

# Public health measures & individualized decision-making

## The confluence of the H1N1 vaccine and Islamic bioethics

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Vaccinations are amongst the most cost-effective and successful public health interventions. During the H1N1 influenza pandemic public health organizations around the world mobilized to procure and deliver vaccinations to the at-risk populations in order to reduce spread of, and decrease morbidity and mortality from, the swine flu. With the focus on delivering vaccines at a population-level, state and national governmental agencies coordinated to procure vaccine supplies within the United States. However all healthcare decisions trickle down to the individual level. In this essay I narrate the tensions and challenges I faced to make decisions for myself and my family on whether we should get the H1N1 vaccines, while being true to both religious values and medical science. At the end of the narration I reflect on ethical and policy questions we must address during public health vaccination efforts.

“The Swine Flu Outbreak Declared a National Emergency,” “Mandatory Swine Flu Vaccination for Healthcare workers” read the headlines. As the Swine flu pandemic raged on, I, as an emergency medicine physician, was placed within the high-priority groups to obtain some of the first vaccinations. During one of my clinical shifts a nurse leader approached me with a consent form in one hand and the intranasal H1N1 vaccine in the other saying “Here’s your vaccine, just sign the form.” Glancing upon the consent form, my eyes paused at the question, “Do you have an allergy to porcine gelatin?” Over the course of my career and travels abroad

I have received many vaccines and had never given much thought to their chemical composition. This simple question, however, initiated a series of questions, concerns, and decisions that illustrate the balancing act many of us perform in our professional, research and personal domains. Public health programs, by their nature, are concerned with population-level decisions, the individual-level choices are left to be discussed between a personal physician and his (her) patient. In this case, however, my roles as an Islamic bioethicist, as a health services researcher, and as a husband and father, weaved a web of complex challenges to finding practical solutions to the obstacles that arose. “I can’t get this vaccine” I replied, “Muslims are not allowed to ingest or use porcine products.” “Sorry, this is all we have,” she replied “The intramuscular vaccine is reserved for pregnant women and other high-risk groups.”

I know the rationale for, and benefits of, vaccination programs and decided to try to obtain the intramuscular H1N1 vaccination from another source. I contacted the lead nurse of the hospital vaccination program and relayed my religious restrictions. She was understanding of my needs and authorized an exemption so that I may obtain the intramuscular H1N1 vaccine. Feeling relieved that I was going to be able to get a pork-free vaccine, I walked into Employee Health services with her authorization in hand and rolled up my sleeve. As the nurse brought out the injection, I casually asked to see the package insert. “Gelatin 0.05% is added as a stabilizer” read the form. Was this porcine gelatin

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as well? “Do you have another brand?” I asked the nurse, as my relief turned to frustration. “No, I’m sorry this is it, we only have limited suppliers” she replied.

We are fortunate to live in a country that has a robust public health system. During the swine flu pandemic it has delivered health information to the populace, collected surveillance statistics, and conducted an immense mass vaccination program. The system-level focus and hierarchy was never intended to maximize individual decision-making; the needs of the many often outweigh the needs of the few. As I inquired about other vaccine formulations in Michigan, I discovered that all supply chains went through the government and it was not known when, or if, the state of Michigan would receive other brands. Well if not in Michigan, then maybe I could get vaccinated elsewhere. I called vaccine companies and public health departments, scoured the internet, and ultimately discovered that three of the five Federal Drug Administration-licensed vaccines intramuscular H1N1 vaccines did not contain gelatin. Unfortunately, these were not yet available in Michigan or Ohio, and nearby Windsor, Ontario was unwilling to vaccinate a foreign national.

### A Solution through Islamic Bioethics?

Having failed at obtaining a different formulation through another supplier, I threw on my Islamic bioethics hat. Perhaps this situation warranted a religious exemption. When dying of hunger it is permissible for Muslims to eat pork or drink wine as long as you eat only as much as necessary to survive; perhaps the H1N1 pandemic was analogous and necessity would allow for overturning normative prohibitions. Unlike some other religions, Islam does not have a formalized clergy system; while there are Islamic legal experts and religious scholars there is no singular religious body that adjudicates matters of faith for the Muslim community. Hence ethicolegal discourse is more of a free-for-all with a continuous dialogue between Islamic jurisconsults and the laity. Through my own studies I knew that recourse to the necessity principle in Islamic law is mainly used to protect the five essentials of life

(*daruriyyat al-khamsah*), namely life, religion, intellect, lineage and property. The crux of the matter is defining the necessity. Perusing various Islamic ethicolegal opinions (*fatawa*) revealed some subtlety. Opinions noted that the use of medicines containing *haram* ingredients (substances considered in Islam to be impure or ritually impermissible, in this case porcine gelatin) was categorically prohibited. These scholars cited the Prophetic statement “God has not made things that are unlawful for you to consume to be your medicine” for support. Overturning this prohibition through necessity required three conditions to be met: (1) the medicine must be necessary for continued life, (2) no alternatives are present and (3) a knowledgeable and trustworthy Muslim physician recommends the medicine. Other opinions noted that “if one knows that the *haram* ingredient’s chemical composition has totally changed from the original, then it becomes permissible... this is something that is not easy to know for certain.”

How well were the conditions for necessity met? Some of my colleagues felt this was easily resolved—swine flu is causing deaths, so the vaccine is necessary. As a health services researcher, I was conflicted; vaccines are not cures. More appropriately vaccines represent preventive measures where we vaccinate hundreds of people in order to prevent a few deaths. Does this constitute a necessity? I felt uneasy equating the swine flu with probable mortality for someone generally healthy like myself, hence I abstained from vaccination until I could get a product without gelatin. Having decided what to do for myself, the frame now shifted to one where I had to think about my family.

