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APPLICATION OF ETHICAL PRINCIPLES TO RESEARCH USING PUBLIC HEALTH DATA IN THE GLOBAL SOUTH: PERSPECTIVES FROM AFRICA

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ABSTRACT

Existing ethics guidelines, influential literature and policies on ethical research generally focus on real-time data collection from humans. They enforce individual rights and liberties, thereby lowering need for aggregate protections. Although dependable, emerging public health research paradigms like research using public health data (RUPD) raise new challenges to their application. Unlike traditional research, RUPD is population-based, aligned to public health activities, and often reliant on pre-collected longitudinal data. These characteristics, when considered in relation to the generally lower protective ethico-legal frameworks of the Global South, including Africa, highlight ethical gaps. Health and demographic surveillance systems are examples of public health programs that accommodate RUPD in these contexts. We set out to explore the perspectives of professionals with a working knowledge of these systems to determine practical ways of appropriating the foundational principles of health research to advance the ever growing opportunities in RUPD. We present their perspectives and in relation to the literature and our ethical analysis, make context relevant recommendations. We further argue for the development of a framework founded on the discussions and recommendations as a minimum base for achieving optimal ethics for optimal RUPD in the Global South.

INTRODUCTION

Global health thrives on large scale population health information and research which have changed considerably in volume and nature.[1] In the Global North, national health data is generally available from government implemented vital registration systems.[2] In the Global South or South, that is developing countries which are located primarily in the southern hemisphere[3] and particularly in Africa, conducting such surveys is often constrained by inadequate resources.[4] Instead, smaller scale household surveys are used to report nationally representative data for public health.[5] The health and demographic surveillance system (HDSS) is one such

[1] Largent EA. Recently proposed changes to legal and ethical guidelines governing human subjects research. *J Law Biosci* Advance Access published 6 Feb 2016. doi:10.1093/jlb/lsw001; Sankoh O. CHESS: an innovative concept for a new generation of population surveillance. *Lancet Diabetes Endocrinol* 2015; Editorial.

[2] Bayer R & Fairchild A. Ethical Issues to be Considered in Second Generation Surveillance. *WHO* 2004

[3] United Nations Development Programme (UNDP). *South-South Cooperation.* New York, NY: UNDP. Available at: http://ssc.undp.org/content/dam/ssc/documents/exhibition_triangular/SSCExPoster1.pdf [Accessed 14 Nov 2016].

[4] Demographic and Health Surveys Program (DHS). 2016. *Demographic and Health Surveys*. Available at: http://dhsprogram.com/ [Accessed 14 Nov 2016]; Sankoh O & Byass P. The INDEPTH Network: Filling Vital Gaps in Global Epidemiology. *Int J Epidemiol* 2012; 41:579-88; International Network for the Demographic Evaluation of Populations and their Health (INDEPTH). 2016. *About us*. Accra: INDEPTH. Available at: http://www.indepth-network.org/about-us [Accessed 14 Nov 2016].

[5] DHS, *op. cit.* note 4.

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framework for collecting, storing, and managing otherwise difficult to obtain public health data. HDSS data is longitudinal and permanently connected to its population. This enables population-based retrospective investigations or the nesting of prospective research into ongoing data collection.[6] In this paper, such systematic investigations designed to develop or contribute to generalizable knowledge[7] and incorporated into the HDSS or extracted from its pre-collected database are referred to as research using public health data (RUPD).

Research ethics has largely been shaped by principles, four of which are espoused in the framework of principlism:[8] respect for persons (study participants and communities), beneficence, non-maleficence, and justice. These principles are contained in a range of international codes, national legislation, and regulations that have effectively guided research for decades.[9] Unlike traditional health research, RUPD's public health dimension, sheer numbers involved due to its population based characteristic, and its database methodology make pursuit of these principles less straight-forward. Scholars and ethicists have argued for waivers on the basis of 'impracticality'[10] while some have suggested reliance on ethics review and opt-out options (where feasible) as adequate ethical safeguards.[11] There is ongoing debate on whether these proposals are the best mechanisms for similar research.[12] The debate is particularly important for the South and Africa in particular, where protective ethico-legal frameworks and levels of individual awareness about rights and abilities to exercise them are generally at developmental stages.[13] Hence, arguments for abandoning proven principles that have safeguarded populations in the name of optimizing science may hold less tightly in this context. We conducted a survey involving professionals with a working knowledge of the HDSS and RUPD, mostly in Africa to (a) explore their perceptions, attitudes, and practices towards the implementation of basic ethical principles; (b) determine practical ways of optimizing the implementation of the principles; and (c) consider the results in relation to the literature to make context relevant recommendations.

