

# Chapter 2

## Essential Cases in the Development of Public Health Ethics

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### 2.1 Introduction

While “public health” has been defined as what society does to “assure the conditions for people to be healthy” (Institute of Medicine 2003, xi), public health *ethics* is a “systematic process to clarify, prioritize, and justify possible courses of public health action based on ethical principles, values and beliefs of stakeholders, and scientific and other information” (Schools of Public Health Application Service 2013). Despite several important characteristics that distinguish public health from clinical medicine, at its start public health ethics borrowed heavily from clinical ethics and research ethics (see Chap. 1). In the 1980s, with the onset of the AIDS epidemic and unprecedented advances in biomedicine, the inability of clinical ethics to accommodate the ethical challenges in public health from existing frameworks led pioneering ethicists to reframe and adapt clinical ethics from an individual and autonomy focused approach to one that better reflected the tension between individual rights and the health of a group or population (Bayer et al. 1986; Beauchamp 1988; Kass 2001; Childress et al. 2002; Upshur 2002). Others called for public health ethics to emphasize relational ethics and political philosophy (Jennings 2007). More recently, some authors have suggested outlining foundational values from which operating principles for public health ethics can be articulated only after careful consideration of the goals and purpose of public health. This approach would require us to establish a clear definition of the moral endeavor of public

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health as a field (Lee 2012) and construct an ethical framework stemming from the nature of it (Dawson 2011).

A versatile framework for public health ethics must accommodate public health in practice and research. In public health practice, an ethics framework must guide decisions about activities like infectious disease control, primary prevention, and environmental health, as well as newer expectations of public health such as chronic disease control and preparedness. In public health research, biomedical and behavioral research ethics provide a great deal of guidance—but research that focuses on population-based outcomes and community concerns reveals additional ethical considerations.

A fundamental tension in public health is one between individual- and population-based interests. Various political traditions place different value on each, and these values can fluctuate within the same political structure over time. When authorities intervene to affect population health, they must find an equilibrium between individual and population interests in all political contexts, whether authoritarian, socialist, or liberal individualist. To consider individual interests as well as population interests, regardless of the philosophical tradition within which these interests are valued, is a challenge for a public health ethics framework. The cases we present in this chapter illustrate how this equilibrium between individual and population interests has been established in the context of dynamic political and historical influences.

One way of approaching public health ethics deliberation is through the method of casuistry, defined as “the interpretation of moral issues, using procedures of reasoning based on paradigms and analogies, leading to the formulation of expert opinion about the existence and stringency of particular moral obligations, framed in terms of rules or maxims that are general but not universal or invariable, since they hold good with certainty only in the typical conditions of the agent and the circumstances of action” (Jonsen and Toulmin 1988, 297). Consideration of case studies and the use of casuistic methods of resolution of morally similar cases through interpretation of ethical principles have played important roles in the development of public health ethics—particularly before public health ethics was viewed as distinct from clinical ethics. Individual case studies enable discussions about which ethical norms we should adopt for the practice of public health and how public health professionals should deliberate to resolve ethical problems in practice (Centers for Disease Control and Prevention [CDC] 2012). In this chapter, we review several seminal cases that shaped the ethics of public health research and practice over the past century to provide the foundation of current public health ethics and lay the groundwork for a casebook to enable casuist analysis.

Our first case example is *Jacobson v Massachusetts*, set in the beginning of the twentieth century. *Jacobson* is a foundational U.S. public health legal case that supports states’ rights to create and enforce laws and regulations that limit individual autonomy to protect the public’s health and stop the spread of communicable disease. Our second case study, from the mid-1900s, looks at two ethically troubling U.S. Public Health Service (PHS) protocols for studying sexually transmitted diseases (STDs) in the U.S. state of Alabama and Guatemala. These experiments, like

most research protocols, were not intended to benefit the subjects; rather their intent was the broader benefit of the public's health. They show however, that researchers, despite the apparent motivation to advance public health, can breach public health research ethics and harm research subjects. The final case, a contemporary example of the New York City A1C Registry to monitor and address the diabetes epidemic in the city, demonstrates how addressing the ethical dimensions of public health interventions can facilitate their implementation. This case moves our focus from public health interventions targeting communicable diseases to those supporting secondary prevention of noncommunicable diseases. It focuses on the ethical dimensions that can arise when technological advances in communication might affect individual privacy. Unlike the consistent movement forward with which casuistry has moved clinical ethics, (Jonsen 1991), the outcomes in the cases we describe here shaped, and sometimes jolted, the nascent field of public health ethics.

These three case studies, occurring within the same political structure over the span of a century, illustrate the tension between individual autonomy and protection of public health in very different ways. The first case depicts a situation where the balance tipped in favor of protection of the public's health in the context of infectious diseases. The second case demonstrates unconscionable exploitation of vulnerable research subjects for the benefit of other communities. Finally, the third case presents a situation in which solutions to public health problems based on technological advances and access to data can strike a balance with individual health privacy concerns. Each case illustrates the quest for equilibrium between individual and population interests.

## **2.2 Case Study: *Jacobson v. Massachusetts***

The earliest activities associated with modern public health are sanitation and infectious disease control. From the first public health surveillance system in colonial America that required tavern keepers in Rhode Island to report contagious disease, to John Snow removing the Broad Street pump handle in London to end the 1854 cholera epidemic, control of communicable diseases has been firmly in the jurisdiction of public health (Thacker 2010). Discovery of the physiological mechanisms of vaccines in the eighteenth century gave us new tools to control infectious diseases but also raised critical questions about how to carry out—effectively and ethically—policies and plans that support individual and community health.

