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Performing Regulation: Transcending Regulatory Ritualism in HIV Clinics

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Sociolegal scholars suggest that regulatory encounters often are occasions for displaying a surface compliance decoupled from day-to-day practice. Yet ethnographic data from five highly regulated HIV clinics show that regulatory encounters open opportunities both for ritualism and—surprisingly—for transcending ritualism. Using a theatrical analogy, we argue that improv performance is the technology that enables regulatory inspectors and clinic staff to transcend ritualism. As regulatory encounters unfold, clinics' carefully prepared performances sometimes change into more cooperative interactions where inspectors and regulatees hash out details about how rules will be applied and even work together on reports for the regulators' supervisors. By "performing together," regulatory inspectors gain access to the clinic's backstage where they can assess clinic workers' deeper conformity to ethical and scientific norms. But such joint performances are less likely where cultural divides and material scarcity make it difficult for clinic staff to gain inspectors' trust.

In 2009, the FDA began the process of disqualifying Chicago HIV specialist Dr. Daniel Berger as a clinical researcher, charging that he had "failed to protect the rights, safety and welfare of subjects under [his] care, repeatedly or deliberately submitted false information to the sponsor and repeatedly or deliberately failed to comply with the cited [federal] regulations, which placed unnecessary risks to human subjects and jeopardized the integrity of data."[1] The infractions were serious: forged or missing signatures; falsified records of physical examinations, electrocardiograms, and labora-

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[1] Berger NIDPOE.pdf. available at http://www.fda.gov/downloads/RegulatoryInformation/FOI/ElectronicReadingRoom/UCM193324.pdf. Viewed July 13, 2011. See also Callahan (2010).

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tory results; enrolling of patients without adequate checks on their eligibility; and disappearance of over two hundred tablets of investigational drugs. Ultimately Berger proved that the fraud was traceable to a research coordinator who was embezzling research subjects' stipends. But Berger had not adequately supervised the employee's work and had failed to uncover his criminal record in pre-employment screening. After months of negotiations, the FDA agreed that Berger could continue conducting drug studies, with the stipulation that an outside monitor review his work.

So how was the fraud uncovered? In 2008 and 2009, a clinical trials monitor noted anomalies in signatures on consent forms and other documents and reported these findings to the FDA, which began an investigation. Here the irregularities were paired with and concealed by forged signatures, making them relatively easy to uncover in routine monitoring. But noncompliance may not always occur in tandem with surface irregularities and may not be visible unless a monitor can secure access to the "backstage" of a clinic's operation. It is the process and effects of getting backstage that this article explores.

Seemingly detached from the serious work of science and treatment, the regulatory encounters we discuss entail arcane rules and endless paperwork. Such regulatory work is just the place where we might expect ritualistic adherence to the "letter of the law." In fact, though, the stakes are very high and regulatory encounters can move well beyond ritualism, as Berger and his research coordinator learned. Clinical research and treatment programs are multimillion dollar enterprises. Without assurance of ethical and scientific integrity in data collection, clinical trial results cannot withstand FDA scrutiny, jeopardizing patients' access to safe and effective drugs and therapies. For government and industry sponsors, regulatory inspections provide crucial evidence that they have invested in scientifically and ethically sound research. And as Berger's case illustrates, researchers' and clinics' access to future research and treatment funding depends on demonstrated compliance with regulations. Mostly the stakes of regulation remain as background in the encounters between monitors and clinic workers. But episodically, clinic staff worried about how they could continue vital work if they lost funding and monitors reflected on their pride in ensuring the integrity of important medical research.

We argue that a closer examination of regulatory site inspections suggests that the social construction of rules, violations, and compliance opens opportunities both for ritualism and for the transcendence of ritualism. Although such classics as *Going by the Book* (Bardach and Kagan 2002 [1982]) and *Environment and Enforcement* (Hawkins 1984b) show that regulatory site inspectors play a key role in interpreting rules, how such encounters unfold remains

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underspecified. To learn how and when ritualism is transcended, we examine regulatory interactions in a highly regulated setting: HIV clinics with both treatment and research programs. We find that as regulatory encounters unfold, clinics' carefully prepared performances for site inspectors often evolve into collaborative interactions in which regulators and clinic staff express frustration about the complexity of the rules, trade tips about how to do their work, and negotiate the findings to be transmitted up the hierarchy. But collaborations between clinic staff and inspectors only occur under limited conditions and are less likely where cultural divides and material scarcity make it difficult for clinic staff to create trust.

Analyzing regulatory inspections as performances draws attention to the existence of these important collaborative responses and helps us understand how they arise. We argue that improv performance is the technology by which regulatory inspectors and clinic staff negotiate a less ritualistic approach to regulation.

Getting By or Aiming for More in Regulatory Encounters

With the dismantling of the regulatory apparatus of states, the connection of rules and regulations to formal law has become looser, more distant, and more varied. With many entities now engaged in producing ever more rules and regulations, performing audits, and monitoring and enforcing compliance, it has become harder for people to determine what the rules actually are, which rules are obligatory and which are merely guidelines, and how to settle disagreements (Hutter 2006; Levi-Faur and Jordana 2005: 6; Schneiberg and Bartley 2008: 40; Vogel 1996). Under these circumstances, neo-institutionalists and responsive regulation scholars concur, we should expect to find ritualism.

Neo-institutional theorists, such as Meyer and Rowan (1977) and DiMaggio and Powell (1991), have argued that organizations experience substantial pressure to bring their practices into line with those of peer organizations. Yet, as subsequent studies confirm, adopting institutionalized practices to bring an organization into conformity with regulations may have relatively little effect on day-to-day activities (e.g., Dobbin and Kelly 2007; Edelman et al. 1999). New offices are created, new routines formally adopted, yet the changes may be mostly ceremonial, at least initially, partly because it is insiders who craft the regulatory solutions. Those being regulated often become adept at following the letter of the law while ignoring its deeper objectives.

Responsive regulation scholars have been more optimistic about the capacity of regulators to move regulatees in the desired direction. Yet they too note the challenge posed by complex

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regulatory environments: "Today the government is a regulator, the firm is a regulator, the profession is a regulator and we are embattled by regulatory oversight; the most widespread response is regulatory ritualism" (J. Braithwaite et al. 2007: 330). Defining ritualism as "acceptance of institutionalized means for securing regulatory goals while losing focus on achieving the goals or outcomes themselves" (Braithwaite 2008: 141), they suggest that both regulators and regulatees "engage in the game of regulatory ritual in order to 'get by' in the regulatory society" (J. Braithwaite et al. 2007: 330).

But even where we expect considerable regulatory ritualism, some opportunities for refocusing on regulatory objectives remain. However detailed a regulation appears to be, its meaning always must be constructed "within the social field that it is designed to regulate" (Edelman et al. 1999: 407; see also Edelman et al. 2011), a process that is more complicated when competing institutions purport to regulate the same area (Heimer 1999) or multiple actors claim the right to define the meaning of key rules (Dobbin and Kelly 2007). This indeterminacy of law and regulation can tip regulators and regulatees in the direction of ritualism or create an opportunity to do regulation together. In introducing the performance metaphor, we offer an alternative account of how rules become specified and explain one mechanism that can modulate ritualism and tip participants toward collaboration. Although we agree with Edelman et al. that meanings are worked out in the social field being regulated, when negotiations occur outside the formal legal system on the turf of the regulatees, local variations may be less likely to shape institutionally accepted meanings of rules but may be more able to keep people focused on the "real norms."

To understand responses to complex, decentered regulatory systems, we examine regulatory encounters in HIV clinics, which receive intense scrutiny from multiple regulatory bodies. But where other scholars have found a willful "loss of focus" on deeper principles and even nefarious intentions, in the situation we examined most players were strongly committed to the goals of treatment and research and supportive of regulation. Although we observed some regulatory ritualism, regulators and clinic staff usually were aiming for something more than "getting by." Rather than regulatory ritualism, we observed regulators and clinic staff collaborating to avoid trivialities. To understand when and why the expected regulatory ritualism was muted, we looked closely at the events surrounding regulatory encounters: preparations, regulatory visits, post-mortems, and the reinterpretations in clinics' oral traditions. By looking at regulatory encounters as improv performances, we can see how ritualism is reduced when inspectors gain

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access to the backstage by joining the performance. Our approach is broadly consistent with Black's "decentred understanding of regulation" in that we show how regulatory compliance is the "product of interactions" (2001: 110).

