Should secondary use of medical data for research be allowed in small nation countries?

Deborah Stijnberg, MD, PhD

Suriname, a country with about half a million inhabitants, has been collecting data for public health surveillance for many years. Incidences of infectious diseases like HIV, tuberculosis, and malaria are reported to the Suriname Ministry of Health. This information is not only being used for reporting purposes but also for tracking clinical treatment and care. This surveillance data is entered electronically, and these surveillance databases often contain individual demographic and clinical information spanning a decade or more. Due to increased clinical reporting requirements, most surveillance data are now collecting individual information from everyone diagnosed with the disease under surveillance. This creates a wealth of readily available medical information that could be used for different purposes, including research projects. This paper examines the ethical dimensions and possible risks and benefits to answer the question if this data should be made accessible for research purposes. I argue that these surveillance data—and other electronic health data - should be made available for research, with emphasis on facilitating access to surveillance databases for Surinamese researchers. Enforceable ethical safeguards must be in place to ensure that benefits of research using these databases do not breach important ethical principles such as respect for autonomy and privacy and social justice.

Surinamese medical data landscape

The Suriname Ministry of Health collects individual-level data on disease diagnoses, diagnostic lab results, treatment, and clinical outcomes. Data are entered and stored electronically. Different databases have been developed for different infectious diseases, namely HIV, tuberculosis, and malaria. Due to increased reporting requirements meant to aid clinical follow-up, additional personal information for example sex, ethnicity, address, are collected. Public and private healthcare institutions also have data that they collect electronically such as hospital admissions, outreach work with vulnerable populations, HIV testing etc.

These data are collected during a process of providing treatment and care services for different diseases and reported to the government regardless the point of care. Figure 1 depicts the HIV data collection system as an example. People go to the different healthcare institutions for services e.g., private and public testing sites and laboratories for diagnostics, clinics for treatment and care, etc. At that point information is either paper-based or electronically shared with the central government data system. Similar processes occur for other diseases e.g., tuberculosis, malaria.

Suriname, like many developing countries in South and Central America, follows the Pan American Health Organization (PAHO) guidance for the implementation of Electronic Patient Dossiers (EPD). The guidance recommends EPD systems that facilitate information sharing between health