### **2.2.1 Background**

By the turn of the twentieth century, public health campaigns—including improved hygiene, sanitation, and access to safer food and water—had already extended the average life expectancy in the United States (CDC 1999). But infectious diseases

were still the leading cause of mortality, with tuberculosis, pneumonia, and diarrheal disease accounting for 30 % of U.S. citizen deaths (Cohen 2000). Evolving support for the government's involvement in protecting public health led to the establishment of hygienic laboratories in 1887 (Kass 1986). These laboratories continue today to provide essential services such as diagnostics, public health surveillance, research, and vaccine development.

Edward Jenner, who discovered that a vaccine for smallpox could be created using cowpox lesions, sent his vaccine from England to Benjamin Waterhouse at Harvard University in 1800 (Riedel 2005). After successfully vaccinating the members of his household, Waterhouse began selling the vaccine in Boston, Massachusetts (Kass 1986). Not all physicians vaccinated as meticulously as Waterhouse however, and in one unfortunate incident, adulterated smallpox vaccine caused an epidemic in the Boston area (Kass 1986).

As interest in and concern about the vaccine grew, the Board of Health of Boston decided to perform one of the first controlled clinical trials in U.S. history, which eventually demonstrated effectiveness of the vaccine (Kass 1986). A century later, Massachusetts had established vaccination campaigns, but smallpox persisted: One hundred cases were reported in Massachusetts in 1900 with 2314 cases by 1902 (Parmet et al. 2005). The Board of Health had originally promoted a voluntary vaccination scheme until January 1902 when two children, one in Boston, died of post-vaccination complications within a month of each other (Willrich 2011). After voluntary efforts stalled, the Board ordered mandatory vaccination in February, but did not enforce the order. After an outbreak sent another 50 adults and children to the hospital and caused seven deaths, the Board voted that the regulations needed to be enforced (Willrich 2011).

Local public health officials employed creative ways to follow enforcement orders, "many of which were scientifically sound but not all of which were apt to inspire public trust" (Parmet et al. 2005, 653). The Boston Herald, for example, reported in March 1902 that public health doctors and guards forcibly vaccinated "Italians, negroes and other employees" (Parmet et al. 2005, 653). Despite the success of the smallpox vaccine in curtailing disease, anti-vaccinationists described compulsory vaccination as "the greatest crime of the age" and as "more important than the slavery question, because it is debilitating the whole human race" (Washington Post 1905; Gostin 2008, 122). Pro-vaccinationists were as polarizing, describing the debate as "a conflict between intelligence and ignorance, civilization and barbarism" (New York Times 1885; Gostin 2008, 122).

### 2.2.2 Case Description

It was in this context that the U.S. Supreme Court heard *Jacobson v. Massachusetts*, which despite, and perhaps because of, the vastly different ways it has been interpreted and applied since then, is arguably the most important legal public health case ever decided in the United States (Gostin 2005). Under the doctrine of "police

power,” it had already been established in the late 1800s that states had the authority to enforce “sanitary laws, laws for the protection of life, liberty, health or property within its limits [and] laws to prevent persons and animals suffering under contagious or infectious diseases ...” within their own boundaries (*R. R. Co. v. Husen* 1877, 465, 472). In 1885, the Supreme Court confirmed that this included ensuring conditions essential to the “safety, health, peace, good order and morals of the community” as “even liberty itself... is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others” (*Crowley v. Christensen* 1890, 86, 89).

In 1902, in response to the increase in smallpox cases discussed above, the Cambridge, Massachusetts Board of Health issued an order, which became law, requiring citizens be vaccinated against smallpox or pay a \$5 fine (the equivalent of about \$135 in 2015) (*Massachusetts Revised Laws* 1902; *Commonwealth v. Henning Jacobson* 1903; *Mariner et al.* 2005). Henning Jacobson, a Cambridge minister, refused both the vaccination *and* to pay the fine. He argued he had previously received the smallpox vaccination in Sweden as a child and had experienced “great and extreme suffering, for a long period” as a result and that one of his sons had experienced adverse events from vaccination as well (*Commonwealth v. Henning Jacobson* 1903, 246). Jacobson argued that the law was thus “hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best ....” (*Jacobson v. Massachusetts* 1905, 26). The case went to trial.

At trial, Jacobson argued that his history of adverse reaction to the smallpox vaccine should grant him an exception from the law. However, the law did not actually provide for such exceptions for adults (as it did for children). Jacobson was found guilty of “the crime of refusing vaccination” (*Willrich* 2011, 285). He appealed to the superior court, where the judge again ruled that Jacobson’s medical history was “immaterial” to his legal violation. The judge also refused Jacobson’s plea to tell the jury that the law was a violation of the constitutions of Massachusetts and the United States because it offered no such exception. The court again found Jacobson guilty (*Willrich* 2011).

Jacobson fared no better in the Massachusetts Supreme Court. It too rejected Jacobson’s evidence of his prior adverse experience with the vaccination as well as his son’s as “matters depending upon his personal opinion, which could not be taken as correct, or given effect, merely because he made it a ground of refusal to comply with the requirement” (*Commonwealth v. Henning Jacobson* 1903, 246). Moreover, it pointed out that even if Jacobson *could* prove that he would suffer adverse effects from the vaccine, the statute did not offer an exception for such a case. In response to Jacobson’s argument that this deficiency rendered the statute unconstitutional, the court responded that the “theoretical possibility of an injury in an individual case as a result of its enforcement does not show that as a whole it is unreasonable. The application of a good law to an exceptional case may work hardship” (*Commonwealth v. Henning Jacobson* 1903, 247). However, the Massachusetts court held that if citizens refused to be vaccinated it was not within the power of public health authorities to vaccinate them by force (as the *Boston Herald* had reported occurring) (*Commonwealth v. Henning Jacobson* 1903; *Parment et al.* 2005).