Embedded in Braithwaite's definition of ritualism (cited above) are three key concepts—institutionalized means, regulatory goals, and losing focus—that we refine and use throughout this article. In the world of HIV research, "institutionalized means" generally involves documentation of some form, ranging, for instance, from IRB ethics certification to SOPs (standard operating procedures) specifying how nurses should measure blood pressure. The "regulatory goals" of HIV research include ethical principles enshrined in oversight documents such as the Belmont Report as well as scientific tenets such as transparency and consistency of measures. The critical point comes, though, when means (or practices) do not match goals (or principles). Confronted with situations where they could either meet documentary standards or adhere to deep principles, clinics can react in several ways. In ritualized compliance, clinics "lose focus"; meeting technical requirements for documentation supersedes or substitutes for meeting regulatory goals and attending to deep principles. Regulators who have been "captured" may sometimes accept symbolic gestures as the real thing. Somewhat to our surprise, though, we instead observed clinics and regulators joining forces to meet documentary standards in order to re-focus on regulatory goals. Rather than devolving to an exchange of empty gestures disguising the divide between merely providing documentation and adhering to principles, the collaborative performances we observed reintegrated the two, yielding local solutions that met regulatory goals and demonstrated compliance in ways that satisfied clinical research's audit culture.

Transitions from ritualized compliance to collaborating to avoid trivialities depended, though, on regulatory site inspectors' assessments of preliminary signals. Regulators were more willing to "perform together" when early evidence suggested that the clinic was making a good faith effort to comply with regulations. Our observations suggest, though, that regulators had more difficulty reading the signals in sites outside the United States and were therefore less open to collaboration there. In a regulatory climate where symbolic compliance is common, we find that shallow responses are often just the first step on the path to deeper compliance, that deeper compliance involves a staged collaboration between regulators and clinic staff, and that regulators judge compliance somewhat differently in clinics in the United States than in our non-U.S. sites.

This article thus revisits a fundamental regulatory dilemma. For many purposes, principles work better than fine-grained,

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strictly-applied rules because they encourage responsiveness to the situation (Bardach and Kagan 2002 [1982]; Braithwaite and Braithwaite 1995; Selznick 1992). One would think, then, that we would want street-level regulators to consider not just technical compliance but also the soundness of a regulatee's reasons for adhering to or violating a rule. Are they are seeing mistake or misconduct (Vaughan 1999)? Is there a pattern of rule breaking or is this just a "one-off" violation (Hawkins 1984b)? As a general matter, worries about accountability and consistency push in the direction of more rules because, as Power (1997) argues, the audits that are made possible by exact rules comfort us with evidence that things are as they should be. A monitor we observed ruefully concurred: "what were once [more flexible] guidelines are now [more rigid] SOPs." Yet even with the contemporary emphasis on audits and strict adherence to rules, we in fact find pockets of flexibility. And this flexibility seems to arise because people worry that sometimes "[t]he pursuit of reliability of parts causes the unreliability of the whole" (J. Braithwaite et al. 2007: 225).

Although there is ample precedent for studying regulation in the field (notably Bardach and Kagan 2002 [1982]; J. Braithwaite et al. 2007; Gilboy 1997; Hawkins 1984a, 1984b; Larson 2004; Rees 1988), the regulatory encounter remains a key area for untangling the dynamics of resistance, ritualism, collaboration, and compliance. Here, as Black (2001) urges, we examine the interactions between actors (regulatory inspectors and clinic staff) who must co-construct knowledge about a clinic's compliance. Our examination of compliance work as it unfolds in regulatory performances allows us to see how regulators and clinic staff reclaim some discretion and overcome doubts that would otherwise push them in the direction of rigidity and regulatory ritualism.

Data and Methods

We draw on fieldwork and interviews in five HIV clinics—two in the United States and one each in South Africa, Thailand, and Uganda—gathered for a larger project on the legalization of medicine. The work of HIV clinics is shaped by clinical guidelines, research protocols, and the other trappings of evidence-based medicine. The demands on such clinics to demonstrate adherence to requirements of donors, research sponsors, and accreditation bodies make them a rich resource for studying high-stakes regulatory encounters.

In planning this research, we selected sites in countries that vary in wealth and levels of development, in turn correlated with health infrastructure and access to drugs. These countries also vary

in epidemic burden (high in Uganda and South Africa, intermediate in Thailand, and lowest in the United States). affected populations (mainly heterosexual in Uganda, South Africa and Thailand; initially mainly gay men in the United States, but now minorities and IV drug users), and government stance on the epidemic (most openly acknowledged in Uganda, intermediate in Thailand and the United States, long denied in South Africa). For the purposes of this article, these countries offer useful variation in resources to comply with regulatory mandates and in status, cultural, and linguistic differences between regulators and clinic staff.

The clinics we studied all have hospital and university affiliations and are engaged in both treatment and research. The composition of regulatory activities varies with the nature of the clinics' institutional ties, the sponsors supporting their research and treatment programs, and their particular mix of programs. One American clinic (US1) is a private clinic that accepts only insured patients and conducts a mix of industry and U.S. government funded research, with research funds coming primarily from the U.S. National Institutes of Health (NIH). The second American clinic (US2) is a public facility that treats mostly uninsured patients, mainly using federal resources. It too conducts both industry and NIH-sponsored research. The Ugandan clinic, once exclusively a research center, now provides HIV treatment funded by international donors and a local government program. Its research is sponsored mainly by NIH. The South African clinic focuses on treatment, with care funded by government programs, insurance, patient payments, and international donors; it also has a growing research program, mostly conducted in collaboration with external partners. The Thai clinic performs research sponsored by local and foreign governments as well as industry, but also provides care for post-trial subjects using funds from insurance, patient fees, and government programs. At the time of our research, all but the Thai clinic received U.S. government funds for treatment and all five clinics received research funding (directly or indirectly) from the U.S. NIH, bringing them under the regulatory gaze of the American government.

Regulatory inspections were significant occasions in all of the clinics, but were especially momentous when regulators were coming from some distance—both culturally and geographically—to inspect clinics in resource-limited countries. In the American clinics, staff generally faced monitor visits with cheerful resignation. In Uganda, in contrast, we were told that the anxiety surrounding regulatory visits "overcomplicated everything" and one research coordinator estimated that she spent an entire month preparing for a single monitoring visit.

As treatment facilities, the HIV clinics we studied operate like physicians' offices. Patients come for check-ups and sick visits, are

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examined by medical staff, have their HIV medications adjusted, and receive bills. In addition, the clinics offer extensive counseling about prevention, testing, disclosure, and treatment. Drugs are often provided through a donor or government program, with the attendant paperwork burden and site visits.

The research programs of these clinics are highly structured variants of treatment programs. Much of the day-to-day work is done by specially trained "research nurses," also known as "study nurses." Patients are enrolled in trials as subjects, assigned randomly to experimental or control arms, and scheduled for a series of "study visits" over the duration of the research project (several months to several years). For each study visit, the protocol specifies physical exams to be conducted, blood samples to be drawn, questionnaires to be administered, and medications to be adjusted. After visits, study nurses complete the case report forms (CRFs) and other documentation. Often, data are collected in many clinics simultaneously and then pooled for statistical testing to establish safety and efficacy. In clinical trials of new drugs, study records may be submitted as part of an application to the U.S. FDA, the key gatekeeper for both U.S. and international pharmaceutical markets. Sponsors place a premium on flawless documentation and periodically send research monitors, whose work is described more fully below, to examine clinic records for accuracy and compliance with protocols. Clinics responded to this pressure by hiring data managers and, particularly in Uganda and Thailand, internal study monitors.

In each fieldsite, one or two members of our team conducted the bulk of the research while others visited the site, usually for a couple of weeks.[2] The fieldwork in the American clinics was of longer duration (nearly two years in US1; thirteen months in US2) but was less intensive (we were not in the field every day). We spent four months doing intensive fieldwork in Thailand, Uganda, and South Africa, with multiple visits of several weeks before and after. We began fieldwork in US1 in the fall of 2003 and last revisited our Ugandan, Thai, and South African sites in the summer of 2007.

We shadowed staff as they went about their work—conducting the study visits of clinical trials; examining patients who came for treatment; making phone calls; going over records with research monitors, site visitors, and accreditors; and attending endless meetings. We gathered copies of forms and policies used in clinic work.

[2] The fieldwork was conducted by Carol Heimer (US1, Thailand, Uganda, South Africa; site visits to US2), Lynn Gazley (Thailand; site visits to US1, South Africa), Rebecca Culyba (US2), and JuLeigh Petty (US1; site visits to US2, Uganda, South Africa). Enid Wamani and Dusita Pheungsamran assisted with fieldwork in Uganda and Thailand, respectively.

