

MODULE 5

Ethics and Infectious Disease Control: STDs, HIV, TB

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In contemporary ethical theory, and biomedical ethics, strong emphasis is placed on the rights of the individual, on principles of autonomy and self-determination. But essential as those values are, the legitimacy of limiting them has long been recognized. When the exercise of one person's freedom results in harm to another, the state may intervene. The "harm principle" provides a widely recognized justification of imposing limits on autonomy. Given its most potent expression by the 19th century philosopher John Stuart Mill, the principle states:

The only purpose for which power can rightfully be exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, both the physical moral, is not sufficient warrant.¹

This principle clearly provides an ethical foundation for establishing public health programs designed to limit the threat of infectious disease.

The public health authority to limit individual freedom when disease threatens has long been recognized in constitutional jurisprudence as well. Nearly 100 years ago in *Jacobson v. Massachusetts*, a case that centered on the question of compulsory vaccination, the Supreme Court held that the U.S. Constitution permits states to enact "such reasonable regulations [to] protect the public health and the public safety and" as long as such efforts did not "contravene the Constitution of United States, nor infringe any right guaranteed or secured by that instrument."² *Jacobson* also underscored the rule that courts should give deference to the government's exercise of the police powers designed to protect the public. Such measures could be invalidated only if they had no real or substantial relation to their purported goal. That standard of constitutional review would in later years be viewed as the least protective of individual right. Capturing the enormous scope afforded to the state acting in the name of public health, a treatise on constitutional law in 1900 asserted that before the demands of public health "all constitutionally guaranteed rights must give way."³

This extraordinary deference to government action prevailed throughout much of the 20th century, persisting into the late 1960's. The past three decades of constitutional development, however, particularly in the area of involuntary confinement of psychiatric patients, have seen increasing scrutiny of the exercise of the police powers of the state, raising questions about the constitutionality of statutes relating to communicable disease, many enacted before the profound shift in the balance between individual liberties and state authority.

As important to the transformations in the view of the state's authority has been the impact of the AIDS epidemic. In the early 1980's when the United States like other democratic nations had to confront the public health challenge posed by the new epidemic, it was necessary to face a set of fundamental

questions: Did the history of responses to lethal infectious diseases provide lessons about how best to contain the spread of HIV itself, a lethal sexually transmitted and blood borne virus? If AIDS were not to be so treated, what would justify such differential policies?

It was the specter of the most coercive of aspects of the public health tradition that concerned proponents of civil liberties and advocates of gay rights as they considered the potential direction of public health policy in the presence of AIDS. Would there be widespread compulsory testing? Would the names of the infected be recorded in central registries? Would such registries be used to restrict those with HIV infection? Would the power of quarantine be used, if not against all infected persons at least against those whose behavior could result in the transmission of infection?

Although there were some public health traditionalists who pressed to have HIV infection brought under the broad statutory provisions established to control the spread of sexually transmitted and infectious diseases, they were in a distinct minority. In the first decade of the AIDS epidemic an alliance of gay leaders, civil libertarians, and public health officials began to shape policy for dealing with AIDS that reflected an "exceptionalist" perspective. That perspective entailed the commitment to rely on prevention measures that were not coercive, and respected the privacy and social rights of those who were at risk. Mass education, *voluntary* testing and counseling were the centerpiece of the public health strategy that sought to avoid interventions that might "drive the epidemic underground." While the force of the exceptionalist perspective has waned since the 1990's as AIDS had been "normalized" the issues posed by the challenge to conventional public health practice remain pertinent: how should the claims of communal well-being be balanced against the claims of privacy and individual rights?

This module will center its discussion on the tension between the rights of the individual and claims of public health as they have surfaced in infectious disease control. The focus will be on: screening to uncover the presence of disease; surveillance and reporting of those with disease to public health registries; contact tracing; mandatory treatment of those with infectious conditions; vaccination of children to prevent the acquisition of disease; and quarantine or isolation of those whose biological condition or behavior pose a threat to the public health. Cases will be drawn from the AIDS epidemic, which provided an infectious disease threat to public health in the United States at a time when many had thought such challenges were all but relegated to history; resurgent tuberculosis in the late 1980's and 1990's, which compelled a contemporary reconsideration of practices which had served to lay the foundations of public health at the end of the 19th and the first decades of the 20th century; and mandatory vaccination policy, which at the end of the 20th century had begun to provoke renewed resistance echoing opposition that emerged a century earlier and set the stage for fundamental constitutional rulings on the scope of public health authority.