When the *Jacobson* case finally made its way to the U.S. Supreme Court, the Court found that the vaccination statute was generally a reasonable protection of the public health while maintaining individual liberty. The Supreme Court did conclude that to subject someone to vaccination who was unfit because of a health condition “would be cruel and inhuman in the last degree;” it stipulated that “we are not inclined to hold that the statute establishes the absolute rule that an adult must be vaccinated if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination or that vaccination, by reason of his then condition, would seriously impair his health or probably cause his death” (*Jacobson v. Massachusetts* 1905, 38–39). However, the Court found that Jacobson was “in perfect health and a fit subject of vaccination” and that he simply “refused to obey the statute and the regulation adopted in execution of its provisions for the protection of the public health and the public safety, confessedly endangered by the presence of a dangerous disease” (*Jacobson v. Massachusetts* 1905, 39). The Court ordered Jacobson to submit to vaccination or pay the fine (*Jacobson v. Massachusetts* 1905). Three years after his legal fight began, Jacobson paid the \$5 penalty (Willrich 2011).

### 2.2.3 Discussion

Legal cases since 1890 had allowed states to require citizens be vaccinated, but around the turn of the century, limits to that right began appearing that included a “present danger” standard requiring a real and immediate threat and adherence to the harm avoidance principle protecting citizens from undue burden as much as possible (Willrich 2011). *Jacobson* has endured as a fundamental philosophical foundation of the reconciliation of individual interests with those of the public’s health in a political system emphasizing liberal individualism.

Despite the limitations of the facts in *Jacobson*, it has been interpreted in many ways to support numerous public health activities over the past century. Notably, the Supreme Court did not require that otherwise healthy citizens submit to vaccination, only that it was constitutional to require citizens to be vaccinated *or* pay a fine. Also, while the Court found that a lack of a health exception to the vaccination mandate would be unconstitutional, it did not grant Jacobson this exception for himself.

However, as with so many examples in the lexicon of medical ethics, one of the most important practical effects of historical cases is how they have been interpreted and applied to future circumstances. Part of *Jacobson*’s legacy has been the Court’s “community oriented philosophy” based in social-contract (or compact) theory (Gostin 2005, 578): “a fundamental principle of the social compact [is] that the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for ‘the common good ....’” (*Jacobson v. Massachusetts* 1905, 26). While the Court recognized individual liberty interests protected by the Constitution, it found that these interests did not impart an absolute right of freedom from restraint because “on any other basis organized society could

not exist with safety to its members” (Jacobson v. Massachusetts 1905, 26). It noted that no citizen could enjoy full liberty in a society that recognized “the right of each individual person to use his own [liberty] ... regardless of the injury that may be done to others” (Jacobson v. Massachusetts 1905, 26).

The Court also found that reasonable regulations to protect the public health and safety were among these constitutional limits on liberty (Jacobson v. Massachusetts 1905). Despite the fact that Jacobson found mandatory vaccination distressing and objectionable, it was the responsibility of the city board of health to “not permit the interests of the many to be subordinated to the wishes or convenience of the few” (Jacobson v. Massachusetts 1905, 29). As discussed above, the Court found that exceptions were needed for citizens with established concerns for their health—but did not apply this exception in Jacobson’s case.

The social contract implied in this case also needed to be reconciled with limits on government and constitutional protections of individual liberty. While the Court had already established a standard of fair application of public health interventions (e.g., not targeting a specific race-based group) (Jew Ho v. Williamson 1900; Gostin 2008), *Jacobson* built on several cases to further explain standards of constitutional protections (i.e., there must be a public health threat to the community, and the state or board of health must design the public health intervention to combat that threat). The Court found that the intervention must be proportionately tailored to that threat creating a “reasonable balance ... between the public good and the degree of personal invasion” and should not harm citizens in and of itself (Gostin 2008, 126–127).

While it is hard to reconcile some of the facts of *Jacobson* with its lofty constitutional deliberation, it is the Court’s desire to reconcile individual interests with those of the public health in a society that values liberal individualism that has become its enduring legacy. Many court decisions following *Jacobson* reaffirmed states’ use of police power for the public health (Gostin 2005), and in 1922 the Supreme Court agreed that states could require vaccinations for children who attend school (Zucht v. King 1922). *Jacobson* was an important step in the lengthy public health battle against smallpox, culminating in its eradication in 1977 (Cohen 2000).

The legal and ethical boundaries between the individual and public health remain mobile in public health law and policy despite the *Jacobson* decision. Notwithstanding its rejection of forced vaccination, coercion—as opposed to the modern emphasis on education—continued as a public health tactic, employed frequently and often directed toward vulnerable citizens (e.g., quarantined sex workers during World War I) (Colgrove and Bayer 2005). And despite the liberty protections it carved out, the Court itself struggled with upholding both individual rights and constitutional liberties. In 1927, citing *Jacobson*, the Court upheld a forced-sterilization law in Virginia of “mental defectives.” The *Buck v. Bell* decision reasoned that “[i]t is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the fallopian tubes” (Buck v. Bell 1927, 207).

