Expertise and Flexibility in Medicine and Law

(What Happens when HIV Guidelines are Hardened by Law)

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Abstract

Clinical guidelines are procedural standards. They tell caregivers (and others, such as researchers) what steps to follow under particular circumstances. The objective in writing such guidelines is to create a higher level performance by giving a skilled practitioner a tool that encapsulates a large volume of information in compact, usable form. Yet, like many tools or recipes, clinical guidelines are most useful when employed by skilled users who have experience with the tools and understand their elements. The difference between skilled workers and others is not that skilled workers don’t use recipes or routines, but rather that routines are for them a foundation for flexible adaptation. A good cook can quickly suggest a half dozen ways of adjusting for a missing ingredient. Likewise, the surgeons in Bosk’s (2003 [1979]) study had rigid routines for their underlings to follow – the recipes all novices are taught, the rules and standards that allow people to coordinate complex activities whether in the clinic or the operating room. But the surgeons also could adjust and correct as circumstances required, which was why residents’ technical errors worried them less than normative errors.

This paper compares two kinds of medical guidelines used in HIV clinics, purely medical guidelines and medical guidelines that have an interface with the legal system. I argue that the special discomfort that clinic staff show when they encounter the second kind of rule arises from their lack of expertise in legal matters. Taught to be flexible users of guidelines, medical staff expect to use their judgment about whether guidelines actually apply. Procedural guidelines are in that sense always also, at the limit, outcome guidelines. Staff are to follow the procedure except when the outcome would be bad, and their medical training equips them to make the judgment calls about when and how guidelines should be put aside.

To be sure, how much people are expected to use their judgment depends on training and rank. As Chambliss (1996) observes, nurses much more than doctors are expected simply to “follow” the rules. Because they are not empowered to make choices, they encounter ethical “problems” rather than ethical “dilemmas.” Discretion thus depends, I argue, on both position and training. When guidelines are strongly tied to the legal system, staff members who lack legal training lose some of their capacity to use discretion. The anxious query, “But what’s legal?” comes because people who can assess good medicine and so are skilled users of medical guidelines cannot assess good law and so are unskilled users of legal part of guidelines. When medical guidelines are tied to law, then, medical staff lose some of their capacity to adapt.

Why does this matter and who will care about it? It matters, first, because it explains an empirical puzzle, namely why people accustomed to working with guidelines have very nervous reactions to some of guidelines (the ones with a legal interface), irritated reactions to others (the

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ones enforced by research monitors or hospital administrators), and welcoming reactions to still others (the ones within their sphere of expertise). For scholars interested in standardization (e.g., in organization studies or in science, technology and society), the distinction between standardization that is strongly tied to law and other forms of standardization usefully extends an argument about the relationship between expertise and standardization. Expert users of a standard may not be expert in all of the kinds of knowledge embedded in a standard; when a standard is grounded in disparate bodies of knowledge, then, groups expected to be expert users may turn out to be less facile than would have been the case for less complex standards. For sociolegal scholars, this paper offers an explanation of why the law may be especially foreign to groups of people who are otherwise quite accustomed to working with guidelines that in some respects strongly resemble law. The rules of medicine remain always soft for experts, while the rules of law can be hard indeed. We might, then, expect medical workers to resist some forms of legalism while embracing others.

**Introduction: A Tale of Two Guidelines**

Since 2004 when the results of a Thai study were published in the New England Journal of Medicine (Lallemant et al. 2004), it has been known that “dual antiretroviral prophylaxis” was much more effective than the use of a single drug in preventing the transmission of HIV from mother to baby. The World Health Organization has adopted this regimen – a short course of AZT coupled with a single dose of nevirapine when a woman goes into labor and then a dose of nevirapine for the child shortly after birth – as its standard. Until January 2008, however, this was not South Africa’s guideline. Rather, South Africa’s regimen was a one-drug regimen – nevirapine but no AZT. The two-drug regimen may carry the endorsement of the WHO, but in South Africa, it is the one-drug regimen that has been backed by the state.

Why South Africa would adopt the one-drug regimen as the national standard is something of a mystery. HIV policy in South Africa has been a flash point during the Mbeki presidency, with exceedingly slow progress in adoption and implementation of such key programs as the ARV rollout (the main treatment program) and the PMTCT program (to prevent mother-to-child transmission; implemented only after a 2002 court order). Activist groups such as the Treatment Action Campaign (TAC) and the AIDS Law Project (ALP) and NGOs like
Médecins sans Frontières (MSF) commonly note that government programs are put in place only in response to pressure. Admittedly, the single-drug regimen is less expensive, but the two-drug regimen is not exorbitantly expensive (AZT is not an especially costly drug anymore) and the real savings of investing in programs to prevent transmission from mother to child (PMTCT programs, as they are called) are very substantial. The South African evidence on this point is striking. In KwaZulu-Natal (KZN), where the official national single drug regimen has been followed, the transmission rate has been 23 percent. In contrast, in the Western Cape, where dual antiretroviral prophylaxis was adopted as the standard, the transmission rate is less than 5 percent (Dugger 2008). The most generous interpretation one might offer would probably be that of a spokesman for the health department itself: “There were a number of issues that needed to be debated” (Dugger 2008).

My concern here is specifically with the effect of adopting a guideline as government policy. In the case of the PMTCT guideline, the single-drug regimen was adopted as policy by the South African government and by most provincial governments. The Western Cape broke with the national government and adopted a two-drug regimen. KwaZulu-Natal stayed with the national policy. In May 2007, a group of doctors pressed the provincial health department to let them give the two-drug regimen. It was unethical, they argued, to give the single-drug regimen when they had the capacity to deliver better options. Dr. Sandile Buthelezi, responding for the province, denied their request saying that the budget did not provide for the added cost of the AZT. Referring to the Western Cape policy, he added “I am wary of us undermining national just because of what other provinces are doing” (Dugger 2008).

Dr. Colin Pfaff, acting medical manager of Manguzi Hospital, decided to raise additional funds so that he could give pregnant women the second drug. In the Umkhanyakude district, where Manguzi is located, the antenatal survey found that 36.3 percent of pregnant women are
HIV positive (TAC 2008a). Although one might expect the province to applaud Dr. Pfaff’s resourcefulness, the KwaZulu-Natal Department of Health charged him with misconduct for “acting beyond his authority” in accepting donations for and implementing the dual-therapy program “without prior permission of his superiors.”¹ Medical groups, clearly believing that Dr. Pfaff’s action fell well within the bounds of professional discretion, responded with outrage. When the charge was withdrawn, Dr. Francois Venter, President of the South African HIV Clinicians Society, credited the health worker campaign and the “spontaneous outpouring of anger at the news that Colin was being disciplined for doing his ethical duty” (TAC 2008b).

Extreme examples can sometimes help us see more clearly by bringing into sharp relief tendencies that have previously been obscured. In recounting the above case, I therefore make no claim that it is representative, only that it highlights a common difficulty encountered in the legalization of medicine. What is interesting about this case is that in using normal medical discretion – offering dual antiretroviral prophylaxis to HIV positive pregnant women once he found a way to make it available – Dr. Pfaff seems to have exercised inappropriate discretion on a legal matter – deviating from provincial guidelines without express permission. Confusion often occurs when guidelines have both medical and legal components and so require both

¹ The February 11 press release by the KZN Department of Health reads as follows:

“The Department of Health in KwaZulu-Natal has charged Manguzi Hospital Acting Medical Manager, Dr. Collin Pfaff for misconduct after he allegedly acted beyond his authority in accepting a donation and implemented a Prevention of Mother-To-Child Transmission (PMTCT) dual therapy to pregnant mothers and newborn babies without prior permission of his superiors.

“Further, it is alleged that he sourced funding from outside the department without following procedures as prescribed by the legislation. If true, this is tantamount to misconduct.

“With all these allegations reported to the Department, the matter was investigated and a charge for misconduct was laid against Dr. Collin Pfaff.

“We have observed that certain opportunistic politicians take pleasure to use this matter as a political pawn to score points. We will not allow anyone to pull vulturistic theatrics to mystify this matter for their own political gains. We will continue to put the interest of our people first, unlike these opportunists.

“We will go ahead with the matter following the prescribed legal process to the letter.” (quoted in full in TAC 2008a).
medical and legal expertise. That interweaving of law and medicine and the resulting uncertainties about what clinic staff must, may, and may not do is the subject of this paper.