Screening for Disease

During the 20th-century, screening for the presence of disease and at times occult infection has been a central feature of public health practice. Often such screening was mandatory or imposed as a condition for undertaking a desired course of action. Screening for venereal disease prior to marriage was imposed as a way of protecting unsuspecting spouses from infection. Screening children for entry into public school was imposed to protect classmates. Screening of newborns for inborn errors of metabolism was enacted to assure that needed remedial actions, dietary or otherwise, was taken. And of course screening for tuberculosis by X-ray and skin test became widespread, in schools and workplaces.

In each of these instances the determination to impose screening represented judgment that the claims of bodily integrity could be subordinated to the claims of the public health. When the rights of the individual in the context of public health were less robustly defined than became the case in the last decades of the 20th century such screening generally went untested. When challenges did arise they typically involved claims that the putative threat to the public health was overstated. It was thus possible to claim that respecting the rights of privacy did not entail a threat to the safety and well-being of the community or of those in need of the community's protection. At times determination could be made that screening programs that had served the public health were no longer warranted. For example, in recent decades premarital syphilis screening as a mandatory measure has all but vanished. Those who were getting married did not have syphilis and those with syphilis were not getting married.

The complex and volatile the issue of screening is highlighted by the furious debate that has centered on the HIV test. While there was no objection to the mandatory screening of blood donations in order to protect recipients, conflict emerged over screening in other settings. There were some who argued for wide scale testing without consent, for mandatory prenatal testing, testing of health care workers, the testing of newborns. In each case they asserted that the claims of public health took precedence over the right to privacy.

The insistence of public health officials, civil liberties advocates and AIDS activists fearful of how AIDS could provide the context for the deprivation of privacy rights led to a rejection of mandatory HIV testing, even as conservative political groups pressed for such measures. In lieu of such a course public health officials embraced the strategy of voluntary testing. Reflective of the impact HIV exceptionalism, testing was to be undertaken only after individuals had been fully informed of the risks and benefits of the HIV test and had given their explicit informed consent. With the advent of effective antiretroviral therapies in the 1990's there was increased pressure "to return HIV testing to the mainstream" to permit physicians to test with the presumption of consent and without elaborate pre-test counseling. More striking were the moves towards mandatory testing, to protect newborns, "innocent victims." Hence it was argued that pregnant women should be tested for HIV as they were tested for hepatitis B in order to permit interventions that could benefit and not yet born child.

The transformation in the debate surrounding HIV screening reflected an attempt to shift the balance between privacy rights and public health. It underscored the extent to which justifications for recourse to compulsion in public health are affected by the prospects of effective intervention.

In the end the ethical question posed by screening is: what prospect of effective public health intervention to protect the vulnerable, however defined, can justify the invasion of bodily integrity and privacy that is always involved in mandatory screening programs?

The ethical challenges posed by screening programs are illustrated by a proposal made in the year 2000 by the Institute of Medicine to require screening of some applicants for immigration the United States for latent TB infection.⁴ After an exhaustive analysis the IOM concluded that the elimination of tuberculosis in the United States would necessitate more than the identification and treatment of individuals with active disease. Such efforts designed to protect third parties posed few ethical challenges. But were ethical and legal principles that justified screening for active disease sufficiently robust to justify mandatory screening for latent infection, infection that could only pose a risk to others were it to progress to active disease?

Since individuals with latent infection developed active infectious TB in only about 10% of the cases, the issues posed by the IOM recommendation were stark: Is it ever appropriate to use compulsory public health powers when the threat posed by an individual is merely statistical? How grave and how likely must the risk be? Is voluntary testing more ethically defensible? The IOM predicated its call for mandatory screening on its determination that mandatory treatment for latent infection could be justified. For the IOM the social benefit of radically reducing the burden of tuberculosis justified mandatory prophylactic therapy of new immigrants and hence mandatory screening. Relying on an expansive view of the ethics of public health law, the committee cited approvingly an analysis by professor Larry Gostin, "While traditional public health law focus principally on present infections, there is no reason to limit the direct threat doctrine in this way."⁵ From an ethical perspective, of course, the question remains how to define what counts as criteria for being "reasonably foreseeable", so that it could provide Gostin with the justification for extending the direct warrant for intervention.

