Governing the Global Clinic

HIV and the Legal Transformation of Medicine

Online Appendices

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Appendix A

Some Funny Things Happened on the Way to the Clinics: Data and Methods[1]

I. Introduction: The Practice of Ethnography, Imagined and Real

Although many social scientists, and perhaps especially those using qualitative methods, would disavow rationalist understandings of social life, they nevertheless embrace rationalist frameworks in presenting the unfolding of their own projects. We apparently like to suggest that we have cleverly designed our projects, carefully formulated research plans that mapped onto the questions we set out to answer, and meticulously executed those plans. Yet we know that as a general matter for both individuals and organizations, these post-hoc accounts are partial truths at best. Instead, human lives, organizational lives, and the lives of research projects are much more likely to unfold in the manner described by Dorothy Smith (1987) and Mary Catherine Bateson (1989). We "compose" our projects from the elements at hand, some of which we purposefully created or gathered and many of which we did not. Our attempts to plan often are thwarted by requirements to coordinate with or adjust to the schedules, needs, and plans of others. Even when we apply the tools of sociology to others' scientific work, revealing in one discipline after another the gap between "science on the books" and "science in action" (to adopt the "gap" language more commonly used in sociolegal research), we nevertheless continue to imagine that in our own field such gaps do not exist. When they clearly do exist, we try not to notice the gaps and certainly try to conceal them from others, much as the HIV clinic workers tried to keep

others from seeing the messiness of their backstages. Ethnographers, like others, aim to close gaps, to align the practice of research with the theory of research. We scold ourselves and our students for our "lapses" and believe we can learn to do better next time.

In this appendix, I examine this gap between ethnography on the books and in action by looking, first, at the stages of a research project. I ask what allegedly and actually happens in each stage. Then I discuss a few of the most consequential discrepancies, considering the entities we study and the locations in which we conduct our work (clinics, in my case) and the comparisons we make among sites. Finally, I ask what this difference between our fieldwork ideologies or theories and the empirical practice of fieldwork imply for the final products and for what we are able to learn and convey to others about the nature of the world (and here I mean both about the sites we study and the generalizations we develop). Many of the gaps between real and imagined in ethnography strongly resemble the gaps in other endeavors. As researchers we are responding to common pressures to secure "release time" and funding to do our research, pass muster with ethics review panels, garner prestigious fellowships and awards, and satisfy our employers with a steady stream of publications. These are not just external pressures; to varying degrees we internalize and embrace these pressures. It behooves us to consider how these pressures shape our scholarship and where we might wish to resist that reshaping.

II. Who, What, Where, When, Why, How?

A few basics about what the research for this book project entailed will provide a more solid foundation for the discussion that follows. This study of the legalization of healthcare, whose objectives and findings are described more fully in the body of the book, involved collecting primary data including observational, interview, and documentary evidence. In

addition I gathered considerable secondary material about both about the early history of HIV and the initial, disjointed moves in the history of healthcare that eventually coalesced in the legal turn in healthcare starting a couple of decades before the HIV became an epidemic. Although the fieldwork and interviews could perhaps stand on their own, the historical materials allow us to see how the legalism of healthcare and biomedical research, the HIV epidemic, and responses to the epidemic all unfolded over time, beginning in each case as events whose significance was easy to miss and growing over decades into linked streams of events that reconfigured individual lives and reshaped parts of our social world.

The five clinics introduced in Chapter 2 and discussed throughout the book served as the main sites for gathering observational data, conducting interviews, and gathering documents. In Chapter 2, I also laid out the main considerations that informed the decisions about which countries to focus on and which particular clinics to select within those countries (national wealth and level of development, features of the HIV epidemic, and government stance on the epidemic, engagement in global rule making). Beyond those key features of countries and clinics that I expected to be important in my analysis of the legalization of healthcare and biomedical research, I paid attention to selecting clinics with roughly comparable institutional environments and funding streams. Table A.1 compares the clinics' research programs, the locations of their research and treatment activities, the medical school affiliations of their staff members, the hospital affiliations of the clinics themselves, and the major sources of funds that supported their work. Notably, all of the clinics received funding from U.S. government sources drawing them under the legal and regulatory umbrella of the United States. Four of the five received American funding for treatment (Cha-on Suesum in Thailand was the exception) and all five of them received some research funding from the U.S. Moreover, because clinic researchers

Table A.1. Comparing the Five Clinics: Institutional Environments and Funding Streams

	Robert Rafsky (U.S., private)	Bobbi Campbell (U.S., public)	Cha-on Suesum (Thailand)	Gugu Dlamini (South Africa)	Philly Lutaaya (Uganda)
Research program	Major research facility	Sub-site of another research program	Began as research facility with treatment program added later	Began as treatment program with research added later	Began as research facility with treatment program added later
Location of research and treatment activities	Outpatient HIV clinic in hospital building	Stand-alone HIV clinic not on main hospital grounds	Stand-alone HIV clinic not on hospital grounds	Outpatient HIV clinic in hospital building	Stand-alone HIV clinic not on hospital grounds
Medical school affiliation	Physicians hold medical school appointments; research nurses are employees of university	Physicians hold faculty appointments in one of two medical schools	Top tiers of physicians hold medical school appointments (in Thailand or other countries)	No formal tie between clinic and local medical school, but collaborations with university faculty; formal ties with U.S. medical school	Top tiers of physicians hold medical school appointments (in Uganda or U.S.)
Hospital affiliation	Research formally part of medical school and treatment formally part of university hospital	Clinic is sub-unit of hospital	Clinic is a 'clinical center' of the medical school hospital; also has ties to other local health organizations	Clinic is sub-unit of hospital	Clinic not subunit of hospital, but clinic research often carried out in hospital and hospital staff are also employed by research facility
Major sources of funds	Research funds from U.S. NIH and pharmaceutical companies; funds for treatment from insurance	Research funds from U.S. NIH; funds for treatment from U.S. government (Ryan White, Medicare, and Medicaid)	Research funds from U.S. NIH, Thai government, and pharmaceutical companies; funds for treatment from Thai government (NAPHA), Global Fund, and some private insurance	Research funds from U.S. NIH (via U.S. university); funds for treatment from U.S. PEPFAR, South African government (roll-out), patient payments, and insurance	Research funds from U.S. NIH; funds for treatment from U.S. PEPFAR and Ugandan government

anticipated that some research results would be used in drug approval processes, the clinics were also attentive to the rules of the U.S. FDA.

As with so many other activities, people are "doing things together" (Becker 1986) when they provide (or receive) healthcare and conduct (or participate in) biomedical research. The same is true for social science research. In all of these situations, though, the contributions of lower-status collaborators tend not to be fully acknowledged, giving the impression that treatment and research are more individualistic activities than is in fact the case. The collective nature of the work and the ever-changing membership of workgroups both facilitate and complicate work, including research, points I return to below.

To gather data for this book, I worked with a team that included three graduate students, JuLeigh Petty, Rebecca Culyba, and Lynn Gazley. As planned, project data provided the foundations for their dissertations and my book as well as a series of article, some co-authored. Other people joined the team to help with gathering data in Thailand and Uganda and, later, to pitch in, especially on coding and analysis. In each fieldsite, one or two members of the team conducted the bulk of the research while others visited the site for brief periods, ensuring that we were able to get the perspectives of more than a single researcher in each location. The fieldwork in the American clinics was of longer duration (just short of two years in Robert Rafsky Clinic; thirteen months in Bobbi Campbell Clinic) but was less intensive (we were not in the field every day). We spent four months doing intensive fieldwork in Thailand, Uganda, and South Africa, with multiple two-week visits before and after. We began fieldwork in Robert Rafsky Clinic in September of 2003 and last revisited our sites in Uganda, Thailand, and South Africa between June and August of 2007. The fieldwork thus took place during the first years of the UNAIDS, Global Fund, and PEPFAR global rollout of ARVs and contemporaneous locally funded programs.

The focus of the research was on what clinic staff did with the voluminous and varied rules that governed their work and professional lives. To put it differently, while it is important to recognize that people do things together rather than in isolation, it is also important to understand how people's activities, commitments, and interpretations are shaped by social institutions, culture, and other supra-individual factors. We shadowed staff as they conducted the study visits of clinical trials; examined patients coming for treatment; made phone calls; attended meetings; and went over records with research monitors, site visitors, and accreditors. We also interviewed them both informally as they were doing their work and taking breaks and more formally at pre-arranged times. When they worked with documents, we were often able to get copies of these materials, including forms (for recording data, reporting serious adverse events, referring patients, etc.) and policies used in clinic work (standard operating procedures, clinic guidelines, etc.). We talked with and observed staff in a variety of positions at all levels — physicians, principal investigators, pharmacists, nurses, administrators, social workers and counselors, receptionists, and data processors. The information we gathered allowed us to observe the operation of both official rules and rules in action and to see how the gap between the two varied from one setting and one kind of rule to another.[1] We all wrote notes endlessly — notes on field observations and informal interviews, but also notes summarizing main points from formal interviews.

Beyond these five clinics, we also did extensive interviewing, talking with people so that we would have a better understanding of the context for the clinic work. We talked with people who worked on HIV in ministries of health, regulatory bodies, in health-related NGOs and social movement organizations activists, and in a handful of other HIV clinics. In total, we conducted well over a hundred formal interviews. These interviews were audio recorded and transcribed. Fieldnotes and interview transcripts were then coded using Atlas.ti. As manuscripts were

prepared and revised, we made extensive use of the coded material, but equally often went back to read interview transcripts and fieldnotes.

One additional caveat is in order here. The "who, what, where, when, why, how" mantra of journalism suggests that firm answers are available and will be produced in relatively short order. Although I have just supplied quick answers to those questions, readers should not take this to mean that the research process was entirely smooth or straightforward. Research projects are not like babies — there is no "moment of conception. And as locations where projects gestate, research sites such as HIV clinics are usually not like wombs. Boundaries are porous, participants come and go, and activities are not confined to the official site. Although the publications reporting on completed research typically suggest that researchers start with a well-formulated question that they have answered with their methodically collected data, many researchers instead go through an iterative process in which they continually refine and reformulate questions as they gather data and try to make sense of what they have seen. That iterative process is even more complicated in multi-sited team ethnographies. The process bears as much resemblance to the garbage can model of organizational decision making (Cohen, March, and Olsen 1972) as to the orderly, rational process envisioned by many early philosophers of science.

III. Clinics as Locus and Object of Study

Organizations are a pervasive and vital part of contemporary social life. They constitute both the foreground and background of our lives. Some parts of the social world simply cannot be fully understood without a thorough analysis of organizations. We cannot truly understand what happens in healthcare only by looking at doctors, nurses, and patients, for instance. To

complete the picture, we also need to study the clinics and hospitals where the encounters among these participants occur and to think about how these institutions both shape and are shaped by key actors. Often, we will need to do even more, because we will want to know how clinics or hospitals fit into larger systems that also include medical schools, pharmaceutical companies, regulatory bodies, insurance companies and other third-party payers, and the systems of conventions, rules, regulations, laws, and background assumptions that bind them together.

Sociologists have often used ethnographic methods to study organizations themselves, the activities they house, the people who inhabit them, and the gaps between formal and informal aspects of organizational life in an astonishing array of organizations. Although sociological studies of organizations are often similar to other forms of ethnographic work in their emphasis on close observation and understanding the meaning of actions, words, and artifacts, they differ from other kinds of fieldwork in what they problematize. Much ethnographic work is focused on describing and explaining individual-level phenomena, such as the behavior and beliefs of certain categories of persons, and the patterns of interactions between individuals. Of course, ethnographers who study groups and other collectivities are often interested in supra-individual phenomena, but generally of a less formalized sort than ethnographers of organizations. Although nearly all ethnographers are attentive to context, the context itself is not as often the object of study. In contrast, organizational ethnographers often are studying the organization itself, not just what happens inside it. But, in the view of organizational ethnographers, the added formality and complexity of the organizations they study are deeply consequential because they transform organizations into distinctive social formations whose unique properties need to be described and explained. Without careful ethnographic study, we cannot know what it means that our social world is now populated with entities with complex internal structures,

opaque relations among parts or between the parts and the whole, extended lifespans, or immunity to many kinds of rewards and sanctions.

In suggesting that increases in formality and complexity bring categorical shifts in social forms and that we should study organizations qua organizations, organizational ethnographers break with some of the truisms of ethnography. Grappling with the problem of how to move from "local truths to general visions," Geertz famously argued that "The locus of study is not the object of study. Anthropologists don't study villages (tribes, towns, neighborhoods . . .); they study *in* villages" (1973, 21–2). But I think he overstated the point, especially as it applies to organizational ethnographers. Organizational ethnographers don't just study *in* organizations; they in fact study organizations, both as social forms important in contemporary societies and, sometimes, as particularly influential individual institutions that have shaped large swaths of social life. This distinction between the warrants of organizational ethnographers and the warrants of other ethnographers is of course a matter of degree rather than bright lines — some organizational ethnographers study *in* organizations just as some anthropologists study the villages themselves, and many are interested in organizations (or villages) as both entities and as contexts.