**Research Context: The Legalization of Medicine**

A bit of context about the larger research project in which this paper is embedded may be useful. The larger project is a study of the legalization of medicine, which grew out of my previous research on infant intensive care units (Heimer and Staffen 1998). In the infant intensive care units, I noticed that staff were continually referencing rules (including protocols, guidelines, standard operating procedures). They also often expressed concern about whether what they were doing was “legal,” a point to which I return repeatedly in this paper. In the infant intensive care unit, staff for instance might worry about whether they were legally empowered to take custody of an infant who whose parents opposed a medically necessary blood transfusion. Sometimes it seemed that the concern with legality had displaced a concern with what was ethical. Undoubtedly the new focus on legality is deeply fused with the patients’ rights movement, worries about medical malpractice suits, the intense scrutiny associated with the Baby Doe regulations, worries about closings of hospitals and uninsured groups, etc. Generally, there are now more rules, and medical staff worry more about them.

In the last quarter century or so, American health care has undergone a major transformation from relatively informal regulation by professional peers to more formal, law- and rule-based regulation. In effect, American medicine has become more “legalized,” with prescriptive statements about what care to give, how to conduct research, and how to interact with patients and colleagues, promulgated by countless professional associations, health care organizations, regulatory agencies, third-party payers, legislatures, and international bodies.

The “legalization” that has occurred in the world of medicine can fruitfully be compared
with legalization in international relations and international organization. “Highly legalized institutions,” Abbott et al. write, “are those in which rules are obligatory on parties through links to the established rules and principles of international law, in which rules are precise (or can be made precise through the exercise of delegated authority), and in which authority to interpret and apply the rules has been delegated to third parties acting under the constraint of rules” (Abbott et al., 2000, p. 43). The more “legalized” arrangements – “hard law” – are those in which parties are clearly and unconditionally obligated to follow the rules, the rules are precise with little room for interpretation, and provisions have been made both for delegated dispute resolution (by a court-like entity) and for rule making and implementation (Abbott et al., 2000; Abbott & Snidal, 2000). Less legalized arrangements can be “softer” on any or all of these dimensions; the three dimensions need not move in tandem.

In international organizations, legalization is about a close dialogue with formal law, the development of quasi-legal institutions in international arenas that then sometimes but not always get ratified by national governments. In the world of medicine, in contrast, “legalization” is often not associated with ties to formal legal systems and governments, but instead comes from the legislative, interpretive, and oversight activities of other entities that govern subparts of medicine. The dimensions are the same, but inevitably the mechanisms are somewhat modified when the “government” is not that of a state, but instead is a less fully institutionalized entity that has government-like functions. Almost inevitably, “law” in this realm is somewhat “softer” because its rules often are not fully articulated with the laws and regulations of the formal legal system. Yet there are in some instances well-developed mechanisms for monitoring and enforcement, a good deal of precision in the rules and sub-rules themselves, and instruction on how to figure out what to do when a situation is not covered by the rule.

Some of the complexity of the quasi-legal system of the medical world arises because of
its multi-cephalic character. In this system, there are many fiefdoms, each with its own “legislators,” “executives,” and “courts.” But because what is being governed is not primarily a geographical area but instead semi-independent functions such as research and treatment, these fiefdoms overlap in space and time, sometimes creating chaos rather than order. To add to the complexity, some of these rules span national borders because in contemporary medicine, research, training, and even some treatment draw funding and some personnel from far away.

With all of this quasi-legal complexity, one very basic question is what people actually do with all of the rules that now populate the medical world. How do medical staff use the rules in their day-to-day work? Do they know which rules are mandated by national law and so are obligatory? Is the difference between regulations and guidelines clear? How much rigidity is added to guidelines when they are reinforced through adoption by a national government, third-party payer, or a clinic itself? Do staff members track the different legal status of disparate rules, some enforced by a research bureaucracy, others by national law on human research subjects, and still others by quasi-public regulatory bodies like the JCAHO (the Joint Commission for Accreditation of Healthcare Organizations)? Do they know which rules are intended only as guidance and which (like research protocols) are intended to be followed exactly?

Although one scarcely needs an excuse to study a disease as important as HIV, HIV is in fact a good example of investigating questions about the legalization of medicine. Because it is a new disease, the imprint of the new legalized culture of medical treatment, research, and administration can be seen especially clearly in HIV, where no pre-existing culture muddies the picture. Moreover, the internationalism of HIV research and treatment can teach us much about the effects of social and geographical distance between those crafting rules and those expected to follow them.

Because some rules become normalized and fade into the background, research on how
medical staff work with rules necessarily must include observation as well as interviewing. In addition to interviewing major decision makers and writers and disseminators of rules, then, I have also looked at the daily work of HIV/AIDS treatment and research in five HIV clinics. Chosen to reflect important differences in prevalence rates, patient access to health insurance, distance between rule makers and rule followers, and government stances on HIV, two of the clinics I studied were located in the US (I’ll refer to them as US1 and US2) and three in other countries (Uganda, Thailand, and South Africa). All of the clinics were engaged in both treatment and research and all had ties to universities.

In fieldwork and interviews I focused especially on three key types of rules – clinical guidelines, rules about the conduct of research, and administrative rules – asking, e.g., what people typically do when attempts to follow one set of rules are stymied by obligations to comply with another. These three main kinds of rules are responses to different kinds of pressures to introduce an element of universalism into the medical world. Treatment guidelines recognize universals about the human body; basic biological processes generally are not expected to vary randomly from one person to another. As a general matter, then, everyone should get the same treatment – people who are HIV infected should start antiretroviral therapy when their CD4 counts start to fall below 200 (although the guidelines on this are now changing), with adjustments made to take account of other biological processes (pregnancy, for instance) or co-infections (TB, for instance). Treatment guidelines are also intended to reduce variability among caregivers, reducing the effects of differences in skill and training and also decreasing the role of medical “art” in favor of harder scientific evidence. Rules about the conduct of research are about two other kinds of universals – the universal rights of research subjects and the need for standardization in research projects. In order to aggregate data collected in multiple, dispersed sites, researchers must introduce a large measure of uniformity in
what they do to or with research subjects in a study, how they collect and record data, and how they analyze data. Finally, rules about administration, finances, and governance are about transparency and trustworthiness in use of resources and the need for consensus about acceptable uses of funds and acceptable evidence about those expenditures and activities.

In the rest of this paper, I focus especially on treatment guidelines and on variation in the importance of the legal interface. Although generally guidelines reduce uncertainty, my argument is that they only have that effect when there is a match between the knowledge base of guidelines and the training of those who are using them. The paper moves back and forth between general information about guidelines – what they are based on, who the intended users are, who adopts them – and observations from my fieldwork about the difficulties that clinic workers encounter in using guidelines. The paper ends by summarizing what we have learned about why making clinical guidelines “harder” can increase rather than decreasing uncertainty.

**Guidelines as Mechanisms for Managing Uncertainty**

The core of medical work is diagnosing, offering prognoses, and treating patients. The practice of medicine is grounded in scientific knowledge that doctors, unlike the rest of us, are supposed to have mastered. As Starr (1982) reminds us in his classic book on the history of American medicine, it is only relatively recently that doctors have been able to convince the public of the legitimate complexity of medicine – that is, that there really is an arcane body of knowledge that undergirds diagnosis, prognosis, and treatment and that medical training programs actually transmit that information and teach relevant skills. Some time ago Becker et al. (1961) argued that medical students had difficulty mastering the material presented to them and described the shortcuts that medical students must take to keep up with their work. The problem can only have gotten worse as the corpus of medical knowledge has grown over the
years, although specialization may have reduced the amount any single person is expected to master. Decision supports such as clinical guidelines (these days conveniently available on PDAs) have surely helped.

Clinical guidelines attempt to summarize research in any given area and to formulate that information as a recommendation about what to do. The recommendation is typically accompanied by assessments of the quality of the evidence\(^2\) and how strongly it supports the recommendation and a list of references. Guidelines can be either deterministic guidelines or branching guidelines or some combination of the two (see generally UNAIDS 1999, p. 10). Deterministic guidelines are more restrictive and offer a fixed list of elements to be used as a recipe for action, e.g., to deal with a life-threatening condition. Most of the guidelines with which this paper is concerned are instead branching guidelines, which guide a clinician’s actions in an unfolding situation, recommending one or more courses of action at each point in a decision tree. Branching guidelines often incorporate flow diagrams or algorithms and typically build on information gathered by the clinician as the situation unfolds. In effect, deterministic guidelines are “harder” than branching guidelines because they mandate a course of action rather than having practitioners choose among several possibilities.

