

To think about ethics in *influenza* surveillance?

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Abstract

Epidemiological surveillance, important in the indication and implementation of public health policies and decision-making, constitutes a link between health services and research. In this context, the ethical issues found in daily surveillance practices require in-depth reflective processes and specific qualified discussions. Some ethical questions related to *influenza* surveillance were considered for the elaboration of this reflective essay. Those questions were held up against a range of bioethical, human rights, right to health, public health and ethics' concepts. The proposed reflections address the principles of bioethics, relating them to the characteristics of surveillance actions directed to the participants of the survey on respiratory viruses circulation.

Keywords: Ethics. Bioethics. Epidemiological surveillance. Influenza, human.

Resumo

Pensar a ética na vigilância da *influenza*?

A vigilância epidemiológica, importante na indicação e execução de políticas de saúde pública e nas tomadas de decisão, constitui um elo entre os serviços de saúde e a pesquisa. Nesse contexto, as questões éticas presentes nas práticas diárias de vigilância demandam processos reflexivos aprofundados e discussões específicas mais qualificadas. Para a elaboração deste ensaio reflexivo, tomaram-se algumas indagações éticas relacionadas à vigilância da *influenza*, confrontando-as com uma gama de conceitos bioéticos, de direitos humanos, de direito à saúde, de saúde pública e de ética. As reflexões propostas enfocam os princípios da bioética, relacionando-os às características das ações de vigilância direcionadas aos participantes da pesquisa de circulação de vírus respiratórios.

Palavras-chave: Ética. Bioética. Vigilância epidemiológica. Influenza humana.

Resumen

¿Pensar la ética en la vigilancia de la gripe?

La vigilancia epidemiológica, importante en la indicación e implementación de políticas de salud pública y toma de decisión, constituye una conexión entre los servicios de salud y la investigación. En este contexto, las cuestiones éticas presentes en las prácticas diarias de vigilancia requieren procesos reflexivos profundos y discusiones específicas más calificadas. Para el presente ensayo de reflexión se consideran algunas indagaciones éticas relacionadas con la vigilancia ejercida a la influenza, abordándolas frente a una gama de conceptos bioéticos, de derechos humanos, del derecho a la salud, de salud pública y de ética. Las reflexiones propuestas abordan los principios de la bioética relacionándolos con las características de las acciones de vigilancia dirigidas a los participantes de la investigación de circulación de virus respiratorios.

Palabras-clave: Ética. Bioética. Vigilancia epidemiológica. Gripe humana.

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Influenza, or cold, is an acute viral disease of the respiratory system of rapid dissemination and global distribution. An individual may contract the flu several times throughout his or her life. The flu is most serious in risk groups such as the elderly, children, immunocompromised individuals, people with heart disease and lung disease. From the public health perspective, this virus presents a combination of different problems that require specific care surveillance and control, given the severity of its clinical manifestations and its pandemic and zoonotic potential¹⁻³.

Influenza causes concern to world health authorities for its impact on morbidity and mortality, its similarity to highly contagious atypical pneumonias and its severity and the probability of emergence and spread of strains with pandemic potential⁴. Thanks to these characteristics, the virus has been the target, since 1947, of a world-surveillance program now called Global Influenza Surveillance and Response System (GISRS), created by the World Health Organisation (WHO)⁵.

The Brazilian government, through the Ministry of Health, introduced influenza surveillance nationwide in 2000. Vigilance is grounded in sentinel units and in the monitoring of indirect morbidity and mortality data associated with influenza. The records of consultations for flu-like illness are considered together with information about the circulation of viruses, which are the etiological agents of acute infections of the respiratory system. The surveillance of respiratory viruses aims to know which strains are circulating in Brazil, respond to unusual situations, assess the impact of vaccination, follow the trend of morbidity and mortality, in addition to producing and disseminating information on epidemiology with a view to strengthening surveillance through the elaboration of contingency plans to deal with pandemic situations¹.