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We attended research team meetings, training sessions, clinic care meetings, meetings about standard operating procedures, research grant application meetings, and even prayer meetings. We interviewed and observed staff in a variety of positions at all levels of the hierarchy—physicians, principal investigators, nurses, administrators, social workers and counselors, pharmacists, lab workers, reception and clerical staff, and data entry clerks.

The information we gathered as observers laid the groundwork for frank discussions about how staff prepared for research monitors' visits, worked with site visitors while they were in the clinic, and recovered from regulatory messes. These data give us an unusually clear portrait of how regulatory events unfold and how the meaning of compliance is jointly constructed by HIV clinic staff and regulators. We turn now to a description of the stuff of compliance work—the kinds of regulatory events that occur in HIV clinics.

Regulatory Oversight in HIV Clinics

Contemporary healthcare and medical research take place in an environment shaped by a mushrooming set of clinical guidelines, research protocols, standard operating procedures, regulations, and laws (Heimer et al. 2005; O'Brien et al. 2000). Some of these rules focus on caregiving, others on research, and still others on administrative matters. Some rules originate inside the medical world, either within hospitals or clinics themselves or in professional associations (e.g., the American Medical Association); others are developed by national governments, government agencies (e.g., the NIH or FDA), or intergovernmental organizations (e.g., the World Health Organization); and still others come from third party payers such as insurers. Existing routines are often deployed for new purposes, although this process is rarely uncontested. For instance, routines for recording medical information are often used for administrative as well as medical purposes (Berg 1997), and this tends to increase rigidity. As sites with nearly innumerable rules, a plethora of regulatory bodies, and considerable ambiguity about the rules themselves and how rigidly they will be applied, medical organizations such as HIV clinics are thus settings in which we might especially expect regulatory ritualism.

"With quarterly monitor visits and five studies, we basically always have monitors here," one research physician in Uganda noted, commenting on the ubiquity of regulatory oversight. But as staff point out, there are several distinct types of oversight: "monitoring" of research projects by external regulators; "site visits" to treatment programs; "accreditation reviews" of hospitals, clinics,

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and affiliated institutions; and internal quality assurance (QA) and quality control (QC).

Research monitors conduct inspections to assure the integrity of clinical trial data. Monitors spend most of their time going through CRFs and "source documents" such as medical records to check whether patients had appropriate specimens drawn and measurements taken, and received the right medications. They also check that symptoms were graded, recorded correctly, and properly followed up. They check dates and signatures on forms (which is how the fraud in Berger's clinic was uncovered), including records of when and by whom errors were corrected. And they carefully inspect regulatory documents such as informed consent forms.

Monitors are typically American or European nationals employed by international third-party organizations (contract research organizations, or CROs) that research sponsors such as the NIH or pharmaceutical companies hire to ensure that the data generated by a clinic will pass muster with the FDA and similar entities. Monitors arrived at the clinic with rolling suitcases loaded with books of general rules, minituarized research protocols, forms to use in their work, and lists of files to review and items to check. At each monitoring visit (one to three days), a monitor usually reviews a portion of the records, conducts a formal debriefing, and eventually produces a formal report (submitted to the clinic and the study sponsor).

In sites with treatment programs funded by donors such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), site visitors review reports on the site's patients, staff, and expenditures to assess whether donor money is being spent appropriately and yielding the intended results. Site visits are typically less structured than research monitoring visits, with site visitors often offering advice about how to improve organizational performance and meet program goals. Site visitors, like the regulators in OSHA's cooperative regulatory model (Rees 1988: 178–83), function much like consultants, carrying information about solutions for common problems from one site to another and arranging small conferences where grantees share "lessons learned."

Clinics may also receive facility-oriented scrutiny when regulators such as the Joint Commission (on Accreditation of Healthcare Organizations) visit the hospitals, pharmacies, or laboratories with which clinics are affiliated. Because the Joint Commission accredits the *facility* rather than overseeing individual *projects*, its visits affect eligibility for Medicare, Medicaid, and other funding and provoke special anxiety.

Not all regulatory site inspectors come from outside, however. Although we observed monitoring and other regulatory work by

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both insiders and outsiders in all five clinics, the Ugandan and Thai sites had especially extensive internal research monitoring. During our fieldwork, the Ugandan clinic developed a multilayered QA/QC program. The Thai clinic's internal research monitoring initially focused on two studies but grew into a universal program. Others have argued that internal monitors can sometimes be more effective than external regulators (Flood and Fennell 1995; Rees 1988). In the clinics we studied, insiders helped correct errors in preparation for visits by external monitors. Outsiders more often wrote formal reports with less opportunity for correction "off the books."

Regulation was a key topic of discussion in all of our fieldsites and we observed and heard about each of these kinds of regulatory encounters. Table 1 provides an overview of the regulatory oversight that occurred in the five clinics and explains what kinds of data we were able to collect.

Ritual Conformity and the Naturalization of Rules

Undergirding clinic workers' responses to regulatory encounters were their varying experiences of the rules themselves. In the high-stakes world of medical research, protocols must be followed precisely in order to assure valid results. But not all of the rules *feel* like rules, a key fact for those interested in regulatory ritualism. A US1 research nurse alerted us to this point as she explained a typical study visit. She often referred to research practices as "what they want" nurses to do and said she occasionally needed to check study documentation to figure out what was required. Nurses would check study protocols to determine what forms to complete at particular visits, how to instruct patients to prepare for an upcoming study visit (Is this a "fasting visit"?), or how to adjust a medication dose (a task assigned to physicians in normal medical care) according to a study's dosing schedule. In contrast, the nurse's comments about practices normally associated with nursing work, such as collecting blood, were prefaced with "you have to," "you always," or "you must."

The nurse's shift in language signals that although the rules of nursing have become naturalized (Douglas 1986), many rules of the research world are still part of the foreground—unnatural, convoluted ways "they" want things done, rather than the normal, appropriate way members of a community of practice do things as a matter of course. When rules change, practices once naturalized revert to the foreground. To the chagrin and amusement of US1 and US2 staff, the Joint Commission introduced new rules prohibiting such ubiquitous abbreviations as "Q.D." (*quaque die*, meaning

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Table 1. Summary of Data on Main Types of Regulatory Oversight

General Type of Regulation	Regulatory Bodies	Entities Doing Monitoring	Subjects Being Monitored	Periodicity of Oversight	Clinics in Which This Type of Monitoring Occurred	Types of Data Collected
Monitoring	Research sponsor such as NIH research network (ACTG, HTPN, PACTG, etc.) or drug company	Third party (sometimes with required rotations of monitors)	Specific clinical trial (integrity of data)	Periodic, announced	US1, US2, Thailand, Uganda	Clinic observations before, during, and after monitoring; informal interviews with monitors at clinics; informal interviews with clinic staff; documents used during monitoring
Site visits	Program funder	Funder or subcontractor (e.g., USAID and CDC but also EGPAF)	Specific treatment program (success in meeting program goals)	Episodic, announced	Uganda, South Africa	Clinic observations before, during, and after site visits; informal interviews with site visitors at clinic; attendance at off-site program events; informal interviews with clinic staff
Accreditation reviews	Public or semi-public agency such as Joint Commission, ministry of health, or national drug authority	Agency staff	Hospital or subunit such as pharmacy	Typically periodic, announced	US1, US2, South Africa, Uganda, Thailand	Interviews with staff at regulatory bodies; clinic observations before and after accreditation reviews; informal interviews with clinic staff
Internal regulatory oversight (monitoring, quality assurance and quality control, monitoring and evaluation)	Highly variable; often ultimate regulatory body located outside hospital or clinic, but delegating oversight to local agents (either formally or informally)	Highly variable, with varying degrees of formality: outsider from research sponsor temporarily joining clinic staff; designated clinic staff members (sometimes in formal QA/QC roles); IRB or research ethics committee; collaborators from other sites	Highly variable: investigator initiated studies (typically not clinical trials); compliance with human subjects requirements; clinic progress in meeting program sponsor goals; clinic procedures and outcomes; record keeping practices; data for specific clinical trial	Usually continuous and regularly scheduled (but similar to external monitoring when main site oversees research work of sub-site)	US1, US2, Thailand, Uganda, South Africa	Interviews with staff working on internal monitoring; observations of meetings to design monitoring programs; observations of ongoing internal monitoring; observations of preparations for ethics reviews; observations of meetings of research projects and discussions with collaborators

every day) and staff were repeatedly urged to consult posted lists of acceptable and unacceptable abbreviations. Protocols can also de-naturalize internalized norms, as occurred in both U.S. sites when research protocols specified that nurses had to make manual rather than automated blood pressure measurements.