But however important it is for ethnographers to study organizations — either as context or as a specific object of study — the methods by which this should be accomplished need scrutiny. As sociologists are quick to acknowledge, because organizations are not unitary entities, they cannot be studied using exactly the same methods used to research individuals and individual-level processes. Yet the alternative to organizations-as-individuals is not entirely obvious. Clearly, organizations are composed of semi-autonomous actors with a variety of interests that are not entirely consonant. At the same time, though, it would be folly to suggest that an organization is merely the sum of those individual parts. Organizations also have

technologies, product lines, routines, contracts, affiliations, identities, histories, and cultures, some of which are properties of the organization as a whole. Given these differences between organizations, on the one hand, and individuals, groups, and other collections of individuals on the other, we need to rethink the methods ethnographers employ to study organizations.

The relationships ethnographers form in the field fundamentally shape the nature and the quality of evidence they are able to gather. That much is surely true of any group of ethnographers. But organizational ethnographers confront a special challenge in sorting out who or what they should form relationships with. An organization is not simply its top brass, so ethnographers cannot get to know the organization by forming ties only with its leaders. But neither is the organization essentially the members of any other sub-group, such as the individuals it employs, cares for, trains, sells to, or serves. Rather, it is more than the sum of these parts in the sense that the relations among elements are mediated by the organization's mission, culture, history, policies, and structure. Organizational ethnographers therefore must distribute their attention differently than other ethnographers do. They need to know both more and less than other ethnographers: more, because they need to understand the organizational context and how organizational culture and policies shape what happens in the organization (which is why the five clinics are carefully introduced in Chapter 2); less, because they are interested in people primarily as organizational participants whose interactions are inflected and limited by the organizational mission (which is why the lives of clinic staff members outside the clinic receive little attention).

But how does an ethnographer relate to the supra-individual parts of the organization? Although in some senses, organizations live through their artifacts and policies, a few parts of an organizational history are actively referenced and influential, for instance, while others parts are dormant but still available for use in the future. Ethnographers mainly know the specifically

organizational elements through what people tell them about the organization and its policies, forms, documents, and artifacts. Artifacts usually are accessed through individuals and typically will need to be interpreted and contextualized by them. Thus an ethnographer relates to the organization by forming relationships with people who know ("have a relationship with") various departments, functions, or features of the organization because they are members of the organization or somehow interact with it or with some of its components. Informants will see only a portion of the organization, bringing to mind the parable of the blind men describing an elephant. This parable reminds ethnographers of the importance of forming relationships with many informants so as to aggregate the partial information that each can supply. Yet the parable also misleads by treating the elephant as merely a body to be palpated rather than as a series of parts that, acting together, can move loads or transport passengers. Informing about each of the parts, the blind men have neglected what it is that the whole can do. In effect, organizational ethnographers need to learn not only what the parts look like but what they can do, particularly when combined into the larger, acting whole. And for this, "being there" is crucial.

This appendix examines the practices of ethnographers carrying out research in and, especially, on organizations. These practices arise from some combination of the bureaucratic and practical constraints of conducting research and the researcher's strategic decisions about information gathering (summarized in Table A.2). Although scholars have commented on some aspects of these practices (complaining about access delays, for instance), organizational ethnographers' research practices and the relationships they form in the field have not been examined with an eye toward implicit assumptions about the nature of the organizations being studied, the down-stream effects on what can be learned, or the knowledge they ultimately produce. In the light of scholarship bringing the tools of the sociology of knowledge to bear on

social science research (Camic, Gross, and Lamont 2011), it is imperative to think about relationality in the production of ethnographic knowledge.

Table A.2. Epistemological Implications of Research Tasks in Clinic-Based Studies

Practices/tasks	**Pressures and Blind Spots**
Submitting project for ethics review	— Ethics review requires researcher to specify who/what is being studied — Assumes bounded organization — Assumes continuity of research subject over time
Gaining access to organization and participants	— Access to "organization" is not access to individuals — Top-down approaches may close off access to or affect rapport with lower-level participants — Side-in access may seem disrespectful or insubordinate to bosses
Observing/shadowing	— Organization or informants may select/exclude activities/areas for observation — Activities vary in how easily they can be observed; activities that are more collective tend to more observable; work with things and people is more observable than work with data
Interviewing, formal and informal	— Informants can only talk about what they are aware of — Informants may give distorted accounts of events — unrepresentative, cherry-picked, defensive, or boastful
Participating in organizational life	— Organization or informants may invite ethnographers to participate in the organization's work, or "give back" in monetary or non-monetary ways — Explicit requests for help may help identify subtle shifts of loyalty
Gathering/inspecting documents	— Documents vary in whether and how they can be accessed — Documents cannot be taken at face value; they often give official portraits of organization or policies — Documents are generally "touched" by multiple people as they are created, used, and interpreted. No single person's perspective will give full picture

Below, I follow the outline of Table A.2, beginning with a discussion of ethics review and its effects on research practices. I next turn to the challenges of gaining access and securing consent in organizations. I then explore the difficulties of participant observation and shadowing in organizations before considering some of the limitations of interviewing organizational

informants. I then examine requests and pressures to participate in organizational life. Finally, I describe the obstacles researchers face in analyzing organizational documents and records. Throughout, I interrogate the epistemological implications of the constraints placed on organizational ethnographers at the various stages of the research process, and provide some examples of methodological workarounds that ethnographers may use to overcome them. Although my aim here is to show how my own multi-sited research unfolded and was shaped by the nature of these research tasks, I have tried to pitch the discussion at a level of generality that will make it useful to others doing similar kinds of work.

IV. Ethics Review:

Negotiating Multiple Reviews and Inappropriate Assumptions

According to university offices of research, research cannot begin until researchers have submitted their proposals for approval by the proper authorities. These days, the "proper authorities" typically include regulatory bodies that review research ethics (for many disciplines), approve proposals for submission for funding, or approve the use of university resources and facilities for research purposes. It is especially ethics reviews that have garnered attention, and scholars worry about the chilling effect of such oversight, suggesting that some important research is never conducted or conducted in degraded form (see, for example, Dingwall 2008, 9) because of the onerous process of securing permission from Institutional Review Boards (IRBs) (Bledsoe et al. 2007, Hamburger 2007, Heimer and Petty 2010, Schneider 2015, Whitney 2023). Here I consider the particular challenges that a multi-sited organizationally-based study might encounter in obtaining IRB approval. I also describe some of the unintended epistemological consequences of the ethics review process.

Collecting data in multiple sites generally means going through additional IRB reviews. In my case, each clinic brought at least one and often several additional reviews because medical organizations sometimes review projects to assess whether they will excessively draw on the facility's resources and because some countries have layered ethics review systems. Recently, American IRBs have begun to have "reliance agreements" (also sometimes called IRB authorization agreements, cooperative agreements, or memoranda of understanding) in which two or more institutions agree to rely on each other's IRB reviews so that researchers need not undergo multiple reviews for the same project. Because such agreements were not in place at the time I began this research, my project was reviewed by the IRBs of both of my employers (the American Bar Foundation and Northwestern University) as well as by the IRBs of all of the clinics where I gathered data. Annual re-reviews were also generally required. Sometimes the IRBs did not see eye to eye. For instance, they sometimes disagreed on the wording of consent forms, with each site having its preferred standardized language. At other times, IRBs wanted evidence that I had a site's permission to gather data before approving my project, while the site was requesting verification of IRB approval before giving me access to their facility. Having local collaborators was always highly desirable, but was mandatory in Thailand, where the IRB would not approve projects whose teams did not include local researchers. The Thai IRB also preferred that the research be initiated and designed locally, which was not feasible with five fieldsites in four countries.

The process of undergoing ethics review is intended to induce reflection on the ethics of research. Beyond this intended effect, though, the obligation to submit projects for human subjects review and the process of going through review also shape ethnographic research in unanticipated ways. The templates of IRBs, originally created for the review of biomedical research projects, have been adjusted only marginally to fit the needs of social scientists. In

preparing for ethics review, then, social scientists often must re-craft their proposals to make them legible to reviewers. Standard IRB templates provide a poor match with ethnographic projects in research objectives, research methods, and research subjects.

The troubles started for me when I needed to say how many subjects my study would be enrolling. Because IRBs assume that those engaged in human subjects research are studying autonomous individuals, their templates do not easily accommodate studies of groups, networks, or organizations. It is not obvious how a researcher studying organizations answer should answer questions about how many "subjects" will be "enrolled" when the plan is to observe a social group or organization with porous boundaries rather than to study individuals, and when no one is in fact being "enrolled." Moreover, it is unclear whose assent or consent should be solicited and how. What, for instance, does it mean to get the consent of a group or an organization? Nor is it clear how should a researcher should proceed if most, but not all, members of a group consent or if one person later withdraws consent (Atkinson 2009).

Moreover, because the process of seeking consent is typically assumed to be a one-off event, researchers are also led to think about their research subjects in a static way. Yes, IRBs occasionally acknowledge that consent is an ongoing process and make provisions for individuals to withdraw consent. More problematically, IRBs imagine an essential continuity over time with the entity giving consent being essentially identical to entity ultimately being studied. That assumption is not always realistic for organizational ethnography. Subparts of organizations may shift boundaries and individuals often flow in and out of departments, work groups, or the organization itself as they are hired, receive promotions, leave for other jobs, or retire. After a period of high turnover, either in employees, leaders, or clients, is the organization really the same entity? And if the organization undergoes change, does an ethnographer need to

renegotiate access and consent? In the rapidly changing world of HIV care, where I conducted much of my recent research, such reconfigurations are quite common.

Especially importantly, fulfilling the requirements of the IRB requires forming a specific series of ties, not because these ties are especially appropriate for answering research questions or even for ensuring that research is conducted ethically, but because they are necessary for initial or continuing IRB approval. The IRB's vision of an organization is hardly neutral. IRBs imagine that permission to study the organization can be granted by the head of the organization (or someone designated to handle such matters). Initial contacts are to be organized around a series of IRB-approved research documents (summaries of the project, consent forms with mandated but distracting, tangential elements, contact information for principal investigator and IRB officials, etc.), which sometimes create anxiety or irritation, however carefully researchers present them. To be sure, although these constraints on entry points can be consequential they generally do not fully determine the shape of the research that follows. In some situations, though, having to start by getting the approval of those at the top can shut down important research before it even begins. Both Jackall (1988), investigating occupational ethics, and Librett and Perrone (2010), conducting research on work-related problems of undercover police officers, faced extraordinary difficulties gaining access to research sites.

My own research illustrates how preparation for IRB review and the review process itself shape research projects. As I went through the IRB process — the many separate reviews, some with multiple layers, required by my employers and the five clinics — I was asked both to identify my research site(s) and the groups from which my research subjects would be drawn. For most biomedical projects the answers would be a medical facility (hospital, clinic) and patients with a specified set of traits (for instance, patients experiencing or at risk for a particular illness, receiving or eligible to receive a particular therapy). In some senses, because I was

studying clinics, my research subjects and my research sites were one and the same. Although my project entailed observing and interviewing individual clinic workers, these staff members were mainly of interest as routes to information about clinics and clinic processes. They were informants, "units of research," but not really my research subjects or "units of analysis."

Equally problematically, I filled out forms saying I was studying HIV clinics, as if these were well-defined entities. In fact, the boundaries of clinics are exceedingly ill-defined and defined differently by different people.[2] At the outset, I naïvely assumed that a clinic was a geographically located site where outpatient medical care, often of a specialized nature, was given. And although this is one common understanding, "clinic" need not refer to the location but can instead refer to the event — the regularly scheduled occasion when a medical caregiver provides services. That is, medical workers commonly talk about various clinics — the mental health clinic, the diabetes clinic, the HIV clinic — but they also speak of "being available for clinic," of what day or time is "women's clinic," and so forth, without this being simply information about the hours when a particular facility is open. In saying I wanted to study HIV clinics, then, was I saying I wanted to observe the times when a group of caregivers offered HIV-related services as in "we have HIV clinic on Tuesday" or did I mean that I wanted to do fieldwork in a location whose primary activity was supplying outpatient HIV-related care? The distinction is important because one of these (observing "HIV clinic") entails more narrowly circumscribed observations of HIV-related caregiving, while the other (observing "the HIV clinic") is likely to include both core HIV caregiving and a broader array of ancillary medical, social service, and administrative activities. The second was more in line with my vision and indeed with the usual agenda of people doing qualitative research in and on organizations.

Even had I understood this distinction between clinic-as-activity and clinic-as-location, I would still not have grasped that people and activities are not as fully or firmly lodged in the

clinic (as location) as one might expect. Staff working in or for the clinic might be employees of a university or hospital or of the clinic itself. Or they might be employees of more than one of these entities. They might carry out their work in the clinic proper or in the hospital or in university offices. In some clinics it was the clinic itself that tested prospective patients for HIV; in others, testing occurred in a separate site. In some HIV clinics, patients who did not yet need antiretroviral therapy (ART) were cared for by the clinic; in others, they were returned to neighborhood clinics to receive prophylaxis against opportunistic infections during the early phases of the disease. As patient numbers grew, some clinics began to "down refer" patients who had been stabilized on ART for follow-up in affiliated facilities; other HIV clinics continued to manage stable patients in their own facility. These complexities were not ones I could have anticipated before beginning my research, but the pressure to represent my sites in relatively simple ways did not prime me to think complexly about what exactly a clinic is or how I should go about studying it.