Clinical guidelines were initially intended to reduce two kinds of uncertainty: by caregivers’ uncertainty about what to do and patients’ uncertainty about whether their caregivers know what to do. For the most part, these are uncertainties about core medical matters. Yet

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\(^2\) The UNAIDS guide to developing HIV/AIDS treatment guidelines provides a table that categorizes evidence into six “levels” (UNAIDS 1999, p. 14). The UNAIDS guide to developing HIV/AIDS treatment guidelines also offers a table on the “grading” of recommendations and how recommendations should be linked to the “level” of the evidence. This guide suggests, for instance that “a recommendation based upon the results of at least one randomized clinical trial . . . would be termed a ‘Grade A recommendation’” (UNAIDS 1999, p. 16). Most guidelines, in turn, explain how they have ranked evidence and graded recommendations. See, e.g., the 2006 WHO guidelines for antiretroviral therapy for adults and adolescents (WHO 2006, p. 8) or the 2008 DHHS treatment guidelines for HIV infected adults and adolescents (DHHS 2008, p. 57).
there are many more uncertainties faced by clinic workers, clinics, and patients. For instance, practitioners and the clinics in which they work face uncertainties about whether they will be paid for the services they provide. If we think of clinical guidelines as a the way that caregivers talk with each other about what care to give, they also become a way to conduct a dialogue with insurers, government agencies, and other third party payers. When an insurer adopts a particular guideline, it agrees to reimburse careproviders when they follow that guideline in caring for patients covered by that insurer. Likewise, when governments adopt a specific guideline, it often is also then agreeing to a payment scheme whereby it covers services, supplies, and medications that are administered to a particular population by a specified category of practitioners working in a particular type of facility. Guidelines can thus be used to reduce uncertainties not only about medical care (by reducing practice variation), but also fiscal uncertainty. Finally, guidelines can also reduce legal risks for practitioners and the medical facilities in which they work. If medical workers follow guidelines, this should reduce the likelihood of malpractice suits and perhaps give them a stronger defense in the event of a suit. Adoption of clinical guidelines by a clinic is then one way a clinic can signal to a variety of publics that it is a careful, law-abiding enterprise.3

The main bodies issuing HIV guidelines are the US Department of Health and Human Services (DHHS) and the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and the International AIDS Society-USA (IAS-USA, a non-profit professional association that develops treatment guidelines and offers educational programs).4

Generally, clinical guidelines become “harder” because more mandatory as they are adopted as

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3 The literature on the use of guidelines as “shields” by practitioners and “swords” by plaintiffs is summarized in Heimer, Petty, and Culyba (2005), which also discusses guidelines as professional and organizational risk management.

4 A point that is often confusing to readers: IAS-USA is not affiliated with IAS, which describes itself as “the world's leading independent association of HIV/AIDS professionals.” IAS is the “custodian” of the International AIDS Conference and the “organizer” of the IAS Conference on HIV Pathogenesis, Treatment and Prevention, which occur in alternate years (www.iasociety.org).
guidelines by successive layers of governments and medical organizations. The HIV treatment guidelines issued by the US DHHS and CDC, the WHO, or the IAS-USA do not really constrain anyone until they are adopted by some other entity. As they are adopted by governments or insurers or clinics and modified to suit the circumstances and purposes of those entities, the guidelines become more constraining because the rules are no longer just about what treatments work best but about how to allocate scarce resources among competing parties and how to manage some of the risks faced by clinics and governments. These points about the increasing constraint of guidelines are summarized for HIV treatment guidelines in Table 1. The same points could be made about guidelines for testing, for prevention of transmission from mother to child, etc.

**Table 1 about here**

**Legal and Medical Content in Clinical Guidelines**

Guidelines issued by the US DHHS and CDC, the WHO, or IAS-USA are complex medical documents but essentially devoid of administrative or legal content. As guidelines are modified for their specific populations and to fit their specific packages of resources and constraints and adopted by governments and clinics, more administrative and legal content gets added. Generally speaking, the medical content of guidelines is essentially fixed from one location to another, but the administrative and financial arrangements and legal content vary a great deal from one country to another and even from one clinic to another.

This paper focuses on the legal content – sometimes spelled out, more often simply alluded to – of clinical guidelines. A complete discussion of the use of clinical guidelines would also include an analysis of administrative and financial elements to complement the discussion of legal elements of clinical guidelines provided here. A quick word about administrative and
financial matters, which will be taken up in a subsequent paper, before moving on. If anything, administrative and financial elements are even more variable than legal content. To do HIV-related work, clinics often draw on a wide variety of resources including payments from patients, reimbursements from insurers and governments, program grants from large donors, and monies from the philanthropic funds of pharmaceutical companies. Each of these sources of funds comes with its own strings – lists of items for which funds can and cannot be expended, mandated reporting schedules and topics, etc. As the “strings” are transformed into routines and embedded in locally designed forms, users and even designers forget the origins of the obligations. If one asks users why they are obliged to record a particular bit of information, many will not remember that the obligation originated in a contract with a donor or a government mandate, or whatever. A similar kind of forgetting occurs when legal content is transformed into local routines.

[Table 2 about here]

Although all clinical guidelines have legal content, this legal content often is not made explicit. Table 2 summarizes the legal content of several clinical guidelines. Clinical guidelines are meant to be used by particular professional groups; which professional groups are empowered to carry out the actions spelled out in a particular clinical guideline depends on the laws and regulations of the country, state, or province in which the guideline is being used. In an appendix on guideline appraisal tools, the UN guideline for guideline development urges that guideline writers be explicit on this point: “Is there a description of the professional groups to which the guideline is meant to apply?” (UNAIDS 1999, p. 27). To take one example, in the most recent South African guideline on preventing mother-to-child transmission of HIV, a diagram shows that it is a “registered health professional” who prescribes AZT and orders a CD4 count (South Africa 2008b, p. 18). The announcement of the new policy is even more explicit on
this point: “The two drugs used in the programme – AZT and nevirapine – are schedule 04 medicines and therefore have to be prescribed by a medical officer after an appropriate assessment of the patient” (South Africa 2008a, p. 1). As I discuss below, because legal content often is not spelled out, medical staff may be confused about the legal status of the actions described in clinical guidelines.

It is perhaps in testing guidelines that legal elements are most fully articulated. As a strictly medical practice, testing is now quite easy, with multiple testing options (antibody tests using blood, urine, or mucosal swabs), some offering results in a matter of minutes. Arrangements for HIV testing have been controversial from the outset. In the early days of the HIV epidemic, there were calls for quarantine and for excluding HIV-infected children from schools, insurers cancelled the health insurance policies of those who tested positive, legal protections for HIV infected people had not yet been put in place, and caregivers could offer little more than treatment for opportunistic infections and palliative care at the end. It was in that social environment that HIV testing guidelines were first developed. Given the concerns about confidentiality and worries about how people would react to the news that they had a fatal disease, the routines mandated a fully voluntary procedure with counseling before and after the test itself.

Over the years, policymakers, caregivers, and activists have begun to shift away from “voluntary counseling and testing” (VCT) in favor of “routine counseling and testing” (RCT), sometimes also called “provider initiated testing”, always with the possibility of “opting out” of the test. The idea is that caregivers should incorporate HIV testing into routine healthcare, screening for HIV just as they would screen for any other serious, treatable health disorder (see, e.g., CDC 2006, pp. 2-7). Because caregivers now have something to offer their HIV infected patients and because people do better if they are treated sooner rather than later, testing is no
longer simply about protecting someone else’s health – although it does also do that, of course. Although the CDC has recommended changes in how HIV testing is done, in the US HIV testing is governed by state laws and regulations and these are quite variable. The National HIV/AIDS Clinicians’ Consultation Center website has a compendium of state laws on HIV, but its “Quick Reference Guide” often points to areas where the law is unclear. As the CDC testing guideline notes, “at least 28 states have laws or regulations that limit health-care providers’ ability to order diagnostic testing for HIV infection if the patient is unable to give consent for HIV testing, even when the test results are likely to alter the patient’s diagnostic or therapeutic management” (2006, p. 6). Only the District of Columbia, which has the highest rate of new cases in the US, has adopted a vigorous program of routine testing (DeParle 2006).

These debates about routine testing are occurring around the world and have been going on for several years. In the clinic where I did observations in Uganda, one doctor advocated routine testing, especially emphasizing the impossibility of preventing the birth of HIV-infected babies if women were not tested in pregnancy. Other staff, including counselors, disagreed, arguing that women had many reasons not to be tested and that it was wrong to second-guess them. The Ugandan testing guideline, issued in provisional form in February 2005, seems to have gone further than the guidelines of other countries in distinguishing levels of consent required in different settings. Using the term “HIV Counselling and Testing (HCT)” as the umbrella term, the introduction comments that “testing may be voluntary but other times the testing is carried out under different circumstances where voluntarism does not apply” (p. 1). The chief innovation introduced in the 2005 guidelines seems to be routine counseling and testing (RCT) for HIV in clinical settings, with some attendant modifications in the counseling process. For situations in which people “seek out service of their own will,” the voluntary counseling and testing (VCT) remains the model. The document also introduces ways of doing
testing where the degree of voluntarism is diminished (some select employment situations or cases where people are “applying for a particular service or privilege”) or entirely absent (in criminal situations; although this situation is mentioned, readers are told that this situation requires consultation with the Attorney General’s office), or where people are unable to consent because they are legal minors or have disabilities that make full consent difficult (pp 3-4).