Clinic staff thus speak about and experience internalized norms of practice and external regulations differently. Although people follow the internalized norms of practice simply by virtue of having been trained as a nurse, doctor, or phlebotomist, they do not automatically and without thought adhere to "regulations." No surprise, then, that clinic staff are expected to be able to prove that they have followed these somewhat arbitrary, external rules, particularly when paying attention to "what they want" may steal attention from activities that seem more important (Heimer 2008). We contend that rules that feel like "what they want" are especially likely to induce regulatory ritualism, particularly during regulatory encounters.

Regulation as Performance

Neo-institutionalists have long reasoned that surface adherence to rules and deep agreement over principles need not go hand-in-hand (DiMaggio and Powell 1991; Meyer and Rowan 1977). However, the surface is often all regulators can see and all that regulatees want them to see. In observing regulatory visits, we saw clinic staff employ several strategies for directing the regulators' attention to their most compliant work. The increased access required for deeper regulatory review risks compromised objectivity—the classic dilemma of regulatory capture (Grabosky and Braithwaite 1986; Kolko 1965). As Larson puts it: "A closely involved regulator gains responsiveness and an inside perspective but risks capture; while regulation from a distance provides a clearer delimitation of regulator independence, it risks formalism" (2004: 751). May's (2004) work suggests, though, that a facilitative regulatory style may bring more benefits than costs. Although formalism decreases the affirmative motivations of those being regulated, a facilitative style simultaneously increases affirmative and decreases negative motivations.

In the clinics we studied, as a monitor became something of an insider, he or she gained access to information about the "true state" of clinic operations. But these regulatory interactions deviated from the traditional depictions of capture both in how they arose (through performance) and where they led (to regulatory responses carefully calibrated to the seriousness and causes of infractions). Finding a pattern of repeated, inconsequential errors,

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a regulator might permit a research nurse to make corrections. When errors arose from a problem in the protocol, a more profound collaboration between regulators and staff might lead to recommendations for protocol revisions. Regulators often seemed to believe that compliance problems could be solved cooperatively and more fully from the inside. Regulatory scholars note that a collaborative regulatory style facilitates the transfer of learning between sites (Rees 1988). Our observations suggest that joint performance can be a mechanism for generating this knowledge. We were especially intrigued when we realized that at the end of a successful regulatory visit, regulators and clinic staff collaborated on yet another task: formulating findings to report to the regulator's supervisors. Ironically, it was by participating in the performance—by "going along with the show"—that monitors were able to move beyond the "show" that staff had prepared for them. Equally ironically, it was by allowing regulators backstage that clinic staff gained the opportunity to help shape elements of the regulatory report.

Studies of regulation contain countless examples of the performative aspects of regulation, with both regulators and regulatees stepping onto the stage (see, e.g., V. Braithwaite et al. 2007 on motivational posturing in taxation; McBarnet and Whelan 1991 on creative compliance; Parker 2006 on compliance traps; Waller 2007 on tax walk-ins). These examples might profitably be reexamined. Thinking of regulatory interactions as performances neatly encapsulates some of their interesting properties. Acting out a regulatory script conveys a sense of surface memorization without internal commitment that is the hallmark of decoupling (Meyer and Rowan 1977). And of course the audience is usually prevented from going backstage and witnessing the messy, embarrassing, and perhaps even incriminating process by which the show is produced (Goffman 1959). Although Lipsky's (1980) work draws attention to the coping strategies of street-level bureaucrats, the metaphor of performance highlights the rehearsed and surface aspects of a regulatory encounter but also the ways that collaboration can create something new, unexpected, and, occasionally, transformative for all participants.

Regulation of any type includes both instrumental and symbolic aspects. But this analytic distinction can be difficult to map cleanly onto empirical reality. Nevertheless, we all recognize the difference between following the rule and putting on a show of following the rule. Yet in our field observations, we found that an alienating experience of putting on a show sometimes changed midstream into an engaged collaborative examination of troubles with rules, perhaps lacking the grace and good chemistry of Chicago's Second City, but nevertheless a smooth performance.

Staged Collaboration: Elements of a Regulatory Performance

We have suggested that regulatory performances unfold in stages, with staff performing *for* an audience of site inspectors at the outset and, if all goes well, performing *with* the audience, for a more distant outside audience (the site inspectors' supervisors), by the end. The staff have somewhat different objectives in these stages: first to convey an overall sense of an orderly and compliant clinic, next to get the regulators to accept staff interpretations of ambiguous rules and explanations for lapses, and finally to get the regulator to give a good report on the clinic.

When clinic staff perform for regulatory inspectors, they of course worry about the quality of their performance. Good performances are technically accurate, but great performances convey authenticity. Stilted performances look "rehearsed" and make the audience suspicious, leading them to look for further evidence of artifice.

Preparing to Perform for an Audience: Making a Good First Impression

> The nurse manager says she's gone over everything with a fine-toothed comb, but is sure she's missed stuff. She mentions having thrown out expired stuff, then coming in this morning and finding more out-of-date lab stuff in the fridge. As usual, there are medical records on the table and she says "if you have a chart in your hands, *look at it*!" (US1)

Before regulatory encounters, the staff prepared for their audience, hoping to create a first impression as a compliant clinic and creating props that would bolster that impression as the encounter unfolded. The monitors expected the staff to prepare, but what they had in mind was setting up a dedicated workspace, reminding people to be available to talk with the monitor, and gathering files and other requested materials. Monitors did not want a rehearsed performance since site visits are supposed to be a check on the normal round of activities.

In fact, staff preparations were usually extensive and tailored to very specific regulatory audiences. As a first step, staff brought the physical space into rigid compliance with the actual and implied regulations. They cleaned the space, tucked things away, closed doors, and threw out expired medicines. They prepared props, always mindful that the props needed to perform well for research monitors are not the same as those needed for an accreditation review. Medical records and CRFs received particular scrutiny during preparations for research monitor visits. In US2, the weekly

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quality assurance/quality control (QA/QC) meetings just before an ACTG (the AIDS Clinical Trials Group, an NIH sponsored HIV research network) monitoring visit were devoted to pre-visit preparations. The clinic staff used special forms to pre-audit the specific patient files they were told the monitors would inspect. They debated about which additional files might be requested once monitors arrived, ultimately agreeing also to pre-audit the files of the one study that had not been reviewed during recent monitoring visits. Likewise, in Thailand, the team for one multi-site project gathered patient files from their sub-sites. When prepping for accreditation reviews, staff in both U.S. sites reviewed recent Joint Commission communications and focused on compliance with new rules about abbreviations, patient identifiers, and handwashing.

Although clinics did much eleventh-hour polishing, they understood that these final preparations should supplement rather than substitute for regular QA procedures. Because monitoring, accreditation reviews, and site visits happen so frequently, in fact clinics are always preparing. Preparation for regulatory encounters penetrated deeply into the clinics' day-to-day work. In Thailand, the internal research monitor supplied an excellent example of the extensive "rehearsal" needed to get the forms just right. ACTG monitors review CRFs, the primary data for clinical research. The internal monitor generated forms to cue doctors on what information to gather at each patient visit so study nurses would have all the data needed to correctly fill out the CRFs. Even these cheat sheets came under scrutiny. Because the internal monitor believed that NIH disliked "a whole lot of prompting and tick boxes," he revised his cheat sheets to meet these new auditing standards. Rather than tick boxes and blanks to be filled in, his forms now included lines for "MD Notes"—which NIH preferred. He still prompted the doctors for all the information, but his cheat sheet looked less rehearsed and more like forms used in "a normal doctor visit." These revisions reflect the deep and detailed contemplation of the particular preferences and norms of oversight agencies to which the clinic is beholden.

All this preparation served three purposes. First, orderliness signaled "regulatedness." Signs of minor noncompliance—open doors, stray coffee cups, medical supplies conveniently awaiting use on countertops—were carefully eliminated. The hope was that the orderliness of the space would be taken as an indicator of the orderliness of the work, the world in a grain of sand. Second, by smoothing the background and eliminating "noise," the staff hoped to allay suspicion. "A 'good' site is one where there are more 'questions' than 'findings'," a couple of monitors explained to us as they reviewed documents in US1. "You can spend four hours figuring something out and then ultimately decide it's okay. It's

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basically detective work, sort of like '20 questions'." Illustrating what might lead to unwanted "detective work," a Thai staff member told us that she would be "very suspicious about their procedures" if a clinic planned for its consent process to take less than an hour. Sites in poorer countries were more likely to encounter suspicious monitors and therefore prepped more extensively.