To summarize, then, beyond its pervasive effects on most social science research, ethics review affects ethnographic research in organizations such as clinics I studied in two additional, unanticipated ways. It affects how researchers conceive the entities they are studying. It fosters an emphasis on individuals rather than organizations or other supra-individual social forms, views of organizations as having well-defined boundaries, and representations of organizations as static rather than evolving. And it affects the formation of initial ties, and sometimes even the possibility of conducting the research, by mandating conversations with particular organizational representatives on specified topics organized around documents and forms required and approved by the IRB. Ethnographers and other qualitative researcher learn by forming relationships in the field. Neither misconceiving the entity they are studying nor placing too much emphasis on forming ties with organizational leaders seems likely to promote and support

the sort of productive fieldwork relationships on which good research in and on organizations such as HIV clinics depends.

V. Access and Consent: Official Permission as Bridge and Barrier

Once IRB hurdles have been cleared, researchers can begin in earnest the process of securing access to their research sites. In addition to the usual questions how initial entry points affect subsequent access, I here consider the benefits and challenges that flow from obtaining "official permission" to conduct research and how the organizational status of fieldsite gatekeepers affects the knowledge ethnographers are ultimately able to produce.

Feldman, Bell, and Berger's (2003) thoughtful collection on gaining access amply demonstrates that there are many routes into organizations. That said, because the members of organizations have relations with one another, how and through whom one enters can be deeply consequential. Because of this, Chambliss (1996) recommends "side-in" access rather than top-down access; the latter, he sagely notes, cannot be assumed to be the same as real access. Although in some official sense, those at the top may be empowered to grant research access on behalf of the organization, anyone with a passing familiarity with organizations knows that people lower in the organization have considerable discretion over how fully they cooperate with researchers. A reluctant informant is surely better than no informant, but an enthusiastic one is a real boon. Some organizational ethnographers thus approach those at the middle and lower rungs directly rather than through their superiors.

An official stamp of approval may give a researcher the right to knock on doors, but may sometimes make it more difficult to get through those doors. When tension between groups is high, being perceived as affiliated with one group may make others reluctant to talk. Researchers may find that they need to convey that having received an official blessing does not

make them the allies of any particular social group. Information about cleavages in the organization — perhaps grounded in very local experience and organizational history, perhaps in the usual social divisions of race and ethnicity, class, gender, age, and occupation — may suggest ways to counteract the worst effects of arriving with the too obvious blessing of the powers that be. In the HIV clinics where I gathered data, my record of research in medical settings helped with the top brass, my knowledge of insurance (also from previous research) improved my rapport with accounting staff, and my difficult-to-pronounce childhood Congolese name closed some gaps with nurses as I garbled their Zulu names.

For a host of reasons, researchers are likely to need to employ both top-down and side-in approaches. Side-in access carries a downside risk that organizational leaders will see researchers as devious if they contact organizational subordinates without first consulting the boss. Profuse apologies, careful explanations, and requests for help often clear things up, but remedial actions occasionally prove insufficient. My side-in attempt to enlist a Thai faculty member as a research collaborator failed when a department chair interpreted my discussions as going behind her back, despite the fact that my proposed collaborator had assured me that the chair did not need to be consulted. In Uganda, I was scolded by an eminent HIV researcher (not in my fieldsite) for scheduling an interview with a subordinate without his permission. When he insisted that I come talk to him about my mistake, all was forgiven, and a wonderful interview ensued.

Although top-down access to an organization is never sufficient, it has clearly become increasingly necessary with the institutionalization of ethics reviews and the corresponding diffusion of concerns about liability (Bledsoe et al. 2007, Dingwall 2008,

2007, Heimer and Petty 2010). Not only will bosses and supervisors object to a researcher coming in without their express permission, but subordinates also will worry about

getting into trouble for talking with an ethnographer or saying the wrong things.

A first refusal can sometimes be turned around, though, if a researcher learns enough about the structure of the organization to locate someone able and willing to override an early no (in a hierarchical organization), to persuade co-workers to change their minds (in a flatter organization), or simply to provide an alternate access point (in an organization in which people operate more autonomously). In my research on HIV clinics, I experienced an early refusal that I was surprised to see reversed when a lead HIV researcher, with whom I had scheduled an interview, took the initiative to convince his colleagues to give me access. At that early stage, I knew little about the relationship between the treatment and research components of the clinic or about who was empowered to make decisions about research access. The relative autonomy of professionals in medical and academic settings — and one physician's passionate support for research — worked to my advantage in this instance. Perhaps more importantly, though, this early introduction to clinic cleavages sensitized me to the importance of building relationships that would lead me into both the world of treatment and the world of research. At a later point in the research, I also encountered heads of organizations who were eager to give me access, apparently feeling that they could speak for the organization without consulting their colleagues. In that case, I had to delicately accept the welcome while making sure that other clinic staff knew that I was not taking their consent for granted.

To reiterate, then, the pressure (including from subordinates) to adopt a top-down approach to access may reinforce a sense that those at the top can speak for the organization as a whole, that leaders, more than their subordinates, *are* the organization. Bosses' self-aggrandizement is not limited to formal organizations, of course, but is particularly pernicious when the "speech" of complex organizations — organizations' charts, blogs, policy statements, websites, and newsletters — reinforce this skewed perspective, despite occasional bows to a

more egalitarian ideology. When an organization such as a clinic is the locus or object of study (or both), researchers must guard against the reification of this view that leaders are the organization, including reflecting on how early contacts shape subsequent encounters and, ultimately, their portraits of the organizations they study. Fortunately, not all pressures push in the same direction, as becomes evident when we look at the realities of studying the day-to-day activities in clinics and other organizations.

VI. Doing Fieldwork:

Organizational Constraints on Hanging Out

When fieldwork is thought of primarily "hanging out" in a research site, it is easy to gloss over the innumerable factors that shape where a researcher will be able to spend time, what they will be able to see, and who they are likely to get an opportunity to talk with. These factors, which include but go well beyond IRB-imposed constraints and the imperative to seek official permission, may have little to do with researcher objectives and preferences and much more to do with the structure of organizational life and the inherent properties of work and talk. Some organizational activities are just harder to observe than others and some topics are simply more difficult than others to access through talk. Here I explore the effects of institutionalized spatial, temporal, and moral boundaries and impediments arising from the organization of work activities. I also consider workarounds that may help a researcher gain access to off-limit spaces and to the frequently private, silent, and "interior" activities of organizational actors.

In clinics, like many other organizations, people arrive at pre-specified times to begin their workday, spend long periods carrying out their duties, and depart with clear plans for their return. This predictability of clinic life is a huge boon to researcher, who can then safely assume

that there will be *someone* to observe or talk with during normal working hours, however those are defined. This apparent advantage of conducting research in organizations should not be overstated though. As Cohen et al. (1972) pointed out in their analysis of organizational decision-making, participation in organizational life is structured. Organizational members are not equally present and equally available, and this shapes what ethnographers can do and see every bit as much as it affects organizational decision-making. The structure of participation also varies, of course, from one time to another, from one kind of organization to another, from one occupation to another. Moreover, if the work of an organization is dispersed because of telecommuting and virtual meetings, as occurs with clinics working on multi-sited clinical trials, for example, the possibilities for researchers are dramatically altered. What researchers can access, what they can see, and the kinds of relationships they can form are modified.

What do we know, then, about who is available and who is not? First, social status matters. Frontline workers — receptionists, guards, secretaries, and program assistants — often are more available, at least superficially, to researchers than are people who work in relatively private spaces. But even those who are relatively exposed to the public may be less accessible than we might expect. Counters and plexiglass dividers offer workers a modicum of privacy and some capacity to ignore members of the public for at least a few minutes until a task is completed. Such counters also separate truly public space from semi-public office space, which members of the public, including ethnographers, cannot enter without permission. HIV clinics, like other medical settings, have waiting rooms where patients and research subjects wait, sometimes for very extended periods, to see doctors, nurses, technicians, pharmacists, and social workers. I too could have spent time in these waiting rooms — and I did — but my research was focused on staff members, not patients (whom I did not have IRB permission to study), so the public spaces of clinics were only marginally useful to me.

Getting into more private spaces — examining rooms, private offices, workrooms, staff lunchrooms, or meeting rooms — typically requires telephoning or emailing in advance, and may require going through several people. Initial requests may land on the wrong desk or simply go unanswered. Information needed to route requests properly often is only secured by doing the research. In practice, then, the hoped-for benefits of doing research in a clinic or other physical site where people are regularly and predictably present may not materialize only somewhat later if at all.

These facts about the structure of participation in organizations affect core aspects of data gathering. They shape the possibility space of the relationships fieldworkers form with organization members and therefore who they are able to talk with and observe; they shape what actually happens in organizations at particular times [3] and therefore what ethnographers are able to see; and they shape access to the documentary evidence that allows ethnographers to understand the organization as an entity, because documents come to ethnographers primarily through contacts with the people who create, work with, preserve, discard, destroy, misplace, file, or conceal these artifacts of the workplace.

As researchers go through the early stages in their fieldsites, suggestions about who to talk with are inevitably offered. When ethnographers go through official channels, organizational representatives have an opportunity to structure at least the initial episodes of observation with suggestions that the researcher will "find it useful" to start with a particular person who knows the organization well, is especially helpful, or happens to have some free time. Organizations may be considerably more proactive, though. At Philly Lutaaya, the senior staff of the clinic designated an expatriate staff member for me to check in with as I made initial appointments. Was this "minder" intended to keep me an eye on me until they were confident I was trustworthy? Or perhaps her job was to steer me away from sensitive topics or prevent

contact with people who might reveal too much. I was handed an organization chart and urged me to "spend time with" people in all subparts of the clinic before settling in for more intensive observation and interviewing. It is conceivable that I did not notice that some doors were closed because so many doors had been opened. Whatever their intention, I did in fact hear about the clinic's troubles, mistakes, and embarrassments. The sole restriction, discussed more fully below, was that I could not accompany caregivers into examining rooms.[4] But my thinking was also shaped by my minder's conception of the organization and by the "organogram" (organization chart), both of which emphasized people and activities fully within the organization rather than alerting me to the porousness of the boundaries between the clinic and other organizations.

In the five sites, my team and I were able to make use of one or another feature of organizational life to expand our access and broaden our coverage. Because documents laying out the relationships among staff members were less available at the other clinics than at Philly Lutaaya and because clinic leaders were less conscientious about making sure I had a well-rounded picture of their organization (and, honestly, there was little reason for them to concern themselves with my work), I was initially less confident of my coverage in the other four clinics. In the two U.S. clinics, however, regularly scheduled meetings of groups of staff member allowed me and my team to keep up with clinic matters and to adjust to new information. Over the months of our lengthy periods of fieldwork in the U.S., we were able to witness events that occurred once a year or even less often as well as events that occurred on a daily or weekly basis. In the American clinics, it was also relatively easy to return to the sites as we discovered omissions. Return visits to South Africa, Uganda, and Thailand were much more difficult, but I had, fortunately, designed in several such trips. But we could draw on other regularities of organizational life in those settings. In Thailand, we were able to learn much about clinic work

through our observations of clinic members at the Bangkok AIDS Conference, where they talked both about their research and their facility. In South Africa, I was assigned a desk in a shared office, giving me easy access to staff members and clinic activities. In fact, I had almost too much access. Having a desk brings an obligation to show up. Being present means observing, and observing increases the pressure to record ever more information in fieldnotes.

Whether supervisors, minders, or other clinic staff try to steer researchers or help them on their way, some activities and topics are simply more amenable to observation and interviewing than others, as my team and I learned. When doctors or nurses interacted with patients in examining rooms, I was able to observe what they did, though of course I could not actually hear what caregivers heard through their stethoscopes or feel what they felt as they palpated patients' bellies. Likewise I could quite easily observe the parts of research that involved interactions with patients — discussing whether all doses of medication had been taken and taken on time, whether the patient had run a fever or had any pain, and so on. Tasks that involved less interaction — preparing email queries about deviations from research protocols, for example — were usually harder to observe. However, group discussions, for instance of protocol committees' decisions about acceptable adjustments of research protocols to take account of patients' symptom patterns, could bring previously unobservable activities (the emailed exchanges) into my line of sight. Observation can also be difficult because work occurs in close quarters — looking into a microscope, performing a delicate medical procedure where only a single person can be close to the task. But when people need to coordinate around such tasks, for instance in surgery, cameras and projection screens can make the work observable to others. Other people's need to coordinate creates opportunities for ethnographers, although they are generally unable to arrange for such observational aids beyond what others have already put in place.

Although the particulars will vary from one setting to another, barriers to observation occur in all fieldsites. Activities that take place in relatively public settings (meeting rooms, collective workspaces, lunchrooms, reception areas), because they entail interaction and conversation among workers will be easier to observe than activities that take place behind closed doors (in single-person offices or examining rooms). And, as a general matter, tasks that involve working with objects or people are likely to be easier to observe than those that entail manipulating ideas or data.[5] Work with ideas can be notoriously difficult to observe because, like the newspaper reading that Benedict Anderson commented on, "It is performed in silent privacy, in the lair of the skull" (2006 [1983], 35). One can see pills being dispensed in a pharmacy and hear the pharmacist review the medical regimen with a patient. One can listen as researchers discuss a paper being drafted for a conference. More difficult, though, is figuring out how to learn about the work performed in the "lair of the skull" — the initial crafting of a conference abstract or the thought that goes into a nurse's delicate request for a physician to correct or elaborate a note in the medical record. In medical settings, much of this "interior" work is ultimately exteriorized when it is rehashed in meetings or hallway conversations. But this advantage may be balanced by the increasing amount of time that people spend in front of computer screens — or, even worse, typing on handheld devices. As researchers learn, to observe a person working with a personal computer or handheld device (or paper and pencil, for that matter) often means either intruding rather uncomfortably into their personal space or continually peppering them with questions. Thus although the computer interface may facilitate the work of the caregiver, it tends to make the work of the ethnographer more difficult. In principle, ethnographers can request copies of templates, of course, though that may require a worker to seek permission from the boss.