Finally, a critical question posed by the IOM report centers on the issue of who should be subject to mandatory screening. Efforts that were over inclusive—those that extended screening beyond what could be justified by the epidemiological profile of risk—unfairly imposed burdensome intrusions on privacy. Programs that were under inclusive—focused on fewer individuals than were at risk—could be viewed as invidiously discriminatory. The IOM chose to target immigrants from nations with elevated background rates of tuberculosis and from those nations that experience revealed contributed substantially to the burden of tuberculosis in United States. In so targeting the proposal for mandatory screening, the IOM sought to balance the need to avoid stigmatization of the vulnerable against the well established principle that the predictive value of screening programs is determined by the extent to which they are directed at populations at risk.

Decisions about how broadly to cast the net for screening are not, however, always dictated by epidemiological factors. When the Institute of Medicine itself issued a report on screening for HIV infection during pregnancy it recommended that voluntary screening be offered to all pregnant women in the United States despite the fact that HIV infection is found primarily among poor African-American and Latino women. That decision was in large measure dictated by concerns about how targeted screening could stigmatize the populations most at risk. Here then even in the context of a voluntary screening program we see a complex interplay of ethical concerns.

Surveillance and Name Based Reporting

If mandatory screening raises questions about the circumstances under which the public health can justify intrusions on the body, public health surveillance poses questions of the tension between privacy, confidentiality and the public good. When does the state have the right to require physicians and health care institutions to report, by name, those with certain conditions? Do such requirements violate the confidentiality that serves as a foundation of the clinical relationship?

It was not until the late 19th century that systematic reporting of infectious diseases began. Since surveillance was undertaken not only to track patterns of morbidity and mortality but to initiate other restrictive measures, e.g. compulsory treatment, and quarantine, it provoked public and professional concern. Hence, physicians, on occasion, challenged the authority of the public health authorities to abridge the sanctity of the doctor-patient relationship in the name of surveillance. In New York City, for example, physicians opposed mandatory tuberculosis reporting and as a consequence it was necessary

to rely upon a voluntary reporting system in which doctors withheld the names of their private patients and reported only the names of the poor dispensary cases.

Eventually, despite such opposition, name based reporting was extended to a host of other conditions practically without any sign of protest. Recognizing that resistance could undermine their efforts, public health officials began to develop the legal and organizational capacity for protecting the confidentiality of names reported to health departments. But what appeared to be a matter of settled practice would become the subject of acrimony at the end of the 20th century. The AIDS epidemic provided the occasion for a furious extended debate on the logic and ethics of name based reporting, dramatizing the ways in which competing notions of privacy and public health could continue to affect public policy.

Soon after the first cases of AIDS were reported by the Centers for Disease Control in 1981, state health departments began to require that physicians and hospitals report by name those with the new disease. It is remarkable that given the intensity of the opposition that would emerge in the case of HIV reporting just a few short years later, little protest to the privacy-limiting act of name based reporting for AIDS emerged.

Once the capacity to test for the presence of the antibody to HIV became possible in 1985 it was only a matter of time before some public health officials sought to extend to such findings the reporting requirement that were in place for AIDS. Those who pressed for name-based HIV reporting asserted that reporting would alert public health officials to the presence of individuals infected with a lethal infection, would allow them to counsel such individuals about what they need to do to prevent further transmission, and would permit the authorities to monitor the incidence and prevalence of infection. Aware of concerns about privacy and confidentiality, the proponents of reporting underscored the existence of administrative, regulatory, and statutory protections of public health registries. There was no reason to believe, they argued, that state health departments would fail to protect the identities of those with HIV when they had protected those with AIDS, tuberculosis and other reportable infections.

The antagonists of name based reporting retorted that HIV was different. Social hostility and HIV related hysteria could lead to changes in policy, legislatively imposed, that would permit breaches which never occurred with other conditions. If that happened, those whose names were in registries would face the prospect of losing their jobs, their housing and perhaps their liberty. Aware of such opposition, many health officials in states with relatively large AIDS caseloads resisted HIV reporting. They believed that reporting would counterproductively drive people away from the testing and counseling essential to AIDS control in the United States. It did not matter that public health departments had an exemplary record in protecting name based reports. If those most at risk for HIV had fears about what could happen to them, that was all that mattered.

As therapeutic advances began to emerge in the late 1980's a number of public health officials began to argue that the time was right to extend to HIV the policies that existed with regard to AIDS itself. Most critically the CDC began to press for name-based reporting of HIV cases, as did the Council of State and Territorial Epidemiologists. Nevertheless, the resistance on the part of AIDS activist organizations and their political allies persisted. As a consequence HIV cases typically became reportable by name only in states that did not have large cosmopolitan communities, well organized AIDS constituencies or high AIDS caseloads.

