

Public Health

Mandating Vaccination: What Counts as a “Mandate” in Public Health and When Should They Be Used?

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Recent arguments over whether certain public health interventions should be mandatory raise questions about what counts as a “mandate.” A mandate is not the same as a mere recommendation or the standard of practice. At minimum, a mandate should require an active opt-out and there should be some penalty for refusing to abide by it. Over-loose use of the term “mandate” and the easing of opt-out provisions could eventually pose a risk to the gains that truly mandatory public health interventions, such as childhood vaccines, have provided over the last 50 years. Already, confusion about what counts as a mandate, and about what criteria should be used to determine when a public health intervention should be implemented as a mandate, has led to some inappropriate public policy decisions. For instance, by any reasonable criteria, the yearly influenza vaccine should be mandatory for health care workers. To enforce this mandate, those who refuse vaccination should be required to sign a waiver, and patients—especially those at high risk from flu—should be informed when they receive care from unvaccinated practitioners.

“Boards of health, if in their opinion it is necessary for public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants of their towns, and shall provide them with the means of free vaccination. Whoever refuses or neglects to comply with such requirement shall forfeit five dollars.”

—Text of the first US mandatory vaccination law, implemented in Massachusetts in 1809 and the subject of the US Supreme Court’s landmark *Jacobsen* decision (Jacobsen 1905)

Public health by its nature mixes medicine and science with politics and sociology, so it’s inevitable that it will sometimes use the same words for their rhetorical value, for political purposes, and at other times for more purely scientific, descriptive purposes. For example, in a prior essay I noted that the term “harm reduction”—meaning public health strategies to mitigate the harmful effects of risky behaviors—was adopted in public health, in part, to help build support for these strategies (Wynia 2005). After all, who could be in favor of increasing harm? I also noted that, in a predictable response to this rhetoric, those in opposition to harm reduction strategies have tried to re-label them as “harm maintenance” programs—because who would want to maintain an ongoing harm?

By the same token, the term “mandate” (or the interchangeable word, “requirement”) can serve as a rhetorical

tool rather than as a strictly accurate description of a public health measure. But “mandate” is even more interesting than “harm reduction” in this regard because it can mean very different things descriptively, as well as serving multiple purposes rhetorically.

WHAT IS A “MANDATE”?

Before we explore the various *rhetorical* purposes of using the term “mandate” it would help to be clear about what the *descriptive* meaning of the word is. Coming from the Latin *manus*, for ‘hand,’ and *dare*, for ‘give’—a mandate is generally considered to be a command or an order, handed down from a superior to underlings. To be generous, however, I think that in public health it is legitimate to call something a mandate if it meets two criteria. First, opting out of the mandate should require some action beyond simply saying no. Second, there should be some enforcement mechanism to encourage compliance—that is, there should be a penalty, however mild, for opting out. In short, a mandate is not the same as a mere recommendation.

Vaccination provides the best set of examples for getting at the specifics of public health mandates. With regard to enforcement, some might argue that a truly mandatory vaccine should carry a significant penalty (such as a fine or jail time) if one refuses it. But in public health the range of penalties can be very broad indeed and enforcement of many

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Comparison of average annual morbidity and mortality before and after introduction of mandatory childhood vaccines in the United States

Disease	Average morbidity in 3 years prior to vaccine licensure	Morbidity in 2000	Percent decrease since introduction of vaccine
Smallpox	48,164	0	100
Diphtheria	175,885	4	99.99
Measles	503,282	81	99.98
Mumps	152,209	323	99.80
Pertussis	147,271	6755	95.40
Polio (paralytic)	16,316	0	100
Rubella	47,745	152	99.70
Congenital rubella syndrome	823	7	99.10
Tetanus	1,314	26	98.00
<i>H. flu type b</i> and unknown (<5 years)	20,000	167	99.10

Adapted from: Malone and Hinman, 2003. For additional data, see Roush et al. 2007.

so-called mandates is quite weak. In fact, strong enforcement of public health mandates has become very rare. Even quarantine, probably the most common area where force is contemplated in public health, is both rarely invoked and probably more successful when it is enforced through less coercive and more cooperative mechanisms (Wynia 2007). So, at least in the recent past, vaccination "mandates" have not been enforced by fines or jail time, let alone by physical force—instead persuasion and outreach have been our preferred methods of raising vaccination rates. This is the case even though vaccination has had near miraculous efficacy (Table) and significant disease outbreaks have occurred in areas where vaccination rates declined because too many people were opting out (Feiken et al 2000; Parker 1996).