Moreover, some work with people may be hard to observe because it is placed off limits by individuals, organizations, or by even by law. Although respect for the sanctity of the examining room is an entrenched part of clinic culture, contemporary regulations and regulatory practices reinforce the boundary. Clinic staff nervously remind patients — and researchers — about HIPAA[6] and informed consent. How such rules applied to my research was never entirely clear. Although my project had been approved by the relevant ethics panels, staff members seemed uncertain about whether it was legitimate for me to observe what happened in the privacy of medical examining rooms. Ultimately four of the five clinics decided that, with oral consent of the patients, I could accompany staff members into examining rooms, though I was asked me to leave at sensitive moments (such as when male patients were asked to "drop trou").[7]

All too often, though, a request to observe or shadow a worker leads to embarrassment and bafflement about what exactly the researcher wants to see. Workers may be incredulous that anyone would want to watch them fill out paper work — as situation my team and encountered often. If it is boring for them to do this work, how could it be interesting for an observer to watch? And if filling out forms requires attention — as it does — how is the worker supposed to behave toward the researcher? People find it exceedingly awkward to work in silence as someone watches. For this reason, work that involves some opportunity for banter is usually easier to observe than work that is mostly silent.

By this principle, meetings are easier to observe than solo work, both because of the easier sociability that occurs with multiple people in the room and because of the diminished awkwardness when responsibility for interacting with the fieldworker is diffused (a rare instance when the diffusion of responsibility is an advantage). To some degree, the awkwardness of observation can be reduced by conflating observation with existing organizational practices. In medical settings, new workers often shadow experienced colleagues; students and visiting

colleagues often accompany staff members into examining rooms and meetings. More than once, I benefited from the instruction being given to medical students, fellows, or visiting colleagues, gaining both substantive knowledge and the chance to observe unobtrusively. (See, for instance, the material at the beginning of Chapter 4, discussing Daniel's sessions with physicians receiving advanced training in infectious diseases in Uganda.) Comparing ethnographers' practices to existing organizational practices normalizes a fieldworker's presence, making it more comprehensible to those being observed.[8] And because, in medical settings at least, status is signaled by having a group of students, residents, or fellows following in their wake, senior staff may be more accustomed to and willing to be observed than ethnographers would expect given the protection that usually comes with high status. Conflating requests to observe with the common practices of an organization can create other challenges, though, a point discussed more fully below.

VII. What Informants Can and Will Reveal in Interviews

Often the most useful conversations with informants are those that arise naturally during lulls in activity when an ethnographer is hanging out, with all of the documents, instruments, and activities of the site available as props for the conversation. When a more extended discussion is needed, though, researchers may need to ask that a period of time be set aside exclusively for talking and may even need to request a formal interview. When conducting interviews, researchers must confront episodic resistance to talking openly with researchers in a more formal setting, the limited perspective that individual informants bring to the table once they arrive, and cognitive impediments to sharing "unavailable" information.

To begin, how formidable is the hurdle of simply asking informants to take the time to sit down for a lengthy chat? For some people the request is difficult to accommodate because individual appointments are not normal occurrences in their work lives (that was the case for many of the lower level staff in the clinics); for others, an interview simply gets folded into the schedule alongside other appointments in busy worklives (a common phenomenon with the physicians and senior researchers). Likewise, the meaningfulness of appointment times can vary widely with local practices, some grounded in the routines of organizations and professions, others in local culture. An interview appointment with a physician is subject to the uncertainties of timing common in doctors' schedules; appointments with government functionaries may be delayed by official business. In addition, some workers may not have access to private spaces for interview; in these circumstances, the privacy that IRBs assume (and more or less require) simply is not possible and in some cases an interview scheduled with a one person becomes a group conversation that includes office mates.

Whether interviews are formal or informal, though, what matters most is the willingness of respondents to talk openly. Reluctant respondents often simply decline a request for an interview, though they may opt for a "slow refusal" instead.[9] More difficult, though, are those circumstances where respondents are unsure about the rules of their organization and anxious about stepping over some ill-defined line, a response especially likely in lower echelon workers in highly bureaucratized organizations with strong accountability pressures. A respondent's reluctance to talk about even relatively innocuous topics can give a researcher valuable (but frustrating) information about the relations of workers to the organization and to one another, which topics are especially sensitive, and how boundaries are policed.

Additional impediments impinge on interviewing, whether it is done formally or informally. Just as some activities are easier to observe than others, some matters are easier to

learn about through discussion than others. Generally speaking, respondents are more able to talk about things they notice—things that have not been thoroughly routinized, for instance—than things that escape their conscious attention. What we do automatically without much conscious thought becomes less accessible to us. Although such things can eventually be retrieved, they are not the matters that people will spontaneously discuss. Thus, in my research, informants were more able to articulate thoughts about the rules and procedures they found annoying than those that had been so thoroughly routinized that they had faded into the background. Respondents, like other people, are affected by the availability bias (Tversky and Kahneman 1974, Heimer 1988) — they remember what is vivid and exciting rather than what is dull, ordinary, and mundane. To be sure, even though they are not representative, the dramatic moments can be important in defining and transmitting key values. But the mundane, which is often of special interest to sociologists, can be hard to recover and hard to place in the proper context without observation to complement material uncovered in interviews. This difficulty in retrieving the mundane through interviews makes fieldwork observation an absolutely essential complement to interviews.

It is not just the mundane that is hard to recover, though. Access to an organization does not automatically give an ethnographer access to organizational secrets or the dark corners of the backstage. Although both individuals and organizations have secrets and backstage areas (as described in Chapter 7), organizational secrets may be more elaborately and (sometimes) more formally classified by levels of confidentiality. Moreover, the resources of the organization can be brought to bear on the production of such classification systems, on enforcement of silence, and on the punishment of breaches. During my time in HIV clinics, I regularly heard staff members strategize about what information to share with outsiders and how to present it. I observed preparations for monitors and site visitors, including relocation of files and other

artifacts, with problematic objects moved to the deeper recesses of the backstage and more conforming artifacts (such as groomed files) placed where they would be readily available for inspection (Chapter 7; Heimer and Gazley 2012).

These three core types of barriers make observation and interviewing difficult. The first of these, institutionalized spatial, temporal, and moral boundaries, such as norms about access to clinic patients and research subjects, are especially likely to govern access to particular spaces and people and to prohibit access when the presence of an outsider would seem morally (or legally) inappropriate. Organizationally or occupationally based patterns of work shape how participants understand ethnographers' requests to observe and may create a second type of barrier. In some organizations, watching someone else work seems quite normal; in others, watching another person work can seem almost voyeuristic. Interestingly, the first and second barriers have different effects. Although observing interactions with patients may be morally laden (because of rules about confidentiality, for instance), it falls comfortably in the range of "normal" activities because students and other trainees often sit in on such encounters. Finally, cognitive impediments can make observation and discussion difficult either because work is "interior," carried out mostly in silence and often with no visible trace (short of an MRI) of what is going on in the worker's mind, or because it has become unavailable to workers themselves by dint of routinization. However desirable it may be for clinic staff to become so accustomed to rules and regulations that they become "routine," that fading into the background does complicate the work of researchers.

At first blush these factors that shape what ethnographers can learn through observation and interviewing appear to be individual level phenomena. After all, the availability effect is a well-known cognitive bias, for instance. In fact, though, they tell us much about clinics, clinic work, and the challenges of studying them ethnographically. In the case of the availability

effect, for instance, it is the processes of routinization in organizations that make some activities (transferring information from a medical record to a case report form) thoroughly automatic and mundane — just a boring matter of filling in some blanks — while other activities (deciding whether something is a serious adverse event) require considerably more deliberation. Likewise, which matters are brought to meetings for discussion, which topics warrant hallway discussions with colleagues, and which actions require formal consultation with colleagues or superiors depend on how things are arranged in a particular organization. And which staff members are considered too important, too insignificant, or just the right candidates to spend time with or babysit the nosey ethnographer also tells us much about who matters in the organization.

VIII. Participating in Clinic Life:

Giving Back and Going Native

Ethnographers inevitably must find some a role for themselves that works for both them and those they are observing. Often in organizations these entails conflating their requests to observe with other common practices of the site. In clinics that engage in research and training, an ethnographer can often can join the group of trainees; when the entire staff attends a continuing education presentation, the extra body of the ethnographer has no discernable effect on the event. Yet this tagging along may create fresh challenges. In the normal course of events, shadowing easily flows into participating for those who are medically trained, and even for ethnographers, who may receive requests for help when their growing knowledge of the local scene and mastery of specialized language occasionally mislead people about the nature and extent of their expertise. Under these circumstances, increased pressures to “give back” can

create ties and loyalties that may shape what researchers are able to see in both advantageous and disadvantageous ways.

All ethnographers will feel some pressure to be friendly and accommodating — that is, after all, part and parcel of the process of developing rapport. And, depending on the circumstance, ethnographers might be asked to give back materially, for instance by making cash donations to needy individuals or local causes.[10] In the clinics I studied, staff members would occasionally be invited to contribute funds to support clinic work. In Uganda or South Africa, staff members might pass the hat to raise funds for the families of particularly needy clinic patients; in the U.S., staff members might be reminded that high participation rates made the clinic look good in a general fund raising campaign. In both of these scenarios, my participation signaled general support for clinic activities, though it did not directly help any of the people I was studying. Rather than contributing *to* the group (or to individuals) I was studying, I contributed *alongside* other members of the group. The contribution marked me as similar to my research subjects rather than as having deeper pockets or other kinds of privilege.

Organizational ethnographers are often asked to give back to individuals as members of the organization, rather than as private persons, or to the organization itself. They may be asked to pitch in on some task, and this may alter what they are able to do and see. Bosk (1985), for instance, noted that he was episodically asked to modify his usual research practices, for instance to refrain from taking notes when he was needed as a legal witness. Ethnographers may also be asked to offer advice, assess a document, or make an introduction. In the clinics I studied, clinic staff occasionally solicited my views on organizational design, research strategy, research ethics, and the social worlds of their patients. As my time in the field drew to a close, some clinics also requested a presentation about my initial findings, premature though that seemed to me, but neither pressured nor advised me about what my presentation should contain.

Do these exchanges affect what can be seen—either by modifying the observer's capacity to see or by altering the behavior of people in the fieldsite? Given the size and complexity of organizations such as clinics, the effects of exchanges are likely to be limited. Even if relationships with a few research subjects are modified by these exchanges, many more will remain unaffected, particularly when relationships are conceived as "professional" or work-related rather than as more fully rounded friendships. Yet the effects of these explicit requests may well be easier to track than the more subtle shifts of loyalty that occur over long periods as one becomes familiar with a site and comes to feel that one is part of the team. Elliott, for instance, suggests that as bioethicists become part of the medical bureaucracy, "it is reasonable to assume that the duties, allegiances, and professional identities of bioethicists will be shaped by the institutions in which they are employed" (2005, 381). Although there is no reason to expect that ethnographers would be immune to such shifts of loyalty, in important ways I, like other ethnographers, remained outside the clinics I studied. We generally are employed elsewhere, split our time between the sites we study and the places we work, and usually exit the fieldsite completely at some point. These and other factors tend to facilitate the distance that is essential for writing up the fieldwork in an objective or even critical way.

IX. Engaging with Documents and Paperwork

Much of what goes on in organizations involves documents – organization charts, mission statements, brochures, annual reports, budgets, time sheets, expense forms, standard operating procedures and other written policies, grade sheets, requisitions, inventories, announcements, calendars, and so on. Documents and other organizational artifacts are important resources for ethnographers in managing the practical problems of studying social

configurations larger than small groups (Brown-Saracino, Thurk, and Fine 2008). Organizational documents can give researchers crucial information about people's responsibilities and relations to one another, the constraints under which people work, and the culture of the organization. Yet, as many ethnographers know, organizational documents are anything but transparent (Riles 2006; Hull 2012). Scholars need to look *at* as well as *through* documents, historian Ben Kafka suggests in reviewing the recent work on the history of paperwork (2009, 341).

Since Weber's (1968, chapter 11; see especially 957) foundational work on bureaucracy, documents have been understood as tools to exert control and to coordinate activity. Crucial as they are in getting work done, documents are equally important in bringing organizations and other entities into existence (e.g., in articles of incorporation) and helping to form their special character (e.g., in vision statements and orientation materials). Documents also play a role in distinguishing among entities (e.g., in systems of classification) and specifying appropriate relations among them (e.g., in employee handbooks and standard operating procedures).