In more communitarian-leaning societies, *Jacobson's* value serves less as a map for navigating public good in an individualist context, and more as an illustration of how individual and community interests can be balanced within the political and social structure. Even within the United States, however, *Jacobson* has been interpreted over the decades to be a foundation for diverse legal opinions supporting remarkable expansions of federal power—including warrantless entry into homes in time-sensitive circumstances of compelling need and a defense of the federal government's right to detain U.S. citizens without due process as “enemy combatants” (in a dissenting opinion) (Willrich 2011). Many of these cases, and certainly *Buck v. Bell* serve as a stark reminder that federal powers ostensibly in the public interest cannot be used solely to maximize perceived public benefit—they must be tempered by justice and fairness to both communities and individuals (Lombardo 2008). But as the legal community continued to struggle with what the implications and contours of what *Jacobson* should be in the United States, officials continued to press on in what was then an unregulated field—that of public health research.

### **2.3 Case Study: U.S. Public Health Service Research on Sexually Transmitted Disease: Alabama and Guatemala**

Since the 1940s, contemporary research ethics has developed rapidly through a desire to protect human participants in research. Internationally, the Nuremberg Trials for Nazi war criminals, including the trial of Nazi physicians who conducted torturous medical experiments on subjects, resulted in the *Nuremberg Code* (1947), a compilation of guidelines for conducting research with human participants. In 1964, the World Medical Association's (WMA) *Declaration of Helsinki* further refined ethical guidance for research with humans, and in particular the participation of vulnerable populations (WMA 1964).

The next case study focuses on two separate mid-century U.S. PHS experiments on sexually transmitted diseases in the U.S. state of Alabama and Guatemala. While one of the ten essential public health services is to “conduct research to attain new insights and innovative solutions to health problems” (CDC 2013b; Harrell et al. 1994, 29), these experiments demonstrate how an imbalance of population and individual interests—coupled with disregard for respect for persons—can lead to tragic results.

#### **2.3.1 Background**

In the early 1900s, STDs—and syphilis in particular—were major concerns for public health. Conservative estimates suggested that syphilis affected 10–15 % of the U.S. population (Jabbour 2000) with symptoms ranging from sores to paralysis,



blindness, and death (CDC 2013a). One leading expert at the time described syphilis as a plague “which, in these times of public enlightenment, is still shrouded in obscurity, entrenched behind a barrier of silence, and armed, by our own ignorance and false shame, with a thousand times its actual power to destroy...” (Stokes 1920, 7). In 1905, German scientists isolated the microbe that caused syphilis, and in 1910 other scientists proposed salvarsan (a preparation of arsenic) as the cure (Jones 1993). Salvarsan treatment involved a painful set of injections over a long period and ultimately turned out to be highly toxic (Jones 1993).

In 1912, the U.S. government established PHS to join other federal public health efforts to improve administration and distribution of public health aid to the states, to oversee interstate infectious diseases and sanitation, and to conduct public health research (Jones 1993). In 1918, PHS established a Division of Venereal Disease to organize and support state prophylactic and treatment work (Jones 1993). World War I had highlighted the harmful effect of STDs on the U.S. armed forces, but after interest in the disease from a wartime perspective abated, public health workers focused on syphilis as a poverty-linked disease—and a disease that reportedly affected African Americans in particular. Some physicians even argued that syphilis was a “quintessential black disease” and African Americans a “notoriously syphilis-soaked race” (Jones 1993, 24, 27).

Funding for and interest in preventing and treating STDs waned during peacetime, though they remained a public health problem. With World War II on the horizon, the director of the PHS Venereal Disease Research Laboratory argued that “[t]he prevention of the primary invasion of the male by the syphilis spirochete, as a means of minimizing the loss of effectiveness which is incident to established disease, still constitutes one of the most pressing problems of military medicine” (Mahoney 1936, 78–79). When the United States became involved in World War II, public health officials once again became concerned about STD rates in American troops and predicted “approximately 350,000 fresh infections with gonorrhea [in the armed forces], [which] will account for 7,000,000 lost man days per year, the equivalent of putting out of action for a full year the entire strength of two full armored divisions or of ten aircraft carriers” (Presidential Commission for the Study of Bioethical Issues [PCSBI] 2011, 12). The cost of treating the anticipated infections was \$34 million (about \$465 million in 2015, adjusted for inflation) (PCSBI 2011, 12).

### 2.3.2 Case Description

In search of a more effective treatment for syphilis, U.S. PHS researchers in the 1930s had turned to African-American communities for public health research in part because of the perception of high rates of infection, as discussed above. PHS surveyed six southern counties and found the highest syphilis rates among black men in Macon County, Alabama, where the city of Tuskegee serves as the county seat. Created in part by a confluence of economic, social, and clinical

factors—including the Great Depression, lack of public and private funds for continuation of development projects, pervasive racism in American medicine, and failed attempts in the pre-penicillin era to treat syphilis with heavy metals—public health researchers decided to conduct a study to observe the “natural progression” of untreated syphilis (Brandt 1978; U.S. Department of Health, Education, and Welfare [HEW] 1973).

The Tuskegee syphilis study or, more accurately, the *U.S. Public Health Service Study of Untreated Syphilis in the Male Negro, Macon County, Alabama*, was an observational study of 399 men with syphilis, and 201 men without, conducted from 1932 through 1972. After 40 years, it finally ended when a PHS STD investigator, Peter Buxton, went to the press with allegations of gross ethical violations, including a lack of informed consent for participation, deception, withholding treatment, as well as racism and lack of scientific soundness (Jones 1993; Brandt 1978).