Household surveys in the Global South

Household surveys are commonly carried out in place of national level registries to support public health activities and research. Two of the most notable organizations that undertake such surveys are the USAID which is responsible for the Demographic and Health Survey program[14] and the International Network for the Demographic Evaluation of Populations and their Health (INDEPTH),[15] involved with the HDSS framework. This paper focuses on the latter as an example of a public health program that accommodates RUPD in the South.

The HDSS and INDEPTH

The HDSS concept started in the 1940s and 1960s in South Africa and Senegal respectively.[16] The system involves house-to-house data collection from whole communities on annual, biannual, or quarterly basis. Apart from the core data on births, deaths, migration, marital status changes, social, and economic indicators,[17] they may conduct assessment of health service effectiveness, mortality, and morbidity surveillance.[18] The data are thus used to analyze the population's health, inform public health decisions, and support the conduct of research.[19] HDSSs generally operate under domestic law[20] and regulatory institutions like the research ethics committee (REC).

INDEPTH was established in 1998 to develop a network of HDSSs, unify them, help them tackle the technical challenges associated with the complexity and dynamic nature of their databases,[21] and conduct research using their data.[22] With a current number of 43 members, the Network collectively observes an estimated 3.5 million people in 20

[6] Sankoh, *op. cit.* note 1; Levira F, Hildon Z, Smithson P & Masanja, H. 2014. Health and *Demographic Surveillance System Report 2000–2011*. Dar-es Salaam: Ifakara Health Institutes.

[7] South African Medical Research Council (SAMRC). 2007. *Guidelines on ethics for medical research: General principles.* Pretoria.; Department of Health and Human Services (DHHS). 2009. *Code of Federal Regulations: Title 45 Part 46*. Human Research Protections. Available at: http://www.hhs.gov/ohrp/humansubjects/commonrule. [Accessed 14 Nov 2016]

[8] Beauchamp TL & Childress JF. 2001. *Principles of Biomedical Ethics*. 5ed. New York: Oxford University Press; Rothstein MA. Ethical Issues in Big Data Health Research. *Law, Medicine and Ethics* 2015; 43(2):425–9.

[9] Largent, *op. cit.* note 1. Rothstein, *op. cit.* note 8.

[10] Sim J & Dawson A. Informed consent and cluster-randomized trials. *Am J Public Health* 2012; 102 (3):480–5; Council for International Organizations of Medical Sciences (CIOMS). 2008. *International Ethical Guidelines for Epidemiological Studies*. Geneva: 2008; Elger BS. 2010. *Ethical Issues of Human Genetic Databases: A Challenge to Classical Health Research Ethics*? Surrey: Ashgate.

[11] CIOMS, Ibid.; Elger, Ibid.; Bull S et al. Best Practices for Ethical Sharing of Individual-Level Health Research Data from Low- and Middle-Income Settings. *J Empir Res Hum Res Ethics* 2015;10 302–13.

[12] Rothstein, *op. cit.* note 8; Largent, *op. cit.* note 1.

[13] Bull et al., *op. cit.* note 11; Emanuel EJ et al. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis.* 2004;189(5):930–7.

[14] DHS, *op. cit.* note 4.

[15] Yazoume Y et al. Health and Demographic Surveillance Systems: A Step towards Full Civil Registration and Vital Statistics System in Sub-Sahara Africa? BMC Public Health 2012; 12(741):11.

[16] Yazoume et al., *op. cit.* note 15.

[17] Levira et al., *op. cit.* note 6.

[18] Sankoh, *op. cit.* note 1.

[19] Levira et al., *op. cit.* note 6; Yazoume, *op. cit.* note 15.

[20] Public Health Ontario. 2012. *A framework for the ethical conduct of public health initiatives*. Ontario: Public Health Ontario. Ontario, Canada: Public Health Ontario.

[21] Sankoh O & IJsselmuiden C. Sharing Research Data to Improve Public Health: A Perspective from the Global South. The Lancet. Available at: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2961211-7/fulltext [Accessed 14 Nov 2016].

