Demographic and health surveillance: longitudinal ethical considerations

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Abstract Longitudinal data gathered from health surveillance, when combined with detailed demographic information, can provide invaluable insight into disease outcomes. Many such surveillance sites exist in the developing world, particularly in Asia and sub-Saharan Africa, and focus on diseases such as HIV/AIDS, cholera, malaria and tuberculosis. The indistinct positions of such surveillance systems, often inhabiting an area between research, treatment and population health monitoring, means that the necessity of and responsibility for ethical oversight is unclear. This regulatory vacuum is further compounded by a lack of attention to longitudinal surveillance systems in ethics literature. In this paper, we explore some key ethical questions that arise during demographic and health surveillance in relation to ethical principles of beneficence, respect for persons and justice: health-care provision, informed consent and study sustainability.

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Une traduction en français de ce résumé figure à la fin de l'article. Al final del artículo se facilita una traducción al español. الترجمة العربية لهذه الخلاصة في نهاية النص الكامل لهذه المقالة.

Introduction

Gross health inequalities between the developed and developing world drive the activities of researchers and public-health practitioners worldwide. The need for empirical evidence to guide further research and to direct health interventions is acute, as reliable data is in short supply and is often based on indirect estimates or geographically limited to urban areas.[1] In developing countries, and in particular those that lack effective vital registration systems, small-scale combined Demographic and Health Surveillance (DHS) systems can provide invaluable field data on longitudinal fertility and mortality patterns.[1–4] DHS systems are distinct from demographic and health surveys. The former represent long-term monitoring of specifically defined populations, typically residing in a small geographic region, while the latter are one-time representative samplings of a country or region.[5] Though the data collected in surveillance and surveys is similar in scope, the timeframe and populations studied are quite different.

Located primarily in Africa and Asia, DHS are effective and comprehensive data collection systems because they focus on the populations of small, clearly delineated geographic areas. Central to all DHS is continuous demographic surveillance, consisting of initial and repeat censuses of the chosen population, registering each individual resident and recording their associated information, such as socioeconomic and behavioural data.[6,7] Health outcomes and vital events in the area are then linked to individual demographic records for precise, rather than estimated, data on fertility, morbidity, mortality and migration.[8] Research findings and interventions that have emerged from DHS in the decades since World War Two include the development of oral rehydration solution; vaccine efficacy trials for measles, cholera and tetanus; an understanding of the relationship between cessation of breast-feeding and malnutrition; and data on the effects of environmental alteration on human health.[7,9] Because DHS study sites are typically chosen for their high rates of infectious disease or their fertility patterns,[8] the interventions and findings that are associated with DHS have direct impact on the health and wellbeing of the populations under study.

Such findings are the primary justification for the intense monitoring associated with DHS. The utility to public health of surveillance data and health interventions that benefit both the local community and global populations is weighed against potential risks to individuals.[4] Such considerations of individual risk versus community benefit, commonly found in medical and research ethics, are in the DHS context rendered more complex by the ambiguous position of surveillance, which transcends traditional distinctions between research, care and monitoring. While the potential for DHS data to increase global health equity and local public health is genuine, the ethical pitfalls associated with decades-long, intense DHS should not be overlooked or go unaddressed.

Current regulatory framework

Balancing general welfare and individual rights is the backbone of ethical regulations regarding the use of human subjects in research. The principles of respect for persons, beneficence and justice outlined in the 1979 Belmont Report are broad categories designed to guide researchers in their selection and treatment of human subjects.[10] The

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Belmont Report differentiates between medical practice and research but no provision is made for surveillance. Surveillance spans practice and research, neither providing treatment for the benefit of individuals nor hypothesis testing. Activities accompanying DHS, such as provision of medical care or vaccine trials, clearly fall into the two categories of practice and research, but what about surveillance?

Helping researchers navigate the ethical issues arising in longitudinal DHS systems is the guidance issued by the Council for International Organizations of Medical Sciences (CIOMS) and the recommendations developed by the International Network of field sites with continuous Demographic Evaluation of Populations and Their Health (INDEPTH), along with the activities of individual ethics committees and institutional review boards. CIOMS's newly developed epidemiology guidelines address observational or other studies that take place at a community or population level, but suggest that standards applied to biomedical research emphasizing individual-level, informed and culturally-sensitive consent are also largely applicable in epidemiological research.[11] The INDEPTH Network is a member organization of 37 DHS systems worldwide, located in 19 countries and representing a monitored population of over 2.5 million.[12] Chartered in 1998 in recognition of both the great potential of DHS systems and the difficulty in situating DHS within broader ethical and regulatory frameworks, one of INDEPTH's primary goals is to facilitate results and best-practice exchange between longitudinal population surveillance systems.[13]