### Family Matters

As physicians we often become the “defacto” clinical consults for our families regardless of our specialty. My wife and I have a standard routine when it comes to medical matters. Whenever she asks me about some personal health issue I respond “Ask your doctor.” She counters with “I am asking you, aren’t I?” One evening as I explained to her my rationale for not getting the H1N1 vaccine, she turned

to me and asked “What should I do? And what about our daughter?” Unspoken was that she was 7 months pregnant and thus my advice would impact three lives. The tone in her voice told me that she was not going to accept the standard refrain. I also knew she wasn’t just looking for medical advice but also wanted ethical guidance. I fell silent not wanting the burden of this decision. While I could hold myself to a high bar on the interpretation of necessity in Islamic law, could I hold my family to that? “Ask an Islamic scholar” I replied.

The advice she received was similar to the ethicolegal opinions I had researched. She was advised to consult a “trustworthy” doctor to see if it was *a necessity* to get vaccinated and if there were alternatives to the gelatin-based vaccine. In the growing field of Islamic biomedical ethics medical practitioners, physician professional societies, academic Islamic studies scholars and devotional jurisconsults (*muftis*) all engage in deliberation. However the discourse is disjointed, often occurs within silos with little cross-talk, and seldom reaches the level of the patients and physicians where it would be given practical meaning. Because of this limited interaction, Islamic scholars’ decisions depend greatly on the framing of the scientific probabilities given by the questioner. The religious scholars wanted the physicians to determine necessity, but *this* physician wanted to know what was within the realm of a necessity; the ball was again returned to my court.

In medical research we often deal with population statistics and as clinicians we struggle to individualize evidence drawn from populations into concrete recommendations for each individual patient. Now, religious ethicolegal deliberation around necessity asked me as a “trustworthy” Muslim physician a similar question. It was easy to do this for myself since I was a healthy person with no comorbidities, but what about my pregnant wife and 2 year old their risks were different. To help resolve my internal conflict I discussed the matter at length with a devotional jurisconsult. I explained what I knew of the statistical benefits of the vaccine and the risks to my family. Naturally, his primary concern was whether the vaccine was “necessary for life,” and mine was

what number needed to treat is sufficient to invoke necessity. After discussing the matter he did not think the principle of necessity could be invoked.

Yet, he did offer a potential solution through another Islamic legal principle, the greater part gets the jurisdiction of the whole. He said some jurisconsults may argue that such a small quantity of porcine gelatin is negligible, permitting the use of the vaccine. The situation would not be totally solved as there was a camp of Islamic scholars that held porcine products to be impermissible for any human use regardless of quantity. Hence there were multiple opinions of when, and if, “impermissible” substances in could be used as medication. One was free to choose opinions based on the strength of their argument as long as they utilized the established framework of Islamic ethicolegal debate. Plurality is possible but honesty to tradition is important.

In the end, my wife, with my taking a conscious step back, chose to receive the intramuscular formulation. Her obstetrician strongly recommended the vaccine and she reasoned that since the formulation did specify a porcine-source of the gelatin, and some Islamic scholars permitted the vaccine, she was being true to her religious values. On the other hand, I continued to abstain from being vaccinated until the state of Michigan procured a gelatin-free formulation. Our two year old daughter received her series of vaccinations a few weeks after I did, as only one of the five FDA-approved formulations was both approved in children and gelatin-free.

### **A Perfect Storm?**

In this case of the H1N1 vaccine I was trying to be true to both my faith and

medical science. Islamic ethics and law are context-based and rely heavily on tradition. Technological advances and modern medicine have presented unique challenges to traditional value systems and cultures; here the tension was between Islamic ethics and a vaccination program that limited vaccine choice. In the traditions of Islamic ethics and law, gelatin-based vaccinations were probably not even considerations. Similarly, when the State of Michigan made its decision on what brands of vaccines to buy, they probably did not consider the sources of components like gelatin, though with the large Muslim population in the state, they should have. Our public health machinations were appropriately mobilized to treat the masses and ensure ready supply, yet at the individual level trying to obtain alternative vaccines proved quite difficult. Perhaps community consultation before the vaccination effort took hold may have revealed reservations to vaccines with meat substrates. On the other hand, our system may not be appropriately setup for such engagement in a timely fashion. As medical practitioners, content experts, researchers and family members, many of us juggle multiple roles to achieve personal and professional balance. In the case of the H1N1 vaccine, this Muslim physician found had many balls in the air.

### **Tough Questions**

My situation is not unique. Colleagues noted that Orthodox Jewish patients faced similar tensions and that some of their religious leaders had allowed exemptions. There is also a long history of religious and/or philosophical exemptions from vaccinations in United States schools for example. The question however is whether

state and local governments should try to procure alternative vaccinations, ones which are in-line with the value systems of their populace. A bit further a field is the question of whether there is an onus upon vaccine researchers and manufacturers to utilize non-controversial solvents and carriers for their products. The loss of herd immunity is a real concern to health services researchers as individual-choice statutes allow exemptions to mandatory vaccination programs. While autonomy and choice are important, as healthcare systems should we try to accommodate and customize vaccines while at the same time educating the populace about their benefits? In my situation we were dealing with a pandemic with tens of thousands of deaths, tenuous vaccine supply, and an Islamic bioethical process that does not have a strict hierarchy and requires negotiation. Perhaps clearer guidance from religious leaders and bioethicists, and better evaluation of the preferences and needs of state populations and communities, will help forge enhanced mechanisms to maximize individual-choice while at the same time protecting our health.

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