The classic examples of mandate enforcement options come from childhood vaccinations, where exclusion from school is typically the threatened penalty for non-compliance, though it is rarely used. That's because, although children can be excluded from school if they remain unvaccinated because their parents simply forgot or haven't bothered, they will almost never be excluded if their parents have chosen to formally opt-out of the mandate.¹ And in most states, to avoid the mandate one must only provide some level of proof that a religious or philosophic belief or, less commonly, a medical contra-indication drives one's

1. The exception would be in the event of an outbreak, when unvaccinated children can, and should, be kept home for their own safety.

objections. All of which raises the question: is something mandatory if you don't really have to do it?

The answer depends on how hard it is to avoid the mandate—which is to say, the penalty attached to getting out of it. Some vaccine opponents and libertarians have noted that formal vaccine opt-out provisions can be a "bureaucratic nightmare" (Association of American Physicians and Surgeons 2007). But this presumably reflects policy makers' decisions to erect barriers against opting out, which in turn actually reflect a reasonable understanding of what a "mandatory" program should entail. In one study, the more onerous the process required to obtain religious and philosophic exemptions to school vaccination laws, the less likely parents were to opt out (Rota et al 2001). In this study, none of the 19 states with the highest level of opt-out complexity had more than 1% of students exempted, while 5 of the 15 states with very simple opt-out procedures had more than 1% exemptions.

So bureaucratic complexity is one means of enforcing a mandate. Another means, separate from state-based enforcement mechanisms, is pressure brought to bear on parents by doctors or others in the community to get their children vaccinated—after all, those who remain unvaccinated are free-riders, taking advantage of herd immunity while not contributing to it (Wynia 1997) and they pose a disease threat to the entire community (Feikin 2000). Moral suasion and guilt certainly count as enforcement mechanisms, though it's not clear how commonly they are used. In one recent study, though, a remarkably large number of pediatricians (39%) reported that they would refuse to care for children whose parents declined vaccinations (Flanagan-Klygis, Sharp and Frader, 2005). This seems to me a very strong punishment, and potentially counter-productive, and it has been questioned (Kemper and Guth 2006).

On the other hand, there is often no penalty whatsoever for declining vaccinations and the opt-out bar is so low that it probably doesn't make sense to call the vaccine mandatory at all. In 15 states one can opt-out of 'mandatory' childhood vaccines, penalty-free, simply by signing a standard philosophical exemption letter. According to one legislator in Virginia, Phillip A. Hamilton (R-Newport News), who sponsored an HPV vaccine "mandate," under his bill "parents [are] given information, and if they choose not to do it, they don't have to do it. They just have to sign a form so the health department knows they opted out" (Craig 2007). In essence, it would be sufficient to just say, or write, "No." Almost the only sense in which such a vaccination program could be considered 'mandatory' is that it would become mandatory for health plans to cover it.

Taking advantage of this blurry definition of a mandate, some consumer advocates in Virginia actually argued that a mandate would be okay, but only if it had an opt-in provision (Coutee 2007). . . which would completely turn the notion of a mandate on its head. Most alarmingly, if this notion of a limp-mandate takes hold and spreads to other vaccines, it could be profoundly damaging to the public's health. Many

vaccines against major childhood killers really should have firm mandates, in part because they save many more lives once herd immunity is achieved. If it becomes too easy to opt out of them, we will see rising rates of significant childhood illnesses.