A portion of INDEPTH's capacity-building programme involves providing training documents for parties interested in initiating or improving an ongoing study. INDEPTH recommends that any parties interested in starting a DHS need to establish three committees: a scientific advisory committee, a management committee and an institutional review board.[14] In addition to these guidelines, INDEPTH has formed an ethical practice working group to explore and address the ethical difficulties associated with surveillance activities.[6] However, aside from these resources, in general a regulatory vacuum remains in regard to longitudinal surveillance systems that is further compounded by a lack of attention to this domain in current bioethics, research ethics and public-health ethics literature. In this paper, we aim to contribute to an ethics of longitudinal health surveillance by briefly exploring three key ethical challenges that arise during the creation, maintenance and conclusion of longitudinal DHS systems and that are closely associated with the fundamental ethical principles of beneficence, respect for persons and justice: provision of health care, informed consent and surveillance system sustainability. As we will indicate, many of the problems faced by DHS involve conflicts between these three ethical principles.

Beneficence and health-care provision

While the provision of health care falls under the ethical obligations of practice, in the case of DHS systems it is complicated by its entanglement with ongoing surveillance activities. Many DHS are affiliated with local health-care organizations,[6] and some operate their own medical facilities, such as the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) Matlab DHS.[15] Though some health facilities predate the DHS activities, the link between provision of care and surveillance can be ethically problematic. How can a DHS do no harm, maximize benefits and minimize risks to the study population in regards to health-care provision?

If health care is associated with the DHS, decisions must be made regarding whether to treat only the diseases of focus and whether to treat only study participants. In the treatment of diseases that constitute the primary focus of the DHS systems, such as diarrhoeal diseases in the ICDDR,B Matlab study[15] or HIV/AIDS in the Rakai, Uganda DHS,[16] providers must strike a balance between caring for the population under surveillance while not overly impacting the topic of study. While providing treatment for individuals is a less ethically problematic option, since their conditions have been identified and recorded, non-interventionist observation may produce data that could improve population health.[4] In this sense, DHS often face ethical conflicts between short- and long-term beneficence. For example, in the case of Matlab, the incidence of diarrhoeal diseases has drastically declined since the initiation of care under the DHS auspices.[17] While improvement of local population health is certainly a goal of DHS systems, declining incidence of events of interest means less data and less information on patterns that could be occurring in untreated areas elsewhere in the country. When the justification for intense longitudinal surveillance is the reliability of information on health and demographic patterns, changes in the study area that are not mirrored in the surrounding area can threaten the reason for existence of a DHS.

In addition to providing treatment for topics of DHS interest, decisions must also be made concerning the provision of ancillary care. Ancillary care is defined as "positive obligations to provide care that participants need, but that is required neither to successfully answer the researchers' scientific question nor to avoid or mitigate harm resulting from participation in the research."[18] In the majority of DHS sites, levels of health need are high and therefore the question of whether ancillary care should be provided arises continually. Belsky & Richardson[19] argue that the extent of ancillary care provided ought to be dependent on several factors, including participant vulnerability and the duration of the relationship, and that funding for ancillary treatment should be built into initial budgets. From this perspective, the obligation to provide ancillary care on the part of surveillance agencies would seem to be very substantial since they monitor the health of poor and unhealthy communities for decades. DHS budgets would have to be increased substantially to meet the demand for ancillary care, raising the vexing question of where the responsibility of DHS ends and that of the local health-care system begins. Increasing the DHS budget for ancillary care also raises questions of justice if the DHS surveillance population receives substantially better health care than the general population.

In addition to the issues regarding whether and to what extent ancillary health care should be provided by DHS, the question of "who to treat" raises ethical and economic dilemmas.

Although DHS confine their data collection to specific communities, disease does not respect such boundaries. Social networks that extend past DHS boundaries or infectious agents that move through the environment make study borders arbitrary. Some DHS, such as ICDDR,B's Matlab, provide free treatment for a range of conditions to anyone who requests it, but only those patients who are DHS participants have their health records linked to their demographic information.

Respect for persons and informed consent

Stringent requirements for voluntary informed consent have been developed to protect the autonomy of human subjects in research activities, and the close interaction between surveillance systems' individual-level data collection and associated research studies makes the process of consent appropriate with DHS participants. However, the complications in the consent process specific to surveillance activities – related to conception of autonomy, the position of individuals within households and communities, and the multigenerational nature of longitudinal surveillance – have received only slight attention in the surveillance ethics literature.

For example, full community participation is essential to DHS since surveillance is only effective when the entire population is monitored and accurate information on demographic and health patterns can be gathered.[20] However, this need for total cooperation can threaten the ability of individuals or households to make truly autonomous opt-in decisions. It is conceivable that those who have already agreed to participate in surveillance will regard other households expressing reluctance as threats to the possibility of free health-care provision or other community-accrued benefits. A DHS must find acceptable strategies to alleviate tension among community members who disagree over the proposed surveillance.