It is striking feature of the opposition to reporting of HIV that it centered on the extent to which those whose names would be reported would be exposed to the possibility of great harms, acts of injustice, discrimination and stigmatization. By esting opposition to reporting on such possibilities—remote given the history of public health registries—a strategic determination was made that invoking the prospects of such danger would serve to effectively mobilize the communities most affected by HIV. An alternative would have been to underscore the fact that even were no harms to befall individuals whose names were reported to registries, they would nevertheless have suffered the injury of having their privacy violated.

As powerful new therapies emerged in the mid-1990s that fundamentally transformed the nature of HIV/AIDS, the effectiveness of the resistance to HIV reporting all but crumbled. While most states, including New York, adopted name-based HIV reporting, a few, including California and Maryland, chose to rely on coded unique identifiers. In so doing, they sought to meet the challenge of surveillance while protecting the privacy of those with HIV.

To those states that have chosen to use names, the history of public health surveillance and the contemporary experience with reporting—in cancer, occupational disease, and vaccine registries—suggested that there was no justification for treating HIV differently. For those states that had chosen to employ unique identifiers in lieu of names, the fears and concerns of those who had HIV provided a warrant for going beyond historical experience and convention.

In examining the possibility of alternatives to the use of name based reporting, it was necessary to consider the question of whether practices that emerged in an earlier era when concerns about privacy were more circumscribed needed to be rethought. Was it possible to merge the necessities of surveillance with contemporary conceptions of privacy? If the use of coded identifiers imposed additional costs, were these justified in the name of privacy? If surveillance that relied on coded identifiers was less effective than relying on names, was it nevertheless good enough given the value of privacy? Finally, the debate over HIV reporting surfaced questions about how public health officials should take into account the concerns of those whose privacy would be violated in the name of surveillance.

Contact Tracing

Case-based surveillance serves not only to monitor epidemiological patterns of disease but as a trigger for contact tracing. In programs designed to treat and control sexually transmitted diseases (STDs), contact tracing has played a central role for more than five decades. Patients diagnosed with STD are urged to reveal the names of their sexual partners so that they may be examined and, if infected, treated. Contact tracing thus serves two functions: case finding and interrupting the chain of transmission. To encourage individuals to provide the names of their partners, a guarantee of absolute anonymity is provided: those who are notified are never informed of the identity of the person who provided their name. In this way, contact tracing has always been voluntary and has always rested on the foundation of confidentiality.

In the early years of the AIDS epidemic, contact tracing programs designed to reach sexual partners who unknowingly may have been placed at risk were greeted with protest. Despite the long history of such programs for STDs, proposals to initiate them were deemed coercive. They were viewed as an intrusion on the privacy of the notified partner. In the absence of a therapy for HIV infection, the

information provided by the public-health official was considered an unwelcome burden (Bayer and Toomey, 1992).

By the end of the first decade of the AIDS epidemic, most of the principled opposition to contact tracing had vanished, and public-health departments began to devote greater resources to such programs.

The issues raised by contact tracing are fundamentally different from those posed to the physician faced with an infected patient who makes clear the intention not to inform sexual partners of that fact. Does the duty to protect confidentiality take precedence over the obligation to protect unsuspecting partners? (Dickens, 1990). If a duty to protect exists, it requires that the clinician act despite the preferences of the patient. It may require that the identity of the threatening patient be revealed to the endangered party. Thus, the duty to warn is in all fundamental respects different from voluntary contact tracing.

As clinicians and public-health officials confronted this issue, they were faced with a dilemma that was starkly presented in the landmark Tarasoff case, in which the California Supreme Court held that a psychotherapist had a duty to protect or warn the potential victims of a violent patient. If it became known that under some circumstances clinicians would breach confidentiality, would this inhibit patient candor? Would such a reduction in candor, if it occurred, deprive clinicians of the capacity to affect patients' behavior? In short, might the duty to warn ultimately subvert the very good it was designed to achieve—enhanced public safety?

Faced with this complex situation in the context of the AIDS epidemic, many state legislatures opted to grant physicians a "privilege to disclose," thus freeing them from Tarasoff-like liability if they did not warn, as well as from liability for breaching confidentiality if they did warn. In a striking reflection of the concerns about privacy provoked by the AIDS epidemic, a number of states have prohibited physicians who do warn third parties from revealing the patient's identity to those being notified.

Monitoring treatment: The case of directly observed therapy

In the face of infectious disease threats, public health departments have at times been involved in attempting to certify that those who could spread disease had undergone appropriate treatment. Treatment in this instance had to be understood as serving both the interest of the individual as patient and the broader community that would be protected from the transmission of disease. As the example discussed below will demonstrate, however, treating those whose conditions were infectious might not be sufficient.