Epidemiological surveillance plays an important role in the indication and execution of public health policies and in the decision-making process. In a broader concept, epidemiological surveillance works as a link between health services and research⁶. The role of research in health surveillance is critical to the building of knowledge and elucidation of health risks. The research in public health and research in health services are intertwined and, although they have different approaches to the traditional academic research, the ethical aspects in common should be considered.

The need for influenza surveillance is indisputable. However, some ethical questions require

reflection. The purpose of this article is to reflect on aspects of the permanent action of respiratory virus surveillance, an essential part of the influenza surveillance from the perspective of bioethics.

Practices, guidelines and surveillance standards

Brazil belongs to the global network of *influenza* surveillance with the participation of three laboratories accredited by the WHO as National Influenza Centers (NIC). The information generated by this network is analysed and discussed each year at a meeting at WHO headquarters which, among other decision-making, indicates the composition of the vaccines to be used the following year.

To place the surveillance of influenza in the broader context of health surveillance activities, it should be clarified that there are different ways to monitor events. The traditional approach, centered on the disease and known as universal surveillance, is based on mandatory reporting and it is called passive surveillance. However, alternative approaches have been advocated in recent years focusing on other moments of the event, or biological cycles, which requires the promotion of diversified actions, called active surveillance. This approach includes the sentinel surveillance strategies.

In the sentinel surveillance of influenza, samples are taken from patients with flu-like illness symptomatology who sought medical care in health facilities, even if the complaints of these patients were not related to the syndrome. It recommends a convenience sampling, and health units should collect samples of five patients per week, every week of the year. Thus, samples are taken after a screening and brief interviews with citizens present in the waiting room, provided that they confirm they are carriers of clinical signs consistent with flu-like illness. Samples are, in order of preference: 1) nasopharyngeal aspirate, or 2) combined swab (nasal and oral), obtained within five days of the early onset of symptoms (acute phase)¹. These samples are forwarded to laboratories of the influenza surveillance network, and not for diagnosis related to patient care.

On the approach and attention to ethical aspects related to patients who are subjects participating in viral research, there is a reference on the subject in the "Epidemiological Surveillance Guide" of the Ministry of Health¹ (page 23), expressed by the statement that the notification must be confi-

dential and should only be disclosed outside the medical and health field in the case of risk to the community, respecting the citizens' right to anonymity. There are no references to ethical aspects in the Ministry of Health Ordinance 2693/2011⁷, which deals with the transfer of funds for the introduction, implementation and strengthening of epidemiological surveillance of influenza.

In the practice of disease surveillance, normative documents are not followed in their entirety, such as the guidance to patients about biological samples, laboratory flow and results. The ordinance 788/2002, issued by the Secretary of Health Assistance (abbreviated as SAS in Brazil - Secretaria de Assistencia a Saude) from the Ministry of Health, recommends that among the main functions of a collection point are the *care and guidance of patients for the collection, identification and receipt of biological materials, as well as proper storage of biological fluids for transportation, release and delivery of report*⁸. Accordingly, the SAS Ordinance 787/2002, as well as establishing basic parameters and technical rules for the organisation of the network of clinical laboratories, recommends the correct identification of samples, an efficient transport system and secure packaging, as well as a clear flow of routing of examination reports to the collection sites and/or unit of origin of the patients, in a safe and reliably way, in order to ensure that the patient has a timely access to the result⁹.

The Resolution 302/2005, from the Executive Board of the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária - Anvisa), also supports that concern and aims for a technical regulation for the operation of clinical laboratories. The resolution applies to all public or private services that perform laboratory activities in the field of clinical analysis, clinical pathology and cytology. According to this legislation, the sample collection unit and the laboratory must meet the expected operational processes and, among other duties, *shall make available written and/or verbal instructions, in accessible language, to the patient or responsible, advising on the preparation and collection of samples having as objective the understanding of the patient*¹⁰. In addition, the resolution states that the patient in ambulatory care or the responsible must receive a proof of the service containing registration number, full name of the patient, date of the service, expected date of delivery of the report, list of requested tests and contact information for the laboratory.