Finally, the preparation of props ensured that any file picked up from a desk had already been checked and was therefore "clean," allowing the clinic staff to control the performance. Clinic staff aimed to be proactive, directing the monitoring visit, rather than reactive.

Improv and Audience Participation: "Derail[ing] Developing Misunderstandings"

> When a medical record was needed to illustrate a point during a regulatory review, the nurse manager grabbed a file from a passing colleague. Although this action suggested that "any old file" would serve, in fact the files available to be grabbed were not "random" files, but had been carefully vetted. (US1)

> Before one monitoring visit, a research nurse talked with the data manager about which files were being requested and which parts of the study would be reviewed. The nurse thought out loud about whether to leave her personal notes in the file. These notes contained useful information, but a skeptical monitor could always use them against the clinic, and the nurse concluded that it was probably best to remove notes. Yet a few days later, after her meetings with the monitor, the nurse seemed to have changed her mind. Now she seemed to think the notes should stay in the file because the monitors might find answers to some of their questions if they looked through the notes. (US1)

The job of the performers is to find ways to incorporate the audience. The quick grabbing of a file from a passing colleague (see excerpt) occurred because of a need to illustrate some point, perhaps followed by a query about whether it would be useful to look at a file together or a suggestion that "it might help if I just show you what I mean," in either case endorsed by the monitor. Improvisation creates an impression of authenticity, which in turn allows trust to grow between regulators and clinic staff. But note that this sort of "staged authenticity" (MacCannell 1973) depends on several elements: confidence that the prop (here, a file) would actually work for the scene (because files had been checked), the performer's (nurse manager) correct reading of the cues that the audience member (monitor) was now sufficiently engaged that she could be incorporated into the scene, and then actually moving the performance along by grabbing the file from the passing nurse.

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Expert performers will also be sensitive to variations in their audience. The nurse manager (in the excerpt) reminded her staff that one cannot always control the attention of regulators by flipping through the chart and talking fast. Regulators who have a nursing background will be facile readers of charts, able to pick up details however smartly staff try to move them through the material. Performers must therefore take account of the characteristics of the audience they are trying to incorporate into the performance.

When clinic staff try to keep regulators from asking a lot of questions, it is not usually because they have something to cover up. Rather, the indeterminacy of rules leaves room for a strict or skeptical monitor to rule against the clinic or require elaborate explanations of minor deviations. One frustrated ACTG monitor recalled pointing out to a supervisor that, depending on how errors were written up, the site could be counted as having "anything from 4 to 37 mistakes." (As might be predicted by scholars of the audit society, the ACTG reacted by eliminating the threshold on what counted as an error, raising the stakes on producing perfect documentation.)

Not wishing to spend their time explaining minor deviations or tangling over interpretations of rules, clinic staff try to game the regulatory encounter by putting forward their most compliant work. Much of the encounter is pre-scripted by regulatory routines, yet it occurs on clinic turf with clinic materials. Clinic staff can shape how the encounter unfolds by which props they bring onto the stage and which they keep backstage (one research nurse in US1 "hid" files temporarily until she could finish cleaning them up) and how they introduce them, drawing regulators' attention to some points and away from others. Yet the possibility for control is limited because regulators also attempt to shape the encounter. Inspectors often used openings provided by staff members to shift course. The regulatory encounter was no longer the clinic's show but instead a joint performance.

A skeptical monitor adopting a punitive strategy and refusing to join a clinic's performance can, as the internal monitor in Thailand put it, "spend weeks and weeks" and produce "huge reports" that take "lots of time to sort out." The Thai clinic's biggest flop came in a performance for a monitor on an NIH funded study. The monitor cited the clinic for a series of errors, both minor (correcting with white-out instead of strike-out with initials) and major (missing documentation and improper reporting of serious adverse events [SAEs]). The internal monitor agreed about the early record of minor errors—this was, after all, why he had been hired. But he vehemently denied the major errors. The study had unique SAE rules with which the external monitor was unfamiliar. Although the

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clinic had adhered to these rules, the monitor adjudicated their performance by a standard body of rules. The medical records, maintained in Thai, contained all required documentation—a fact that the English-speaking monitor could have ascertained with even minor consultation.

Similarly, in US1, a monitor reported a "deviation"—that clinic staff were not making height and weight measurements at study visits—to the sponsor, who in turn reported it to the IRB. The IRB then asked to see the checklist for study visits and insisted that the clinic "implement the checklist." Yet the protocol said nothing about making height and weight measurements at study visits. All this bureaucratic trouble occurred because of a monitoring error that could have been avoided had the monitor collaborated with clinic staff. In the high-stakes environment of clinical research, such flops can bring a lot of trouble, including more intense monitoring and decreased funding.

Given the risks, why did each side welcome collaboration? Initially, clinic staff welcome joint performance as an opportunity to direct the regulatory encounter. As they lose directorial control, they continue to seek collaboration as an opportunity to limit damage. One US2 research coordinator arranged to meet with monitors at the end of each day of their visit to "derail developing misunderstandings and misinterpretations." We observed clinic staff explaining and justifying lapses, filling in gaps, being given the chance to correct minor errors, and bargaining over error counts. Monitors, in turn, got better access to sensitive information, help in matching rules to local conditions, clarifications about protocol-specific deviations from general practices, assistance in filling in details about clinic policies, and reduced ambiguity about whether the clinic's performance was actually compliant. And by doing regulation together monitors and clinic staff reduced drudgery, quickly agreed on interpretations of rules and solutions to minor problems, and avoided embarrassing gaffes. A few examples illustrate these points.

One key rule requires that confidential data be "double locked"—placed in locked file cabinets in locked offices. Yet even this apparently straightforward rule could be hard to interpret in situ. In US1, research nurses shared a large office with separate cubicles. They used locking cabinets, but their office door had no lock. The research coordinator pointed out that the office suite was locked and, after a bit of back and forth, the monitor agreed that this arrangement satisfied the double-locking requirement. A similar double-locking problem arose in Thailand. One protocol specified that the study drug be stored in a metal box inside a sub-zero freezer affixed to the wall of a dedicated, locked room. With limited space, though, the clinic had to re-purpose a closet

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whose layout precluded affixing the freezer to the wall. In order to meet study security requirements, the clinic added a lock and chained the metal box containing the drug to the inside of the freezer. Monitors gave their approval, although the lead researcher remained embarrassed at the "messy, messy" solution they had crafted.

We observed many instances where adopting tools recommended by previous inspectors facilitated a compliant performance: a pharmacist's QA audit sheet originated with the ACTG monitor; a research nurse adopted a monitor's method for tracking specimen collection dates. This practical advice often gave insight into the monitors'—and by proxy, the regulators'—assessment of conflicting rules. One study monitor gave advice on how to maintain a study personnel list, admonishing the US1 research coordinator not to "make it hard on [her]self," essentially telling her what to emphasize and what to ignore. When faced with protocol requirements that would be difficult to execute in their site (a common problem outside the United States), another monitor explained to the overwhelmed Ugandan team that although following clinic SOPs was mandatory, they could write SOPs tailored to their site. In effect, the monitor pointed out pockets of discretion built into the system, giving the Ugandan team permission to create rules that they could actually follow and that the monitor could cite as evidence that they were working in an orderly, rule-governed way.

As inspectors completed preliminary reviews, consultation with clinic staff increased—monitors became more eager to perform together. They checked clinic policy documents and clinic records to verify that clinic staff had understood and followed the rules. But to ensure that they themselves had not erred, inspectors prepared long lists of queries to review with clinic staff. These query lists opened a space for negotiation. As queries were answered, clinic staff in turn worked to ensure that they were not misrepresented in regulatory reports. We observed research coordinators writing on the monitors' worksheets, correcting minor errors, or inserting additional items in descriptions of staff responsibilities. This collaboration, evident at points in all of the clinics, develops gradually, with minor concessions on the part of regulators (e.g., coding a mistake as a "transcription error" rather than a more serious infraction because this would be "nicer") and caution on the part of clinic workers who understand that they remain under scrutiny. Answering a query about QA, for instance, a US1 research coordinator told the monitors about auditing software but carefully clarified that the program was not "altering" the study records—which would be a major breach—but correcting minor errors like typos.