To guard against this, policy makers should distinguish truly mandatory vaccines from recommended vaccines that health insurers ought to cover. In this regard it would be far more accurate to label programs with either opt-in or extremely simple opt-out procedures as "routine" or "standard" vaccination programs rather than "mandatory" vaccination programs.

Meanwhile, among adult vaccines, few are mandatory. The yellow fever vaccine is mandatory, *if* one wants to travel to certain countries where the disease is endemic. The meningococcal vaccine is similarly mandatory for travelers to Mecca. Many jobs in health care mandate vaccination against Hepatitis B. These few examples aside, however, the great majority of adult vaccines are not mandated at all, they are merely recommended (e.g., tetanus, influenza, Pneumococcus, and so on). As a result, adult immunization rates are often very low, sometimes to the great detriment of individual and public health.

RHETORICAL USES OF "MANDATORY"

While noting the various descriptive meanings of the term "mandatory," the astute reader will have begun to note some of its rhetorical uses as well. Interestingly, the term is used as a rhetorical tool both by opponents and proponents of public health measures.

For opponents, calling a recommendation a mandate can be a way to raise hackles—no one likes to be forced to do anything, and the term mandate suggests the use, or at least the threat, of force. Hence one sometimes sees the distinction between routine and mandatory purposefully blurred, as it has been in recent discussions around HIV testing. Proposals by the CDC to make HIV testing a routine part of adult medical care (i.e., not requiring special informed consent or counseling prior to the test) have sometimes been portrayed as mandatory HIV testing. One commentator, opposed to the new CDC guidelines, wrote that they are, "requiring health professionals to test most, if not all, patients for HIV" (Frye-Revere 2007). Yet the CDC guidelines are clear that no enforcement of any sort is envisioned, the terms "mandate," "mandatory" and "requirement" do not appear in the document at all in relation to testing (except to say that pre-test counseling should not be required, for example), and the testing is to be entirely voluntary. Specifically, the recommendations state repeatedly that, "HIV testing must be voluntary and free from coercion. Patients must not be tested without their knowledge." (Branson et al. 2006).

Similarly, opponents of recommendations for routine childhood HPV vaccination have successfully portrayed these initiatives as "mandates," despite their typically generous opt-out provisions and frequent lack of any meaningful enforcement mechanism. From these examples, it appears that opponents of public health measures use the term

"mandate" to describe any recommendation that requires an opt-out, even if the procedure for opting out is as minimal as a verbal "no thanks."

At the same time, however, many *proponents* of public health measures—such as the Virginia legislator mentioned above—have also portrayed them as 'mandates' even when they don't entail any meaningful barrier to opting out. This is apparently an effort to get people to take the recommendations more seriously and, perhaps more importantly, to get insurers to cover the cost of implementing the intervention. Prenatal testing for HIV has also been called "mandatory" even when few or no penalties have existed for patients who refuse. Instead, the mandate attaches to the physician and health care facility, who must document that the test was offered.

WHEN SHOULD A PUBLIC HEALTH INTERVENTION BE MANDATORY?

Assuming a two-part definition of mandatory then (i.e., an opt-out that requires more than a mere "no," and some form of penalty), we should now consider the appropriate criteria for making a public health intervention mandatory rather than a recommended or routine part of care. In this regard, there are three conditions that should hold.

First, there should be clear medical value of the intervention—to the individual. You read that right—vaccination is not about risking a few to protect the many, it's about protecting all the individuals receiving the vaccine. Public health must consider the benefits to individuals, not just the community as a whole, especially when determining whether individual liberties should be abridged. The argument to infringe on liberties with a mandate is much stronger if both beneficence and justice are on one's side. That said, of course the calculation of the value of vaccination to the individual should be conducted using the rates of disease transmission at the pre-vaccine baseline. This is because it would be unfair, and in the long run, unrealistic, to consider the risk-benefit ratio to the individual only in the presence of herd immunity, which has been obtained by using a mandate. Instead, if a new mandate is being contemplated (or if rolling one back is on the table), one should calculate the effects on individuals assuming low vaccination rates and little or no herd immunity. In sum, policy decisions about whether to adopt or maintain a mandate should rest, first, on the benefits of vaccination to individuals, without assuming that everyone else will choose to be vaccinated.