For the purposes of organizational ethnographers, documents are especially important because of what they can tell us about supra-individual matters. They may, for instance, help ethnographers understand how organizations see themselves and represent themselves to insiders and to outside audiences, a point well illustrated by Strathern's (2006) examination of university mission statements. Yet in Kunda's (1992) analysis of the texts and recordings of an engineering company, even when organizational texts are broadly consistent, organizational ideology is not adopted fully or uncritically by organization members. Moreover, internal conversations can diverge quite sharply from statements for public consumption. Even when few people believe the ostensible message of a document, a "fantasy document" may nevertheless enable an organization to move on with its work (Clarke 1999). Because texts cannot be taken at face

value, researchers need to consider not only how, by whom, and with what purpose organizational texts are produced but also who they are intended for, how they are disseminated or concealed, and how they are received and used. In short, organizations' texts and artifacts need to be analyzed as cultural products (Griswold 1987).

Documents created for one use are also often redeployed for other purposes, sometimes even in other organizations. Pressure to modify documentary practices continues unabated, as does resistance to that pressure. Administrators urge physicians to write fuller records to support claims that encounters are "complex" and should be billed accordingly (a point discussed at several points in the body of the book); medical professionals debate over enlarging the group permitted to write in medical records and what restrictions should be put on those entries.[11] Staff members are Fully aware that medical records are available to patients, their families, and lawyers, staff members worry about what these outsiders will glean from medical records and adapt their inscriptions accordingly (Heimer and Staffen 1998). Medical records have thus evolved from a physician's personal record (Timmermans and Berg 2003) into institutional boundary objects (Bowker and Star 1999) used for tracking what has been done, deciding what to do next, communicating with other staff members, training students, supporting the submission of bills to insurers and other payers, and a host of other medical and administrative functions. As documents are redeployed and move from one department or organization to another, labels, tables of contents, tracking sheets file folders, and binders get added to categorize documents, track their flow, guide transformations of data, and ensure that data and documents are used in permissible ways by authorized staff members.[12] Paperwork begets paperwork.

Perhaps more surprising is the seamless mixing of instrumental and symbolic uses of official documents. The very documents that play a role in coordination and control also support

individual and collective status and identity claims. The right to participate in preparing important documents supports workers' claims about their standing in the workgroup. For instance, it was a coup for nutritionists when they received permission to add their notes to the medical records in one of the neonatal intensive care units (NICU) I studied (Heimer and Staffen 1998). Likewise, having a reputation for good documentation was important to the status of both the clinics I studied and individuals who worked in them (Heimer and Gazley 2012). Ambivalent as they were about research monitors, HIV clinic research nurses were nevertheless proud to be praised for meticulous record keeping. The regulatory affairs specialists of clinics proudly showed me their elaborate and meticulously maintained records and filing systems. Although some documents were lightly modified versions of widely used templates, others were thorough revisions of imported templates or completely original local creations. The Ugandan clinic SOPs, for instance, covered all of the topics mandated by the U.S. National Institutes of Health, but had been carefully adjusted for local conditions. And one South African nurse had a well-deserved reputation as the go-to person when a new form needed to be designed.

Finally, beyond looking at overt messages, ethnographers must attentive to the pattern of silences and lapses in documents (Espeland 1993, 315). All this suggests that organizational records, those "most despised of all ethnographic subjects" (Latour 1990, 54), lead a far more complex life than many ethnographers have imagined. Documents and paperwork are one of the means by which organizations "live." In a deep sense, organizations do not simply *have* documents; rather, organizations are constituted through the interaction of documents and people. Getting to know an organization thus inevitably means getting to know its documents. Documents and paperwork cannot be treated as disembodied artifacts or transparent collective representations, but instead need to be examined carefully to discern how people make, use, and live with texts (Smith 1984). The clinics where I did my research produced endless documents,

with most staff members involved in one way or another in document production and some whose whole worklives were devoted to producing, compiling, disseminating, and storing documents. Yet the clinics' relations to these documents was anything but simple. Some documents were taken seriously and treated reverently, at least by some people; others were regarded as purely symbolic. Not surprisingly, the role of documents could change quickly as they crossed organizational boundaries for regulatory encounters, for training people in other locations, or for governing "down referrals" from one clinic to another. Also not surprisingly, the seriousness or levity with which documents were treated varied from one individual to another, posing a challenge for an ethnographer negotiating the signing of consent forms at the start of an interview.

But where does that leave people doing research in and on organizations? Briefly, it leaves them with the obligation to ask a long series of questions that will enable them to read organizational documents and paperwork more critically in order to discern what they mean, what they are meant to do and to convey, to and by whom. In a sense, then, documents are to organizational ethnographers what the blinks, winks, and fake winks discussed by Geertz (1973) are to anthropologists. Rather than providing quick and definitive answers about the life of the clinic, then, documents and paperwork provide hints about where to look and what to think about. Among other things, they should be understood as mediating the relationships among individuals and thereby helping to constitute the organization. In effect, documents and paperwork have to be treated more as enticing clues in the long treasure hunt of organizational ethnography rather than as the ultimate prize.

X. Conclusion:

The Challenges of Clinic Ethnographies

Because ethnographers studying organizations like clinics do their work mainly by forming relationships with people at all levels of the organization (Heimer 2019), they must necessarily cede some control; the organization and its activities shape the aspects of organizational life that a researcher is able to study. For this reason, as I argued at the outset, the lives of research projects, like the lives of individuals and organizations, are likely to be "composed" of available elements rather than to closely adhere to a pre-existing plan. This gap between plan and execution has been noted by others. Grounded theory (Glaser and Strauss 1967) and the extended case method (Burawoy 1998), common touchstones for ethnographers, Zussman argued, are "honored more in citations than in practice" (2004, 356). What we have failed to see clearly, though, is that although our attempts to plan are sometimes thwarted by research bureaucracies (including IRBs) and the like, they are at least as often thwarted by the necessity of coordinating with and adjusting to the schedules, needs, and plans of others and taking advantage of the serendipities of field work. We have often seen this gap between plan and execution as a failure rather than as part and parcel of the process of doing fieldwork.

I looked at how ethnographic work unfolds and, in particular, how it unfolds when conducted in clinics. I looked first at the early tasks — undergoing ethics review and gaining access — that set the stage for a project and then turned to the realities of data collection in clinics. For each of these stages and research activities, I noted the successive constraints and challenges that are introduced as projects unfold and the points at which projects can go off the rails as ethnographers attempt to form relationships with organizations and the people in them. In my own project, for instance, my early (mis)understanding of what a clinic is and who,

therefore, can grant research access nearly cost me access to a very valuable site when I formed ties more selectively than was appropriate given the bifurcated research-and-treatment structure of the organization.

The impediments I considered arise in three quite different ways. First, regulatory regimes, some internal, others external, may erect barriers to prevent unauthorized research or to place some people, activities, topics, or documents off limits. Second, social arrangements and physical barriers may be put in place to protect the integrity of work, work time, workspace and work materials, and to prevent others from intruding on organizational routines. Finally, inherent properties of social life can make some activities difficult to observe and some topics difficult to discuss, whether one is a researcher, a fellow worker, or a supervisor. Some of these barriers have been put in place with the express purpose of excluding research that has not been appropriately reviewed (by an ethics panel or organizational representative), but others are simply "naturally occurring" features of the organizations and activities in organizations, not specifically intended to make fieldwork or other kinds of research difficult. Overcoming them may nevertheless impose extra costs on both sociological researchers and their research subjects and so may decrease access.

But what about the specific challenges of clinics as locus and object of study? Knowing a clinic and its staff depends primarily, I suggest (Heimer 2019), on an especially intensive construction of relationships that together permit a thoroughly layered understanding — each set of primary observations supplemented and interwoven with secondary observations that allow a researcher to see the relationships among people, the structure of positions, the historical evolution of work, the construction and maintenance of crucial ties across organizational boundaries, the evolving and varied understandings of the organization's policies, practices, and culture. Yes an organization is more than the sum of its parts, but ethnographers nevertheless

access the parts, the something more, and the constructive process through relationships with the people who inhabit the organization, remaining continually sensitive to how those relationships are mediated by organizational structures, formal policies, norms, and culture. Once they have secured the raw materials for their analyses, ethnographers must indeed do the sifting, sorting, juxtaposing, abstracting, and reordering that allows ethnographers to learn things that people in the organization may not know about themselves and their organization, and may even be chagrined to learn. But in that process, researchers need to be clear-eyed about the subtle and not-so-subtle pressures that shape their access to organizations, the relationships they are able to form, and their understandings of what they are seeing.

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Appendix B

Timeline of HIV/AIDS Disease and Responses

(including key events for the five HIV clinics discussed in this book)

1959

- Léopoldville, Belgian Congo (later renamed Kinshasa, Democratic Republic of Congo), identified by team of scientists in 1998. Other early case definitively identified as HIV include a 1960 frozen sample from a Congolese woman, 1973 frozen samples from 50 Ugandan children, 1975-76 infection of a Norwegian sailor subsequently transmitted to his wife and child.

Late 1970s

- Cases of an unidentified illness begin to occur among gay men in New York and San Francisco. The disease is believed to have spread from central Africa (perhaps DRC) to Haiti around 1967, to have arrived in New York from Haiti around 1971, and to have moved from New York to San Francisco. Some evidence suggests that HIV had also been taking hold among IV drug users and homeless populations, who were reluctant to seek medical care and whose illnesses and deaths were not investigated.

1981

- First official report of what will later be referred to as AIDS when U.S. CDC article in *Morbidity and Mortality weekly Report* (MMWR) notes unusual occurrences of PCP

(Pneumocystis Carinii Pneumonia, subsequently renamed Pneumocystis Jiroveci Pneumonia), an opportunistic infection later understood to be common among people with HIV. CDC publishes several follow-up articles on elevated rates of PCP, Kaposi's Sarcoma (KS), and persistent lymphadenopathy (swollen lymph nodes common among people with weakened immune systems) among young gay men. Articles appear in popular press discussing the MMWR reports.

- The U.S. CDC forms the Task force on Kaposi's Sarcoma and Opportunistic Infection that year.
- National Cancer Institute and U.S. CDC co-sponsor first conference on new (AIDS) epidemic.
- Severe immune deficiency and opportunistic infections observed in five infants in New York, at least some of whom are children of women who use drugs and/or engage in sex work. Diagnoses dismissed by medical colleagues.
- Bobbi Campbell becomes the first person to openly acknowledge his AIDS diagnosis. Campbell, a gay activist and nurse, was often referred to as the "AIDS Poster Boy."

1982

- Gay Men's Health Crisis (GMHC), first community-based AIDS service provider, is founded in New York.
- Kaposi's Sarcoma Research and Education Foundation, later renamed the San Francisco AIDS Foundation, is founded in San Francisco.
- U.S. CDC reports (in *MMWR*) on observations of immunosuppression in people with hemophilia.

- The name AIDS (Acquired Immune Deficiency Syndrome) is proposed at a meeting of gay-community leaders and U.S. federal government officials including members of the CDC, as a replacement for GRID (Gay-Related Immune Deficiency), a term introduced by the New York Times earlier in 1982. At the time, nearly half of the people identified as having the disease were not gay men. This alternative nomenclature is later formalized by the CDC and used in *MMWR*, where a first case definition is also provided.
- CDC issues first precautions for clinical and laboratory staff working with people with AIDS. In subsequent years, these are followed by other precautions, culminating in 1987 in a recommendation that all healthcare workers practice Universal Precautions. These precautions ultimately become the standard of practice in healthcare settings worldwide.
- South Africa's first AIDS case reported.
- Uganda's first AIDS cases reported.

1983

- First dedicated outpatient AIDS clinic in the world, Ward 86, opens at San Francisco General Hospital. Staff (with contributions from Bobbi Campbell) develop the San Francisco Model of Care, which becomes the gold standard for HIV patient care and is credited as a forerunner of the Ryan White HIV/AIDS Program.
- CDC reports first AIDS cases in women.
- Kaposi's Sarcoma Foundation sponsors first AIDS Candlelight Vigils in New York and San Francisco — first time people living with AIDS gather for public demonstration.
- U.S. Congress passes first bill providing funding for AIDS research and treatment.

- French researchers Françoise Barré-Sinoussi and Luc Montagnier at the Pasteur Institute isolate a retrovirus in several gay men and people with hemophilia that could be the cause of AIDS. In 2008, they are awarded the Nobel Prize in Medicine for this work.
- The Denver Principles, a key document of the PWA (People with AIDS) self-empowerment movement, outlines the right and responsibilities of healthcare professionals, people with AIDS (not "AIDS *victims*"*)*, and all people concerned with the epidemic. Bobbi Campbell was among the dozen or so gay men with HIV who drafted this manifesto.
- First dedicated in-patient AIDS ward in the U.S., Ward 5B, opens at San Francisco General Hospital.
- CDC rules out transmission by casual contact, food, water, air, etc.
- First AIDS discrimination law suit filed by NY Attorney General and Lambda Legal Defense and Education Fund when physician Joseph Sonnabend is threatened with eviction from office building for treating people living with AIDS.

1984

- First case of HIV reported in Thailand. Thai HIV infections were initially concentrated among intravenous drug users before spreading to female sex workers and then to the rest of the population.
- The cause of AIDS is identified as a retrovirus later named HIV, when U.S. Health and Human Services Secretary Margaret Heckler announces that Robert Gallo and colleagues at National Cancer Institute have identified a retrovirus that is the cause of AIDS. Gallo is not included when French HIV researchers receive Nobel Prize in 2008.