[22] Sankoh, *op. cit.* note 1; Levira et al., *op. cit.* note 6.

countries across Africa, Asia, and Oceania.[23] New technological and analytical advances have opened immense possibilities for HDSSs to generate unbiased empirical data that is essential for developing and assessing interventions[24] while contributing to scientific productivity[25] like RUPD. INDEPTH has several innovative programs. Its latest concept, the Comprehensive Health and Epidemiological Surveillance System, is for instance planned to integrate population and health facility data systems that will link demographic, epidemiological, mortality, morbidity, clinical, and household data among others with a unique electronic individual identification system[26] in the future. The HDSS thus offers an effective alternative for testing new hypotheses through RUPD without the rigors of starting research from scratch. Although RUPD can be smoothly incorporated into HDSS activities and be recognized for its role in the promotion of public health, it remains research. There is therefore a need to optimize the implementation of ethics in the interest of participants and communities.

Contextual issues surrounding RUPD and public health ethics

For many communities in the South, the protection and awareness of individual rights and liberties that support international research ethics implementation may be limited, unknown or undesired.[27] This is due to differing perceptions and interpretations of essential values that form the basis of international ethical deliberation, as well as cultural practices which are more communal.[28] Ethical frameworks in these contexts are generally not fully developed and regulatory authorities including RECs are limited in numbers.[29] General protections instituted through national constitutions and awareness creation about human rights and individual liberties[30] that spur ethical developments are also generally low.

Concerning design, the connectedness of RUPD to core HDSS activities which have direct public health ends makes it difficult to balance research ethics and public health ethics principles. Applying the former privileges individuals over the public[31] and the latter does the opposite.[32] One can either safeguard the implementation of protections at the broader population level or for the individual. For an appropriate balance, scholars have suggested to focus on principles or issues of confidentiality and privacy, data ownership, data sharing and integrity,[33] transparency, trust, accountability, openness, and global justice.[34] Issues surrounding the underexploited value of databases are also gaining attention.[35] Challenges such as the impracticalities of obtaining consent and providing benefits to the population have been documented.[36] The discussions have favored a focus on the 'public' that understates the interests of the individual[37] mainly because of challenges to implementation. The debates however, miss two important issues that are unique to RUPD in the South: (1) opportunity availed through the routine re-contact with residents during the HDSS activity; and (2) the huge populations that could have their welfare, interests, and protections better safeguarded when research ethics principles are upheld for the individual, especially in light of otherwise less protected environments.

METHODS

A questionnaire based survey was conducted in Ghana from October to December 2014 and during an INDEPTH

[23] INDEPTH, *op. cit.* note 4; INDEPTH. 2015. *Who are Current Members of INDEPTH*? INDEPTH Network. Available at: http://www.indepth-network.org/index.php?option=comcontent&task=view&id=649&Ite mid=5 [Accessed 14 Nov 2016].

[24] Sankoh, *op. cit.* note 1.

[25] Sankoh & IJsselmuiden, *op. cit.* note 21.

[26] Sankoh, *op. cit.* note 1.

[27] Metz T. African and western moral theories in a bioethical context. *Developing World Bioethics 2010*; 10: 49–58.

[28] Ibid.; H3Africa Working Group on Ethics and Regulatory Issues (H3A). 2013. *H3Africa Guidelines for Informed Consent*. Available at: http://h3africa.org/images/PDF/H3A%20WG%20Guidelines%20Informed %20Consent _FINAL_01082013.pdf [Accessed 14 Nov 2016].

[29] Council for International Organizations of Medical Sciences (CIOMS). 2002. *International Ethical Guidelines for Biomedical Research involving Human Subjects*. Geneva: CIOMS/WHO. Available at: http://www.cioms.ch/images/stories/guidelines_demo/AllGuidelines-1-25.pdf [Accessed 14 Nov 2016]. Klitzman RL. US IRBs confronting research in the developing world. *Dev World Bioeth* 2012;12 (2):63-73; Mduluza T, eds. 2007. *A Gateway to Biomedical Research in Africa*. New York: Nova Science; Kruger M, Ndebele P & Horn L. eds. 2014. *Research Ethics in Africa. A Resource for Research Ethics Committees*. South Africa: Sun Media; Available at: http://www.sun.ac.za/english/faculty/healthsciences/paediatrics-and-child health/Documents/ 9781920689315 %20Research% 20Ethics.pdf [Accessed 14 Nov 2016].

[30] Capron AM et al. Ethical norms and the international governance of genetic databases and biobanks: findings from an international study. *Kennedy Inst Ethics J* 2009; 19(2):101–24.

[31] Vayena E et al. Ethical Challenges of Big Data in Public Health. *PLoS Comput Biol* 2015.

