03	Allergy—Eggs	1	2	530.81	GER	1	2	788.42	Polyuria
1	2	V14.0	Allergy—Penicillin	1	2	007.1	Giardia	1	2	600.0	Prostate, hypertrophy
1	2	477.0	Allergy—Pollen NOS	1	2	098.0	Gonorrhea, acute	1	2	601.9	Prostatitis NOS
1	2	V15.04	Allergy—Seafood	1	2	288.0	Granulocytopenia	1	2	791.0	Proteinuria
1	2	V14.2	Allergy—Sulfonamides	1	2	784.0	Headache	1	2	590.80	Pyelonephritis NOS
1	2	285.9	Anemia NOS	1	2	346.90	Headache, Migraine NOS	1	2	569.42	Rectal/Anal Pain
1	2	283.9	Anemia, Hemolytic	1	2	389.9	Hearing Loss	1	2	569.41	Rectal/Anal Ulcers
1	2	285.29	Anemia, Chronic disease	1	2	578.1	Hematochezia/Blood in Stl.	1	2	099.3	Reiter's Syndrome
1	2	285.21	Anemia, ESRD	1	2	599.7	Hematuria	1	2	592.9	Renal Calculus NOS
1	2	280.9	Anemia, Iron deficiency	1	2	455.6	Hemorrhoids NOS	1	2	584.9	Renal Failure—Acute
1	2	281.9	Anemia, Megalocytic	1	2	070.10	Hepatitis, A	1	2	585	Renal Failure—Chronic
1	2	528.5	Angular Cheilitis	1	2	070.30	Hepatitis B acute	1	2	569.42	Renal Insufficiency
1	2	783.0	Anorexia	1	2	V02.61	Hepatitis B carrier	1	2	362.10	Retinopathy NOS
1	2	528.2	Aphthous ulcer	1	2	070.32	Hepatitis B chronic act.	1	2	780.39	Seizure Disorder NOS
1	2	716.90	Arthritis NOS	1	2	070.54	Hepatitis C	1	2	038.9	Sepsis NOS
1	2	789.5	Ascities	1	2	789.1	Hepatomegaly	1	2	786.06	Shortness of Breath
1	2	493.90	Asthma NOS	1	2	550.90	Hernia-Inguinal NOS	1	2	461.9	Sinusitis, acute NOS
1	2	790.6	Azotemia	1	2	115.90	Histoplasmosis NOS	1	2	473.9	Sinusitis, chronic NOS
1	2	266.2	B_{12} Deficiency NEC	1	2	276.7	Hyperkalemia	1	2	789.2	Splenomegally
1	2	724.2	Back pain	1	2	272.4	Hyperlipidemia NOS	1	2	571.8	Steatosis/Fatty Liver
1	2	790.7	Bacteremia	1	2	401.9	Hypertension NOS	1	2	695.1	Stevens-Johnson Synd.
1	2	796.2	BP Elevated (not HTN)	1	2	401.0	Hypertension, malignant	1	2	091.0	Syphilis, Early
1	2	490	Bronchitis NOS	1	2	257.2	Hypogonadism Male	1	2	097.1	Syphilis, Latent NOS
1	2	799.4	Cachexia/Wasting Dis.	1	2	276.8	Hypokalemia	1	2	094.9	Syphilis, Neuro NOS
1	2	425.4	Cardiomyopathy NOS	1	2	458.9	Hypotension NOS	1	2	785.0	Tachycardia NOS
1	2	V58.1	Chemotherapy	1	2	458.0	Hypotension, orthostatic	1	2	786.06	Tachypnea
1	2	V67.2	Chemo-Follow up	1	2	244.9	Hypothyroidism NOS	1	2	795.5	TB, PPD positive only
1	2	786.50	Chest Pain NOS	1	2	380.4	Impacted Cerumen	1	2	V12.01	TB, personal history of
1	2	571.5	Cirrhosis NOS	1	2	487.1	Influenza NOS	1	2	V01.1	TB, pot. infection risk
1	2	558.9	CMV, colitis NEC	1	2	564.1	Irritable Bowel Syndrome	1	2	018.90	TB, Miliary NOS
1	2	078.5	CMV, Retinitis/Other	1	2	176.9	Kaposi's Sarcoma NOS	1	2	011.90	TB, Pulmonary NOS
1	2	286.7	Coag. deficiency acq.	1	2	528.6	Leukoplakia/OHL	1	2	287.4	Thrombocytopenia
1	2	428.0	CHF NOS	1	2	272.6	Lipodystrophy	1	2	453.9	Thrombosis—Venous
1	2	460	Common Cold	1	2	785.6	Lymphadenopathy	1	2	446.6	Thrombotic TTP
1	2	372.30	Conjunctivitis NOS	1	2	202.80	Lymphoma, CNS	1	2	112.0	Thrush—Oral/Candida
1	2	564.0	Constipation NOS	1	2	201.90	Lymphoma;*Hodgkin's	1	2	525.9	Tooth Pain
1	2	496	COPD NOS	1	2	200.00	Lymphoma, Other	1	2	130.9	Toxoplasmosis NOS
1	2	786.2	Cough	1	2	031.2	MAC, disseminated	1	2	790.4	Transaminasemia NEC
1	2	V65.3	Counseling—Dietary	1	2	031.0	MAC, pulm. or M.Kasas	1	2	597.80	Urethritis NOS
1	2	V65.44	Counseling—HIV	1	2	136.8	Microsporidiosis NEC	1	2	465.9	URI—Acute NOS
1	2	V65.40	Counseling—Oth. Health	1	2	336.9	Myelopathy NOS	1	2	595.9	UTI/Cystitis NOS
1	2	V65.45	Counseling—STD	1	2	359.4	Myositis	1	2	780.4	Vertigo/Dizziness
1	2	V65.42	Counseling—Sub. Use	1	2	787.02	Nausea	1	2	276.5	Volume depletion
1	2	117.5	Cryptococcosis	1	2	787.01	Nausea with vomiting				**DERMATOLOGY**
1	2	321.1	Cryptomeningitis(+117.5)	1	2	581.1	Nephropathy/HIVAN	1	2	682.9	Abscess Cellulitis
1	2	007.4	Cryptosporidiosis	1	2	356.9	Neurop., periph. NOS	1	2	702.0	Actinic keratosis
1	2	294.10	Dementia in HIV	1	2	357.6	Neuropathy-due to drugs	1	2	680.9	Boil NOS
1	2	250.00	Diabetes, no compl.	1	2	278.00	Obesity	1	2	112.3	Candida-skin & nails
1	2	250.90	Diabetes, complicated	1	2	792.1	Occult blood in stool	1	2	078.10	Condyloma/Viral Warts
1	2	787.91	Diarrhea NOS	1	2	787.2	Odynophagia/Dysphagia	1	2	692.9	Dermatitis-conact/ecz.

