AMA Journal of Ethics®

September 2018, Volume 20, Number 9: E819-825

CASE AND COMMENTARY

Should Genetic Testing for Variants Associated with Influenza Infection Be Mandatory for Health Care Employees?

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Abstract

Scientists are beginning to understand more about the role of host genetics in individuals' responses to influenza virus exposure. This fictional case addresses a situation in which a health care organization proposes requiring all health care practitioners with direct patient care responsibilities to undergo mandatory genetic testing for genetic variants used to (1) predict individuals' responses to the influenza vaccine, (2) determine individual susceptibility to influenza infection, and (3) identify individuals at increased risk for severe disease. This commentary will discuss ethical and legal issues associated with use of genetic test results to determine employee work assignments during an influenza pandemic.

Case

Influenza is an acute infectious illness spread by casual contact via respiratory droplets. Depending on the strain of virus and the characteristics of the infected individual (host), the severity of illness ranges from a mild, self-resolving upper respiratory tract infection to severe respiratory compromise and death. Due to the virus's high transmissibility and constantly changing genome, influenza can cause pandemic infections. However, the efficacy of current vaccines and treatments are variable, suggesting that limiting exposure and transmission is the most promising strategy for improving health outcomes during pandemics.

Scientists have begun to identify host genetic variants that confer resistance to influenza or limit its transmission. If a genetic test is developed to identify whether individuals possess these variants, the information could be used to determine the genotype of the clinical and public health workforce and to predict whether these workers are resistant to influenza or whether they easily transmit infection to others.

Health care organization (HCO) A is considering mandating that all health care professionals who have direct patient care responsibilities be tested for genetic variants associated with influenza infection. Such host genetic variant information might allow a structured response to influenza that limits the spread of the infection. However, collecting and using this information might place unacceptable limits on individual autonomy. Some of the professionals working for HCO A do not want to consent to be tested; others are willing to be tested but do not want their genetic information to be stored. How should the HCO A leadership respond?

Commentary

The World Health Organization defines a pandemic as "the worldwide spread of a new disease."¹ The 1918 influenza pandemic caused the deaths of an estimated 50 million to 100 million people, 3% to 5% of the world's population.² In contrast, the 2014–2016 West Africa Ebola outbreak resulted in 11 310 deaths in Guinea, Liberia, and Sierra Leone as of April 13, 2016.³ The Ebola outbreak was not as widespread or as destructive as the 1918 influenza pandemic, but it demonstrated how ill prepared the world is to address infectious disease outbreaks. For decades, experts have warned that another severe infectious disease pandemic could occur at any time.² It is not a question of "if" but "when" the next serious pandemic will occur. Like earthquakes, what worries infectious disease experts is the occurrence of "the big one."

Seasonal influenza must be distinguished from pandemic influenza. Human influenza A and B viruses cause seasonal epidemics of disease. These viruses circulate in all parts of the world and cause seasonal epidemics when there is widespread occurrence of influenza infection in a particular geographic community at a particular time. Seasonal influenza epidemics typically occur during the winter months in temperate climates but can occur throughout the year in tropical climates. An influenza pandemic is a global outbreak of a *novel* influenza A virus. Because the virus is new to humans, very few people will have immunity against the virus, and many people might become ill. For both seasonal and pandemic influenza, the strain of the influenza virus and the characteristics of the host affect the severity of disease.⁴ A number of host genetic variants associated with response to the influenza vaccine, susceptibility to influenza infection, and severity of disease if infected recently have been identified.⁵⁻⁷

Because health care delivery systems might become overwhelmed during an influenza pandemic, all health care organizations in the United States should be prepared to respond when an influenza pandemic arises. Vaccination, monitoring, and management of health care personnel will be key to limiting exposure to the influenza virus in the health care setting. Information about whether individual health care practitioners possess genetic variants associated with influenza could be helpful in the management of health care personnel during an influenza pandemic and potentially could reduce the spread of disease, both to patients and to other health care practitioners.