Recognizing that parents and guardians may not always see eye-to-eye with children, the Ugandan testing guideline provides both for children to refuse HIV tests (that their parents might be urging them to have) and to test without the approval of their parents or guardians starting at age 12 (p. 22). The guideline also acknowledges that there will be some children who are emancipated at even younger ages because they are themselves parents, heads of households, or abandoned (p. 22). In practice, such children are unfortunately not very likely to make their way to an HIV clinic. But the Ugandan guidelines do at least reduce ambiguity about their legal status should they arrive at the clinic door. With legal impediments minimized, medical staff are more likely to be able to move on to testing and treatment. (The legal issues of testing and treating children are discussed more fully below.)

In South Africa, sentiment seemed to be shifting toward routine testing. Among the most eloquent spokesmen for routine testing is Edwin Cameron, one of the judges of the Supreme Court of Appeal. Reviewing the history of HIV testing in South Africa, Cameron argues that it is time to dispense with the “fuss and palaver and hullabaloo” that accompanies testing (2006, §41). Necessary as they were in an earlier era, these safeguards now mainly “accentuate the differentness and distinctness and horror of HIV” (2006, §42) and “may constitute a barrier to diagnosis and treatment” (2006, §44). In the South African clinic where I observed the activities of workers, staff were fully aware of these ongoing conversations and therefore somewhat uncertain about how they should be acting. Their counseling-testing-counseling routine was well
institutionalized, so for now they continued to do their work just as before. But they seemed worried that in simply “inviting” people to be counseled and tested, they were reinforcing the stigma associated with the disease.

Particularly the PMTCT programs, there is discomfort about moves toward routine testing. On the one hand, many practitioners are intensely concerned with preventing transmission to babies and find it nearly impossible to believe that prospective mothers would not share their sentiments. This tends to make them feel that if a woman is reluctant to have the test it must mean that she has not understood the grave risk to her baby or that the risk can be much reduced with prophylaxis. The “fall off” at every stage between presentation of information, individual counseling, testing, receiving prophylaxis for herself, and receiving prophylaxis for the baby is difficult to explain and tends to make staff favor routine testing. Yet the law in South Africa has not moved much in this direction. The January 2008 regulations say that women “should be given routine information about voluntary HIV testing and the PMTCT programme” (South Africa 2008b). This is not quite the “opt out” arrangement that people like Edwin Cameron advocate. But there also seems to me to be some ambiguity in the guideline. After all of the parsing of words in the discussion of testing, the guideline doesn’t actually use language that gives a clear signal that it means “opt in” (as in the past) or “opt out.”

Questions about how to handle confidentiality are a big part of testing, though they also extend beyond testing to treatment. In all of the countries where I observed clinic work, staff seemed uncertain about what exactly it meant to keep things confidential. Although staff were fairly confident that they understood the rules in the abstract, they tended to be less sure about how they applied to particular situations. In US1, workers were scrupulous about concealing even the identity of the clinic as an HIV clinic. In answering the phone, the staff referenced the floor and the building, but didn’t say anything so obvious as “HIV clinic.” Oddly, this meant
that the clinic had opted to forgo the opportunity to educate patients with literature on HIV in the waiting room. Other clinics did not feel that confidentiality necessitated anything that extreme. On the few occasions when someone would come to the clinic with a family member who did not know that the patient was HIV infected or being tested for HIV, the secret was easily kept by staff. But what were the rules about discussing patient cases among staff members? One staff member tended to refer to patients by initials rather than names. Initially I worried that this was because she felt that I should not be privy to confidential information, but when I asked a leading researcher whether this would be the case, he said no, it was rather that the clinical staff had been drilled more thoroughly in HIPAA (Health Insurance Portability and Accountability Act) regulations. In any case, he added, in his view we were all within the circle of confidentiality. But that was exactly the problem – no one seemed entirely sure what the rules really were on that point, only that they couldn’t do their work if their colleagues weren’t within the sphere of confidentiality.

In Thailand, some parts of clinic work were supposed to be governed by American rules about confidentiality. That meant, among other things, that names of research subjects were not supposed to be included in some kinds of records and should not be easily visible on others. Yet normal Thai practice is different than American practice in these matters. Although Thailand has a long history of concern with ethical questions in medicine and clinical research, the Thai medical establishment had not adopted the same solutions as promulgated by HIPAA. But when Thai researchers carry out clinical studies funded in part by the American government, they are obliged to follow a host of American rules. Despite considerable training on these rules and general agreement about the principles, people are often surprised to discover that they have overlooked places where local practice and international rules have not been fully harmonized. It may not be entirely clear which Thai conventions have to be modified to fit American rules
and which ones can be left undisturbed.

Sometimes there were pressures to reveal information, for instance to employers. Staff generally knew that this was prohibited; moreover these rules generally lined up neatly with their own impulses. But occasionally they would be caught off guard, e.g., by a patient requesting them to tell an employer about a negative test result. Or clinic staff might realize that they might inadvertently have revealed information, e.g., in Uganda when clinic drivers gave patients ride home, making husbands, mothers-in-law, or neighbors suspicious. But there were also times when the rules seemed to require that information be revealed. In South Africa, for instance, when an HIV-infected patient is not taking precautions to protect an uninfected and unaware partner, staff are permitted [obliged?] to inform the partner so that he or she can avoid infection. They must first put the patient on notice that they are going to make the disclosure, allowing the patient time to follow through and make the revelation him or herself. Several staff members worried in meetings and privately with me about what their obligations really were and how they should meet those obligations – the obligation to protect the confidentiality of the patient and the obligation to protect the welfare of the patient’s partner could not easily be reconciled and created acute anxiety for caregivers.

More common, though, was the situation that arose in Uganda, where one of the treatment programs required that people disclose to their intimate partners. This was a family-oriented program and the objective was to get the whole family treated. But all staff knew of instances when telling the partner had gone very badly. Husbands did occasionally beat their wives or throw them out of the house, leaving the woman and the couple’s children homeless and without any financial support. Did it make sense to insist that an HIV positive woman run this risk? Wasn’t the objective of the program to improve the health of HIV infected parents and their children? How was that accomplished if a woman lost her tie to the man who put food on
the table for her and her children? Strictly speaking, the program rules did not entail any violation of confidentiality because staff were not themselves informing anyone of their partner’s HIV infection. Yet these rules seemed to staff to conflict with the spirit of confidentiality required by the law.

When staff members worry about legal issues, often they are worrying about how the state has decided to balance the interests of one party against those of another. Such questions are especially prominent in PMTCT programs, where the rights of mothers – e.g., not to accept treatment – may conflict with the rights of a fetus to be protected from infection. Although doctors, and especially pediatricians, feel strongly about protecting the health of unborn babies, the conflict between maternal and fetal rights is much more vigorously debated in the US than in Thailand, Uganda, or South Africa, perhaps partly because pregnancy is more medicalized in the US and because the state has the resources to follow through with a full program of prophylaxis during pregnancy. In developing countries, the state cannot offer HAART (the drug cocktail used to treat people as their HIV progresses), cannot provide caesarian deliveries when indicated (this is when the virus in the mother’s body has not been fully suppressed by drugs), and cannot offer a good program of alternative feeding to prevent transmission via breast milk. Because the state cannot make good on a threat to protect the child against the mother’s wishes, doctors may be less eager to use the muscle of the state to induce unwilling mothers to accept treatment. It is thus only in the US that one hears much talk about protecting fetuses from irresponsible mothers.\(^5\) This talk of protecting babies from their mothers may also be more common in the US because of the association of the disease with IV drug use. When the disease is a general heterosexual epidemic, as it is in Africa, mothers who are HIV positive are not assumed to be

\(^5\) In the US, there is then a corresponding, subterranean discussion about the toxicity of antiretroviral therapy, ways to evade doctors and state officials who may try to prevent a mother from breastfeeding, etc.
inadequate mothers from the start. How far the law supports coercion of pregnant women is thus usually unclear and staff members in the clinics I studied often feel unsure of their legal footing in urging women to be tested and treated during pregnancy.

The South African case usefully illuminates the ambiguities that caregivers encounter in the PMTCT guideline. The foot-dragging of the South African Department of Health is an important backdrop for any discussion of the South African PMTCT guideline. Although there was ample information about the magnitude of the HIV epidemic in South Africa and the transmission rate from infected women to babies and although nevirapine prophylaxis had been used successfully in other developing countries, the Department of Health did not offer prophylaxis for pregnant women until ordered to do so by the Constitutional Court (see TAC 2001, South Africa 2002). Another court case was required in 2007 to force the government to offer dual antiretroviral prophylaxis for pregnant women (see TAC 2007). In the meantime, the Minister of Health so frequently expressed her opposition to antiretroviral treatment that her resignation was publicly called for at the Toronto AIDS conference in 2006 and in a letter from 60 international AIDS experts (Mail and Guardian 2006, BBC 2006). Even when a guideline is put in place, one needn’t do much reading between the lines to get the message that the national government is not very enthusiastic about treatment. Despite official policies supporting treatment, all of the pressure has been against treatment: drugs haven’t been supplied; protesters have been arrested (Mail and Guardian 2006).