Where data collection structures are often organized at three levels: the residential unit, the household and the individual, concerns are raised over who precisely is consenting to participation.[6] Does consent need to be obtained from every individual, or every household, or will residential unit suffice? Community consent to participate is often the first step in choosing the site of a DHS: if there is no community agreement to take part in surveillance then another location must be found. But community consent is far from sufficient given the intense scrutiny of the DHS on individual and household lives. Is consent at the household level adequately respectful of individual autonomy? While household-level consent would likely be rejected in surveillance studies held in developed countries, the location of DHS in developing countries (where values of autonomy may be partly or not at all present) could make this a feasible alternative to individually obtaining consent from thousands or tens of thousands of residents. But is it ethical for a male head of household to consent for his entire family to participate in surveillance? And would choosing household over individual consent express cultural sensitivity or "ethical double standards"?

In addition to questions of individual versus household consent, duration of consent raises ethical questions unique to surveillance systems. While research protocols typically outline a specific start and end point for consenting activities or sample usage, demographic and health surveillance can continue for decades. DHS administrators must consider whether previously obtained consent counts as consent for future members of the household. For instance, in studies initiated in the 1960s with continuous household participation (e.g. the Niakhar, Senegal DHS),[21] does the consent of a grandfather extend to his children and grandchildren even if they were not alive at the time the study began? Although central to research ethics, re-obtaining consent from households annually would likely be too expensive and time consuming for DHS administrators. Obtaining consent from successive generations could be feasible and protective of DHS participants, though questions remain concerning when to ask new generations for consent (e.g. in adolescence or age of majority). Furthermore, even if given the option of opting-out of surveillance, it is possible that individuals whose households and community have participated for years might not feel that leaving the DHS is a legitimate decision.

A further, related complication to the consent process in DHS is that, over time, the division between research and treatment may be blurred in the mind of participants who do not distinguish between the DHS as a care/surveillance organization and the DHS as a research entity. The INDEPTH Network advises that when approaching a community as a possible site for a DHS, community members must be alerted that they "might be called upon from time to time to assist carrying out certain [research] activities" beyond the scope of surveillance.[14] While DHS participants are always asked to consent to a research protocol, it is conceivable that DHS with adults who were raised entirely within the surveillance period could feel that any requests from DHS personnel are legitimate or obligatory. Researchers working with DHS populations must strive, perhaps more than during other kinds of health research, to develop approaches that balance autonomy and beneficence, i.e. provide adequate assurance of voluntary and autonomous participation without negative repercussions on access to study benefits.

Justice and study sustainability

Changes to or dissolution of a surveillance system raise issues of justice, pertaining particularly to the continuation of care or other benefits afforded by surveillance participation. While DHS boundaries are determined at study onset, what happens if a DHS decides to shrink the study area? Will health care and other benefits still be provided to DHS "alumni" who have been phased out? In the case of DHS that provide health care regardless of participation status, shrinking study boundaries will have little to no effect on benefits afforded to former participants. However, in DHS systems that do not provide health services to non-study populations, should former survey participants receive study benefits when they are no longer providing personal information? Consent to participate in DHS does not usually delineate a specific timeframe of benefits received. Although few studies mention during surveillance initiation what will happen at the end of the process, perhaps the ethical course for DHS administrators would be to advise prospective participants

about what they can expect if or when the DHS no longer requires their participation.

Issues of study sustainability pertain not only to decreasing survey boundaries but also to ethical obligations when a DHS ends surveillance. While DHS foci of infectious disease, malnutrition and maternal health are unlikely to vanish soon, it is entirely possible that DHS funding will disappear or that a DHS will decide to move locations because health patterns have substantially changed in the current location. In such cases, does the DHS have an ethical obligation to provide health care even when it is no longer collecting data from a population? Or do the benefits a community has already accrued, such as prior health care, increased health education, worker training, or improved infrastructure, constitute a mutual exchange that renders a DHS free from future obligation, as suggested by the "fair benefits" framework?[22] Analyses of these problems from a research standpoint (particularly in terms of HIV/AIDS research) have concluded that guaranteed post-study treatment, as reciprocity for participation, does not resolve the problem because one population can still be unfairly privileged over another.[23] Perhaps, in the case of DHS, if the surveillance and care networks remain in place the best option would be to work with the Ministry of Health to gradually turn these services over to the local or national government. However, this requires an active and participatory national government with funding to continue providing services, a tall order in many resource-strapped developing countries.

