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COMMENTARY
Procedures for the ethical review of public health surveillance protocols

Carlo Petrini
Unità di Bioetica, Presidenza, Istituto Superiore di Sanità, Rome, Italy

Abstract
The present commentary is based on the following considerations:
1) for the purposes of authorisation, a distinction is drawn between "research" and "intervention". The procedures for authorising the former are more complex, the relevant controls are stricter and approval has to be granted by a Research Ethics Committee (REC);
2) although the debate is still open, it is barely credible to claim that public health surveillance is not a form of research. It should, therefore, be subject to rigorous ethical assessment;
3) when addressing specifically the issue of surveillance, it would be appropriate to shift the focus of attention from the type of procedure (research/intervention) to the risk implied in that procedure;
4) much emphasis has hitherto been placed on the risks that public health surveillance may imply for the protection of personal data;
5) the emphasis on the protection of personal data is frequently excessive and the risks should be examined in a broader context.

Key words
- bioethics
- informed consent
- privacy
- public health surveillance

INTRODUCTION

The distinction between "research" and "intervention" involving humans is of crucial importance. Regulations introduced in recent decades, for instance, require that research studies with human subjects be authorised only after a competent ethics committee has approved them. Medical interventions, treatments and current practices, on the other hand, generally require no such authorisation [1]. A clear definition of the different procedures is thus essential.

Many regulations adopt the definitions and distinctions stated in the "Belmont Report" of the National Commission for the Protection of Human Subjects [2]. The Federal Policy for the Protection of Human Research Subjects (informally known as the "Common Rule") states that "research mens a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" [3].

The World Health Organization (WHO), in its Resolution WHA58.3, defines surveillance as "the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary" [4]. Gostin defines it as "The public health practice of continual watchfulness over the distribution and trends of risk factors, injury, and disease in the population through the systematic collection, analysis, and interpretation of selected health data for use in the planning, implementation, and evaluation of public health practice" [5]. The debate as to whether public health surveillance should be considered as "research" is still open [6].

PUBLIC HEALTH SURVEILLANCE AS RESEARCH

If we adopt the definition of research used in the Belmont Report, *i.e.* that it is "designed to develop or contribute to generalizable knowledge", we must recognise that a large portion of surveillance falls within it. On a more general level we could even say that everything to do with public health is research: according to the Oxford textbook of public health one of the core functions of a public health system is "to gather health information and deploy those data for the welfare of the community" [7].

If we agree with the WHO that "All research with human participants is presumptively subject to REC (Research Ethics Committee) oversight" [8] we must deduce that public health surveillance must be assessed and approved by an REC before it can proceed. In other words, recourse to RECs becomes indispensable. At most, a simplified procedure to accelerate matters could be contemplated. In fact the WHO states elsewhere that "Specific categories of research may be exempted from REC review or subject to expedited re-

Address for correspondence: Carlo Petrini, Unità di Bioetica, Presidenza, Istituto Superiore di Sanità, Via Giano della Bella 34, 00162 Rome, Italy. E-mail: carlo.petrini@iss.it.

view" [8] and, more specifically, "Protocols involving no more than minimal risk and burden to research participants may be reviewed on an expedited basis by one or more members (rather than the full committee), if the REC has established written procedures permitting such a procedure" [9].

Thus a debate focused on defining "research" and "surveillance" is unlikely to conclude that "surveillance" is not "research" and is thus exempt from even a simplified procedure of referral to an REC.

FROM A DISTINCTION BETWEEN RESEARCH AND INTERVENTION TO RISK ASSESSMENT

In the particular matter of surveillance it would be helpful to shift the focus from forging a distinction between research and intervention to weighing the risks associated with each procedure, particularly the type of risk, the probability of its occurrence and its magnitude.

"Research involving humans should be initiated only if the anticipated benefit(s) for the individual research subject and society clearly outweigh the risks. Although the benefit of the results of the trial to science and society should be taken into account, the most important considerations are those related to the rights, safety, and well being of the research subjects" [10]. There may nonetheless arise specific situations in which research may be legitimate even in the absence of direct benefit. This is generally acceptable so long as the level of so-called "minimal risk" is not exceeded. According to the Department of Health and Human Services a risk is "minimal" if the "probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" [11]. The risks involved in public health surveillance do not often exceed the "minimal" level, or even the recently proposed level of "de minimis risk". According to its proponents, "de minimis risk" is "a subcategory of minimal risk that would apply to studies involving only negligible physical risk where nothing dangerous is done to the body and no likely or significant social or psychological harms are foreseen. Obtaining informed consent should not be an absolute requirement for studies that involve only this subcategory, vanishingly small level of de minimis risk" [12].

MINIMAL RISK AND THE PROTECTION OF PERSONAL DATA

Public health surveillance poses a number of ethical problems [13], most of which concern the protection of personal data [14]. As noted in the Canadian Institutes of Health Research (Institute of Population and Public Health), "the problems involved in managing the data used as inputs to surveillance plans have received ongoing attention in the literature" [15]. However, while recent decades have seen increasing attention to the protection of personal data in the research and public health settings, more recent proposals "suggest the regulatory pendulum is taking a swing to the permissive" [16]. The Institute of Medicine, for instance, is now recommending that all research be exempted from the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and that all "information-based" research be freed from informed consent requirements [17].

CONCLUSIONS: SIMPLIFICATION OF THE ASSESSMENT PROCEDURE

In the case of public health surveillance, when no procedures are envisaged that directly involve individuals the interests of the community at large may, in specific circumstances, override the requirement to protect personal data. This is not the same as adopting a utilitarian ethical stance, but rather an acknowledgement that there are different kinds of risks to the individual, and that they are not all equally significant. It is therefore to be hoped that procedures for the authorisation of public health surveillance studies can be kept in proportion to the risks involved without becoming an obstacle to their completion.

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