During this study, public health researchers posed as physicians and told the men, who were already infected with syphilis, that they were going to *treat* them for “bad blood” (which, in common vernacular referred to a range of chronic conditions of unknown origin that could have included anything from syphilis to anemia). In reality, the researchers were not treating the subjects for any of these diseases. While during the salvarsan-era, nontreatment would not necessarily have made a large difference *clinically*, once the Venereal Disease Research Laboratory established that penicillin was a safe, effective, and inexpensive cure for syphilis in 1943, the profound clinical detriment of being a study participant became clear. After 1943, the researchers actively kept subjects from receiving penicillin for other ailments so as not to interfere with their ability to analyze the primary outcome of interest, which was the natural progression of untreated syphilis (CDC 2013c).

Throughout the study, the public health researchers practiced active deceit resulting in 399 infected men being kept from penicillin treatment until their death or 1972 when the study was stopped. The Assistant Secretary for Health and Scientific Affairs, under the then U.S. Department of Health, Education, and Welfare, chartered an advisory panel to investigate the circumstances surrounding the study. The panel later issued the Final Report of the Tuskegee Study Ad Hoc Advisory Panel in April 1973 (HEW 1973).

Meanwhile, the experience of soldiers during World War II had confirmed the need for improved diagnosis and treatment of STDs. After the war, these efforts were revitalized by animal studies that demonstrated the effectiveness of a new post-exposure prophylaxis called “orvus-mapharsen.” PHS was interested in whether this solution would be effective in humans, and it was believed that establishing efficacy in humans required controlled intentional exposure in humans—preferably via the “natural method” of sexual intercourse. Because, in part, commercial sex work was legal in the prison in Guatemala City, Guatemala, the researchers planned to conduct prophylaxis experiments there. The plan was to intentionally expose prisoners to STDs through sexual intercourse with commercial sex workers carrying infection (PCSBI 2011).

As a result, from 1946 through 1948, the U.S. government funded, via a federal grant from the National Institutes of Health and approved by the highest echelons of

PHS (including Surgeon General Thomas Parran), STD, serological, and inoculation experiments in Guatemala (Spector-Bagdady and Lombardo 2013). The researchers, led on the ground by a senior surgeon in the PHS, John C. Cutler, soon discovered that they could not reliably infect prison subjects with STDs through sexual intercourse with commercial sex workers; the researchers were thus unable to compare the effectiveness of the prophylaxis regimen they were testing. In an effort to increase infection rates, researchers expanded to other vulnerable populations, such as soldiers and psychiatric patients, and engaged in more invasive methods of intentional exposure, such as abrasion of genitals and manually applying syphilitic emulsion—despite objections of their PHS supervisors that the latter methods of inoculation were scientifically unsound (PCSBI 2011).

By the end of these experiments, considered by some at the time to be “ethically impossible” in design (Kaempffert 1947), public health researchers intentionally exposed approximately 1300 Guatemalan prisoners, soldiers, commercial sex workers, and psychiatric patients to syphilis, gonorrhea, and/or chancroid without informed consent. The researchers documented some form of treatment for only half of the subjects they exposed to infection (PCSBI 2011).

The Guatemala STD experiments ended in 1948 when the researchers decided not to apply for a continuation of funding due to concerns about reporting project activities to the approving study section and the new surgeon general in the United States (PCSBI 2011). The Guatemala STD experiments remained undiscovered for nearly 65 years until Cutler’s papers, uncovered in 2003, were brought to the attention of the U.S. government and presented at a professional meeting in 2010 (PCSBI 2011; Reverby 2011). Upon learning of the experiments, President Barack Obama requested that his Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) conduct a historical review and ethical analysis of the studies in Guatemala. The Bioethics Commission concluded its analyses and reported its results to President Obama in September 2011 (PCSBI 2011).

### 2.3.3 Discussion

The U.S. PHS Study of Untreated Syphilis in the Negro Male unmasked a range of important ethical issues that fit into three fields of bioethics we now call professional ethics, public health ethics, and research ethics. Through the lens of professional ethics, the untreated syphilis study calls into question what it means to be an ethical scientist, an ethical physician, and an ethical government steward of public trust. Through the public health ethics lens, it raises issues of imposing the risk of harm to individuals to benefit the community, appropriate engagement with the affected community, and justice and fairness.

Far and away, however, the untreated syphilis study in Tuskegee had the most substantial impact on research ethics. It was not the first study to egregiously disrespect personal autonomy and grossly exploit vulnerable populations. Indeed, by 1966, Henry Beecher had outlined 22 such studies in clinical research, some

involving children, mentally and physically compromised patients, and incarcerated individuals (Beecher 1966). Nor was it the first instance of African Americans being mistreated by the medical establishment (Gamble 1997), but it was the first unethical study of this magnitude scandalously exposed by the mainstream media involving and funded by the U.S. federal government. While the original intent of the untreated syphilis study in Tuskegee was to contribute to the greater and seemingly more urgent social good, it has been remembered for withholding treatment from a socially and politically vulnerable group by actively deceiving them.

Comprehensive scholarship has examined the legacy of the untreated syphilis study. Its impact is as deep as it is broad in the bioethics community and the social culture of the United States. This case study examines only the policy outcomes that resulted from the ethical review and analysis of the untreated syphilis study, which is but a small slice of its legacy, yet one that has profoundly shaped the way clinical and public health research is conducted in the United States.