The 2008 South African PMTCT guideline reviews a bit of this history:

The original Department Plan for PMTCT was to implement 18 pilot sites in all provinces; one in a rural setting and another in an urban setting, both to establish the operational requirements of a nationwide programme but also to assess the effectiveness of the intervention in a real life situation. Systems were being developed to implement the pilot phase when in July 2002, lobby groups won a case against the Department of Health. The Constitutional Court ordered the Department of Health to, with immediate effect, make Nevirapine and the provision thereof, available to all HIV positive pregnant women who wish to
receive it in public health facilities.

The Department of Health implemented the court rulings to the letter and the PMTCT programme is now widely available (South Africa 2008b, p. 24).

No mention is made of the pressure by “lobby groups” required to get the Department of Health to offer dual antiretroviral prophylaxis rather than monotherapy.

But where do the provincial governments stand when the national government seems not to be supportive of PMTCT prophylaxis? The provincial government of the Western Cape elected to use provincial funds for a dual antiretroviral program when the national government was still not fully supporting even the nevirapine-only program. But the Western Cape is anomalous, both richer than other provincial governments and more willing to challenge the national government. In KwaZulu-Natal (KZN), home of the clinic I studied, clinic staff joked that depending on the audience, their successful PMTCT program was “a jewel in the crown or a thorn in the side” of the provincial government. And it was, after all, the KZN provincial department of health that brought charges against Dr. Pfaff for offering dual antiretroviral prophylaxis to his patients.

The South African national PMTCT guideline is largely silent on all of the controversial matters alluded to above. It alludes to staff qualifications (“professional nurses” are mentioned as those who should get training; distinguishes between “health care providers,” giving citations to statutes, and “health care workers”; in text and graphs notes that it is a “registered health professional (in line with the relevant legislation and regulations” who would prescribe drugs)(pp. 34; 9-10; and 17-19 and 29 respectively). It mentions that professional nurses “should be trained in performing the rapid HIV tests and on the importance of confidentiality” (p. 34; more mentions of staff training specifically mention training for dual therapy, p. 72). It discusses the role of provinces in implementation (p. 70) and provides detailed discussion of reporting (pp. 62-68 on “monitoring and evaluation”). In a section on “guiding principles,” it summarizes the
“rights of women, pregnant women and mothers to information, treatment, management and care,” discusses what’s entailed in “protecting and respecting children,” and lays out the “duty and responsibility of ALL health care personnel” (p. 27). Perhaps we should not be surprised, given that this document was produced under pressure from activists and the courts, that the emphasis is much more on rights to testing and treatment than on rights to refuse testing or treatment. On any conflict between maternal and child rights, the document is silent, beyond stating that “the child’s best interest is of paramount importance” (p. 27). Throughout, the language is either of “offering” women counseling, testing, and PMTCT interventions or of “informing” them about HIV and PMTCT (see, e.g., pp. 29 and 30). When offered the test, a woman is “asked to provide verbal and written consent to the testing” (e.g., on p. 30), but the document acknowledges that she “may refuse and HIV test” (p. 30). Women who refuse testing are to be offered counseling and testing at each subsequent visit. Earlier in the document, it sounds as if refusal is followed by “post-refusal counselling” (p. 11).

The South African PMTCT guideline is strikingly different than the US DHHS guideline for PMTCT (DHHS 2007). Many of the differences are just what we would expect as a guideline moves from being a treatment guideline offered as guidance for professionals to being a set of recommendations promulgated by a government to create rights (for patients) and obligations (for careproviders). The South African guideline has much more law in it: lists of statutes on professional jurisdictions, reporting obligations for clinics, lists of rights of women and children. It also of course has medicine and science in it, but a lower proportion of the pages are devoted to these topics, and particularly there is much less reviewing of the scientific evidence supporting recommendations. This is not surprising, in some sense, because guidelines adopted by governments and clinics for their specific jurisdictions are intended to be used in conjunction with the guidelines of bodies like the WHO and US DHHS on which they are based.
But much of the training people get is on the medical part; their expertise and previous professional training is as medical caregivers; their professional identity is as doctors, nurses, pharmacists, etc. The complexity of medicine “comes with the territory” in a way that the administrative and legal complexity does not. Medical or scientific complexity is expected, even interesting and challenging; legal complexity is unnerving, disconcerting, and a source of anxiety. Uncertainty about medicine stimulates problem solving, uncertainty about law, because law is not their expertise, instead tends to stimulate paralysis.

Some of the very most difficult issues arise in testing and treating children. Only in developing countries are there very many HIV infected children. Although practitioners in poorer countries have often relied on the guidelines developed in richer countries as a starting point for treating adults, for the treatment of children they found that rich countries had less to offer. In the clinics I studied in South Africa and Uganda, treatment of children was a high priority. In the Ugandan clinic, most of the children being treated were quite young, so still very much under the wing of their parents or guardians. In South Africa, because the patient population included older children and adolescents as well as infants and younger children, the clinic staff often found themselves confronting legal and ethical questions for which no one had clear answers.

The pediatricians in my fieldsite were enthusiastic about the South African pediatric AIDS guidelines (South Africa 2005) – except that they had trouble getting copies of the guidelines. The pediatric guidelines are clear and comprehensive with a practical, humane tone. On non-medical points, though, they seem less confident. For instance, the section on adherence confesses that it was “originally written with adult patients in mind” (South Africa 2005, p. 96). How one ensures that children or adolescents being initiated on antiretroviral therapy understand that they have to take the drugs – with a high level of adherence – for life is far from clear. The
section on legal issues opens with a carefully crafted statement that touches on intertwined obstacles to normal consent procedures:

Currently the law does not permit any person other than a parent or legal guardian to consent to HIV testing and medical treatment in the case of a child below the age of 14 years. In the absence of consent from a parent or legal guardian, consent may be obtained from the Minister of Social Development or an application may be made to the High Court.

The provisions of the Children’s Bill have widened the scope of who may provide consent by introducing a definition of caregiver and giving this class of persons certain legal rights, which include the right to consent to medical treatment. The Bill also lowers the age of consent to 12 and in cases where a child has sufficient maturity, a child below the age of 12 may also give consent.

The Children’s Bill is currently in the process of being passed into law (South Africa 2005, p. 108).

A “general statement” that follows this “explanatory note” observes that when many adults have died of AIDS, children end up living in “informal care situations without legal guardians to assist them” (South Africa 2005, p. 108). Later the authors add that “Abandoned children have the same rights as other children” (p. 109). As one Ugandan document (citation?) on succession planning put it, children have sometimes “been succeeded” (i.e., been passed from one relative to another as their family members died of AIDS) several times and that often means that arrangements for guardianship have not been formalized.

Often the legalities of guardianship were simply ignored in practice. Whoever repeatedly brought the child to the clinic was treated as his or her legal parent or guardian. Questions about familial ties were asked to fill out forms, but then ignored when it came time to get consent for treatment. The staff worried more about ensuring that there was someone taking care of the child and that this person was committed to tracking a complicated treatment regimen and schedule of clinic visits. Questions about family ties were taken a bit more seriously when decisions had to be made about who qualified as family for purposes of receiving care as part of a “family package” at the clinic (with details varying from one clinic to another). Staff were inclined to be generous, partly because they were deeply committed to getting people treated, partly because
they understood that a target child was more likely to remain healthy if his or her caregivers were sufficiently healthy to earn a living and provide childcare. Also inclined to be generous, administrators were under some pressure to keep clinic commitments within manageable limits and to follow the rules of granting agencies in the interest of protecting the clinic income stream.

The most troubling cases, though, were those where parents or guardians seemed unable or unwilling to get treatment for children or where parents and adolescents disagreed about what to do. One early adolescent had been on and off treatment as her mother’s willingness to let her receive ARVs waxed and waned. Delegations from the clinic made home visits, but made little progress. Sometimes the mother wasn’t there, sometimes she taunted them about “white” medicine, and sometimes she threatened not to let her daughter participate in the support group. Over several months, the counseling staff and medical staff considered whether they should initiate legal action against the mother. “What were the child’s rights?” they wondered. After consulting a local AIDS law group, they believed that they were legally empowered to intervene on behalf of the child. But it was never clear how to intervene. Rights not attached to clear mechanisms don’t mean much. Rights have to be claimed, and almost by definition vulnerable children can’t claim their rights. Moreover, in situations such as this, it really isn’t clear that a child is better off being taken away from her mother even if her mother is not supporting treatment. By the end of my months in the field, the situation still had not been resolved.