HCO A has proposed a requirement that all health care personnel with direct patient contact undergo genetic testing for these variants in order to structure its response to an influenza pandemic to limit the spread of disease. This requirement would serve three main purposes: (1) allow HCO A to fulfill its obligation to provide a safe work environment

for its employees; (2) minimize the risk of additional harm from exposure to influenza to persons who seek health care from HCO A; and (3) preserve the employee workforce, a resource that is vital to the ability of HCO A to continue to provide health care services during an influenza pandemic. However, HCO A employees might have significant concerns about the fairness of such a policy and about their <u>autonomy</u>, genetic privacy, and potential loss of employment opportunities if this requirement is implemented. This commentary considers this tension between the needs of employers and the concerns of workers.

Rationale for Mandatory Genetic Testing of Employees for Variants Associated with Influenza Infection

HCO A's rationale for mandatory genetic testing is based on the duties owed by a health care delivery system to its employees, its patients, and society.

Duty to provide safe work environments for employees. Health care organizations are obligated by law to provide a safe work environment for their employees. The US Occupational Safety and Health Administration promulgates standards to protect health care workers from exposure to bloodborne, droplet, and airborne transmissible infectious agents. In addition, the General Duty Clause of the Occupational Safety and Health Act of 1970 requires that employers provide a workplace that is free from recognized hazards that are likely to cause death or serious physical harm to employees.⁸ A health care institution by its very nature cannot eliminate all risk of contagion from infectious disease for its employees, but it is required to take steps to minimize this risk.

During an influenza pandemic, occupational exposure to the influenza virus during direct patient care is likely to occur. A genetic test for variants associated with increased susceptibility to influenza infection and for vaccine nonresponders could allow HCO A to identify those employees at increased risk of contracting influenza if exposed to the virus. During an influenza pandemic, these employees could be given patient care assignments with lower risk of exposure to the virus, ie, they could be assigned to care for patients who need medical care but are not known to be infected with influenza. Assignment of patient care duties based upon genotype may be one way to decrease risk of exposure and infection in both patients and employees.

Duty to minimize risk of nosocomial infections. Health care institutions also owe legal and ethical duties of care to patients. These duties entail an obligation to safeguard patients from harm and minimize the likelihood of nosocomial infection while they are in the care of the health care institution. HCO A has a responsibility to its patients to limit their risk of exposure to influenza when they seek medical care from HCO A. Current standards of care require that health care institutions have protocols in place to limit the spread of infectious disease. These protocols can include a range of precautions, from requiring that health care practitioners wash their hands before and after patient contact to isolation of patients with specific suspected or confirmed infectious diseases when

possible. The assignment of employees who are more susceptible to influenza infection or who are vaccine nonresponders to low-risk patient care activities during an influenza pandemic is another way HCO A could minimize patients' risk of exposure to influenza while they are receiving medical care.

Duty to preserve the health care workforce during an influenza pandemic. Health care practitioners are a vital resource that may become scarce during an influenza pandemic as health care personnel become ill with influenza themselves. Although elective medical care might be deferred during an influenza pandemic, health care institutions must continue to provide urgent care to patients who do not have influenza as well as treat patients infected with the virus. Consideration of how this health care workforce resource should be <u>allocated</u> must be part of the pandemic preparedness planning of any health care organization.

Employee Concerns about Mandatory Genetic Testing for Variants Associated with Influenza Infection

This type of mandatory genetic testing may raise concerns for some employees about fairness, autonomy, or how the information may be used.

Fairness. The requirement that HCO A employees with direct patient care responsibilities undergo mandatory genetic testing for variants associated with influenza potentially could reduce the risk of influenza infection in certain employees; however, this risk cannot be eliminated entirely. Employees who do not possess the variant that confers increased susceptibility to infection are still at risk of contracting the disease if exposed to the virus. A practice of assigning employees who are more susceptible to the virus to low-risk patient care activities confers benefit to these at-risk employees but also means that employees who are less susceptible to the virus must be assigned to care for the patients with influenza. From the standpoint of these less-susceptible employees, it can be argued that random assignment of patient care responsibilities, not assignment based upon employee genotype, would more fairly balance the risk of exposure among individual health care practitioners.