In the late 1980's and early 1990's, the resurgence of tuberculosis in the United States and the pattern of drug-resistance made it clear to public health officials that strategies for managing the disease had failed. Those who began treatment but did not complete their therapy not only ran the risk of reactivating their disease but of developing resistance that could be very costly to treat and, in the case of those with compromised immune systems, could prove fatal. And, of course, drug-resistant disease could be transmitted to others.

Among the strategies designed to enhance patient compliance with treatment is directly observed therapy, a practice that involves having the patient take his or her medication in the presence of health care providers or other responsible parties. First proposed for individuals with poor records of

treatment adherence and for those whose demographic or psychological profile suggested a higher prospect of failure, directly observed therapy (DOT) has emerged as the standard of care for all tuberculosis patients.

From an ethical, legal, and constitutional perspective, the important question posed by DOT is not who should be *offered* the support provided by such supervision but whether such monitoring can be *imposed*. And if DOT were to be imposed, how broadly should such requirements be extended? To the extent that DOT was selectively imposed, what procedures, guided by what standards of evidence, should be used? While there were many who argued for the selective use of DOT in the case of those likely to be nonadherent, in the early 1990s such a posture was increasingly viewed as inadequate to the challenges posed by tuberculosis. There was no evidence that physicians or other health care workers could predict which of their patients could be trusted to complete their treatment. Efforts to distinguish among patients, using social or demographic factors, not only were unsuccessful, they ran the risk of being invidiously discriminating. As a consequence the argument for universal DOT gained increasing support. Three veterans of public health work in TB thus wrote:

*We believe it is time for entirely intermittent directly observed treatment programs ... to be used for all patients. Some argue that it will be impossible to treat every patient with directly observed therapy and that many people with tuberculosis do comply with treatment and would be offended by having to submit to direct observation while they swallow medications. Unfortunately, the literature is replete with studies demonstrating that professionals are not able to distinguish the compliant from the noncompliant.*⁶

Given the price of failure in morbidity, mortality and the cost of treating resistant strains of TB, they concluded, "We cannot afford not to try it."⁷

Calls for universal directly observed therapy provoked sharp opposition. First, it was argued that such an effort would entail an enormous waste of scarce resources. Funds that could best be used to provide services to those most in need would be diverted by the provision of service to those who would be compliant on their own. But most critically, universal directly observed therapy was challenged as an unethical intrusion upon autonomy, as " gratuitously annoying," as a violation of the constitutional requirement that the least restrictive alternative be used, and as contrary to requirements of the Americans with Disabilities Act that decisions involving restrictions on those with disabilities be based on an individualized assessment. One opponent thus stated,

*I cannot see how mandatory directly observed therapy can be reconciled with the principle of the least restrictive alternative in the exercise of governmental power since it would require the imposition of the coercive treatment regime on a class of people without any showing that they, as individuals, will fail voluntarily to follow course of medical treatment. Nor does it comport with basic constitutional due process principles which require individualized determination when state sanctions are imposed.*⁸

Legal commentators have generally rejected mandatory DOT as overly broad and as violative of constitutional principles. However this opposition to universal DOT should not be construed as a rejection of a mandatory DOT in all cases. The advocates of patients' civil liberties accept mandatory, court ordered DOT in cases of clear noncompliance, especially when the alternative appears to be involuntary confinement.

The issue posed here, therefore, is not whether tuberculosis patients should have a choice about whether or not to undergo therapy—there is universal agreement that the threat posed to public health necessitates that all patients with infectious TB be treated. Nor is the issue whether tuberculosis patients who are no longer infectious should be required to undergo treatment until cured of their infection. There is universal agreement that the threat to the public health justifies that imposition as well. What is at the center of controversy is the nature and scope of the mechanism that should be employed to assure that those who are in treatment adhere to the course of therapy required for their own good and that of the community. As we turn to the issue of quarantine we will have an opportunity to explore the question of the context within which the state may exercise the authority to deprive someone of liberty because of noncompliance with their treatment.