1	2	995.2	Drug Reaction/AE NOS								
1	2	704.8	Folliculitis NEC								
1	2	705.83	Hidradenitis supperat.								
1	2	054.10	HSV-genital/perianal								
1	2	054.9	HSV-oral								
1	2	053.9	HZV-zoster								
1	2	053.19	Post herpetic Neu. NEC								
1	2	078.0	Molluscum Contagiosum								
1	2	110.1	Onychomycosis								
1	2	698.3	Pungo nodularis								
1	2	698.9	Pruritis NOS								
1	2	696.1	Psoriasis NEC								
1	2	782.1	Rash NEC								
1	2	133.0	Scabies								
1	2	690.10	Seborrhea NOS								
1	2	110.8	Tinea NOS								
1	2	708.9	Urticaria NOS								
1	2	706.8	Xerosis NEC								
			WOMEN'S HEALTH								
1	2	626.0	Amenorrhea								
1	2	610.1	Breast, fibrocystic								
1	2	611.6	Breast galactorrhea								
1	2	611.1	Breast, gynecomastia								
1	2	611.0	Breast, mastitis								
1	2	616.0	Cervicitis								
1	2	233.1	Cervix, cancer in situ								
1	2	180.9	Cervix, cancer								
1	2	622.1	Cervix, dysplasia								
1	2	V25.09	Contraception/Family Plan.								
1	2	625.3	Dysmenorrhea								
1	2	625.0	Dyspareunia								
1	2	617.9	Endometriosis NOS								
1	2	256.39	Hypogonadism, female NEC								
1	2	625.6	Incontinence, Stress								
1	2	626.2	Menorrhagia								
1	2	620.1	Ovarian cyst								
1	2	614.9	PID NOS								
1	2	V22.2	Pregnancy—diagnosis								
1	2	626.8	Uterus, dysfunct. bleeding								
1	2	218.9	Uterus, fibroid NOS								
1	2	616.10	Vaginitis, bacterial NOS								
1	2	112.1	Vaginitis, candida								
1	2	099.53	Vaginitis, chlamydia								
1	2	131.01	Vaginitis, trichomonas								
			MENTAL HEALTH								
1	2	305.00	Abuse—Alcohol								
1	2	305.70	Abuse—Amphetamine								
1	2	305.20	Abuse—Cannibis								
1	2	305.60	Abuse—Cocaine								
1	2	305.50	Abuse—Opioid								
1	2	305.90	Abuse—Polysubstance NEC								
1	2	300.00	Anxiety State NOS								
1	2	296.7	Bipolar Disorder NOS								
1	2	311	Depression NOS								
1	2	309.0	Depression—Situational								
1	2	305.10	Dependence—Tobacco NOS								
1	2	300.4	Dysthymia								
1	2	301.9	Personality Disorder								
1	2	298.9	Psychosis NOS								
1	2	295.90	Schizophrenia NOS								
1	2	780.50	Sleep Disturbance NOS								
1	2		Other_____								