However, despite the existence of these guiding norms, situations still exist where patients do not

know which laboratory will process the sample, is not given a receipt to monitor the laboratory analysis of their biological sample, nor receive the analysis results. Once the collection of the clinical sample is done, it is the duty of the public service (or private) to ensure the identification, the packaging and adequate and timely submission of the sample for laboratory analysis. Likewise, one must ensure the processing of the sample within the given deadline and the delivery of laboratory results to patients on an individual basis (for each patient, a report). In the practice of surveillance, what is observed is that the results of laboratory tests are disclosed, in aggregate form, by epidemiological week, in the "Bulletin of Influenza Epidemic", available on the website of the Surveillance Secretary of the Health Ministry.

In influenza surveillance activities at the time of collection at the health unit, the consent or assent for viral investigation is informed orally by the patient, after having received a brief explanation. There isn't a free and informed consent, the same as there is no formalised signing of a document similar to the free and informed consent as it happens in scientific researches, or a recording of a manifestation of acceptance. And there is not any clear evidence that the information was correct and timely provided by the health professional and understood by the patient. And, as it is known, the information must be understandable in order to produce an informed consent, it is not enough that the person is simply a recipient¹¹. There isn't here a suggestion to formalise the documentation, but a questioning about the information and proper communication to the research subjects. Formal procedures, mere compliance with bureaucratic determinations lacking reflection and conscious choice¹², do not contribute to the respect for the rights of the citizens taking part in the research.

In surveillance research, even when based on a different understanding, in the light of the Resolution 466/2012¹³ of the National Health Council (abbreviated as CNS in Brazil - Conselho Nacional de Saude), which establishes the guidelines and regulatory standards for research involving human beings, patients participating in viral investigations, who are the subjects of the research, may be considered vulnerable. Or, patients may be counted as vulnerable, given their living conditions, including their health condition¹⁴. After all, these patients sought a health facility for medical care, not specifically a respiratory problem, and then during the screening, they are asked by a health care professional to perform a collection of material for examination

because that specific medical service unit happens to be part of the sentinel network for *influenza*.

While individual and social effects of researches on respiratory viruses are highly relevant, as they will benefit directly or indirectly, immediately or later, the participants and/or their community, those participants must be informed about the nature of the research, its objectives, methods, expected benefits, potential risks and the discomfort that such research may cause to them. The information should consider the participants' understanding and respect their singularities, as it is recommended by the Resolution CNS 466/2012¹³.

We are not proposing here the use of the CNS Resolution 466/2012¹³ to support aspects about the ethics of influenza epidemiological surveillance. The academic biomedical research is different from the investigation or research in health surveillance; however, it is necessary to observe surveillance practices. It is well known that the decision-making in epidemiology involves both technical knowledge and reflection on important issues for the public health service. Similarly, the relationship between ethics and epidemiology unfolds between political commitment and practice in health services as well as production of knowledge. Besides the political commitment or the social relevance of knowledge and interventions, it is essential to highlight the need to elect priorities for individuals in the society. Add to this the issues of ethics in research involving human beings and concepts of risk and vulnerability, which raises the question of informed consent and return of results to the society¹² - Return discussed here both as an individual result and as a benefit of the research to the community.

While individual principles do not apply to public health or to epidemiological studies, it is important to observe rules and practices that consider the particularities of groups and populations. In epidemiological studies, even with a commitment to acquisition and application of scientific knowledge for the maintenance and restoration of public health, individual rights must be respected¹⁵.

To set criteria and standards for ethical conduct in epidemiological research is a constant concern of scholars and researchers, whose discussion topics are contained in international documents aimed at epidemiologists, such as in the following examples, mentioned by Coughlin¹⁶: the "International Ethical Guidelines for Epidemiological Studies", prepared by the Council for International Organisations of Medical Sciences(CIOMS) in collaboration with the WHO and published in 1991; the "Ethics Guidelines"

of the American College of Epidemiology (ACE), published in 2000; and the guidelines of the "HIPAA privacy rule and public health", guidance from the Center for Disease Control and Prevention (CDC), published in 2003.