Quarantines

Ethical, legal, and constitutional principles have long recognized the authority of the state to confine individuals with dangerous infectious diseases because of the threat they posed to others. This power to deprive an individual of his or her liberty in the name of public health has vested public health officials with an authority that, from the perspective of the individual, may seem indistinguishable from that wielded by the criminal justice system. Yet, until relatively recently, the protections accorded to defendants in criminal prosecutions have not been extended to those viewed as a threat to the public health. As late as 1966 a California appellate court upheld the confinement of a TB patient pursuant to a statute that provided virtually no procedural protections for the patient. In its ruling, the court stated that regulations "enacted by the state under its police power and providing even drastic measures for the elimination of disease ... in a general way are not affected by provisions" of state or national constitutions.⁹

This broad deference to the legislature and to the exercise of public health powers would come to look archaic just a few years later as the jurisprudence of confinement underwent a radical revision in the wake of a series of far-reaching constitutional challenges to the power of the state to confine patients with psychiatric disorders. These cases, although framed in the language of law, embody important ethical considerations. In 1979 the Chief Justice of the Supreme Court would state in *Addington v. Texas*,

This Court has repeatedly recognized that [confinement] for any purpose constitutes a significant deprivation of liberty and requires due process protection. Moreover it is indisputable that involuntary commitment to a mental hospital... can engender adverse social consequences to the individual. Whether we label this phenomena "stigma" or choose to call it something else is less important than that we recognize that it does occur and [has] a very significant impact on the individual.¹⁰

In 1980 in the first reported appellate court decision upholding the procedural rights of tuberculosis patients, the Supreme Court of Appeals in West Virginia articulated a standard reflective of the U.S. Supreme Court's standards. The state's Tuberculosis Control Act was ruled unconstitutional because it did not guarantee the right to counsel, did not provide the right cross-examine, confront and present witnesses, and failed to hold the state to the stringent "clear and convincing" standard of proof required by the Supreme Court.

In 1993 when the Advisory Council on the Elimination of Tuberculosis recommended changes in state tuberculosis control laws it declared that commitment proceedings had to afford those who might be confined because of TB with a full range of procedural protections. Furthermore, in recognition of the liberty-depriving nature of compulsory hospitalization, the council asserted the importance of viewing such measures as a last resort after all less restrictive approaches had failed.

The council's incorporation of both procedural due process protections and the doctrine of the least restrictive alternative into its recommendations were specially crucial because it was calling for the expansion of existing tuberculosis laws to permit the involuntary isolation and detention of noninfectious patients who could not or would not adhere to regimens or to complete their TB therapy. This expansion in the conception of who posed a threat to the public health was driven by concerns about multi-drug-resistant tuberculosis and presented a move of great significance. No longer did the person to be confined have to represent an immediate threat of transmission, rather it was the prospect of reactivation and the prospect of the development of drug-resistance that provided the grounds for state intervention. Just as was the case with the IOM's call for mandatory prophylactic treatment of immigrants with latent TB infection, the concept of threat employed here was informed by population-based concerns. It was concern about the collective consequences permitting many individuals to conduct themselves in a way that posed some threat that motivated the extension of public health powers. This was a calculus far different from one that would center on the potential risk posed by a given individual.

In New York City, which confronted an outbreak of multi drug resistant tuberculosis (MDR-TB), the health department adopted regulations that permitted the confinement of those who it believed could not or would not complete their TB treatment. Among most significant features of those new regulations was a provision that would have permitted the imposition of quarantine even if the health authorities had not exhausted each and every element of the least restrictive approach. In the face of a public health threat officials asserted that they need not be required to wait for the patient to fail each set of interventions. In an ultimately unsuccessful challenge to these regulations civil liberties opponents sought to argue that while measures like those proposed by the municipal authorities might have been appropriate with contagious patients that was not the case with those whose TB was no longer infectious. Since there was no imminent risk in such situations it was more appropriate to protect the right of the patient against state authority.

Here again we can see how the concepts of risk, and of imminent risk, reflect more than a matter of measurement. As a trigger for state intervention, in this instance involving a deprivation of liberty, the concepts are suffused with moral considerations. In fact they compel us to confront the question of what threat, to whom, with what degree of certainty, and with what consequence all justify a limitation on freedom in the name of public health.

Vaccination Program

To this point we have focused on public health interventions designed to discover or monitor infectious disease and prevent the spread of such conditions. It is now necessary to turn to the question of whether liberty-limiting interventions can be justified to prevent the spread of disease from those not yet infected and to protect those who might become infected in the future. These are the questions posed by compulsory vaccination programs.