- San Francisco public health officials close bathhouses to reduce the spread of AIDS.

1985

- U.S. FDA grants a license to Abbott Laboratories for an HIV antibody test. The test, which can be used both to test individuals and blood samples, effectively eliminates the risk of infection via medical blood transfusion. Because of concerns about privacy and discrimination and uncertainty about what the test means, many people are reluctant to test.
- First meeting of the International AIDS Conference in Atlanta, organized by U.S. CDC, the WHO, and Emory University.
- Indiana teen Ryan White, who contracted HIV through blood products used to treat his hemophilia, is refused entry to middle school, setting off a protracted legal battle.
- Pasteur Institute files suit against U.S. Government asking for recognition that French researchers were discoverers of virus that causes AIDS and addressing rights to profits from the resulting blood tests.
- U.S. CDC publishes article first recommendations on preventing mother-to-child transmission of HIV. The recommendations include delaying pregnancy until more is known about transmission risk and avoiding breastfeeding.

1986

- Creation of U.S. Division of AIDS as a branch of the NIH's National Institute of Allergies and Infectious Diseases.

- Bobbi Campbell Clinic (pseudonym) founded in the U.S. to care for HIV patients and conduct clinical research.
- HIV receives its name when the International Committee on Taxonomy of Viruses announces that the virus that causes AIDS will be known as the "Human Immunodeficiency Virus."
- U.S. CDC report show that HIV is disproportionately affecting minority populations, with African Americans and Latino infants being disproportionately likely to be infected perinatally.

1987

- World Health Organization creates Special Programme on AIDS, the predecessor to the Global Programme on AIDS.
- ACT UP (AIDS Coalition to Unleash Power), an international, grassroots political group working to end the AIDS pandemic, is founded in New York. ACT UP stages first protest on Wall St.
- AZT (azidothymidine, also called zidovudine or ZDV, brand name Retrovir) becomes the first drug approved by the U.S. FDA for treatment of HIV.
- FDA issues regulations expanding access to promising medications that have not been approved or licensed. Other antiretrovirals are approved in subsequent years.
- U.S. President Reagan and French Prime Minister Chirac end dispute, agreeing that the two countries' researchers will share credit for the discovery of the AIDS virus and that patent rights will also be shared.

- U.S. Public Health Service adds HIV to list of "dangerous contagious diseases" that merit immigration exclusion and mandates HIV testing of all visa applicants. Ban lifted only in 2010.
- U.S. President Ronald Reagan makes his first public speech on HIV and signs Executive Order creating the Presidential Commission on AIDS. By that time, over 20,000 Americans had died of the disease.
- U.S. CDC publishes "Recommendations for Prevention of HIV Transmission in Health-Care Settings," specifying precautions for the handling of blood and other bodily fluids, regardless of infection status.
- During the National March on Washington for Lesbian and Gay Rights, activists display the AIDS Memorial Quilt (conceived by AIDS activist Cleve Jones) on the National Mall. By that time, the quilt already covered more space than a football field and included 1,920 coffin-sized panels. Currently, the Quilt includes nearly 50,000 panels, each representing an individual or individuals who died of HIV/AIDS. In 2022, the National AIDS Memorial marked the 35th anniversary of the AIDS Memorial Quilt by displaying 3000 panels of the Quilt in Golden Gate Park. The Quilt is warehoused in San Francisco when not on display.
- Demonstrations occur for the first time at the Third International AIDS Conference, held in Washington, D.C.
- Dr. Peter Duesberg publishes an article in *Cancer Research* challenging the consensus that HIV causes AIDS, fueling subsequent AIDS denialism, including in South Africa during Mbeki's presidency.

- Cha-on Suesum diagnosed with HIV and fired from his job as factory guard in Thailand, subsequently agreeing to have his case publicized and accepting work as AIDS educator for Population and Community Development Association.
- The AIDS Support Organization (TASO) is founded in Uganda.
- South Africa's apartheid government adds AIDS to its official list of communicable diseases, granting state authorities the power to quarantine people suspected to be HIV-positive. That same year, a law introduced by the Minister of Home Affairs declares individuals with AIDS to be "prohibited person[s]."

1988

- ACT UP sit in at FDA to protest slow pace of federal drug approvals for HIV/AIDS treatments.
- Elizabeth Glaser creates the Pediatric AIDS Foundation (later renamed the Elizabeth Glazer Pediatric AIDS Foundation) to fund research on treatments for children with HIV and to help create protocols to prevent mother-to-child transmission.
- The first World AIDS Day, December 1st.
- Robert Rafsky Clinic (pseudonym) founded in the U.S. and begins conducting HIV research and providing treatment.
- Philly Lutaaya Clinic (pseudonym) founded in Uganda and begins work as an HIV research consortium, later adding more treatment programs.

1989

- Ratchaburi province in Thailand initiates its "100% Condom Programme," mandating that sex workers use condoms in every sex act.
- Reported U.S. AIDS cases reach 100,000.
- Philly Lutaaya announces his HIV status at Kampala Sheraton Hotel, becoming first prominent Ugandan to acknowledge having HIV. He spent last months of his life writing and performing songs about HIV and speaking in Ugandan schools, churches and mosques. His song "Alone" became the anthem of TASO, a Uganda AIDS support group.
- Wednesday Friends Club, a support group for people living with HIV, formed in Thailand.

Early 1990s

- AIDS incidence reaches its peak in the US, followed by sharp declines in 1996.

1990s

- Rapid increase in HIV prevalence across sub-Saharan Africa.

1990

- U.S. Congress passes the Ryan White Care Act, providing funding for (some) AIDS care in U.S. Program continuously funded since that time.
- AIDS Information Centre, an NGO, founded in Uganda to provide HIV counseling and testing services throughout the country.

1991

- Visual AIDS Artists Caucus launces Red Ribbon Project, creating what became the international symbol of AIDS awareness.
- AIDS Access Foundation founded by former member of Thai Senate. AIDS Access Foundation later works with other organizations to secure access for treatment, including through compulsory licensing.

1992

- Robert Rafsky, media coordinator for ACT UP, confronts U.S. presidential candidate Bill Clinton ("I'm dying from AIDS, while you're dying of ambition") and challenges him to define his proposed AIDS agenda.
- In response to pressure from activists (notably, ACT UP and GMHC), the U.S. FDA introduces its "accelerated approval"/interim licensing program, a modification of standard procedures to hasten drug-approval processes and facilitate "compassionate use" of drugs not yet approved by the FDA.

1993

- U.S. CDC expands case definition of AIDS classifying people with CD4 counts below 200 as having AIDS. CDC also adds 3 new conditions (pulmonary TB, recurrent pneumonia, and invasive cervical cancer) to list of clinical indicators of AIDS. Adding these conditions means that more IV drug users and women are diagnosed with AIDS.

1994

- U.S. Public Health Service recommends that pregnant women receive AZT to reduce the risk of maternal-child transmission of HIV.

1995

- 500,000 cases of AIDS have been reported in U.S. Worldwide new HIV infections reach their historic peak, with 3.2 million new infections per year.
- The TRIPS agreement comes into effect, threatening access to patented medicines in poor countries and limiting the capacity of middle-income countries to create pharmaceuticals for domestic consumption and exportation.
- TNP+, the Thai Network of People Living with HIV/AIDS is formed. TNP+ has been important in advocating for access to HIV treatment, including lobbying for compulsory licenses

Middle 1990s

- HIV prevalence reaches its peak in Thailand, before rapidly declining shortly thereafter.

1996

- Cha-on Suesum Clinic (pseudonym) founded in Thailand as an international research consortium and begins enrolling patients in studies, later adding additional treatment components.
- Gugu Dlamini Clinic (pseudonym) founded in South Africa and begins providing care for HIV patients, later adding a research component.

- At 11th International AIDS Conference in Vancouver, researcher announce research results that patients treated simultaneously treated with three or more antiretroviral medications with different modes of action achieve long-lasting reductions in viral load. This announcement brings advent of effective treatment for HIV (variously referred to as triple therapy, drug cocktail, HAART, and eventually simply ART). North American medical facilities swiftly adopted the new treatment strategy.
- UNAIDS (the Joint United Nations Programme on HIV/AIDS) begins operations.

1997

- U.S. CDC announces first substantial decline in AIDS deaths in U.S. Attributed largely to antiretroviral therapy (ART or HAART). AIDS deaths in U.S. deaths declined by 47% compared with previous year.
- U.S. FDA approves first fixed-dose combination. With two drugs in a single tablet, Combivir reduces the pill burden for people living with HIV.

1998

- U.S. CDC reports that African American death rates from AIDS are ten times those of whites and three times those of Latinos. Congressional Black Caucus leads initiative to provide funds (Minority AIDS Initiative) to improve prevention and treatment of HIV in African American, Hispanic, and other minority communities.
- U.S. CDC releases first national treatment guidelines for ART in adults and adolescents
- U.S. Supreme Court rules that Americans with Disabilities Act (ADA covers people in earlier stages of HIV, not just those with AIDS.

- Gugu Dlamini, South African HIV activist, discloses her HIV status on radio program and in stadium and is then brutally murdered near her home. Founding of Treatment Action Campaign (TAC) in South Africa and creation of HIV positive T-shirt, important symbol of solidarity around HIV, both were direct responses to her murder.

1999

- Thabo Mbeki inaugurated as President of South Africa. Mbeki's AIDS denialism and sparing budget for HIV-related issues considerably exacerbated the HIV/AIDS crisis in South Africa. Mbeki's presidency ended in 2008.
- WHO announces that HIV/AIDS has become the number 4 cause of death globally and the number 1 cause in Africa. WHO estimates that 33 million adults and children are living with HIV around the world, with 14 million having died of AIDS.

2000

- UNAIDS, WHO, and other groups announce a joint initiative with drug manufacturers to negotiate reduced prices for HIV/AIDS drugs for poorer countries.
- UN adopts the Millennium Development Goals, including a goal of reversing the spread of HIV/AIDS, malaria, and TB.

2001

- Thailand introduces GPO-VIR, its generic fixed-dose combination, costing US $1 per day, and begins scale-up of ART.

- Thailand introduces its Universal Coverage Scheme ("30 Baht Scheme") making healthcare financially accessible. Universal access to antiretrovirals was introduced in 2003.
- WTO adopts the Doha Declaration, clarifying the flexibility of TRIPS and the importance of patient access to life-saving medicines.
- UN General Assembly hold its first Special Session on AIDS.
- Pharmaceutical companies drop their case against the South African government, conceding that the South African law allowing the government to purchase brand-name drugs at the lowest rates available anywhere in the world complies with international trade agreements. This outcome is huge symbolic victory, though AIDS drugs still remain unaffordable for most AIDS patients.
- Right to Care, a healthcare NGO created in response to HIV/AIDS emergency in South Africa, becomes an early provider of treatment to public patients in South Africa.

2002

- Thai patients successfully challenge Bristol-Myers Squibb (BMS) patent on antiretroviral drug. This is first case in which plaintiffs in pharmaceutical patent case are individuals rather than another company.
- South African Constitutional Court, following a legal case brought by TAC and other organizations, orders South African government to make nevirapine, an antiretroviral, available to all pregnant women in state hospitals and clinics in order to reduce mother-to-child transmission.

- Global Fund to Fight AIDS, Tuberculosis, and Malaria (generally referred to simply as Global Fund) is created as partnership between governments, civil society organizations, private sector, and affected communities. A few months later, Global Fund approves a first round of grants to governments and private-sector organizations in developing countries.
- UNAIDS reports that average life expectancy in sub-Saharan Africa has dropped from 62 years to 47 years because of HIV/AIDS.
- U.S. FDA approves first rapid HIV diagnostic test kit.

2003

- U.S. President George W. Bush announces the President's Emergency Plan for AIDS Relief (PEPFAR) providing funding for AIDS care in other countries. Funds are authorized the following year. Program funding continuously funded since that time, despite controversy over requirements for abstinence only programs, anti-prostitution pledge, and guarantees that funds to not support abortions. PEPFAR is later credited with saving millions of lives.
- Clinton Foundation secures price reductions for HIV/AIDS drugs from generic drug manufacturers on behalf of developing countries.
- WHO announces the 3 by 5 Initiative, an effort to provide antiretroviral treatment to 3 million people living with HIV/AIDS by 2005.

2004

- Worldwide HIV deaths reach their historic peak, with 2.0 million deaths per year.

- U.S. FDA issues guidance for approval of low-cost co-packaged and fixed-dose combination HIV therapies to improve drug access in poorer countries through PEPFAR. Tentative approval of first generic, co-packaged ART regimen for PEPFAR use is granted in early 2005.
- Thai researchers publish an article in the New England Journal of Medicine, demonstrating that "dual antiretroviral prophylaxis" outperforms single-drug approaches for preventing mother-to-child transmission of HIV. WHO guidelines quickly update to reflect this finding. South African guidelines not updated until January 2008.
- South Africa government begins rollout of antiretrovirals in the public health system
- Uganda begins an antiretroviral rollout, initially targeted at severely immune compromised patients, with PEPFAR support

2005

- UNAIDS and other groups announce that efforts to increase availability of ART in developing countries has resulted in 700,000 people being reached by end of 2004. (3 by 5 goal was 3 million on ART by 2005.)