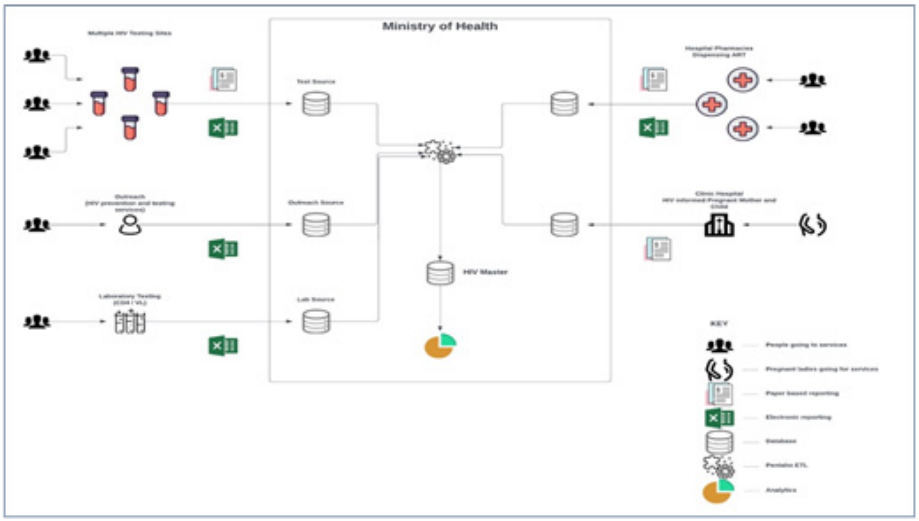

Figure 1. Schematic overview of Suriname's HIV surveillance system

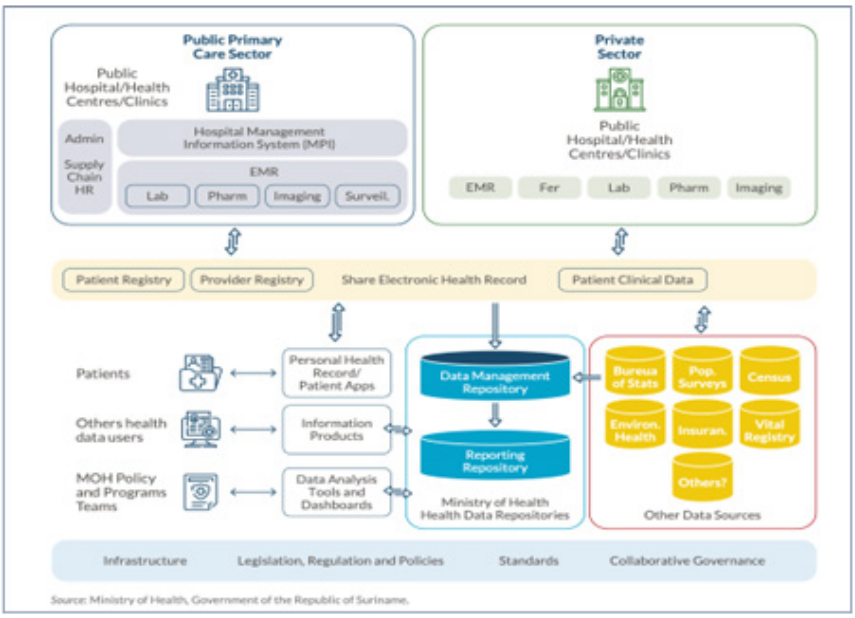

Figure 2. Conceptual digital health structure
Figure 2: Ministry of Health, Government of the Republic of Suriname (1)

care systems as well as with the Ministry of Health. The government is now talking to different stakeholders to develop a national health information system that would combine different data sources—including government-housed infectious disease databases and clinical EPD databases—into one centralized system.

The goal of putting these data together is to improve clinical decision-making and public health policymaking. This requires the sharing of these electronically available data with policymakers, healthcare providers, and researchers. In the following sections benefits and risks in sharing of this data specifically for research, are evaluated. First consideration is given to the beneficial intent of public health surveillance and data produced in clinical care, the benefits for the research community and the community in general. Benefits must be pursued while being cognizant of autonomy, confidentiality and privacy issues of people and their data, especially in small country like Suriname. Implementing international guidance on the secondary use of data would safeguard ethical use of these data for research purposes.

Benefits of data from public health surveillance and clinical information systems

The collection of medical information has a long history within public health surveillance systems. Public health surveillance is the continuous, systematic collection, analysis, and interpretation of health-related data. Many governments, including those of small countries, have invested in setting up systems for collecting information to promote evidence-based interventions and policies. Public health surveillance facilitates early recognition of public health emergencies, evaluation of public health interventions' impact, monitoring the epidemiology of conditions, and ultimately informing public health policies and interventions. Additionally, setting up information systems are a means to improve healthcare delivery and access to services.

These data sources create big volumes of data which allows secondary use to identify inefficiencies in healthcare delivery but also notice patterns in care. This can lead to for example mitigation of preventable readmissions and can support preventive measures. Furthermore patient safety issues, pharmacovigilance and appropriate medicine use can be identified. There is even report of secondary use of medical data for professional development, highlighting that analysis of these data by health professionals can lead to clinical improvement and teaching moments.

With these beneficial outcomes for public health and individuals, it is not strange that organizations as PAHO and WHO defend the secondary use of medical information collected at points of care and urge the implementation of electronic data systems.