The Tuskegee Study Ad Hoc Advisory Panel (Advisory Panel) submitted its final report to then Assistant Secretary for Health, Charles C. Edwards, in April 1973 (HEW 1973). The Advisory Panel found that the study was ethically unjustified in 1932 due to the lack of evidence that any consent was obtained from participants, breaking "... one fundamental ethical rule... that a person should not be subjected to avoidable risk of death or physical harm unless he freely and intelligently consents" (HEW 1973, 7). Also, the lack of a study protocol or plan left the study's scientific soundness highly suspect, especially in light of the "disproportionately meager" scientific data it produced (HEW 1973, 8).

Besides the lack of informed consent, other important ethical violations noted by the Advisory Panel included researchers lying and withholding penicillin even after it was established to be effective as a treatment for syphilis. The insults to basic dignity and respect for persons forced on the men in the study convinced the Advisory Panel to recommend a permanent body to regulate all federally supported research involving human participants. This permanent body was to formulate policies for establishing institutional review boards (IRBs), compensating research participants who suffer research-related injury, and reviewing protocols at local institutions before beginning research studies. It also called for creating local subject advisory groups to monitor consent procedures (HEW 1973). While the U.S. Department of Health, Education, and Welfare (now the U.S. Department of Health and Human Services) had guidelines for research grants and contracts, the Advisory Panel recommended "... that serious consideration should be given to developing, through Congressional action, rules and procedures which apply to the entire human research enterprise without reference to the source of funding" (HEW 1973, 37).

The Advisory Panel report paved the way for creation of the first congressionally formed national bioethics committee: the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission). As a direct consequence of the ethical investigation into the untreated syphilis study, and acknowledgment that this was not an isolated incident, the National Commission began work in 1974 developing national guidelines for research involving human participants.

The National Commission's most cited work, the *Belmont Report*, outlined three ethical principles for research still in use today: respect for persons, beneficence, and justice (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979). It also provided guidance on informed consent, special rules for vulnerable populations, and requirements for review of protocols by IRBs. These recommendations, later codified into federal regulations that govern federally funded research with human participants, continue to influence human research today—helping ensure the respectful and ethical treatment of participants in biomedical and public health research (U.S. Department of Health and Human Services 2009).

A more subtle, but enduring impact of the National Commission's efforts specific to public health research was its focus on engaging the community in which research is to be conducted. Although only anecdotally reported, a lack of trust in government, health care, and research is widely believed to be a lasting consequence of the untreated syphilis study (Gamble 1993; Swanson and Ward 1995). Empirical data suggest, however, that the untreated syphilis study itself did not deter participation (Katz et al. 2008), but rather a lack of trust stemming from a larger social legacy of racism and fears of exploitation originating in the era of slavery in the United States (Gamble 1993). In recent times, these fears resurfaced at the onset of the AIDS epidemic in the 1980s in the form of suspicion of intentional infection and genocide (Jones 1993). This mistrust resulted in the distribution of misinformation and difficulties in delivering education and care for those at high risk for HIV (Thomas and Quinn 1991). Since then, methods and best practices for community engagement have been developed and published both in the United States (Barnett 2012; U.S. Department of Health and Human Services 2011) and internationally (World Health Organization [WHO] 2012; UNAIDS 2011).

When analyzing the effect of the Guatemala STD experiments on public health ethics, it is important to note that while the experiments took place in the 1940s, they were critically investigated only recently—65 years after their occurrence. Despite the stark contrast of today's regulated research context with research conducted in the 1940s, scholars continue to examine the original research documents, and our ability to learn from past errors continues. That the U.S. government, at least, had learned lessons from the Tuskegee study is evident by the swiftness of its response to the discovery of the Guatemala STD experiments. While it took 25 years for a U.S. president to apologize to the Tuskegee syphilis study participants, families, and community (The White House 1997), President Barack Obama called President Alvaro Colom of Guatemala to apologize for the STD research immediately following the announcement of its discovery to the public in 2010.

The PHS research studies in Tuskegee and Guatemala demonstrate the serious consequences that can result when the relative interests of the individual and the population are inappropriately reconciled. Indeed, these abuses of individual research subjects have created an enduring legacy of cautionary tales that, together with an orientation toward liberal individualism, have provided a lasting and powerful check on public health authority in the United States. Major policy changes were put into practice after the discovery of the syphilis studies in Alabama.

These policies were intended to protect research participants from being treated as mere means to an end, to bring back into equilibrium the individual and population interests that public health must reconcile. Still, public health interventions continue to face resistance to actions perceived to limit individual choice—making substantive engagement of the relevant community even more critical for turn-of-the-century public health campaigns. The case that follows describing the New York City A1C Registry highlights how, even after all of the regulatory and ethical work accomplished over the past four decades, innovative approaches to public health advances interpreted to curtail some individual liberty can still inspire debate about the optimal role of government in promoting public health.

## 2.4 Case Study: *The New York City A1C Registry*

Public health increasingly has focused on secondary prevention, or the prevention of disability from disease. As the burden of disease in the United States has shifted from communicable diseases like smallpox and STDs to noncommunicable diseases, public health professionals face new ethical challenges related to monitoring chronic conditions and inspiring individuals to improve their health. The following case illustrates how new technologies affect public health interventions and can limit the precedent set by *Jacobson* when health risks are neither communicable nor imminent. Such cases call for a recalibration of population and individual interests when considering dramatically different health and social settings.