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We were able to watch these collaborative performances evolve over single monitoring visits and sometimes over multiple visits. Often early ventures into cooperation occurred when lapses uncovered by monitors were clearly not the fault of the research nurse. For instance, monitors talked with a US1 nurse about a physician who "need[ed] some lessons in error correction," the lapses of a recently departed colleague, and a patient who failed to tell the nurse about a key symptom. When the nurse jokingly asked if she would get put in jail for these errors, the monitor laughed that this was "just small stuff." Not missing a beat, the nurse retorted that she "sweat[ed] the small stuff too!" "Good!" the monitor exclaimed. The monitor also praised the records as "vastly improved" after this particular nurse took over one study. The nurse subsequently said that she was happy to "take *full responsibility*" for another study that had been hers from the outset. It was this nurse who, by the end of a monitoring visit, was changing her mind about leaving the explanatory notes in the files (see excerpt). Discussing the importance of collaboration, another monitor astutely commented that if she is not out to "nail them for the fun of it," clinic staff are more willing to accept her findings of serious violations.

Although joint performance provides a mechanism for collaborating to avoid trivialities and feels less conflictual than the skeptical monitoring seen in the Thai example, clinic staff remain very clear that poor reviews have serious consequences, and that individual monitors are part of a larger system with its own communication difficulties.

Performing Jointly for a New Audience: Co-creating Site Reports

> Now it's time for debriefing. After the monitor has summarized what they have reviewed and what kinds of problems they have found, she concludes by pointing out that there were no trends [systematic, repeated errors] in any of this. The research coordinator talks a bit about how DAIDS will react to this and groans. It's going to seem like *more*. ACTG used to cite only the biggest things, but now the monitors have to write down *everything*. The monitor seems sympathetic, noting that on the older records if the site has caught the mistakes and made adjustments it doesn't make a lot of sense to write them up as mistakes. (US1)

> "We [the monitors] have to go through the same thing as you, with them [the monitors' supervisors] looking over *our* work." (US1)

By the end of a successful regulatory encounter, key staff and the inspector work together on the best way to present the material to still another audience, the inspector's supervisor. They are now backstage together, jointly preparing a performance for an offsite audience.

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This shift in orientation is illustrated in a discussion of the list of queries from the monitor's chart review. The monitors' work area was strewn with research charts and cheat-sheets (e.g., week-by-week roadmaps of the study visits), all covered in a blizzard of stickies. After some back and forth with the study nurse over the relatively trivial, single errors, the monitor raised a possible systematic error: whether US1 weighed patients without shoes. She opened this discussion confrontationally, stressing that the protocol specified that patients must be weighed without shoes and asking for documentation. She then softened her approach, saying "it's enough to drive you crazy," apparently trying to deflect blame from nitpicking monitors (such as herself) to fussy protocol writers. With a mix of humor and sympathy, monitor and nurse continued their collaborative problem solving: Do both pages of a single document need to be dated? No. Is it sufficient to check a box indicating that the study nurse filled out the form rather than writing in the nurse's name? Yes, because this corresponds to the CRF.

Near the end of their conversation, the monitor apologetically explained to the research nurse (see excerpt) that the monitors' supervisors scrutinized their work. Returning to the issue of weighing with or without shoes, the monitor now suggested that US1 revise its SOP to specify how clinic patients were weighed. Modifying the clinic SOP would neatly provide the needed documentation without creating additional work for nurses. Because an SOP is taken as evidence that staff members are following a routine rather than doing things haphazardly, a clinic often can get by with a variant of the prescribed practice as long as that variant is incorporated into its SOPs. By the end of this interaction, the roles of monitor and nurse had altered dramatically. The monitor was no longer the audience for the nurse's performance but instead had joined the nurse as a performer and was asking the nurse to help craft a performance for the monitor's superiors.

After the monitor completed her investigations, she met with the research coordinator to discuss her findings. The site's research coordinator acknowledged most of the mistakes ("yes, that seems to be missing"), but pushed back on others (for instance, arguing that because there was no requirement to record height at every visit, it should not be considered "missing" on the CRF). The monitor in turn complimented the clinic on its "lovely" SOPs, but remained firm on other points ("it is clear that a patient gave the right information, but source documentation is still missing").

Once the negotiation over errors was complete, the two began discussing the final report (see excerpt). The monitor noted that the clinic had done well overall, with only eight minor errors. The research coordinator expressed concern that, with a recent change in oversight criteria, these eight minor errors might prove conse-

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quential. (Under previous rules only major errors "counted.") The monitor offered sympathy, adding that it was good the monitors had come early in the study, allowing the clinic to adjust its procedures as the study unfolded.

Conversations among monitors confirmed that they worried about how their own supervisors would receive their work. Reviewing the data for one study, for instance, the monitors feared that they would be "dinged" if they failed to carry their review forward to the present and were relieved when the newest data were easily available. Noting the increasing frequency of references to their supervisor's reactions, we asked the monitors how their focus shifted over the course of the visit. Did their focus in fact shift from examining the site's records to preparing their own reports and worrying about the monitoring they would themselves undergo? Did the perspectives of research monitors and clinic staff tend to converge near the end of the visit as the monitors began to think of themselves as also subject to monitoring? "Yes," they agreed, "that's what happens." With one performance nearing completion, the next was already beginning, this time with the regulators as the main performers.

Although this progression from observing clinic performances to performing alongside clinic staff is common, we also observed two important variants on this pattern. In our Thai fieldsite, an unusually close collaboration developed between the clinic and a pharmaceutical company that sponsored some of its research. When a respected audit company's monitors visited the site, they uncovered significant departures from good clinical practice. This early regulatory performance was such a flop that the sponsor could justifiably have terminated the relationship. Instead, the sponsor hired a full-time monitor to oversee its studies at the Thai clinic. This intense investment paid off. Monitoring reports improved and the Thai data proved crucial to approval of a drug for pediatric use. Embedding a monitor, who functioned as a coach, got the sponsor a permanent "backstage pass" at the clinic. Although performances improved, there was now no room for artifice.

Performances unfold a bit differently when regulatory inspectors visit a treatment program rather than a research project. At the time of our research, our South African fieldsite's HIV treatment program was funded largely by PEPFAR. EGPAF (Elizabeth Glaser Pediatric AIDS Foundation) administers some PEPFAR grants, including this one, giving it oversight responsibility for the site. JSI (John Snow Inc.), in turn, monitors and evaluates some PEPFAR-funded organizations. As they talked with staff and attempted to gain access to the clinic's backstage, JSI monitors carefully differentiated themselves from EGPAF, the oversight agency. The JSI

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monitor saw his role as problem solving and mentoring—not providing a "report card" that could be used to punish a site. In effect, he suggested, the clinic did not need to "perform" for him because JSI was not actually evaluating the site. Using the example of site readiness, he explained that the objective of site visits was both to identify deficiencies and to help clinics overcome those deficiencies so they would be ready to start treatment programs. If a clinic had significant deficiencies, it was the funder's job, not his, to decide what to do. In his view, he and clinic staff should be performing together from the start; he should not wait for their invitation to join the performance.

To be clear, monitors and clinic staff may not always agree on whether to perform together. Regulatory inspectors do sometimes decide that performing together is precluded by the quality of a site's work. Recall that "good sites" raise "questions" which are pursued in consultations like those discussed above. The "findings" about less adequate sites go directly into the site report. Although we did not directly observe regulators reacting to any really egregious infractions, such experiences were part of the lore in all of our sites.[3] One research monitor told us about a research coordinator (elsewhere) who had filled in patients' temperature and blood pressure measurements weeks in advance of study visits. Some pre-filling of forms is common, but it is limited to patient identification numbers, the site number, and so forth. In this case, the research coordinator reasoned (erroneously) that pre-filling was okay because these measurements were tangential to the study. This willingness to falsify data indicated a profound mismatch between the norms of the clinic and the norms of science, and was confirmed as a systemic problem by the attitude of the principal investigator during the debriefing. "So how did we do other than that?" he asked. Concluding her story, the monitor confided that the site was probably being closed over this infraction.

In the sites we studied, staff did sometimes encounter annoying "surprises" in regulatory reports. Deciding to perform solo (at least for some portions of the report), regulators reported errors that they had not discussed with clinic staff. In the view of the Ugandan clinic staff, for instance, a monitoring report misrepresented a clinic error that arose partly because a patient's baby was born early and outside the hospital. "Yes, we made a mistake [not following up immediately]," staff conceded in an internal discussion of the report, "but the report is not technically correct because we caught our own error, though too late to fix, apparently."

[3] To be clear, we did observe mistakes in all of our sites, but they were typically discovered and managed by the sites rather than by regulators.