About the rights

Whereas the surveillance strategy should be based on the concept of the citizen as a subject of rights, it is vital to establish instruments that protect the health of the individual integrated to the population group, recognised as equal in the rights, even when defending differentiated positions or socio-cultural values. It is rather important that ethics is closely linked to public health practices, since ethical issues are confined only to technical, legal or administrative areas. Ethical interference, whether direct or indirect, can affect people in their decision-making¹⁷.

According to the WHO document¹⁸, which discusses solutions for pandemic *influenza*, human rights are universal legal guarantees that protect individuals and groups against actions which confront fundamental freedoms or human dignity. One of the most important characteristics of this document, the international consensus on guarantees that individuals and peoples should enjoy in the health sphere, has been ratified by the governments of the signatory countries, which thus undertake to apply international standards in their local contexts. Thus, both by the force of the law in national dimension as well as a result of moral consensus among countries, human rights can not be disowned or withdrawn.

The right to health is a primary requirement of the right to life¹⁹. To a large extent, the development of the right to health stems from the increasing urbanisation that came with industrialisation since the nineteenth century as well as the fact - defined by law - that health has become the responsibility of the State²⁰. Similarly, epidemiological surveillance is a function of the state, and should be a prerequisite in the development of health programs and an evaluation tool of the impact of their implementation. Disease and injury surveillance systems should be subject to frequent reviews and adjustments as well as any necessary changes in order to ensure good performance, quality, efficiency and effectiveness of their actions. Only then will it be possible to show the epidemiological situation of the problem, its trends, the impact of control measures and the

proposition of new actions. The epidemiological surveillance system remains efficient when its running is measured regularly with a view to opportune adjustments²¹.

It is therefore important to have the collective good in mind when assessing epidemiological research, but with a point of view which respects individual rights. The improvement of public health has been marked by the incorporation, by the State, of roles and responsibilities based on the consideration that collective rights, and even diffuse social rights, are defined as inexorable conditions of citizenship. Sanitary control measures stem from the set of measures that societies established in the course of time, in order to prevent or reduce risks and damage to the health of the population. Relations between public health and human rights permeate the political aspects, programs and public health practices. It is essential, therefore, to find a balance between the collective good and individual rights²².

Bioethical principles

Bioethics may be defined as ethics directed to human survival, since it covers social and environmental issues, in addition to biomedical and biotechnological conflicts²³. The field is a discipline committed not only with the moral in the area of health and disease of humans and animals, but also with the reflection and discussion of ethical conflicts indicated by bioethics, conflicts which have always been present throughout the history of human society²⁴.

The Universal Declaration on Bioethics and Human Rights²⁵ meant a new phase for the field of bioethics, which left the narrow confines of the clinic and research to consolidate itself as a discipline which provides a framework of human rights. The document contains a number of principles: human dignity and human rights; benefit and harm; autonomy and individual responsibility; consent; persons without the capacity to consent; respect for human vulnerability and personal integrity; privacy and confidentiality; equality, justice and equity; non-discrimination and non-stigmatisation; respect for cultural diversity and pluralism; solidarity and cooperation; social responsibility and health; sharing of benefits; protection of future generations; protection of the environment, the biosphere and biodiversity.

In Brazil, ethical motivation is seen by principles similar to each other: a) respect for people, be

it obtaining an informed consent or on confidentiality and protection of those who are unable to take decisions; b) beneficence or “do no harm” (non-maleficence), maximising benefits and reducing risks; c) distributive justice, with a favourable balance of risk-benefit and an equitable selection of patients. This motivation was discussed in a study by Novaes and collaborators²⁶, and its principles are regulated by the Resolution 466/2012 13 of the National Health Council (Conselho Nacional de Saude)

Bioethical challenges with a focus on public health deserve critical reflection *on key topics such as global health and global bioethics, social justice and health equity, vulnerability factors in the poorest countries, respect for cultural autonomy of the people, responsibility towards solidarity and cooperation among nations, universalism versus ethical relativism in the face of human dignity*²⁷.