2006

- U.S. CDC announces revised testing recommendations for healthcare settings, urging routine testing for all people aged 13-64, and yearly screening for people at high risk.
- Study results indicate that circumcision reduces men's risk of acquiring HIV during heterosexual intercourse by 53%.

2006-07

- Thai Ministry of Public Health issues compulsory licenses for two HIV medicines, whose patents were held by Merck and Abbott.

2007

- Doctors in KwaZulu-Natal urge their provincial health department to allow them to use the superior two-drug regiment for preventing mother-to-child HIV transmission, as per the 2004 findings. Provincial officials denied the request, leading to further conflict between doctors and the KZN Department of Health.
- WHO and UNAIDS issue new recommendation for provider initiated HIV testing (PICT, or RCT, routine counseling and testing) in healthcare settings.

2008

- South Africa updates guidelines for prevention of mother-to-child transmission.
- WHO issues the Kampala Declaration to curb brain drain of medical professionals from poorer countries to richer ones.
- U.S. CDC releases new estimates of HIV incidence that are much higher than previous estimates as result of more accurate methods of estimating new infections. The new estimate is 56,300 new infections per year, as compared to previous estimate of 40,000 per year.

2009

- Report by District of Columbia Health Department shows that Washington, D.C. has higher rate of HIV (3% prevalence) than West Africa, essentially a "severe, generalized epidemic."
- U.S. Department of Veterans Affairs drops requirement for written consent for HIV test (oral consent still required) to increase rate of testing.
- U.S. FDA approves 100th antiretroviral drug.
- U.S. ban on funding for needle exchange programs partially lifted.
- Uganda company, Quality Chemicals Limited (QCIL) begins manufacturing antiretrovirals.

2010

- U.S. lifts travel ban on HIV infected individuals making possible the return of International AIDS Conference to U.S. (in 2012) after hiatus of more than 20 years.
- South African study of antiretroviral-based vaginal microbicides shows that they are safe and reduce risk of HIV infection in women.
- U.S. NIH releases study results showing that risk of infection in HIV negative men who have sex with men can be reduced by taking daily dose of antiretrovirals. These results support concept of pre-exposure prophylaxis (PrEP).
- Universal Access Report of WHO, UNAIDS, and other organizations estimates that 1.2 million people started ART that year, largest annual increase to date. By now, 5.25 million people are estimated to be receiving ART.

2011

- HPTN 052, the clinical trial demonstrating that antiretroviral drugs can prevent HIV infection ("treatment as prevention") is chosen as 2011 Breakthrough of the Year by *Science*.

2012

- U.S. DHHS issues new HIV treatment guidelines recommending treatment of all HIV infected adults and adolescents as soon as feasible after diagnosis. (Previously recommendations for initiation of ART had been pegged to CD4 count or viral load.)
- U.S. FDA approves first at-home HIV test.
- The International AIDS Conference is held in Washington D.C., its first time in the U.S. since 1990.
- U.S. FDA approves PrEP (pre-exposure prophylaxis) (under brand name Truvada) to prevent HIV infection. U.S. CDC issues guidelines for PrEP in 2014.

2013

- PEPFAR, celebrating its 10th anniversary, announces that as a result of its support more than 1 million babies of HIV infected mothers have been born HIV free.
- UNAIDS announces that new HIV infections have dropped more than 50% in 25 low- and middle-income countries in past two years.

2014

- European researchers announce results of an observational study showing that when HIV positive people were being treated and had undetectable viral loads, none of their sexual partners became infected.

2015

- Shining the spotlight on testing, the U.S. CDC announces that more than 90% of new infections could be prevented by diagnosing people living with HIV and getting them on treatment.
- Cuba becomes the first country to eliminate mother-to-child transmission of both HIV and syphilis, with results certified by WHO.
- Results from decade-long study, HPTN 052, show that ART is highly effective in preventing sexual transmission of HIV from a person living with HIV who is virally suppressed to a heterosexual partner who is not infected, confirming results of smaller observational study.
- WHO announces new treatment guidelines recommending that people diagnosed with HIV begin ART as soon as possible. WHO guidelines also recommend daily oral PrEP for people at substantial risk for HIV infection.
- UNAIDS announces that 15.8 million people are now receiving ART, doubling the number receiving treatment in 2010.

2016

- Thailand becomes second country in the world to eliminate mother-to-child transmission of HIV, with results certified by WHO.
- Researchers report worrying evidence about increasing drug resistance in a study of HIV patients who failed to respond to tenofovir, a key antiretroviral.
- Researchers find preventing HIV infection ("treatment as prevention") requires a different PrEP regimen for women (Truvada daily) than for men (Truvada twice a week).
- After 50 nations blocked participation of groups representing LGBT people, UN 2016 High-Level Meeting on Ending AIDS issues a final resolution that barely mentions men who have sex with men, sex workers, transgender people, and people who inject drugs, the groups most at risk for contracting HIV.

2017

- New York Times reports that gay and bisexual African American men have a higher HIV prevalence rate than that of any nation.
- Taking a public health approach aimed at increasing testing and acknowledging that with treatment people with HIV are very unlikely to transmit the infection, California reduces the penalties for knowingly exposing a sexual partner to HIV or donating blood without disclosing HIV infection.

2018

- Australian researchers announce results of study of population-level effectiveness of PrEP, showing that rollout of PrEP was associated with 25% reduction in new HIV diagnoses.

2019

- Researchers announce second instance of person being cured of HIV (first was in 2007), again following bone marrow transplant from a donor genetically immune to HIV. This finding is regarded mainly as proof that HIV can be cured, but has no practical implications given the cost and risks of the procedure.

2020

- U.S. CDC study shows that HIV-related deaths were cut nearly in half between 2010 and 2017, attributing the reduction to early testing and diagnoses and getting people on treatment earlier.

2021

- FDA approves an injectable, extended release HIV treatment that is administered monthly. An injectable, extended release form of PrEP, to be administered once every two months, is also approved by the FDA.
- Commemorating 40 years into the epidemic, many organizations honor the 38 million people are living with HIV.

2022

- 2022 International AIDS Conference, with its theme of "re-engage and follow the science" emphasizes a key effect of treatment: U=U (undetectable = untransmittable).
- State of the global epidemic at the end of 2022:

  — 39.0 million people living with HIV (peak during current period because of increased longevity of people living with HIV plus new infections)

  — 1.3 million new infections/year (peak 3.2 million in 1995)

  — 630,000 deaths/year (peak 2.0 million in 2004)

Appendix C

List of Acronyms

ABC: Abstinence, Be faithful, use Condoms, a slogan summarizing the HIV prevention program of PEPFAR. Recipients of PEPFAR funds may then sometimes identify one or another specific U.S. government representatives as an "A&B man," that is, a person who advocates only A&B.

ACTG: AIDS Clinical Trials Group, an HIV/AIDS research network funded by the U.S. NIH. At the time of the research for this book, the ACTG had 34 CTUs. Sometimes an additional letter was added at the start of the acronym: AACTG would then identify the Adult AIDS Clinical Trials Group, while PACTG would identify the Pediatric AIDS Clinical Trials Group. Both Robert Rafsky Clinic and Bobbi Campbell Clinic worked with AACTG.

ACT UP: AIDS Coalition to Unleash Power, an influential and creative U.S. activist group formed in 1987, involved in reforming the FDA drug approvals process.

ADAP(s): AIDS Drugs Assistance Program(s) are state level programs funded largely by the federal Ryan White Care Program in the U.S. ADAPs provide HIV-related prescription drugs to low-income people living with HIV/AIDS who have limited or no prescription drug coverage through insurers or other healthcare programs.

AETC: AIDS Education and Training Center(s), the training arm of Ryan White Program, originally founded through U.S. federal funding in 1987.

AIDS: Acquired Immune Deficiency Syndrome; the late stage of infection with HIV virus.

ALP: AIDS Law Project South Africa, a Johannesburg based NGO that has often worked with TAC on key legal cases to improve drug access and force the national and provincial governments to provide HIV-related care. Its broad agenda also includes employment, housing, and other issues.

ART: Antiretroviral therapy became the standard treatment for people with AIDS in 1996 following the announcement of research results demonstrating the effectiveness of this form of treatment. Also sometimes referred to as HAART (highly active antiretroviral therapy), cART (combination antiretroviral therapy). ART uses a cocktail of drugs, carefully selected from different classes so that their varying mechanisms for combatting the virus make viral replication essentially impossible. Initially patients began ART as their CD4 counts dropped and they developed full-blown AIDS. Now the recommendation is to start ART as soon as feasible after HIV infection is confirmed.

ARV: Antiretroviral drugs, used in antiretroviral therapies.

CD4: Cluster of Differentiation 4, a protein identifying the cells targeted by HIV; reduced CD4 levels (may) signal disease progression in HIV/AIDS patients.

CDC: U.S. Centers for Disease Control and Prevention, created in 1946, is the national public health agency of the U.S.

CMS: Center(s) for Medicare and Medicaid Services, oversees the conditions and terms by which other organizations can deem healthcare providers eligible to receive Medicare and Medicaid reimbursements ("deeming authority"). Originally labeled the Health Care Finance Administration (HCFA), it was established as a sub-agency under the Department of Health and Human Services in 1977.

CPG: Clinical Practice Guidelines

CRC: Contract Research Centers provide technical expertise and development support during all phases of development to pharmaceutical, biotechnology, and medical device companies on a contractual basis. Among other things, the earliest phases of clinical trials are often carried out at CRC facilities.

CRFs: Case Report Forms are used in clinical trials to record data from patients' "study visits." Research monitors rely CRFs to assess the quality of clinical trial data, comparing CRFs with source documents, among other things.

CROs: Contract Research Organizations are companies that provides services for clinical trials work in the pharmaceutical, biotechnology, and medical device industries. They might, for instance help with regulatory affairs, clinical trial planning, site selection and initiation, recruitment support, clinical monitoring, data management, trial logistics, biostatistics, medical writing, and project management.

CTU: Clinical Trials Unit, a clinic or a clinic and its subsites, responsible for carrying out the activities of clinical trials on behalf of a research network (such as ACTG). Statistics about performance were calculated for CTUs, which were then compared on a large number of indicators. Periodic "recompetitions" determined which CTUs would continue to be part of a research network. A single research study typically involved numerous CTUs and a particular CTU generally participated in multiple studies.

DAIDS: Division of AIDS, formed in 1986, is a subpart of the National Institute of Allergy and Infectious Diseases (NIAID), within the National Institutes of Health (NIH), within the U.S. Department of Health and Human Services.

DHHS (or sometimes just HHS): U.S. Department of Health and Human Services involved in developing internationally-recognized treatment guidelines, though these guidelines are

typically developed for the U.S. context. Also conducts and funds research, and produces ethical and recording guidelines for clinical research.

Doha Declaration: See TRIPS.

EBM: Evidence-Based Medicine, an ideal of medical practice emphasizing use of clinical trials and the development of general standards.

ECRI: originally the Emergency Care Research Institute and now merely ECRI — a non-profit NGO responsible for hosting treatment guidelines previously hosted by the National Guidelines Clearinghouse.

EGPAF: Elizabeth Glaser Pediatric AIDS Foundation, an internationally active non-profit engaged in research, advocacy, and efforts to prevent and treat childhood AIDS. Sometimes works as an intermediary between PEPFAR and clinics receiving PEPFAR funds.

FDA: U.S. Food and Drug Administration, created in 1906, is the federal agency responsible for assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the country's food supply, cosmetics, and products that emit radiation. Because the U.S. drug market is so big, pharmaceutical manufacturers generally seek FDA approval of new drugs, with the result that FDA rules shape how data are collected and processed during clinical trials.

FDC: Fixed dose combination, a single pill combining several antiretroviral drugs. FDCs dramatically reduce the pill burden for people living with HIV and therefore also improve adherence to drug regimens. GPO-VIR, the drug produced by the Thai government, is an example of an FDC. As of 2023, the U.S. FDA had approved 21 FDCs for use in treating HIV.

FWA: Federalwide Assurance an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research and is required for entities conducting U.S. government funded research in other countries.

GCP: Good Clinical Practice, guidelines and training regimens intended to ensure ethical, scientifically sound research conduct. Good Clinical Practice, which went into effect in 1997, is an international quality standard that speaks to such matters as the rights of human subjects and volunteers in clinical trials, standards on how clinical trials should be conducted. It defines roles and responsibilities of institutional review boards, clinical research investigators, clinical trial sponsors, and monitors. GCP is under the aegis of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), a non-profit legally registered in Switzerland, that brings together regulatory authorities and representatives of pharmaceutical industry to discuss and work out scientific and technical aspects of pharmaceutical development and registration. Individual countries or groups of countries then craft statutes and regulations from the GCP standard.

GFATM: Global Fund for AIDS, Tuberculosis and Malaria, often simply referred to as the Global Fund, is an international NGO, that receives funding from both public and private donors to finance programs developed and implemented by recipient countries. It began operations in 2002.

GMHC: Gay Men's Health Crisis, created in 1982, is a NYC-based NGO that is volunteer-supported and community-based AIDS service organization.

GPO: Thai Government Pharmaceutical Organization, responsible for manufacturing GPO-VIR and other drugs.

GPO-VIR: GPO-VIR is an inexpensive, generic fixed dose combination of the antiretroviral drugs lamivudine (3TC), nevirapine (NVP), and stavudine (d4T) produced by GPO. GPO-VIR became available in 2002.