### 2.4.1 *Background*

Although infectious diseases accounted for more than 80 % of deaths in the United States in the 1900s (Steinbrook 2006), in 2011, WHO estimated that *noncommunicable* diseases were responsible for 66 % of deaths worldwide (WHO 2013). These changes in the causes of morbidity and mortality are typical of an “epidemiologic transition,” a population health phenomenon that occurs when populations carry out public health measures such as sanitation and immunization, which decrease death rates from infectious diseases, increase life expectancy, and simultaneously begin to increase risk for noncommunicable conditions (McKeown 2009).

Of noncommunicable disease deaths worldwide in 2008, deaths from diabetes alone accounted for 1.3 million (WHO 2011). In the United States, 8.3 % of the population (about 25.8 million people) had diabetes in 2011 (CDC 2011). Because of the significant impact that noncommunicable diseases, such as diabetes, have on health systems, WHO has promoted lifestyle modifications and other public health interventions (WHO 2011).

Several interventions, such as providing advice about physical activity and a healthy diet to people with impaired glucose tolerance, have lowered rates of diabe-

tes (Dornhorst and Merrin 1994; Ramachandran et al. 2006). Research also has shown that controlling blood sugar levels (measured by A1C levels), blood pressure, and LDL cholesterol can reduce the risk of long-term complications and death among people with diabetes (Chamany et al. 2009). Some evidence suggests improvements from educating patients in diabetes management, but more evidence is needed (Chamany et al. 2009).

Although there are effective ways of controlling risk factors for complications once diabetes is diagnosed, management of these risk factors across the United States has been deemed inadequate (Chamany et al. 2009). In New York City the percentage of adults who reported having diabetes more than doubled from 3.7 % in 1994 to 9.2 % in 2004 (Chamany et al. 2009). A 2005 report of the New York City Department of Health and Mental Hygiene (NCY DOHMH) showed that diabetes prevalence was higher among non-white residents (NCY DOHMH 2007; NCY DOHMH 2006a). In 2004, NCY DOHMH found that diabetes was the fourth leading cause of death in the city's population (NCY DOHMH 2004), and a survey of New York City adults in 2004 showed that fewer than 10 % of those with diabetes were able to manage blood sugar, blood pressure, and cholesterol satisfactorily according to city public health standards (Chamany et al. 2009). In New York City, 37 % of diabetes patients on state and federally funded Medicaid had an A1C level (reflecting average blood sugar) greater than 9 %—which suggests poor glycemic control (Barnes et al. 2007). WHO has found that policies that promote management of these risk factors have potential to reduce spending for individuals and the public (WHO 2011).

### **2.4.2 Case Description**

In December 2005, the NCY DOHMH submitted a proposal to the New York City Board of Health that would require laboratories with electronic reporting capabilities to submit A1C test results for New York City residents to the NCY DOHMH (NCY DOHMH 2005a). After a period for public comment, the New York City Board of Health approved this proposal, creating the first U.S. program requiring public health reporting of A1C results. Supported by evidence from the success of other disease control programs (such as programs targeting lead poisoning and tuberculosis), this program established a public health surveillance system to track diabetes in the population and to support those who could benefit from diabetes control (Chamany et al. 2009).

The mandate required applicable laboratories to submit A1C test results to the NCY DOHMH within 24 h of completion. Data to be reported included date of the test; name of the testing facility; name and address of the ordering facility or provider; and name, address, and date of birth of the individual tested (Chamany et al. 2009). The NCY DOHMH proposed to use the reported A1C results to generate a registry to monitor glycemic control in the New York City population and to provide mechanisms to support patients and physicians in controlling diabetes

(NCY DOHMH 2005a). The data in the registry were analyzed by various factors including age, location, and type of health care facility to determine distinctions in testing patterns, health care usage, and glycemic control. However, race and ethnicity data were not reported and therefore not included in the longitudinal analysis (Chamany et al. 2009).

After the A1C test results reached the NCY DOHMH, if the average blood sugar level exceeded a predetermined threshold, the patient and provider were notified. Providers were mailed a roster of their patients ordered from highest to lowest A1C level, listing the patients' two most recent test results calling special attention to A1C levels greater than 9 % (NCY DOHMH 2006b). Patients at least 18 years of age with an A1C level greater than 9 % or who were overdue for testing also received a letter informing them of their test results, advising them on how to control their A1C level, and specifically recommending a follow-up appointment with their provider. The letter was printed in English and Spanish (NCY DOHMH 2005a).

The goals of the provider and patient notification program were to increase providers' knowledge about glycemic control in their patient population, facilitate providers in assisting and guiding patients at high risk for complications, and inform and aid patients at high risk for devastating sequelae (NCY DOHMH 2012). While patients had the option to opt-out of the provider and patient notification program, laboratories were still required to report their data to the registry (NCY DOHMH 2005b). Reported data were held confidentially and were unavailable to insurers, licensure organization, or employers (NCY DOHMH 2005c). In 2009, 3 years after initiation of the program, 4.2 million A1C test results for almost 1.8 million individuals were registered with the NCY DOHMH (Chamany et al. 2009).

### 2.4.3 Discussion

The mandated reporting of A1C results in New York City and the interventions that followed stimulated discussion about the role of government in preventing noncommunicable diseases. Mandated communicable disease reporting is a longstanding and widely accepted essential public health practice, but the modern technology available to collect, analyze, and respond to health data today is unprecedented. While there are clear population interests in controlling the sequelae of diabetes—preventing limb amputations and reducing care disparities, for example—there are also individual interests such as privacy and self-determination at stake. Current public health ethics frameworks must consider the tension between individual and population interests in conjunction with the social, epidemiologic, technologic, and economic context of the case.