Considering the changes experienced by society, we must think of a bioethics guided by respect and encouragement of individual freedom in decision making, in addition to the principles of solidarity, justice, equity and accountability, reinforcing the need for protection of the disadvantaged or vulnerable. We have to think of a bioethical action able to assist in the search for balanced solutions between individual freedoms and collective interests²⁸.

Bioethical principles should be observed even in the interdependence between surveillance and health research. These interfaces in *influenza* surveillance activities should be detailed in order to guide and regulate the decision-making about the service actions, which should prioritise the respect for citizens. The ethics of life should guide the surveillance actions, as they turn to the collective, in order to ensure, by the State, the citizens rights.

Final considerations

This paper presents some reflections on influenza surveillance from the perspective of ethics. What is observed is that services and health professionals have not expressed explicit interest in changing the system, while participant patients don't show concern about the obtention of diagnostic results nor with the progress of the research.

The considerations about the resizing of surveillance activities included, as a starting point, the fact that they constitute a duty of the State and the fact that they affect the community. These reflections occurred, in part, during the period of the surveillance

decentralisation and at the time when it was realised that traditional surveillance - passive, based on compulsory notification - was insufficient and often not opportune⁶. This fact reinforced the need to innovate the forms of surveillance by introducing active sentinel surveillance strategies, which affected the very concept of surveillance. At the same time, the role of research both induced and expedient (*ad hoc*) has been emphasised to elucidate events relevant to health surveillance, either on a serial or continuous basis, in order to strategically monitor the progress of diseases and practices or risk habits. Such investigations can be carried out either by the health service or by academic institutions and research institutes. In epidemiological research, in general, there are important ethical considerations^{15,16}. It is important to consider that the interface and the profound connection between epidemiological research and surveillance practices entail new challenges in addressing the ethical aspects, and, given its social and political relevance, should take into account their relation to the care or health care.

Issues related to ethics often go unnoticed by services and health surveillance professionals; consequently, they are not included in their programs and protocols. Ethical aspects in the practice of *influenza* surveillance are important and should be observed as any other necessary factor for its management.

The procedures adopted for the taken samples, timely and necessary explanations about the use of biological material obtained, and the duty and the right relating to the results of laboratory tests are of interest for further study. Other issues

relating to contingency plans should also be checked from the perspective of ethics, such as measures restricting freedom (quarantine), the use of antiviral drugs and vaccines (to ration or to rationalise?), access to health care and its physical resources, the risk and tiredness imposed on health professionals and their responsibilities, as well as communication of the risk and the role of the press.

It is necessary that rights and responsibilities are discussed from an educational focus, in the area of continued education²⁹ and in the training in the services and technical supervision. In the production of epidemiological knowledge, ethical issues in research involving human beings, as well as the social significance of risk and vulnerability are important aspects of reflection for guidance of epidemiological surveillance practices.

Here we portrayed some points about the *influenza* sentinel surveillance as an exercise of reflection. Ethical concerns are indispensable in everyday surveillance practices. As rights of every citizen-patient, the obtainment of clear information about the laboratory processing of the sample at the time of collection and the adequate communication of the examination results are examples of situations that need to be reviewed in the context of health services. In addition, it is necessary to take into account the creation and adherence to routines based on ethics in the relationship with participants studies. Such concerns should be foreseen in the guidelines as well as surveillance guidelines and ethical regulations aimed at the research in public health surveillance.

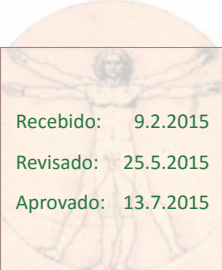
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