REVISED 07/02/03

FOLLOW-UP APPT: _____

REBECCA J. CULYBA

EDUCATION

2008 **Ph.D., Sociology, Northwestern University**, Evanston, IL

Dissertation: *Classification and the Social Construction of Disease in Medical Systems: A Historical Comparison of Syphilis and HIV/AIDS in the United States*

Committee: Carol A. Heimer (chair), Wendy Espeland, Arthur Stinchcombe

2002 **M.A., Sociology, Northwestern University**, Evanston, IL

1999 **M.A., Sociology, University of London, Goldsmiths College**, London, U.K.
Program in Communication, Culture and Society

1997 **B.A., Sociology, Smith College**, Northampton, MA

COMPUTER PROFICIENCIES

Adobe Acrobat, ArcGIS, Atlas.ti, CAREWare, HyperResearch, Microsoft Office (Excel, Access, PowerPoint, Word, Outlook, Publisher), QDA, SPSS, SPSS Data Entry Builder, Teleform v.10

AREAS OF EXPERTISE

Sociology of medicine and organizations, public health policy, research methods, health database development and administration, HIV/AIDS, program evaluation, quality management

EMPLOYMENT

2007-present **Director of Research and Evaluation, Southeast AIDS Training and Education Center, Center for Applied Research and Evaluation Studies, Emory University School of Medicine,** Atlanta, GA http://www.seatec.emory.edu/research/
Summary: The Southeast AIDS Training and Education Center (SEATEC) conducts HIV clinical training, consultation and technical assistance in a six state region. The Center for Applied Research and Evaluation Studies (CARES) works with federal, state, and local governmental agencies and community-based organizations to conduct program evaluation, needs assessments, and quality improvement plans; *Duties:* Responsible for securing funding for the Data and Evaluation Branch, inclusive of obtaining external funding beyond the AETC grant; design, implement and manage evaluation and research program activities including study conceptualization, quantitative and qualitative methods, data analysis plans and technical writing; direct data and evaluation activities for a federally funded six state AIDS Education and Training Center region and ensure grant reporting requirements are met; secure funding including proposal writing and Institutional Review Board applications to support program activities; develop budgets and manage fiscal operations for multiple grants over varying fiscal periods; recruit, hire, train and supervise staff; present study findings and represent program at local, regional, statewide and national meetings, committees, and working groups; provide technical assistance to community agencies, local and state public health agencies related to data collection including methodological considerations, interpret and integrate data analysis into program planning and grant applications; participate as a key member of SEATEC management team in strategic planning and delivery of HIV training, quality assurance,

evaluation and public relations; invited to participate in departmental (Department of Family and Preventive Medicine) strategic planning activities.

2008 **Peer Consultant, Write Process, Inc.**
Provided training, technical assistance, and consultations services to TGA grantees and providers about CAREWare data entry and report functions, network configurations, program policy and procedures, and federal report requirements.

2006-2007 **Research Project Manager, Southeast AIDS Training and Education Center, Center for Applied Research and Evaluation Studies, Emory University School of Medicine,** Atlanta, GA
Duties: Design, implement and manage program evaluations and applied research studies, including development of methods, analysis plans, and preparation of publications; supervise and hire staff; manage databases including analysis, data quality reviews and data submission; provide technical support to local public health agencies related to data collection, data quality and analysis; review budgets, staff effort, and contracts; represent Center at local and national meetings; *Accomplishments:* developed and codified data management plan, including quality improvement; developing codebook, data entry policies, training, application customization, and collaborative work plans as part of implementation of server-based client-level database for local Ryan White Title I grantee; trained in ArcGIS mapping software