In an analysis of the last phase of the smallpox eradication campaign in India a CDC officer assigned to the effort wrote,

*Infected villages were revisited—often repeatedly—to check [for cases that] had been left out. Almost invariably a chase or forcible vaccination ensued in such circumstances ... We considered the villagers to have an understandable but irrational fear of vaccination ... We just couldn't let people get smallpox and die needlessly. We went from door to door and when they ran, we chased. When they locked their doors, we broke down their doors and vaccinated."*¹¹

This striking description captures in an unvarnished way the extent to which concerns about disease prevention could provide a warrant for the untrammelled exercise of power. But even where the exercise of public health authority has not been used in so brutal a fashion, the history of vaccination is, in large measure, a history of the imposition of inoculations in the name of public health. In the United States, this issue was addressed by the U.S. Supreme Court in 1905. In a case noted in the introduction to this module *Jacobson v. Massachusetts*, the Court held,

In every well ordered society charged with the duty of conserving the safety of its members the right to the individual and respect of his liberty may, at times, under the pressure of great dangers, be subjected to such restraint to be enforced by reasonable regulations as the safety of the general public may demand.

Immunization in the United States has attained all-time highs. In 1998 the rates had reached 90% for 19- to 35-month-old children for most vaccines. To a very large extent this achievement can be viewed as a consequence of both persuasion—physicians routinely urge parents to immunize their children—and compulsion. All states require evidence of vaccination against a host of diseases including measles, polio and diphtheria. Children who are not immunized may not attend school or be registered in licensed day care centers. There are exceptions for religious reasons. 48 states permit parents to refuse immunization on religious grounds, and far fewer, 15 states, permit "philosophic exemptions." But such provisions affect only an extraordinarily small number of children. Nevertheless, it is worth thinking about the ethical justification for recognizing the religious and, for that matter, the broader philosophical exemption. At stake is the recognition that in matters touching on deeply held beliefs, the state should only with great reluctance intrude. But how much risk and to whom would be tolerable given such restraint? Do parents have a right to place their children at some risk by failing to immunize them? How much risk would be sufficient to tip the balance against parental religious beliefs? And what if the risk were not simply to the child but to others?

As a result of immunization programs diseases that were formerly a common occurrence among children have declined by well over 99 percent. For example in 1941 there were 890,000 cases of measles, and by the late 1990's the number had fallen to 89. In 1968 there were approximately 150,000 cases of mumps, by 1998 the number had fallen to 61. These achievements have, ironically, set the stage for the emergence of challenges to mandatory childhood vaccination.

As the experience of disease has receded, what has emerged is concern about the remote prospect of adverse reactions. With the possibility of disease so small why subject a child to any risk? The issue of vaccination places into sharp relief the clash between the rationality of public policy and rationality of decision making on the part of individuals for themselves or for those they have a duty to protect.

Because it involves children who cannot consent for themselves the issue of compulsory vaccination also raises questions about when the state may substitute its judgment for that of parents.

In an unusually thorough discussion of the ethical issues posed by childhood vaccination, Douglas Diekema and Edgar Marcuse have identified three broad questions that need to be considered:

First, do parents who withhold vaccination from their children harm them to such an extent that parental refusal ought to be overridden? Second, what duties do parents owe others in the community to avoid causing harm through an unvaccinated child? Third, does the social value of having a vaccinated population—for the sake of herd immunity and the eradication of disease—justify coercive efforts to vaccinate all children?¹²

In their analysis Diekema and Marcuse note that what makes the discussion of these linked questions so intriguing is the fact that immunization involves both a direct benefit to the individual child as well to those in the community who remain unimmunized who benefit from the immunization of the vast majority.

The question thus emerges of whether those who choose not to immunize their children and to rely on the benefits provided by herd immunity are "free riders"? From an ethical perspective the issue can be framed as one of justice and fair distribution of risks and benefits. Those parents who choose to immunize their children assume risks on behalf of the community that those who choose not to immunize can avoid. Finally, in this regard it is critical to recognize that the existence of free riders may erode the commitment to immunization, thus lowering the overall rate of protective coverage—undercutting the very foundations for herd immunity. Thus a paradox emerges: Herd immunity allows individuals to choose not to be vaccinated, but recognizing the right of parents not to vaccinate their children may subvert that very herd immunity.

The situation is somewhat different in cases such as measles, where immunization offers only imperfect protection. Thus the vaccinated remain at risk from the unimmunized who may develop disease. In such circumstances do the ethics of public health justify mandatory vaccination of all children for measles? What of the religious exemption?