Proponents of the A1C Registry argued that outreach for noncommunicable disease is an integral part of public health practice and indeed is an obligation of public health agencies, especially for a disease deemed epidemic (WHO 2011). They argued that the A1C Registry allowed practitioners to identify patients in greatest need of follow-up or referral—often patients with fewest resources—and develop



disease management strategies (Chamany et al. 2009). One of the program's goals in mailing test results to patients was to enable them to better manage their own diabetes (e.g., only 10 % of people with diabetes know their own A1C level) (Berger and Silver 2008).

Others criticized some of New York City Mayor Michael Bloomberg's public health policies and interventions as creating a "nanny state" (characterized by being overly controlling of the lives of its citizens) (Magnusson 2014). Some patients believed that the A1C Registry represented an unwarranted invasion of privacy (Barnes et al. 2007), and some providers considered it an intrusion in the provider-patient relationship (Goldman et al. 2008). Many who argued against public health interventions such as the A1C Registry view choices about food and health—even when damaging—as choices that should enjoy a high degree of autonomy uninfluenced by government (although they generally are silent about the influence of food and beverage industry advertising). A public health entity with fiscal and moral interests in the well-being of its citizenry should also work to ensure that individuals have accurate and actionable information with which to make their health decisions (Thaler and Sunstein 2008).

Unlike the early 1900s when *Jacobson* was decided, or the 1940s when the U.S. PHS STD research was conducted in Alabama and Guatemala, we now have several public health ethics frameworks that help us approach ethical issues more systematically (Kass 2001; Childress et al. 2002; Baum et al. 2007; Bernheim et al. 2007). These frameworks reflect attempts to reconcile individual and population interests outlined by the *Jacobson* Court. For example, the A1C Registry case raised issues relating to principles of least infringement, social justice, health equity, and evidence of benefit.

When applying these ethical precepts to the A1C Registry case, the principle of least infringement requires that public health pursue the least intrusive course of action that still achieves the public health goals. The A1C Registry attempted to accommodate this principle by allowing people to opt out, which prevented NCY DOHMH from contacting patients and their clinicians, but did not relieve the laboratory from submitting reports to the registry. While the opt-out mechanism gives individuals some control over how their data are used, it can still allow a public health entity to seek to improve constituents' well-being with minimal infringement.

Policy makers must also explain the aims of the program and whether benefits and burdens are expected to be distributed equitably throughout the population. In the A1C Registry case, these foundational values of social justice and health equity in large part motivated the reporting system. In New York City, substantial differences in morbidity and mortality by race/ethnicity and neighborhood income level were evident. NCY DOHMH use of the data to identify and then reduce these differences promoted public health goals. One challenge in addressing such disparities is to ensure efforts do not inadvertently increase disparities or cause other social harms, including stigma or loss of social capital.

Finally, policy makers have a duty to ensure public health programs are effective, including empirically evaluating programs to provide evidence of this effectiveness. In developing the A1C Registry, policy makers compiled evidence from effective

public health programs to help explain the need and potential effectiveness of this program. As the NCY DOHMH evaluates the program and collects evidence of the A1C Registry's effect on diabetes in the city, it might alter policies and procedures. Empirical data on the effectiveness of the registry are pending, and those results will certainly play an important role in assessing the program's scientific and ethical rationale. As this brief analysis demonstrates, contemporary frameworks to guide ethical public health decision making offer additional nuance to the foundational tension between individual and population interests.

The case of the A1C Registry draws attention to important implications of the *Jacobson* precedent and the continued influence of major historic breaches of public health ethics. The current agreed-upon equilibrium in the United States emphasizes individualism, even as similar noncommunicable disease public health campaigns continue to be established (e.g., attempting to control the addition of trans fats to foods and the size of sugar-sweetened beverages) (Gostin 2013). These contemporary cases in the United States are being established and deliberated in a climate of changing health care policy and in the absence of an agreed-upon framework for public health ethics. The challenges they elucidate, however, are likely to have an important impact on the future role of public health in health care.

## 2.5 Conclusions and Implications

The cases discussed here demonstrate how providing essential public health services requires ethical principles and analysis as varied as the goals they hope to achieve. Clinical and research ethics play a role, but are not sufficient for the consideration of competing public health values. More substantial limits on liberty and privacy can be justified as public health ethics aims to alleviate the "collective hazard," as opposed to individual risk, for both motivation and validation of interventions (Bayer and Fairchild 2004). However, as the cases in Alabama and Guatemala underscore, limitations on power are as important as justifications.

In different ways, the cases outlined here shaped public health practices and ethical expectations in the United States. However, as our world grows more connected and our work increasingly crosses jurisdictional boundaries, it is clear that there are common values that motivate public health ethics even in vastly different political, social, and economic contexts. The global setting in which many public health professionals work requires attention to such contextual factors.

Many of the cases outlined in the chapters that follow uncover additional ethical considerations affecting daily public health practice wherever that practice occurs. Whether it is social duty or political feasibility of the negative right to noninterference, case studies can clarify ethical dimensions, help us examine alternatives for approaching decisions, and remind us that ethical decision making in public health is not an optional endeavor in *any* case. These case studies underscore the need to identify decision-making frameworks that lead to careful consideration of individual and public interests, as a disregard for one or the other is perilous to both.

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