2000-2006 **Research Assistant, American Bar Foundation,** Chicago, IL
Summary: Contribute to collaborative study comparing the sociolegal aspects of AIDS treatment and research in the U.S., South Africa, Uganda, and Thailand entitled, "Clinic-Level Law: The 'Legalization' of Medicine in AIDS Treatment and Research" (Principal Investigator: Carol A. Heimer); *Duties:* negotiate and maintain access to research sites; perform required human subject protections including institutional training; manage and implement ethnographic data collection; manage and conduct interviews with research subjects in the United States and South Africa; attend conferences on management of HIV disease; code data using Hyper RESEARCH 2.6; conduct literature reviews; *Accomplishments:* prepared site report on impact of multiple rule systems and fiscal constraint on daily work of AIDS care; contributed to design of study and writing of grant proposals; implemented progress reporting mechanism; implemented centralized meeting scheduler

2002-2005 **Adjunct faculty, Piedmont College, Department of Social Science,** Demorest, GA
Courses: Marriage and the Family; Media, Technology and Society; Research Methods and Analysis.

2000 **Teaching assistant, Northwestern University, Department of Sociology,** Evanston, IL
Course: Introduction to Sociology.

1999-2000 **Data Collector, Center for Research in Human Development and Education, Temple University,** Philadelphia, PA
Observed and recorded teacher and student interactions in Chicago public schools for national school reform project.

1997-1998 **Research Associate, University of Pittsburgh Medical Center, Diabetes Prevention Program,** Pittsburgh, PA
Collected, managed, and maintained participant data for national multi-site clinical trial; coordinated review of participant records for biannual data monitor; trained employees in data management and clinic support; created and maintained recruitment database.

PUBLICATIONS

Culyba, Rebecca J. (2009). "HIV/AIDS." *Encyclopedia of Gender and Society.* Jodi O'Brien, ed. Sage

Culyba, Rebecca J. (2008). Martha McCaughey's *The Caveman Mystique: Pop-Darwinism and the Debates Over Sex, Violence, and Science.* Reviewed for *Contemporary Sociology.* 37(6): 564-566.

Culyba, Rebecca J., Carol A. Heimer, and JuLeigh Coleman Petty. (2004). "The Ethnographic Turn: Fact, Fashion, or Fiction?" *Qualitative Sociology*. 27(4): 365-389.

Heimer, Carol A., JuLeigh Coleman Petty, and Rebecca. J. Culyba. (2005). "Risk and Rules: The 'Legalization' of Medicine," *Organizational Encounters with Risk.* Powers and Hutter, eds. Cambridge University Press: 92-131.

SELECTED GRANTS AND STUDIES

"Atlanta EMA HIV Consumer Survey." Co-investigator. Fulton County Government Ryan White Program. 4/07-4/08. Approximately $52,000.

"An Evaluation of Clinical HIV Trainings." Co-investigator. Southeast AIDS Training and Education Center, Health Resources and Services Administration.

"A Longitudinal Evaluation of Two Ryan White Title III Clinics." Co-investigator. Southeast AIDS Training and Education Center, Health Resources and Services Administration.

"An evaluation study of the 'Well 2 Do' HIV Prevention Program at AIDS Athens." Principal Investigator. American Sociological Association, Sydney S. Spivack Program in Applied Social Research and Social Policy Community Action Research Award. 2004. Approximately $2000

Northwestern University. Graduate Research Grant. 2004. $1500

MacArthur Foundation, Northwestern University. Summer 2000. $500.

SELECTED CONFERENCE PRESENTATIONS, POSTERS & WORKSHOPS

Invited panelist, "Managing CAREWare over a Wide Area Network," Ryan White Grantee Meeting, Washington, DC (August 26, 2008)

Panelist, "Collaborating on Data Standards across Parts: Practical Steps and Lessons Learned from Atlanta, GA," Ryan White Grantee Meeting, Washington, DC (August 27, 2008)

Poster with Sinafikish Sahlu, Dianne Weyer, Felicia Guest and Ira Schwartz. "What Difference a Year makes! Improving Knowledge and Skills through Longitudinal Training at Part C Clinics in the Southeast," Ryan White Grantee Meeting, Washington, DC (August 2008)

Poster with Sridevi Wilmore, Jeff Cheek, and Kathy Whyte. "Developing a Centralized Client Level Database using CAREWare: An Atlanta EMA Approach," Ryan White Grantee Meeting, Washington, DC (August 2008)

Poster with Sahlu, Sinafikish, MPH, Mobley, Brandy, MPH, and Dianne Weyer. "Improving Knowledge & Quality of Care through Effective Longitudinal Training and Evaluation Program in the Southeast" 20th Annual Conference of the Southeast Evaluation Association, Tallahassee, FL (February 2008)