Growing research interest in Suriname

Historically, research in Suriname was primarily initiated by researchers coming from other countries, especially developed countries. But there is a growing interest among Surinamese people to conduct their own research, with many Surinamese people now aspiring to complete a PhD and pursue a career involving research and implementation science. As is the case in many developing countries, primary data collection often is too expensive for aspiring or new PhDs. this explains in part the increased interest in secondary use of existing electronic data sources to answer research questions. Previous literature indeed identified the growing availability of electronic medical data as facilitating research, and even as an option to replace setting up expensive clinical trials. Furthermore, like many developing countries, Suriname invests very little in government-sponsored research. Secondary use research is much less expensive than research involving novel data collection. Suriname has one national research ethics committee for review of research with human subjects. I know as a member of that committee that each year there are more requests for research uses of data from public health surveillance or EPD databases within healthcare institutions. Of course, encouraging research culture and empowering local researchers could be beneficial for public health outcomes. Local researchers have closer proximity to the community, and they know the context better for interpretation and understanding of results to the local context. On the other hand, with a small population, granting access to a group of researchers, especially inexperienced ones, people's identity could be revealed, and health information misused.

While looking out for their own interests, researchers and those tasked with research oversight have the obligation to uphold the ethical guides attached to doing research with humans or about humans as in cases where individual level data are queried. Values as beneficence, proportionality, and specifically respect for persons should guide decision-making. Scientists also have the obligation to consider societal benefit, meaning proposing research that would benefit the community. This while not losing sight of things like participants' privacy, confidentiality, and autonomy to decide whether to participate in research or authorize research uses of their personal health information. With secondary use of data for research, these principles still stand and academic rigor in design and analysis are still key requirements to guarantee internal and external validity.

My data, my decision

Very important stakeholders in this issue of secondary use of medical information, are of course the people whose data are being captured and stored in public health surveillance and EPD databases.

Normally when participating in research, the goals, methodology, use of data is explained extensively, and persons can give consent if in agreement. In the case of public health surveillance data, people are often not even aware that their data are captured electronically and stored in the government's databases. Patients in a healthcare institution are unlikely to be aware that their EPD data may be made available for research purposes. For individuals in small nations, confidentiality and privacy are even bigger issues to consider than in larger populations; as the saying goes "everyone knows everyone." The data are collected during a process of regular treatment and care for a certain disease, so information was given by persons to a healthcare worker in confidence with the implicit understanding that it would not be shared with third parties. This is still a main ethical principle in medical practice. Maintaining confidentiality respects people's autonomy as they decide what and with whom their personal information can be shared. People are free to decide what details of their life they want to remain private. A breach of confidentiality and a loss of privacy can easily result in recognition which may result in social, physical, or emotional harm. This is perhaps a bigger risk in small nations, where it is more likely that people engaged in research have some connection to the individuals contained in public health surveillance and EPD databases. In Suriname, the population size is small, and people easily recognize or know each other, in urban and even more in rural areas. People even know each other's car license plate and can tell where and when they saw your car. We see this familiarity even expanding to people from Surinamese origin living abroad with cases where someone comes to the hospital for care, is recognized and family in the Netherlands find out, while family living in Suriname is not even aware of the hospital admission. So, guaranteeing confidentiality is a challenge.

Considering threats to privacy in small nation countries, willingness of the community to share and link their health data is a key issue to discuss when talking about secondary use of medical data. Perceptions about data-sharing among people living in the Caribbean region are not known but studies of people in other countries found an acceptance of sharing of medical data (5). This for the common good of the society. They also recognize that availability and use of electronic information could lead to improved quality of care and health outcomes. Still, concerns such as confidentiality, misuse, and control over their own data, were raised. They didn't want certain groups such as family members, insurance companies, private pharmaceutical companies and academic researchers viewing their data. On the other hand they were more inclined to share data for regional research. This seems to imply a preference for the individual benefits of health information system but somehow still a fear for privacy breach when local researchers get access to their information. Efforts should be made to understand Surinamese perspectives on secondary use of data for research, and to incorporate those into governance of these data.

Ethical safeguards on secondary use of public health surveillance and clinical data

Different ethical issues have already been mentioned when reviewing the secondary use of electronically available medical information for research. The benefits of facilitating use of public health surveillance and clinical data for research have been established. Potential positive outcomes include improvement in health outcomes as result of research and clinical implantation of findings, educational benefit for Surinamese researchers, and evidence-based public health policymaking and planning.