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Joint performances are common, but by no means the rule. Performers on both sides face strategic choices about whom they will perform with and for. Clinic staff sometimes decide not to allow inspectors access to the backstage and inspectors sometimes choose to keep their distance and adopt the "bad cop" role.

Post-Mortems and Preparations for Future Performances: Moving Beyond Ritualism

> It was clear that they had all gone over the monitoring report very carefully. The regulatory affairs specialist, for instance, had marked up her copy with highlighters and also tagged lots of pages with notes. (Uganda)

> "Nothing major," the PI says, "but more minor stuff than usual. Very picky stuff." . . . The research coordinator gets serious: "When you're in with a monitor, make sure you clear up anything you can and then make sure it gets crossed off when you're able to clear something up." The PI adds that the monitors did say they'd "noticed a trend" of increasing minor problems. That could lead to a special assignment to check on some aspect of the record keeping the next time the monitors come. (US1)

The clinic's staff engages in a final stage: the post-mortem. Regulatory visits typically result in lists of errors. By looking for patterns in error lists, staff hope to avoid similar mistakes in the future. A quick review of a list received by US1 revealed that the clinic was being "dinged" mainly for repeated failures to indicate whether weight measurements were in pounds or kilos. Because the scientific convention of using the metric system is not imposed in the United States, staff members thought it obvious that their measurements were in pounds, not least because the numbers would be absurdly high had they been in kilos. Nevertheless, clinic staff were now obliged to specify units of measure whenever they recorded weight. After much discussion, they agreed to modify the forms rather than to retrain the staff (Heimer 2008: 34–35). By issuing new forms with preprinted units of measure, staff smoothed the background and avoided repeating this particular flub in their next regulatory performance. Occasionally, such careful preparation is for naught because the monitors have been instructed to scrutinize something else. But often it is precisely where clinic staff seemed not to have followed the rules that they will be asked to demonstrate compliance at the next performance.

Yet dwelling on the immediate aftermath of a monitoring visit would grossly underestimate the long-term effect of such regulatory encounters. Our direct observations of regulatory visits were supplemented by staff accounts of previous regulatory encounters, including some from the distant past. Those historical accounts

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focused disproportionately on vivid and exceedingly unpleasant flops, which deeply marked clinic practices.

In the Thai clinic, for instance, the study team had made an error in classifying and reporting an SAE. Clinic staff considered this error especially regrettable, as SAE rules are heavily enforced. Given their record of having erred, they assumed that monitors would scrutinize any future SAEs. To preclude a repetition of this type of error, the clinic used precious staff resources to create a special SAE team. Perhaps the most extreme response to a performance flop occurred in our Ugandan site. There, the experience of previous scrutiny and concerns about whether their clinical trials data would stand up to FDA review led staff to create an elaborate, three-tiered quality assurance/quality control (QA/QC) program that even reached into hospital units that helped with clinic data collection. The objective of the Ugandan site seems to have been to internalize regulatory pressures and naturalize QA/QC—to make regulation feel like "we always" rather than "what they want."

Beyond these formal programs to prevent the repetition of mistakes, clinic staff also admonished their peers to keep the monitors in mind while doing day-to-day paperwork. This emphasis on documentation parallels the pressure experienced by local OSHA inspectors to "fully document" every case as if it would be appealed (Rees 1988: 190) and the significant increase in documentation by hospitals preparing for accreditation reviews (Duckett 1983). During a counselor training session in Uganda, for instance, a staff member with special responsibility for regulatory documents reminded counselors to provide a "clear trail" in their notes, with supplementary information "for people who may have little or no knowledge of the local situation." At a subsequent QA/QC meeting, another regulatory specialist emphasized that staff should include *everything* in their reports—that the SOP has changed or why a binder has not yet been reviewed—because otherwise monitors have no explanation for variations or errors. She explained:

> . . . you need to do what you can and record the reason that the rest of it hasn't been done. The monitor needs to be able to tell whether it is this level [in the hierarchy] not doing its job or some other level not doing its job. The monitor needs to be able to see that in this instance the problem was with the doctor.

Most adjustments were in the production of research and clinical records, but we also heard about changes in clinical practice. Ugandan doctors worried that monitors would be as uncharitable in evaluating clinical decisions as they were in evaluating research records. Believing that monitors "could read variability in treatment decisions as people really not knowing what they're doing,"

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clinic doctors began an extensive guideline writing program and moved toward documented, standardized approaches to treatment. For Ugandan medical staff, intense regulatory scrutiny denaturalized rules of professional practice so they too were sometimes experienced as "what they want" rather than "you always."

What we see in post-mortems, then, is clinic workers first reviewing and rethinking their most recent performances and then gradually incorporating preparation for monitoring into their regular round of activities. The contrast between the naturalization of rules about documentation in the Ugandan QA/QC program and denaturalization of clinical rules in their guideline writing project usefully reminds us that rules can migrate between background and foreground as they are included in training programs, embedded in routines, and scrutinized by regulators. Staff members constantly imagine how their records will look to monitors and how they will explain their decisions. This constant rehearsal shows a true performers' orientation, but it also shows how maturing organizations begin to see themselves as intertwined with their environments. With the contemporary emphasis on regulation and audits, everyone has regulatory responsibilities and compliance work becomes part of the daily routine.

Reflection about how to do better next time can also be read as evidence against decoupling. Before rules have been spelled out and consensus reached about how they apply, it makes little sense to discuss compliance (Parker 2006). It also makes little sense for clinics to invest in adjusting before they are confident that they and regulators see eye-to-eye. Ceremonial responses may simply signal that rules are still unsettled. Whether a clinic's response to rules is superficial or deeply transformative may then depend on whether clinic staff and inspectors have performed together often enough to negotiate the meaning of rules and trade tips about how to demonstrate compliance. If joint performance is the mechanism for working out the details, then deep compliance is more likely to occur after a few cycles of preparation and rehearsal, performance, and post-mortem. The embarrassment of a flop surely encourages a clinic to give a deeper and more authentic performance the next time.

Collaborating to Avoid Trivialities

> Staff violate their SOPs, though in small ways. They don't violate the *protocol*, one staff member clarifies. Staff were a bit worried about violating the SOPs, talked to the monitor about that. The monitor whispered that they violate their own SOPs as well. (Uganda)

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We have suggested that looking at regulatory encounters as performance sheds light on the relationship between the symbolic and instrumental aspects of regulation. In concluding, we address this point more explicitly and offer an analysis of the challenges of moving beyond ritual when rules created in rich societies are applied in poorer ones.

In contemporary medical settings, regulatory encounters must create a judicious balance between accommodating the absurdities inherent in technical compliance with a mushrooming set of rules, on the one hand, and acknowledging the importance of ethical and moral responsibilities to patients and to medical science, on the other. Sensible people know that rules have to be interpreted and that compromises with empirical realities are necessary. Good monitors acknowledge these conundrums and encourage appropriate accommodations. Violating SOPs in small ways is better than violating a research protocol, staff members in Uganda reasoned; the monitor concurred (see excerpt). Both the accommodations and the lowered voices are common features of regulatory encounters.

Research monitors, site visitors, and other regulatory inspectors see only a small slice of clinic life and that slice is primarily the paper or electronic record of research or treatment encounters. Because it is difficult to assess compliance with deeper ethical and moral obligations, regulatory inspectors often treat technical compliance as an indicator of deep compliance. If staff keep their research records properly, have supporting source documents and signed consent forms for all research subjects, can document that they have reported all serious adverse events, and so forth, then this technical compliance and their apparent seriousness of purpose are taken as signals that they almost certainly also are compliant at a deeper level. This way of thinking about the relationship between orderliness and deep compliance is not unique to medical settings. As one of Larson's securities inspectors observed, "If they breach one rule, we get a lot of others [rule breaches]. . . . [A rule violation about completing a record] sounds trivial, but it is critical" (2004: 750; brackets in original).

Producing technical compliance is harder in some settings than others, though, because it requires resources. Technical compliance rests on a foundation that includes a culture of record keeping, rules about good clinical practice, and conventions regarding the confidentiality of records. "We're research experienced, they're not," explained one foreigner working temporarily in Uganda. Technical compliance also depends on ample storage space, easy availability of computers and photocopy machines (in turn requiring reliable electricity), and the commonplace routines of American healthcare organizations. Producing technical compliance was therefore more work in poorer countries than in richer ones. In

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Thailand, for instance, an internal monitor explained that the new scanner allowed them to send pdf files instead of faxes, eliminating complaints from the United States about blurry documents and obviating the cumbersome tracking (numbers of pages, study names, patient numbers, etc.) that enabled them to resend faxes when glitches inevitably occurred. It had been challenging to put on a good show without adequate props.