Conclusion

In the first years of the HIV epidemic it became a convention in AIDS advocacy and among some public health officials to assert that there was no tension between the claims of privacy and civil liberties on the one hand and public health on the other. The argument was that restrictions on rights were inevitably counterproductive to the pursuit of public health goals. It was with that perspective as a guiding principle that efforts were made to rethink public health practices that bore the imprint of their origins in the late 19th and early 20th centuries. Most provocatively this perspective informed the first formulations of the linkage between health and human rights. More radically, the human rights perspective, building on the long tradition of social medicine, underscored the extent to which the vulnerability to disease, including infectious disease, was rooted in poverty and social inequality. Tuberculosis provided the paradigmatic case. TB had declined in United States and elsewhere long before antibiotic treatment became available, and as Thomas McKeown had demonstrated, the fundamental cause of the decline of tuberculosis was the transformation of the social conditions under which people lived. Indeed tuberculosis in the contemporary period was largely restricted to the poor.

If health was in large measure a function of broad social conditions what role could be played by public health intervention? This is one of the great challenges of public health analysis. But to the extent that interventions are critical to protecting the public health, it is inevitable that decision makers will have to confront the question of how the interests and rights of the individual are to be balanced against the public good. Demonstrating the enduring nature of these issues is the very recent debate over the extent to which the threat of bioterrorism can justify the exercise of public health measures like name reporting, mandatory vaccination and quarantine in situations defined as a public health emergency. As should be clear, the very determination of what constitutes an emergency warranting such measures is more than a technical matter. It is suffused with value questions regarding the balance of risks and benefits, tolerable uncertainties, and our conceptions of rights.

In encountering these matters, careful ethical analysis can make a singular contribution to the practice of public health.

Cases In Infectious Disease

The six case studies embedded in this essay that highlight critical ethical challenges in the ethics of infectious disease control are:

1. *Screening for HIV infection and latent TB infection* – Highlighting the tension between the integrity of the body and the imperatives of identifying those who harbor infections that may be transmitted to others.

2. *Disease surveillance and the reporting of disease to public health registries* – Highlighting the tension between the confidentiality of the doctor-patient relationship and the necessity to obtain accurate information about the incidence and prevalence of infectious disease.

3. *Contact investigation and the duty to warn* – Highlighting the tension between the desire of patients to maintain their privacy and the obligation of public health officials and others to want and protect those who may have been placed at risk.

4. *Directly observed therapy for TB patients* – Highlighting the right to refuse treatment and the risk poised by individuals whose untreated disease poses a risk to others.

5. *Quarantine of individuals who could not or would not complete their TB treatment* – Highlighting the tension between personal liberty and the *potential* risk posed by those with TB that has not been completely treated.

6. *Mandatory childhood vaccination* – Highlighting the tension between parental rights and the public health obligation to protect children from preventable disease and the public from infectious threats.

For Further Reading

R. Bayer, *Private Acts, Social Consequences: AIDS and the Politics of Public Health*, Rutgers University Press, 1991 - Chapters 4, 5, 6.

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D. Diekema and E. Marcuse, "Ethical Issues in the Vaccination of Children," *Primum Non Nocere Today* (Elsevier, 1998), pp. 37-47.

S. King, "Vaccination Policies: Individual Rights v. Community Health," *BMJ* 319 (December 4, 1999): 1448-1449.

¹ John Stuart Mill, *On Liberty* (Cambridge: Cambridge University Press, 1989), 13.

² *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)

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⁴ Institute of Medicine, *Ending Neglect: The Elimination of Tuberculosis in the United States*, Washington DC: National Academy Press, 2000.

⁵ Lawrence Gostin, "The Resurgent Tuberculosis Epidemic in the Era of AIDS: Reflections on Public Health, Law and Society," *Maryland Law Review* 54: 1-131.

⁶ Michael D. Iseman, David L. Cohn, John A. Sbarbaro, "Directly Observed Treatment of Tuberculosis," *New England Journal of Medicine* 328;8 (1993): 576-578.

⁷ *Ibid.*

⁸ "Tuberculosis in the 1990s: Ethical, Legal and Public Policy Issues in Screening, Treatment, and the Protection of Those in Congregate facilities: A Report from the Working Group on TB and HIV." In United Hospital Fund of New York, *The Tuberculosis Revival: Individual Rights and Societal Obligations in a Time of AIDS* (1992). Dissent of David Hansell.

⁹ *In re Halko*. 54 Cal. Report. 661 (1966)

¹⁰ *Addington v. Texas*, 441 U.S. 418 (1979)

¹¹ Paul Greenough, "Intimidation, Coercion and Resistance in the Final Stages of the South Asian Smallpox Eradication Campaign, 1973-1975," *Social Science and Medicine* 41;5 (1995): 633-645.

¹² D. Diekema and E. Marcuse, "Ethical Issues in the Vaccination of Children," In *Primum Non Nocere Today* (New York: Elsevier, 1998), pp. 37-47.