These pediatric cases were ones where the law seemed to have something to say, yet its message was unclear. It seemed to offer tools, yet the tools couldn’t be accessed. Treating HIV-infected children is difficult under the best of circumstances. The purely medical problems were challenging; often doctors were working in new medical terrain. Yet they felt they had the tools to tackle those problems. When families or guardians were unwilling to let children be treated or did not give medications properly, medical and counseling staff felt much more helpless. To
solve those problems required tools that no one seemed to have.

Compared to these really intractable uncertainties that arise because of the different interests and needs of mothers and children and those that arise sequentially as children grow into more autonomous beings, the more mundane uncertainties of initiating antiretroviral therapy and switching regimens seem almost trivial. Is the pre-therapy training offered in some sites mandatory or merely advised? What should be done when a patient does not complete the training but desperately needs to start therapy – and is the proposed solution legally acceptable? In a country offering a limited range of antiretroviral drugs, what are the rules about switching a patient from a first-line regimen to a second-line regimen, which will almost always be more expensive?

In South Africa, as the government rollout (finally) began, clinic staff worried that their flexibility in dealing with these medically-complex cases. In the past, because their funding did not come from the government, they had been able to make decisions about regimen changes without consulting anyone beyond their own staff. Now, as they understood it, they were obliged to make a case to government officials before making a regimen change. Of particular concern, the clinic’s strongly held view was that the official first-line regimen often led to lactic acidosis, a serious, life-threatening side-effect. When this side-effect was detected, the regimen change needed to be made quickly, and it wasn’t clear that there was time for the kind of back and forth that the government seemed to be requiring. The clinic had developed and implemented its own routine (including purchasing some special equipment) for quickly detecting lactic acidosis. Staff were determined not to go back to their previous way of practicing, which they believed endangered a subgroup of patients. Although the clinic had collected evidence to support its internal guideline, the government had not (yet) begun to track this side effect.
The problems were three: the regimen itself, the inadequate mechanisms for reporting and tracking serious side effects, and a cumbersome process for switching patients to second-line regimens. In a system oriented to public health, as the South African system is, much more attention is given to formulating a set of alternatives that works for the infected population than for individual patients. In Thailand, Uganda, and South Africa, the interests of individual patients do not trump collective interests as they do in the US. In countries where policymakers struggle to find affordable treatments during an epidemic and where the ministries of health worry about whether AIDS will swallow the whole health budget, it is imperative that patients adhere to their regimens so that the less expensive first-line regimens can be preserved as a treatment option for as long as possible. The department of health thus has every interest in ensuring that doctors pressure patients to take first-line drugs correctly and that those who switch patients to second-line regimens are doing so for sound reasons.

In this climate, clinic doctors had every reason to expect that the government would devise a complicated routine and that the sinister language about “getting permission” really did mean that permission had to be received in advance of the switch. Not following the rules in this case could mean losing their position as a rollout site and therefore losing access to funds to cover the expenses of hundreds of patients. Given the reputation of South African government bodies, clinic staff had every reason to expect a cumbersome process with long delays that could put patients at risk. As it turned out, their concerns were this time unfounded and “ask permission” actually was being interpreted (at least for the staff of this very reputable clinic) as “inform us after the fact.” What is important about this example, though, is that the intertwining of legal and medical created a dilemma for healthcare workers. They believed they had solved the medical problem – deaths from a side effect (lactic acidosis) – and done it better than most other sites. But as medical experts they were ill equipped to take on the legal questions. This could
adversely affect the health of their patients, and such discretion was at the core of their medical obligations, ethical and legal.

**Reaching Higher with Guidelines**

Clinical guidelines, including those referenced and discussed above, are procedural standards. They tell caregivers (and others, such as researchers) what steps to follow under particular circumstances—how to decide when is time to start a child on antiretroviral therapy, how to proceed when a patient has both TB and HIV, or how to determine why a patient is no longer doing well on antiretroviral therapy. Guideline writers review the voluminous clinical literature, attempting to sort the well-supported findings from the conjectures. Their recommendations are coupled with ratings of the evidence on key points. The result is a highly compressed summary written in the form of a suggested course of action. The objective is to create a higher level performance by already skilled practitioners, and the anticipated results are fewer mistakes, less wasted time, and better outcomes.

Medical staff in my field sites frequently referred to guidelines. They referred to them in discussing the mistakes of other practitioners, for instance, commenting (in South Africa) on doctors who ignorantly started patients monotherapy (one drug) rather than on HAART (a multi-drug regimen) or doctors who didn’t know that the symptoms of TB are modified by HIV infection and so failed to diagnose and resolve TB before starting their patients on antiretroviral therapy (in Uganda). They also referred their students to guidelines and went over guidelines in teaching (most notably when a group of us sat squeezed together onto a hard wooden bench for several hours of instruction in a doctor’s office in Uganda). Aware that guidelines are “always in development,” doctors also talked about which guidelines did not fit local conditions. For instance, dosages needed to be modified for the lower body mass of Thai patients and some
antiretrovirals seemed more prone to cause kidney problems in Thai patients than in Westerners. Similarly, the South African doctors in my field site believed that recommendations about first-line regimens needed to be modified to include a warning about watching closely for lactic acidosis when people with high body mass indexes are prescribed d4T.

In each of these examples, the conversation could move to a higher level and arrive at more complex questions because it could start with the guideline as a base. Much of the literature on guidelines discusses guidelines as a floor beneath the feet of practitioners, a minimum level of performance. As a floor, guidelines should reduce error, help physicians incorporate new scientific findings into their practice, and ensure that doctors track side effects, complications, and drug interactions. Yet floors can also be foundations for even better performances. In several of the clinics, staff were actively involved in writing guidelines. In some instances they were doing this with international bodies (e.g., the names of some of the clinic doctors appeared in lists of contributors to major guidelines); more commonly they were involved in reworking guidelines for clinic use. In the Ugandan clinic, for instance, the doctors had embarked on a process of preparing clinic guidelines on a long list of topics and were meeting regularly to review the drafts. In South Africa, one doctor seemed to enjoy boiling down large tomes (e.g., on TB) for hospital use, and other doctors regularly updated loose-leaf binders of the most important guidelines that were kept in all of the examining rooms. Other staff went through guidelines and prepared forms that guided activities, reminding staff and patients of the schedules of visits, which visits required what lab tests, when patients had to fast before clinic visits, that female patients needed annual pap smears, etc. That there were guidelines available as references, as starting points for conversations, as documents from which schedules of lab tests could be extracted and then perhaps modified all meant that conversations were more detailed and more sophisticated than they would be if everyone had to reinvent the
wheel each time a piece of work needed to be done.

This is what Timmermans and Berg (2003) mean in arguing that the good effects of standards come about only when people “actively submit” to standards. Neither standards nor workers can produce the results alone; it is rather the interaction of the workers and guidelines, the result of workers allowing their work and thought to be shaped by the guidelines. To put it another way, the most positive results of these guidelines are achieved when workers use them as a basis for further deliberation; guidelines are intended to be used mindfully rather than robotically. Rather than a way to avoid thought (Heimer 2008) then, guidelines encourage and discipline thought. It may not always be deep deliberation that is required, of course, but guidelines at least encourage an assessment of whether the guideline fits or whether a caregiver needs to deviate from the guideline.

Guidelines and the Deskilling of Labor

But what of the argument that standardization is part of a process of deskilling work? If it is possible to routinize work, to produce guidelines for workers to follow, then does that not mean that less skilled workers can be hired to fill those jobs? That routinization deskills workers has been a common claim in the sociology of work and the sociology of organizations (citations). Yet there have always been contrary findings. In research on life insurance sales and fast food franchises, Leidner (1993) found that workers confronting social awkwardness – for instance in trying to sell life insurance in the living rooms of strangers – welcomed the help of scripts.

Scripting of work with guidelines, protocols, or recipes, makes complex work possible. But only with training and practice do people become fully competent users of complex scripts.

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6 On this general contrast between ways of organizing activity to minimize the need for thought or to encourage thought, see DiMaggio 1997, Heimer 2001 and 2008, Sabel 2007, Weick and Sutcliffe 2007.
Just as someone who cannot cook well may be able to read a menu or cookbook without being able to produce any of the dishes, so an untrained reader of guidelines may be able to get the gist of what they recommend, but would be completely unable to carry out the instructions. Having read many guidelines does not, for instance, mean that I am equipped to practice medicine.