HAART: Highly Active Antiretroviral Therapy, one of the names used for antiretroviral therapy. As of 2023, ART is the preferred term. See ART.

HCT: HIV Counselling and Testing, testing guidelines instituted by the Ugandan government combining elements of VCT and RCT in clinical settings.

HIPAA: Health Insurance Portability and Accountability Act, U.S. regulations protecting patient privacy. Passed in 1996, the rules on privacy are often a source of confusion for practitioners and patients alike.

HIV: Human Immunodeficiency Virus, the virus that causes AIDS.

HPTN: HIV Prevention Trials Network, an HIV/AIDS research network funded by the U.S. NIH. Philly Lutaaya Clinic in Uganda worked with HPTN.

HVTN: HIV Vaccine Trials Network, an HIV/AIDS research network funded by the U.S. NIH.

IAC: International AIDS Conference. These conferences are sometimes referred to simply as the AIDS Conference or AIDs and the year ("AIDS 2022," for example).

IAS: International AIDS Society, an international professional association (including people living with HIV) that hosts the biannual International AIDS Conference (the 24th IAC was held in 2022), the IAS Conference on HIV Science, and the HIV Research for Prevention Conference.

IAS-USA: International Antiviral Society–USA, publishes frequently-consulted HIV/AIDS treatment guidelines.

IHR: International Health Regulations are intended to prevent the spread of infectious diseases

and manage other global public health threats. They are legally binding on the member states of the World Health Organization. The IHR were first adopted by the World Health Assembly in 1969. The latest revision occurred in 2005.

IMPAACT: International Maternal Pediatric Adolescent AIDS Clinical Trials. The IMPAACT Network resulted from the merger of two predecessor networks: the Pediatric AIDS Clinical Trials Group and the perinatal scientific working group of the HIV Prevention Trials Network. Support and funding for the IMPAACT Network is provided by the National Institute of Allergy and Infectious Diseases and National Institute of Child Health and Development and the National Institute of Mental Health.

IRB: Institutional Review Board: IRBs are administrative body established to protect the rights and welfare of human research subjects who have been recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. They are governed by U.S. federal statute, namely 45 CFR 46 (the "Common Rule"). The Office of Human Research Protections (OHRP) oversees the work of IRBs. In some locations, the bodies conducting ethics reviews are known as Institutional Ethics Committees (IECs).

JCI: Joint Commission International, a branch of the Joint Commission that work similar to that of the Joint Commission beyond the borders of the U.S.

Joint Commission: Founded in 1951 and previously known as JCAHO, the Joint Commission on Accreditation of Healthcare Organizations is a U.S. based NGO that plays a big role in the regulation of American healthcare because it is the main accreditor of U.S. healthcare organizations and programs.

Kaposi's Sarcoma (KS): Kaposi's Sarcoma is a cancer that causes lesions in the soft tissues.

Purple, red, or brown skin blotches are a common sign. It often affects people with immune deficiencies, such as HIV/AIDS. The increased incidence of KS in young gay men drew CDC attention, prompting the creation of the CDC Task Force on Kaposi's Sarcoma and Opportunistic Infections in 1981.

MCC: The Medicines Control Council is South Africa's medicines regulatory authority, responsible for monitoring, evaluation, regulation, investigation, inspection, registration, and control of medicines, scheduled drugs, and so forth. Its responsibilities are outlined in the Medicines and Related Substances Act of 1965.

MoPH: Thai Ministry of Public Health.

MSF: Médecins Sans Frontières, also known as Doctors Without Borders in the U.S., is a non-profit, member-based organization. Founded in Paris in 1971 by a group of journalists and doctors, it provides medical help to people who have been affected by conflict, epidemics, disasters, or by being excluded from healthcare. MSF is composed of 26 member associations (as of 2023), registered in the countries or regions where they operate. MSF has played an important role in providing HIV care, including preparing guidelines for local use, compiling information about drug prices, and sourcing inexpensive drugs.

MTN: Microbicides Trials Network, an HIV/AIDS research network funded by the U.S. NIH. In 2021, MTN was moved under the umbrella of HPTN.

NAPHA: National Access Program for HIV & AIDS (medicine), a Thai governmental program.

NIAID: National Institute of Allergies and Infectious Diseases, a branch of the U.S. NIH.

NGC: National Guidelines Clearinghouse, shuttered in 2018, was a U.S. government entity that hosted up-to-date information on treatment guidelines for physicians.

NIH: National Institutes of Health, the U.S. government agency responsible for medical research. It is part of the U.S. Department of Health and Human Services (DHHS). It began as a one-room laboratory in 1887 and was officially designated by the U.S. Congress in 1930. The NIH is the primary agency of the United States government responsible for biomedical and public health research and one of the main funders of health-related research.

OHRP: Office of Human Research Protections, an office within the U.S. DHHS. See IRB.

PCP: Pneumocystis Jiroveci Pneumonia, previously named Pneumocystis Carinii Pneumonia, an opportunistic infection associated with HIV. Unexpectedly high rates of PCP were one of the first indicators that led the CDC to begin tracking the viral disease that was subsequently labeled HIV/AIDS.

PEPFAR: President's Emergency Plan for AIDS Relief, a U.S. government program created in 2003 during George Bush's Presidency to support HIV-related prevention, care, and treatment in more than 50 countries.

PI: Principal investigator, the lead researcher on a study.

PMTCT: Prevention of Mother-to-Child Transmission, a key type of treatment program used to combat and hopefully end HIV/AIDS.

QA/QC: Quality Assurance/Quality Control programs are widely adopted by healthcare (and other) organization to reduce risk, prevent error, raise the quality of work, and reassure both insiders and outsiders that the organization is paying attention.

RCT: Routine Counseling and Testing, a testing regime in which patients are told that HIV testing is a routine part of medical care and that they will be tested for the virus unless they decline. HIV testing is given on an "opt-out" rather than an "opt-in" basis.

Sometimes called provider initiated testing (PICT). RCT has become standard practice, particularly in healthcare settings, and began to supplant the voluntary counseling and testing regime (VCT) once effective treatment became available.

RCT: Randomized controlled trials (RCT) are prospective studies that measure the effectiveness of a new intervention or treatment. Consider the "gold standard" for assessing the efficacy of interventions, and therefore the preferred kind of evidence in evidence-based medicine. Used both in drug approvals processes and in guideline-writing.

SAE: Serious adverse events are unexpected and untoward medical occurrences in patients or clinical trial subject that must be treated and also tracked to determine whether they have any causal relationship with the treatment or therapy being investigated.

SOP: Standard operating procedure is a set of written instructions that describes the step-by-step process that must be taken to properly perform a routine. Organizations adopt SOPs to routinize their work, for use in training, and to assure outsiders (some of whom may require SOPs as part of a funding arrangement or approvals process) and insiders that they have carefully thought through work processes.

TAC: Treatment Action Campaign, a South African HIV/AIDS activist NGO that combined mobilization, negotiation, and litigation, going to court over drug access and a host of HIV/AIDS treatment programs. TAC was founded in 1998, fifty years after the adoption of the Universal Declaration of Human Rights.

TASO: The AIDS Support Organization, a Ugandan NGO created in 1987 to offer counseling and medical services to people infected or affected by HIV/AIDS.

TB: Tuberculosis, an infectious disease caused by a bacterium. TB is the oldest infectious disease known to affect humans and has been with us since prehistoric times. Although it

mainly affects the lungs, TB can spread to other parts of the body, and can be fatal if it is not treated. Worldwide, over 10 million people are infected with TB annually. Although effective treatment has been available since 1943, drug resistant and multi-drug resistant variants of TB (MDR TB and XDR TB respectively) have developed in recent years. TB is opportunistic infection in HIV/AIDS patients.

TRIPS: The World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights was signed in 1994 and went into effect in 1995. TRIPS establishes minimum standards for national governments' regulation of intellectual property rights. Included among these intellectual property rights are patents on pharmaceutical products, a set of rules that strongly favor the interests of rich countries. TRIPS is important for HIV because of its restrictions on the production and sale of patented medications, including medications used in the treatment of HIV/AIDS. Prior to TRIPS, middle-income countries often produced drugs both for domestic use and for export, undercutting the expensive products of richer country pharmaceuticals. As TRIPS provisions gradually came into force, these same countries were prohibited from producing cheap drugs for sale beyond their borders. These restrictions were eased somewhat in the Doha Declaration on the TRIPS Agreement and Public Health (usually just called the Doha Declaration) adopted in 2001. The Doha Declaration reaffirmed member states' rights to use the legal flexibilities of compulsory licensing (useful for countries that had the capacity to produce pharmaceuticals) and parallel importation (useful for countries that could not themselves produce drugs) to improve access to essential medicines and to circumvent burdensome patent agreements in the case of national emergencies, such as HIV. And of course voluntary licensing (in which patent

holders voluntarily give up exclusive rights during the patent protection period) remained an option.

UNAIDS: Joint United Nations Programme on HIV/AIDS was created in 1994. It brings together 11 UN system organizations to work together on HIV. Headquartered in Geneva, it is the main advocate for accelerated, comprehensive and coordinated global action on the HIV/AIDS pandemic.

VA: U.S. Department of Veterans Affairs, a department of the federal government with responsibility for providing lifelong healthcare services to military veterans at VA medical centers and outpatient clinics.

VCT: Voluntary Counseling and Testing, the original testing regime for HIV that placed heavy emphasis on counseling both before and after testing and careful protection of confidentiality and was often legally mandated. It has now largely been supplanted by routine or provider-initiated testing.

WHO: World Health Organization, founded in 1948, is a specialized agency of the United Nations responsible for international public health. It is headquartered in Geneva.

WMA: The World Medical Association is an international organization, founded in 1947, whose purpose is to represent physicians and ensure their independence. WMA's constituent members are national professional associations (currently numbering 116), with associate memberships available to individual physicians. The WMA has played a pivotal role in discussions about medical ethics, creating the International Code of Medical Ethics (adopted in 1949, last revised in 2022), and the ethics of human subjects research, issuing and revising the Declaration of Helsinki (adopted in 1964, last revised in 2013, but under revision again in 2023).

WTO: World Trade Organization, founded in 1994 at Marrakesh. TRIPS is Annex 1C of the Marrakesh Agreement. See TRIPS.

Endnotes, Appendix A

[1] This appendix is derived, in part, from Carol A. Heimer, "What Is a Clinic: Relationships and the Practice of Organizational Ethnography," *Sociological Methods and Research* 48(4):763-800. 2019. Available online at https://doi.org/10.1177/0049124117746426.

[1] Given our interest in how rules are used, this research project was focused on staff members not patients. Although we encountered and spoke with some patients as we were observing the activities of caregivers and researchers, the terms of my agreements with the IRBs that approved this project did not permit me or my team to gather additional information on or from patients.

[2] I am grateful to Mitchell Stevens for pointedly asking "But what is a clinic?"

[3] Caesarian deliveries are a particularly consequential example of how activities change with changes in the presence of key personnel. Entwistle and Doering (1981), for instance, found that the odds of a woman having a caesarian delivery were lower on weekends and in the middle of the night when obstetricians were less likely to be present in the hospital. In Uganda, if the one obstetrician had to attend an IRB meeting, there was no one available to perform caesarians.

[4] In the long run, I concluded that Philly Lutaaya clinic staff were less worried about what I might see or write than about providing fodder for hypercritical monitors or site visitors who might question the appropriateness of allowing someone other than a staff member or trainee into clinic examining rooms.

[5] Some idea about which occupations would therefore be hard to study ethnographically

might be gleaned from the Dictionary of Occupational Titles, which classifies of jobs according to the complexity of work with data, people, and things (Attewell 1990, 426–7; Cain and Treiman 1981).

[6] The U.S. Health Insurance Portability and Accountability Act (1996) established national standards for the protection of health-related information.

[7] The logic of this arrangement was that because I was studying the caregivers and researchers, not the patients/research subjects, I would be collecting data in a one-sided fashion focusing on the activities of one member (the clinic worker) of the interacting pair but not the other (the clinic patient or research subject).

[8] In some instances, those being studied may conflate the work of ethnographers with applied or operational research. This seems especially likely in "corporate ethnography" where researchers are commissioned to inform an organization about itself (Fayard and Van Maanen 2015).

[9] One Ugandan interviewee kept me waiting for several hours past sunset at an office building on the outskirts of town, invited me to start our conversation as he completed paperwork, suggested we continue as he was driven home, accompanied by several colleagues, and then, declaring our interview over, dropped me at a bar/restaurant where I could hail a cab. I was not entirely sure whether his assistant had failed to enter our interview on his calendar or was this just an extreme version of a "slow no"?

[10] Some researchers have shared royalties with those they studied, being careful to make the arrangement only at a point when it could not affect either willingness to participate or the content of participation (Duneier 2010, Lewis-Kraus 2016). In truth, given the small size of most royalty checks, this offer would often be more important symbolically than materially and

might prove disappointing to participants.

[11] See, for example, Kirch (2014) on concerns about medical student documentation in electronic health records.

[12] For painstaking ethnographic work focused specifically on the use of documents, see Latour (2010) on the use of legal documents and Moreira (2005, 2007) on how documents reporting medical research are used in the construction of clinical guidelines.