As previously mentioned, pursuit of these benefits must not breach other essential ethical commitments, such as respecting privacy and maintaining confidentiality. Individual values such as autonomy, privacy and individual rights should not be overlooked. For example, ethical safeguards should attend to the process of informed consent or the possibility of a waiver of consent. The consent process is an important ethical guideline when doing research with human subjects. It is the responsibility of researchers to obtain informed consent from potential participants. The main elements of this process are voluntariness, disclosure of relevant information, and comprehension; informed consent should be obtained in an environment free from coercion and without undue influence. With electronically available data, collected either in the context of clinical practice or as part of public health surveillance, consent in using this data for research is an issue. Council for International Organizations of Medical Sciences (CIOMS) mentions in guideline 11 that data collected in routine clinical care can be used for research if it was collected under an opt-out procedure. The

opt-out procedure is adhered to when persons are informed about the possibility that their information can be used for other purposes and are given the opportunity to explicitly object. Participants should be able to withdraw their data at any point in time. Contrary, the CIOMS guidelines 10 and 12 state that in the case of mandatory population-based registries, such as seen with tuberculosis, HIV and malaria surveillance in Suriname, this option of withdrawal is not relevant. If opt-out informed consent is not in place, the research, should be reviewed by a Research Ethics Committee (REC). They can then consider granting a waiver of informed consent if the following requirements are fulfilled:

- The research is not feasible or practicable without the waiver.
- The research has important social value.
- The research poses no more than minimal risk for participants.

Agencies in Suriname interested in making electronic health data available for research uses should consult with the country's REC to develop standards by which waivers of consent to use previously collected data will be granted. Looking forward, the opt-out informed procedures should be widely discussed among stakeholders, especially patients. From the start it should be clear that personal health data could be used for other purpose.

Agencies holding data must put in place technological systems to secure and share data to maintain confidentiality. The WHO guidelines on ethical issues in public health surveillance addresses security and recommends that the owners or stewards of these data put in place operational and technical safeguards to protect from unauthorized access or disclosure. This also means regulating access to information and deidentification if data is being shared for research purposes.

Another ethical issue to consider is social justice. Social justice for health data can be defined as equitable opportunities for access and use of these data among researchers and equitably distributed benefit from health research so that people who have contributed data achieve a higher standard of health and wellbeing because of health research catalyzed by secondary use of their data. Thinking about researchers, this means the processes to utilize and access health data should be transparent and fairly applied. It might also mean limiting some uses of the data to Surinamese researchers or Surinamese-led teams of health researchers and being on guard for potential exploitation of Suriname from external research entities. From the side of the community, it should mean that the use of the data should be beneficial to all and not exuberate already existing health inequalities. Special attention should be paid to making sure the databases are representative of the Surinamese population.

WHO ethical guideline for public health surveillance, emphasizes the secondary use for research purposes when it serves the common good; this with ethical oversight, anonymization of data, data security and clear agreement over data use, re-sharing, acknowledgements, destruction and ultimately sharing of findings afterwards. This approach reiterates the importance of accountability when allowing secondary use of data. Both WHO ethical guidelines as CIOMS guideline 24 emphasize that findings of studies should be made readily and widely available.

Conclusions

Setting up systems that allow the electronic availability of medical information for research purposes could benefit both clinical care and public health outcomes. Especially in developing small nation countries the secondary use of this medical information holds significant potential for improving healthcare delivery and health outcomes, since the research budgets of these countries do not permit significant primary data collection. So, with beneficence and looking at the common good, the secondary use of electronic medical information is justified. However, as noted, competing ethical values like respect for autonomy and privacy must be considered to ensure ethical use. Protecting patient privacy, maintaining social justice, ensuring scientific and social values, and putting in place robust ethical governance structures are requirements for the ethical secondary use of these data for research. For example, making sure that the data shared with researchers are de-identified. This may mean using codes to identify unique individuals, and that if individual-level data across databases must be linked, this is done by the daily executors of the databases.

Small nations like Suriname have an interest in research initiatives aimed at improving healthcare outcomes, reducing health disparities, and addressing local public health needs. Secondary use of electronic public health surveillance and clinical data may advance these aims. Small nations should take steps to enact and enforce the types of safeguards mentioned in this paper and in international guidance to facilitate ethical secondary use research.