Even when people have acquired the basic skills and professional training necessary to use these guidelines, though, differences in skill and training remain. One common misconception is that guidelines are only for the unskilled. But that, as it turns out, is not the case. In the five clinics, all of which were elite facilities, guidelines were widely used.\footnote{A recently published study of cardiac units confirms this point. In a study that compared hospitals involved in clinical trials with hospitals that were not, Majumdar et al (2008) found that hospitals that were more involved in clinical trials were more likely to use guidelines – and consequently had lower in-hospital mortality rates. Their argument was that participation in clinical trials led to changes in the hospital environment, with the same skills and practices required to participate in clinical trials – namely protocol-driven work – being adopted for caregiving as well. (See Hughes 2008 for a summary of this piece.)}

The difference between skilled workers and others is not that skilled workers don’t use recipes or routines, but rather that routines are for them a foundation for flexible adaptation. Just as a good cook can quickly suggest a half dozen variations on a recipe or several substitutions for a missing ingredient or a handful of fixes for a mistake, so a skilled medical practitioner uses guidelines to help him or her think about ways to solve complex problems. People use guidelines less flexibly when they are just learning, and indeed their teachers may require more rigid adherence to rules during apprenticeship. In his study of surgery residents, Bosk 2003 [1979]) found that heads of surgical services had rather rigid routines that they expected their underlings to follow. These routines facilitated the learning of residents and permitted coordination of complex activities in the operating room. Although their junior staff initially lacked the skill to do this, the senior surgeons themselves could use rules more flexibly and could adjust and correct as circumstances required. This capacity to adjust and correct meant that subordinates’ technical errors were less
worrisome than normative errors (which might undermine communication about errors).

Standardization can of course allow employers to do the same thing with less skilled workers, and indeed that is what many public health programs hope to accomplish in poor countries. If antiretroviral rollout programs are to succeed, they will have to use less trained medical workers to do tasks initially assigned only to the most skilled physicians. But often the objective in standardization is not to do the same thing with cheaper labor; instead the aim is to do something more or better with skilled labor. Skilled workers may be able to move more quickly through their work and do it with fewer errors when the steps have been spelled out in a guideline. They are more likely to be able to transfer work to a colleague midstream when both workers are accustomed to working with the same guideline. They may spot anomalies more quickly and see how to manage them when guidelines point out the main variations that are likely to arise. The trick of course, is to use guidelines to increase the capacities of all of the workers – so both less and more skilled workers are doing better work than they would without the guidelines. The best guidelines are also written so that they make people think – about when they need to refer, what to do about anomalies, etc. – rather than shutting off thought. And in fact, good guidelines encourage more innovative thinking because people do not have to think as much about truly routine parts.

Rights and obligations to use judgment are unevenly distributed across status hierarchies of course. Chambliss (1996) notes that although nurses are trained to be caring professionals, their capacity to exercise professional judgment is severely curtailed. As hospital employees and subordinates in the medical hierarchy, nurses often are expected simply to “follow” the rules. Because they are not empowered to make choices, nurses thus encounter ethical “problems” rather than the ethical “dilemmas” faced by doctors. But discretion depends on training and educational qualifications as well as status. However high a person’s rank, when guidelines are
strongly tied to the legal system, staff members who lack legal training lose some of their capacity to use discretion. Highly placed, skilled users of medical guidelines may nevertheless be untrained, unskilled users of the legal part of guidelines. When medical guidelines are tied to law, then, even high status medical staff lose some of their capacity to adapt.

[Table 3 about here]

As summarized in Table 3, different categories of workers will have different experiences with guidelines and will be differently affected by the medical and legal elements in those guidelines. This is partly a matter of skill base – that medical guidelines are of course about medicine, so those at the top of the medical hierarchy are most likely to have the training that will make them facile users of the guidelines. But it is also a matter of status. Thus, although neither doctors nor nurses are likely to have the legal training that would equip them to be facile interpreters or users of the legal elements of medical guidelines, the legal system gives more rights to doctors and fewer to nurses. Doctors have more privileges, but nurses have more legal cover than doctors. Counseling staff are more likely than most medical workers to work at the interface of law and medicine. They typically are not legally trained, though, which can make for a great deal of anxiety about what they can and cannot do. In the clinics and hospitals of rich countries, some ancillary staff are likely to have received a bit of training on legal matters – a few workshops perhaps. The hospital also may have its own legal staff or hire outside legal experts episodically. Generally speaking, though, medical and legal expertise tend to be located in different people and even in different parts of the organization. All this makes for complex relationships to guidelines. It is not simply that some people have the skills to use guidelines and others lack those skills; instead it’s that different people have the skills to work with different elements in the guidelines. Often no one is an expert in all of the elements.
The Locus of Discretion in Law and Medicine (summary)

The management of discretion varies by field. In medicine, discretion is local and is concentrated in doctors. In law, in contrast, discretion is concentrated at the appellate level than at the first encounter between case and law (Stinchcombe 2001, Llewellyn 1960).

In any given medical institution, the right to interpret and adjust is in the hands of the doctors first encountering the case; interpretation and adjustment generally does not have to wait for the judgment of higher-ranking, specialist doctors. One needs to be careful not to overstate this point, though. Within medical institutions, occupations are partially ranked, with doctors having authority over nurses and so having a larger sphere of discretion than nurses. Within this system of ranked occupations, though, nurses and other professionals (phlebotomists, physical therapists, various technicians), workers do retain some control over their separate jurisdictions and some discretion within that special sphere despite the overall dominance of doctors. And within the sphere of doctors, there are of course some medical problems that require referral and some categories of doctors (interns, residents) who have less autonomy.

In addition to tailoring their actions to fit the cases they encounter, in many places doctors also can modify the rules that they work with so that these rules have a better fit with the stream of cases they typically encounter. To put it differently, the medical “law” that doctors work with can be adjusted in the place where this “law” encounters the “cases.” Clinical guidelines can be recrafted to be local documents.

As medicine has become more “legalized,” though, some of this local flexibility has disappeared. More of the work of doctors (and other medical workers) has come to be organized around clinical guidelines, and this has disciplined the dialogue between cases and medical knowledge by making it more often a dialogue that takes place in the context of medical “law,” a particular summation of medical knowledge. At the same time, these guidelines have been
adopted as standards of practice by governments, granting bodies, insurers, and clinics. As the “soft law” of medicine is “hardened,” doctors are more often required to justify their decisions to senior doctors or external review panels. Discretion is thus less local, more constrained by medical “law, and more subject to review.

Conclusion: Doctors within Borders (summary)

It would be a mistake to overstate the uniformity of arrangements for social control and governance in medical care. Although I have argued that medicine has become more “legalized” in recent decades, that the regulation of medicine has become more formal and more organized around explicit rules, it is nevertheless more legalized in some places and less legalized in others. Table 4 tries to capture some of this variability by comparing systems of medical “law” on two dimensions: whether guidelines speak to medical matters and whether they speak to legal issues.

[Table 4 about here]

The “pre-guideline” period (and places where guidelines continue to play only a small role) is represented in this chart by the cell in which guidelines are silent both on legal and medical issues. In such times and places, the practice of medicine is not strongly regulated either by a body of peers working through codification of scientific knowledge or by state bodies attempting to regulate the work of professionals.

When the medical profession is very much under the control of doctors, as described by Light (1995, but check citation), guidelines will address mostly medical matters and be mostly silent on legal questions. If states are involved in the regulation of medicine, it will often be when they are enlisted by one branch of medicine (e.g., allopaths) in the battled to delegitimate another branch (e.g., homeopaths) (Starr 1982). Medicine can also be the handmaiden of the state, though, and in such circumstances, it is the state rather than the medical profession that
decides how medicine will be practiced and with what purposes. In such situations, guidelines will especially address the legality of procedures such as abortion or involuntary hospitalization of people judged to be mentally ill, rather than addressing strictly medical and scientific issues.

The argument of this paper is that increasingly guidelines have both medical and legal content, so jurisdiction is now shared. This sharing of jurisdiction usefully diffuses guidelines to places they otherwise would not have reached and raises questions about the allocation of medical resources. The difficulty, of course, is that sometimes the rigidity that is introduced by an increasing emphasis on rules undermines the very important local adjustment that is the hallmark of medicine. Doctoring within borders established by the state has its costs.

This paper has looked at how the use of medical guidelines changes when those guidelines have a legal element. Because they lack expertise in legal matters, I argue, clinic staff are often quite uncomfortable with these legal interfaces. In long years of training, medical staff are taught to use guidelines flexibly. It is their responsibility to asses whether and how guidelines actually apply. Although clinical guidelines may allow doctors to stand on the shoulders of generations of other doctors and scientists, they are always aware that there will be exceptions. Their medical training thus equips them intellectually and morally to make the judgment calls about when and how guidelines should be put aside. But doctors do not routinely know when to put the law aside or how they can do that even if they should.