Invited speaker, "Ryan White Data Update: Reporting, Collaboration, and CAREWare" Georgia Ryan White Statewide Video Conference, Atlanta, GA (December 17, 2007)

"HIV Transmission and Prevention Counseling Trainings: Building Capacity for HIV Prevention at Historically Black Colleges and Universities," with Tonia Poteat, PA-C, MPH; Renata Dennis; Johnetta Holcombe, MPH, National HIV Prevention Conference, Atlanta, GA (December 3, 2007)

Invited speaker, "2007 Data Update: Program Data Report and CAREWare" Georgia Ryan White Statewide Conference, Atlanta, GA (October 24, 2007)

Invited organizer and panel chair, "Sociologists in Community Action Research: AIDS," Professional Workshop, American Sociological Association Annual Meeting, New York, New York (August 12, 2007)

"From Dirty Work to Skilled Expertise: The Professionalization of HIV/AIDS Care in the U.S." with JuLeigh Petty, American Sociological Association Annual Meeting, New York, New York (August 12, 2007)

"Technologies of Uncertainty: The Paradox of Standardization in the Treatment of Syphilis and HIV/AIDS," American Sociological Association Annual Meeting, Montreal, Quebec (August 2006)

Selected poster, "Paying for Performance and Gaming the System: The Standardization of Nomenclature since HIPAA," student poster session, The Public's Health and the Law in the 21st Century: 5th Annual Partnership Conference, Atlanta, Georgia (June 12-14, 2006)

"Doing Classification: The Mutual Tuning of Multiple Trajectories in AIDS Care," Couchstone Symposium, University of Georgia, Athens, GA (February 11, 2006)

"Routines under Constraint: How Classification Systems Shape the Work of AIDS Care," American Sociological Association Annual Meeting, Philadelphia, PA (August 13, 2005)

"Classification and Standardization in HIV Medicine: Expertise and Treatment Guidelines," with JuLeigh Coleman Petty, American Sociological Association Annual Meeting, San Francisco, CA (August 17, 2004)

PROFESSIONAL AFFILIATIONS

Member, American Evaluator's Association
Organizational Affiliate, American Public Health Association
Member, American Sociological Association (sections: Medical Sociology, Sociological Practice)
Member, Sociologists' AIDS Network

UNIVERSITY AND PROFESSIONAL SERVICE

2008	Professional Affiliate for Hubert H. Humphrey Fellows: Komi Abalo (Togo), Mikhail Volik (Russia)
2008	AETC National Evaluation Center Advisory Committee, Barriers and Facilitators Subcommittee
2007-2008	MPH Thesis Committee: Jennifer Nicole Davis, Rollins School of Public Health, Emory University (Title: Routine HIV Testing Training Needs Assessment of Emergency Department Personnel in the Southeast U.S.)
2007-2008	Practicum Advisor, Rollins School of Public Health
2007	Annual Meeting Planning Committee, AIDS Education and Training Center (AETC)
2007-2008	Career Contributions to the Sociology of HIV/AIDS Award Committee, Sociologists' AIDS Network
2006-2007	Data Workgroup, National AIDS Education and Training Center (AETC)

PEER REVIEW

Law and Social Inquiry, Qualitative Sociology, Social Science Quarterly, The Sociological Quarterly

AWARDS & DISTINCTIONS

2005-2006	American Dissertation Fellowship, American Association of University Women
2005-2006	University Scholar, Northwestern University
2005	National HIV Prevention Conference, attendance scholarship
2002	Northwestern University, Gender Studies, Selected to participate in Faculty/Graduate Seminar, "Gender, Sexuality, and Politics in Postmodernity" (declined)
2001	American Sociological Association, Section on Sociology of Religion, Student Paper Award, "Who Can Find a Virtuous Woman?': Gender Ideology in a Black Holiness Church"
2000	North Central Sociological Association, Student Paper Award for "Tongues of Fire: The Articulation of Resistance in a Black Pentecostal Church in Britain"
1997	Smith College, Department of Sociology, Samuel Bowles Prize for "Empowered by the Spirit: Collective Identity and the Dialectic of Gender in a Pentecostal Church"

COMMUNITY SERVICE

2008-present	Library volunteer, The Children's School
2007-2008	Class Auction Project Coordinator, The Children's School
2007-present	Smith College Alumnae Club of Atlanta, Admissions Committee
2004-2005	Chair, Board of Directors, AIDS Athens, Athens, GA, www.aidsathens.org
2003-2006	Member, Board of Directors, AIDS Athens
2001-2003	Volunteer, AIDS Athens