Conclusion

While longitudinal DHS systems focusing on small, well-defined communities can provide invaluable information on health patterns and behaviours,[2] their need for the intense study of specific populations raises many ethical questions. While we have addressed some of those questions that relate to the provision of care in DHS, to the informed consent process and to changes in study activities, many more remain. Balancing risks and benefits to research participants and communities is typically a delicate task but the addition of long-term surveillance activities adds another level of complexity. While current DHS utilize ethics committees to review research activities taking place among study populations, there are also serious ethical questions that are raised by the initiation, maintenance and conclusion of surveillance: processes that are not necessarily considered under standard ethical review. Perhaps there is a need for a supranational organization, distinct from institutions such as CIOMS, dedicated to advising and regulating ethical aspects of population-based surveillance. Though each DHS site would have ethical questions specific to local populations and surveillance foci, overarching questions related to beneficence, respect for persons and justice as outlined in this paper would be applicable across sites. However, in the interim, the need for accurate data to assess health interventions and the needs of general populations over the rights of individuals do not exempt demographic and health surveillance from facing difficult ethical questions and protecting the dignity and safety of participants. ■

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Résumé

Surveillance démographique et sanitaire : considérations éthiques longitudinales

Combinées à des données démographiques détaillées, les données longitudinales recueillies par la surveillance sanitaire peuvent donner un aperçu extrêmement précieux des résultats sanitaires. Il existe de nombreux sites assurant une telle surveillance dans le monde en développement, notamment en Asie et en Afrique subsaharienne, qui se focalisent sur des maladies comme le VIH/sida, le choléra, le paludisme ou la tuberculose. La position floue de ces systèmes de surveillance, souvent à cheval entre la recherche, le traitement et la surveillance sanitaire des populations, fait que les besoins et les responsabilités en matière de surveillance éthique sont peu clairs. Ce vide réglementaire est en outre aggravé par un manque d'intérêt pour les systèmes de surveillance longitudinale dans la littérature consacrée à l'éthique. Nous explorons dans cet article certaines questions éthiques essentielles, soulevées par la surveillance démographique et sanitaire en relation avec les principes éthiques de bienveillance, de respect des personnes et de justice, à savoir : la dispensation de soins de santé, le consentement éclairé et la durabilité des études.

Resumen

Consideraciones éticas en los sistemas longitudinales de vigilancia demográfica y sanitaria

Los datos longitudinales aportados por la vigilancia sanitaria, cuando se combinan con datos demográficos detallados, pueden ofrecer una información inestimable sobre la evolución de las enfermedades. En el mundo en desarrollo, sobre todo en Asia y el África subsahariana, hay muchos sitios de vigilancia centrados en enfermedades como el VIH/SIDA, el cólera, la malaria y la tuberculosis. La función poco definida de esos sistemas de vigilancia, en los que se solapan con frecuencia la investigación, el tratamiento y la vigilancia sanitaria de la población, lleva parejo un dudoso reconocimiento de la necesidad de una labor de supervisión ética y de la responsabilidad de tal labor. Ese vacío normativo se ve agravado por la indiferencia mostrada hacia los sistemas de vigilancia longitudinal en las publicaciones sobre ética. En el presente artículo se analizan algunas cuestiones éticas relevantes que plantean la vigilancia demográfica y sanitaria en relación con los principios éticos de beneficencia, respeto a las personas y justicia: prestación de atención sanitaria, consentimiento informado y sostenibilidad de los estudios.

ملخص

الترصُّد الديمغرافي والصحي: اعتبارات أخلاقية طولانية

من شأن الجمع بين البيانات الطولانية الناتجة عن الترصُّد الصحي وبين المعلومات الديمغرافية المفصَّلة، أن يقدم أفكارا قيِّمة حول الحصائل المرضية. ويوجد في العالم النامي العديد من مواقع الترصُّد هذه، ولاسيَّما في آسيا وبلدان أفريقيا جنوب الصحراء، وهي تركِّز على أمراض مثل الإيدز والعدوى بفيروسه، والكوليرا، والملاريا، والسل. أما الوضع المبهم لنُظُم الترصُّد هذه، والتي عادةً ما تشغل مجالاً بين البحوث والمعالجة ورصد صحة السكان، فيعني أن الحاجة إلى الرقابة الأخلاقية والمسؤولية عنها غير واضحة. ويتفاقم هذا الفراغ التنظيمي أكثر فأكثر من جراء نقص الاهتمام بنُظُم الترصُّد الطولانية في الدراسات المنشورة حول الضوابط الأخلاقية. ويستطلع الباحثون في هذه الورقة بعض المسائل الأخلاقية الرئيسية التي تنشأ أثناء الترصُّد الديمغرافي والصحي في ما يتعلَّق بالمبادئ الأخلاقية للخير، واحترام الأشخاص، والعدالة: تقديم الرعاية الصحية، والموافقة المستنيرة المرتكزة على علم واطِّلاع، واستمرارية الدراسة.

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