To be clear, our evidence suggests that the problem was technical compliance not deep compliance. But because technical compliance is taken to indicate deep compliance, the presence of technical errors can make monitors skeptical about a clinic's adherence to norms of treatment or research. If clinic staff cannot manage such mundane chores as making copies in triplicate, regulators may wonder, how can they possibly manage the more complicated tasks of good science and good caregiving? Regulatory inspectors seem to assume that the relation between technical and deep compliance is constant across clinics. Although this assumption may be valid within countries, it seems less likely to hold across national borders. Without some understanding of how records are produced in a "foreign" setting, monitors may incorrectly assume that technical problems indicate deeper noncompliance and so may judge the clinics in low- and middle-income countries too harshly.

During a site visit in Thailand, for instance, American monitors found significant non-compliance, including a "major finding" of incomplete records. Read as a breach of the principle of transparency, this technical error jeopardized the believability of the data. The necessary documentation was in fact in the files, but in Thai rather than English. Because some documents had to be read by Thai-speaking patients and research subjects, Thai versions were kept in the sub-site, with English copies stored in the main site's clinical trial file. The deviation indicated only an adaptation to language differences not anticipated by the study protocol.

Encountering such anomalies tends to make monitors more skeptical of performances in "foreign" clinics, clinics new to a study or research group, clinics with new personnel in key positions, or clinics with blemished records. Non-western clinics are thus vulnerable to overly critical monitoring, particularly when their native language is not English. One worker in the Thai clinic, worrying about technical compliance, explained that he wanted a box of samples packed just right so "we look as good as possible. If these go out wrong, we look stupid." The site had received more than its fair share of monitoring, he believed, because of "being in the boonies." In our study, regulators visiting non-U.S. sites behaved more formally, were less willing to engage in "joint performance," and were more insistent on adhering to standards that would be a challenge even in richer countries.

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Both regulators and those they regulate would readily acknowledge, though, that they really care about deep compliance with clinical and research ethics and fiscal responsibility; technical compliance is merely an indicator. As long as they believe a clinic is adhering to the spirit of the regulations, regulatory inspectors will join clinic staff in working around "inconsequential" technical mistakes. Noticing minor errors in a CRF, one US1 research monitor mentioned the mistakes and then indicated she would go to lunch and look more closely at the records later. Without spelling it out, the monitor gave the study nurse permission to correct the errors without penalty. Such an opportunity to correct mistakes only occurs when there is trust on both sides—when regulators believe the clinic staff is competent and good-willed and the staff in turn are willing to acknowledge errors because they expect to be treated fairly.

Because their reclaimed discretion is never entirely legitimate, regulatory site inspectors worry about being caught out. Because they cannot be confident that their supervisors will approve of their judgment calls, site inspectors need to be certain that superficial failures do not in fact indicate deeper noncompliance. Given their greater uncertainty about how to interpret technical noncompliance, regulatory inspectors were more reluctant to reclaim discretion in regulatory encounters in foreign than in American clinics.

A key finding of our research is that, contrary to the literature on regulatory capture, "performing together" is less about regulators being "taken in" and more about collaborating to avoid trivialities and to reduce ritualism. "Performing together" decreases the sense of alienation of those being regulated and makes them less inclined to limit the "show" to the rehearsed, fully scripted performance. A good monitor knows when and how to join the performance and therefore how to get backstage to see what is really happening. Joining the performance shifts the balance between the symbolic and the instrumental, between technical compliance and deep compliance, creating a collective sense that "we know what's really important." When regulators and clinic staff cannot "perform together," they also cannot align on what the rules are or what constitutes deep compliance. Under these conditions, more common in poor than rich countries, clinic staff may be forced to overspend on ensuring full compliance with all of the rules, trivial and serious alike.

Conclusion

The argument we have made is about regulatory encounters in HIV clinics that are engaged in both research and treatment. We

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have shown that our findings hold, with some crucial variations, in both the richer clinics of the United States and in the poorer clinics of Thailand, South Africa, and Uganda. For poorer clinics, meeting regulatory requirements was always a stretch because of budgetary constraints and mismatches between rules and local conditions. Initially skeptical, regulatory inspectors became more willing to perform together after the clinics of Uganda and Thailand invested deeply in internal monitoring and the South African clinic, less involved in research, created a careful monitoring and evaluation system for its treatment program. Able to avoid the extra scrutiny brought on by cultural, linguistic, and material differences, the American clinics could generally move smoothly to joint performance with regulatory site inspectors, more quickly reaping the benefits of collaboration.

To assess the generalizability of our findings, it is useful to note some salient, peculiar features of these regulatory encounters. As noted earlier, both clinic staff and regulators were deeply committed to the scientific and caregiving activities in which they were involved. Moreover, the regulatory process was a rather formalized pluralistic system with some rules originating with the state (albeit often not the state of the country in which the clinic was located) and others originating in non-state actors. Monitoring and enforcement was delegated to non-state actors, through site visits occurring on a regular basis (though with some change of personnel), with formal reports transmitted upward for review. Although this regulatory scheme also often included formal processes to accomodate local conditions, regulatory rules remained stable enough that prior experience mattered for future planning, yet varied enough that new problems continually arose. Further research is needed to determine whether our findings about improv performance as a mechanism for moving beyond technical compliance holds in settings with different characteristics.

Our objective has been to advance the discussion by making four points about regulatory site inspection. First, because of the indeterminacy of law and regulation, some collaboration between regulatory inspectors and regulatees is nearly inevitable. Rules always must be worked out in dialogue with empirical reality. To gain some sense of what the empirical reality is, a regulator necessarily must engage with those whose work is being inspected. It is often during site inspections that working definitions of rules are initially hashed out, with some definitions becoming institutionalized and others being repeatedly constructed during subsequent regulatory encounters. When regulatory systems explicitly allow for adjustment to local conditions (as the NIH rules on SOPs are intended to do), collaboration becomes an important tool for distinguishing between appropriate local variation and unacceptable

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deviation. But we must also acknowledge the effects of differences in where regulatory activities occur. Site inspections allow regulatory workers to verify compliance—to see what regulatees are actually doing. But they also allow regulatees to show regulators why and how rules have to be adapted in order to have their intended effects. Our claims about collaboration are thus especially germane to regulatory arrangements where the work is done in site inspections rather than in central offices or courts.

Second, although each party has its own objectives, compliance work often becomes a common project. Clinic staff want to get on with their work without undue attention to distracting rules. Regulators want to be able to file an acceptable report at the end. In the middle lies considerable common ground where regulators and clinic staff work together. As Gilboy found in her study of INS inspectors at American airports, regulators and regulatees cooperated on "practical work concerns" because they had a "community of interest" (1997: 507, 527). Having something to do together, whether it be interpreting a research protocol or correcting a personnel list, allows both parties to display their goodwill. Much regulatory work does not offer these opportunities, particularly if the work is done in central locations. But wise regulators and regulatees will look for and create such common tasks.

Third, improv performances are the technology by which regulators and clinic staff haltingly feel their way toward cooperation. Clinic staff try to influence the initial terms of that engagement by opening the show with ample evidence of being a careful, compliant site. Wary of losing their objectivity and concerned about those to whom they are accountable, regulators join the performance only as they become more confident that something solid lies behind the show. Like any other audience, regulators can decline to participate in the improv performance, and the tentative character of the invitation to join the performance allows clinic staff to invite participation without being unduly embarrassed if they are rebuffed. The performances we describe obviously take some time to unfold. The regulatory inspectors we observed were typically but not always repeat players and regulatory encounters often unfolded over several days. People can perform better together when they know each other, but preparations for improv performances enable people to draw their interaction partners in even when they know little about each other and anticipate a relatively brief encounter.

Finally, if performance is the technology for moving beyond technical compliance, it is a technology that is less available when people cannot read each other's signals well enough to perform together. Mime translates easily across cultural divides because it relies on universal gestures and facial expressions. Because the

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language of regulation is not as universal, clinic staff in poorer countries may find it difficult to prepare scenes that induce foreign inspectors to join the performing group. We would thus expect collaborative performance most often within settings where regulators and regulatees share institutional, cultural, and material conditions. And, of course, we expect the absence of collaboration to be most keenly felt—and to result in overspending of scarce resources, attention, and staff time—in settings where even if regulations account for local variation, regulators continue to distrust regulatees' commitment to deeper values. Ironically, when it is hard to put on a show together, it is also difficult to do anything more than put on a show.

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