Similarly, if employees who do not possess the variant associated with severe disease are assigned to care for infected patients, they could still become ill even though their illness may not be severe. Illness nevertheless has consequences for these employees. They may suffer loss of wages from not being able to work; they and their families could be <u>quarantined</u>; they could spread the disease to others, including those who are at risk of severe disease; and they could face family and child care difficulties.

Finally, for those employees who receive the influenza vaccine because they do not possess the genetic variant associated with vaccine nonresponse, the vaccine might not be completely effective. If these employees are assigned to care for patients with influenza because they have received the influenza vaccine and the vaccine is not

completely effective, it can be argued that these employees were unfairly exposed to the virus while other employees were not exposed.

These fairness issues are unavoidable under HCO A's policy, but requiring groups of employees to assume differential risks may be justified during a pandemic that causes severe disease with a high mortality rate.

Employee autonomy. Absent extraordinary circumstances, mandatory genetic testing for variants associated with influenza might be unacceptable to some employees. In general, competent adult patients have the right to make their own decisions about their health care, including decisions about whether to undergo genetic testing. Some patients decide not to undergo genetic testing because they do not want to know whether they possess genetic variants that indicate increased risk of disease. The requirement by HCO A that employees undergo mandatory testing for genetic variants associated with influenza would limit the autonomy of their employees in this regard and deny them the right not to know whether they possess genetic variants associated with influenza.

Concerns about HCO A possession of genetic information. Employees might prefer that HCO A not obtain knowledge about their personal genetic information for a number of reasons. Some employees may have concerns about the security of their genetic information, including concerns about where genetic testing results will be stored and who will have access to the information. Employees also might be concerned that the genetic information could be used by HCO A to discriminate against employees with a particular genotype by limiting the amount or type of work they do or limiting their opportunities for professional advancement.

Current Policies

Genetic testing for variants associated with influenza infection has not yet been developed, so implementation of mandatory genetic testing for these variants by HCO A would not be possible at the current time. Furthermore, the federal Genetic Information Nondiscrimination Act of 2008 (GINA)⁹ and genetic privacy laws in some states¹⁰ currently prohibit the <u>use of genetic information in the employment setting</u>. However, the Public Health Service Act allows the US Secretary of Health and Human Services (HHS) to determine that a public health emergency exists in cases of severe infectious disease outbreaks.¹¹ A public health emergency determination gives the HHS secretary broad powers to assist states in the prevention and treatment of disease.

A severe influenza pandemic could jeopardize the lives of millions of people. If an influenza pandemic of this level of severity and magnitude develops and genetic testing for variants associated with influenza infection is available, overriding the prohibitions against the use of genetic information in the workplace may be justified and necessary. The extent to which a determination of an influenza pandemic as a public health emergency could be used to override GINA's and state genetic privacy laws' prohibitions

on uses of genetic information in employment settings is unclear. It is possible, perhaps likely, that these provisions would be overridden in the face of a severe influenza pandemic in which millions of live are at stake.

Conclusion

A requirement that all health care employees with direct patient care responsibilities undergo genetic testing for variants associated with influenza infection might provide HCO A with information that could be used to determine patient care responsibilities during an influenza pandemic. Assigning health care practitioners at increased risk from influenza exposure to low-risk patient care activities during an influenza pandemic could protect these individuals from exposure and limit the spread of disease. However, this practice could expose individuals at lower risk from influenza exposure to a greater extent than they would have been if genotype was not used to determine work assignments and therefore may be unacceptable to some employees. Moreover, this practice would limit employee autonomy, and some employees might have concerns about genetic privacy or the potential use of genetic test results to limit employment opportunities. Current state and federal genetic privacy laws prohibit HCO A from mandating this type of genetic testing. In the future, these considerations may be overridden in the face of a public health emergency caused by a severe influenza pandemic.

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Editor's Note

The case to which this commentary is a response was developed by the editorial staff.

Citation

AMA J Ethics. 2018;20(9):E819-825.

DOI

10.1001/amajethics.2018.819.

Acknowledgements

This work is supported by grant number 1RM1HG009038-01 from the National Human Genome Research Institute.

Conflict of Interest Disclosure

The author(s) had no conflicts of interest to disclose.

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.

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