References
Guidelines


Table 1: Clinical Guidelines (for treatment of HIV infected adults and adolescents)*

<table>
<thead>
<tr>
<th>Entity Producing or Adopting Guideline</th>
<th>What is it?</th>
<th>How “hard” or “soft” is it?</th>
<th>How precise are the requirements? Are there provisions for delegation?</th>
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<tbody>
<tr>
<td><strong>International Treatment Guidelines</strong></td>
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<td>DHHS/CDC (January 2008 revision)</td>
<td>Produced and regularly updated by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, a working group of the Office of AIDS Research Advisory Council. The first versions of these guidelines were aimed at the US population, so offered little guidance on how to make apply the guidelines in resource-constrained settings (where, e.g., lab tests could not be performed); this is somewhat less true now. Available on website.</td>
<td>As a general matter, international treatment guidelines are not legally “obligatory” unless made so by other bodies (e.g., by mandate of national government, clinic adoption, or third party payer). In some places, caregivers might be held liable, e.g. in malpractice suit for failure to give patients care that complied with guidelines. They are very precise. No provisions are made for delegation (that is, for enforcement).</td>
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<tr>
<td>IAS-USA</td>
<td>Available on website and published in JAMA. 17 pp.</td>
<td>Same as above</td>
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<td><strong>International NGO Treatment Guidelines</strong></td>
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<tr>
<td>MSF (Médecins sans Frontières)</td>
<td>Clinical Guidelines: Diagnosis and Treatment Manual. The HIV guidelines are included in this general manual which is “for curative programs in hospitals and dispensaries.” Available on website. Section on HIV is 13 pp.</td>
<td>Available for use by others; not clear whether these guidelines are in any sense binding on MSF clinics. Guidelines based on those issued by bodies such as WHO</td>
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<td>Examples: South Africa, Thailand, Uganda; not US</td>
<td>Available on websites. Typically modified from WHO guidelines to take account of local conditions (special disease combinations, availability of laboratory facilities, access to and local production of medicines, availability of trained staff, fiscal constraints). Apply universally within country.</td>
<td>Mandatory for health facilities participating in government treatment programs. Recommendations very precise. Some provisions for delegation (e.g. mandatory reporting when switch regimens).</td>
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<td><strong>National Treatment Guidelines</strong></td>
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<td>US2 (but not US1) Thailand South Africa Uganda</td>
<td>Available to clinic staff, e.g. in loose-leaf binders in treatment rooms. Updated episodically, especially when new guidelines released by WHO or DHHS, when national governments modify their guidelines, or when funding bodies (e.g. Ryan White funds or Medicaid in US) change their rules</td>
<td>Typically mandatory within clinic, though clinic staff generally sensitive to need for flexibility. Very precise; more precision added through reference to other guidelines. Oversight sometimes mandated (e.g. by requiring formal discussion of regimen changes).</td>
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*There are many other guidelines, including guidelines for other groups (children), people with particular conditions (pregnancy), for particular activities (counseling), for managing special problems (occupational exposure), or carrying out particular tasks (developing treatment guidelines).
Table 2. Legal and Medical Elements of Clinical Guidelines

<table>
<thead>
<tr>
<th>Guidelines*</th>
<th>Medical Elements in Guidelines</th>
<th>Legal Elements in Guidelines</th>
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<tbody>
<tr>
<td><strong>Testing Guideline</strong></td>
<td>Medical elements present, relatively constant across settings, not complex. Testing staff typically a mix of specially trained counselors and nurses.</td>
<td>Legal elements often specifically addressed (e.g., in 2006 CDC revised guideline on testing), but laws highly variable by locale and in flux. Legal issues: Is informed consent required, and if so must it be written consent? Is counseling required (pre-test? post-test? both?)? Must exposed partners be notified? Must HIV infections be reported to the state (anonymously or by name?)? At what age can children and adolescents consent to testing? In the event of a needlestick injury to a health worker, is there some provision for testing the blood of the patient (whether or not the patient consents)?</td>
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<tr>
<td><strong>Initiating Antiretroviral Therapy (ARV) in Adults and Adolescents</strong></td>
<td>Medical elements present, relatively constant across settings, but with some variability with which drugs are available, complex. Typically done by doctors, though sometimes by specially trained HIV nurses; ARV training often done by specially trained counselors</td>
<td>Legal elements usually addressed only indirectly. Legal issues: Are training programs mandated? Do doctors have discretion over which regimens to use or are limits placed by the ministry of health (or similar body)?</td>
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<td><strong>Switching Regimens</strong></td>
<td>Medical elements present, somewhat more variable across settings because of variations in access to alternative regimens and adequacy of lab facilities, highly complex. Always done by doctors. When adjustment is because of side-effects, switching may be less medically complicated than when switching is necessitated by drug resistance; when resistance is suspected, patient often referred to doctor specializing in this problem.</td>
<td>Legal elements usually addressed only indirectly. Legal issues: Does the government program provide for switching regimens? Must a doctor request permission or notify a government body before switching a patient to a different regimen?</td>
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<tr>
<td><strong>Preventing Mother-to-Child Transmission (PMTCT)</strong></td>
<td>Medical elements present, some variability across settings (because rich countries have option to start women on ARV and to deliver surgically), complexity depends on whether pregnant women receive full ARV or prophylactic regimen. Typically done by doctors.</td>
<td>Legal elements usually addressed only indirectly (e.g., in South African 2008 PMTCT guideline: women “... should be given routine information abut voluntary HIV testing and the PMTCT programme”). Legal issues: Will women be tested routinely as part of antenatal care? Are signed consent forms required? Will women be required to take prophylaxis to protect their babies?</td>
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<tr>
<td><strong>Treating HIV Infected Children</strong></td>
<td>Medical elements present, some variability across settings because of drug availability, quite complex (partly because less is known about pediatric HIV). Always done by doctors.</td>
<td>Legal elements sometimes addressed directly (e.g., in South African pediatric guidelines). Legal issues: At what age can children consent to testing and treatment? Who can consent on behalf of a young child? What should medical practitioners do if parents oppose treatment?</td>
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*These guidelines do not stand alone, but typically appear alongside other guidelines in the HIV guidelines issued by a guideline writing panel, a ministry of health, or a clinic.
Table 3: Occupation and Expertise

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<tr>
<th>Types of Workers</th>
<th>Medical Elements</th>
<th>Legal Elements</th>
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| **Medical Doctors**  
(Physicians, Medical Officers) | Fully competent to deal with medical elements, but two kinds of expertise are recognized: HIV specialty and special expertise within HIV, such as with pregnancy, pediatrics, opportunistic infections, or drug resistance. | Typically not legally trained, often legally empowered to carry out particular actions. Because of lack of legal training, likely not to know limits, exceptions, etc.; general reaction is caution. |
| **Nurses (Professional Nurses, Licensed Practical Nurses, etc.)** | Competent in many medical matters, but subordinate to doctors; specialist nurses may practice with little supervision from doctors; in some locales, nurses can prescribe some categories of drugs. | Not legally trained, less scope to legal empowerment than is the case for doctors; typically practice under the supervision of doctors and so some legal cover provided by doctors. |
| **Other Medical Staff**  
(Pharmacists, Phlebotomists, Lab Workers) | Competent in specialty, but perhaps not in the matters generally addressed in the guideline. | Not legally trained, empowered to carry out specific activities. |
| **Counseling Staff**  
(Psychologists, Counselors, Peer Counselors) | Generally not competent on medical matters, though usually more knowledgeable than general population; may be trained to do HIV testing and counseling (also psychological counseling for psychologists); often interact with patients. | Generally not legally trained, but more of their activities put them at boundaries jointly governed by law and medicine; sometimes great uncertainty and anxiety about what can and cannot legally be done. |
| **Ancillary Staff:**  
Administrators, Financial Officers, Legal Counsel (Positions, Titles, Job Descriptions Vary by Locale) | Generally not competent in medical matters; may have little or no contact with patients. | Generally not legally trained (exception is legal counsel, but not all institutions have this position), though some knowledge of law. Many of their activities put them at boundaries of medical institutions, which are often jointly governed by law and medicine. Often consulted by others about what can and cannot legally be done. |

Table 4: Guidelines and Jurisdiction in Health Care

<table>
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<tr>
<th>Guidelines</th>
<th>Guidelines Silent on Medical Issues</th>
<th>Guidelines Speak to Medical Issues</th>
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<tbody>
<tr>
<td>Guidelines Speak to Legal Issues</td>
<td>health care fully controlled by state and legal professionals</td>
<td>shared jurisdiction</td>
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<tr>
<td>Guidelines Silent on Legal Issues</td>
<td>no formal regulation</td>
<td>health care fully in jurisdiction of health professionals</td>
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</tbody>
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