Second, to infringe on liberties with a mandate the *public health* benefit of the intervention must also be clear. There is no standard formula for this calculation, but the cost/benefit ratio for society should be positive in reducing the burden of disease. And this time, since one is assessing the value of a proposed mandate to society, it is fair to assume that the mandate will be more or less effective, in the sense that it *will* be used by almost everyone. In other words, this second calculation can and should include the benefits of developing herd immunity.

Third, consideration should be given to whether a mandate is the only way to obtain individual medical and/or public health benefits. If it is possible to obtain herd immunity, for example, without a mandate but through education, insurance coverage, public outreach and so on, then a mandate would be unneeded and should not be used. Moreover, when this is the case the term should not be invoked, so that its meaning and force will be preserved when it is used. Given this understanding, it should generally take some time to determine whether a mandate on individuals is the most appropriate way to disseminate a new vaccine—which is one reason the push to mandate the new HPV vaccine has been so troublesome to many (Wynia 2007b).

IMPLICATIONS: CONFUSION ABOUT MANDATES LEADS TO INAPPROPRIATE PUBLIC HEALTH DECISIONS

Over-loose use of the term “mandate” could eventually pose a risk to the gains that truly mandatory interventions have provided over the last 50 years. But confusion about what counts as a mandate, and about what criteria should be used to determine when a public health intervention should be implemented as a mandate, is already leading to some inappropriate public policy decisions. Recently, some interventions have been mandated that shouldn’t have been, while other mandates that would provide clear benefits are not being imposed.

An example of inappropriate mandates (from the standpoint of public health) are efforts by a number of states to adopt mandatory HIV testing for men accused of rape (Iotti 1998). In this instance, the impetus for mandatory testing seems clear and the proposals are for firm mandates—the accused cannot opt-out of testing. But the benefits of testing are largely illusory and non-medical, even though they are related to a desire to help the victim. Rape victims, for obvious reasons, want to know the HIV status of their attackers. Sadly though, rapid testing of an alleged attacker won’t help the victim make a better decision about HIV prophylaxis and could well provide false comfort and hence lead to a worse decision. A negative test might be inaccurate, perhaps because the attacker is in the window period. Or it could be that the person being held is not the actual attacker (according to the Innocence Project, 88% of those exonerated by DNA evidence so far have been wrongfully convicted of sexual crimes; Innocence Project 2007). So these laws, though properly called mandates, don’t meet either the individual medical or public health criteria for appropriate use of a mandate.

In another arena—influenza vaccination of health care workers—a mandate is sorely needed, but so far hasn’t been implemented. Yearly influenza vaccine in health care workers pulls double duty, protecting both the worker and the vulnerable patients with whom they come in contact. Yet only about 40% of health care workers annually are vaccinated against the flu (Kimura et al. 2005). This large proportion of unvaccinated health care workers has documented negative effects on patient mortality (Carmen 2000) and

costs to health care institutions (Boersma, Rhames and Keegan, 1999). Yet efforts to increase vaccination rates are focusing almost entirely on incentives and making vaccination more convenient, even though the best such programs are only weakly effective, reaching vaccination rates of 50-75% at most (Kimura et al. 2005). Given the benefits to individual health care workers and the subsequent impact on patients and costs—not to mention our professional obligation to do no harm—flu vaccination should be mandatory for health care workers. To enforce this mandate, there should be significant barriers to opting out. Refusal should require a written statement of why the individual chooses not to protect himself, his colleagues and patients. More importantly, patients (especially those at high risk of death from flu) should be informed when they are seeing a health care worker who has refused vaccination. After all, flu is easy to transmit: patients certainly have a right to choose to receive care from practitioners who are vaccinated.

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