[32] Public Health Ontario, *op. cit.* note 20; N.E. Kass. An ethics framework for public health. *Am J Public Health* 2001; 91(11):1776–82.

[33] Bull et al., *op. cit.* note 11; European Commission. 2013. *Guidelines on open access to scientific publications and research data in Horizon 2020*. Available at: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/oa_pilot/h2020-hi-oa-pilot-guide_en.pdf [Accessed 14 Nov 2016]; Jao I et al. Research Stakeholders' Views on Benefits and Challenges for Public Health Research Data Sharing in Kenya: The Importance of Trust and Social Relations. *PLoS One* 2015; 18.

[34] European commission, *op. cit.* note 33; Vayena et al., *op. cit.* note 31.

[35] Manyika J et al. 2011. *Big Data: The next frontier for innovation, competition and productivity.* Available at: http://www.mckinsey.com/business-functions/business-technology/our-insights/big-data-the-next-frontier-for-innovation [Accessed 14 Nov 2016]

[36] Sim & Dawson. *op. cit.* note 10; H3A, *op. cit.* note 28.

[37] CIOMS, *op. cit.* note 10 ; Elger, *op. cit.* note 10; Public Health Ontario, *op. cit.* note 20.

Scientific Conference held in Addis Ababa, Ethiopia in November 2015. In Ghana, the questionnaires were administered to personnel at the Dodowa and Navrongo HDSSs. The INDEPTH Conference was organized for HDSS-member and partner institutions worldwide. It offered a unique opportunity to reach stakeholders with a working knowledge of RUPD.[38] We did not aim for representativeness of the population, but rather sought knowledgeable participant availability, willingness to participate, and a quest to ensure that relevant issues were discussed to arrive at a useful view of how the ethics of RUPD could be cast in the South.[39] Of the 350 questionnaires administered, 142 were returned, representing a response rate of 40.6%. Completed questionnaires from eleven Ghanaian respondents at the conference who had earlier been administered questionnaires in Ghana were matched for hand-writing and socio demographic characteristics to enable exclusion based on possible double participation: six questionnaires were excluded. An inclusion criterion of completing at least two of the three sections of the questionnaire was implemented. In total, 130 surveys were included in the analysis.

The Survey Tool

A questionnaire was formulated, approved by all authors, and put through an internal review session by ethicists working at the Institute for Biomedical Ethics, University of Basel. It was pilot-tested using five HDSS practitioners who did not participate in the main survey. Questions were based on a vignette (Appendix 1) informed by features of RUPD and relevant literature to assure face validity. The questionnaire was examined by the supervisory team of experts to assure content validity.[40] The vignette gave a short scenario of a retrospective RUPD, but questions relevant to prospective RUPD were also surveyed. We posed closed-ended questions on familiarity with RUPD and specific expectations of what respondents deemed ethically acceptable practices linked to research ethics principles. The closed-ended questions were either dichotomous (yes or no) or five point Likert-type questions (strongly agree, agree, neutral, disagree or strongly disagree). Blank spaces were provided to enable respondents to add information if they chose to. Although not exhaustive, the information given in the vignette was adequate to offer respondents an equal understanding of the research topic.

Data Analysis

Using IBM SPSS Statistics Version 21, closed-ended questions were analyzed via descriptive statistics. We examined issues documented as problematic in other population and database research including informed consent and benefit provision.[41] Open-ended responses were collated into relevant themes. We characterized the HDSS as 'custodian' in line with literature that support organized systems' data creation and holding status.[42] By implication, we assumed that while HDSS communities may not own their data in practical terms, they have a stake in its ownership.[43]

Ethical Considerations

Ethical approval for the project was sought from the Ethics Commission of North Western and Central Switzerland and six other committees in Ghana and Tanzania where separate in-depth interviews were planned. In Ethiopia, where conference delegates completed the questionnaires, ethics review was not required. Questionnaires and consent documents were self-administered, anonymous, and returned to the researcher on site in Ghana, during the conference, or by email.

RESULTS

The socio-demographic characteristics of the 130 respondents are shown in Table 1. Most respondents (84.6%) were based in Africa and were less than 50 years old. On average, participants had spent 8.7 years (range 1 - 33 years) at their current roles. More than two-thirds of respondents (66.7%) had undergone some levels of training in research ethics: around half (n = 66) had a month or less of training, six undertook fellowship programs, and eight had degrees in various fields of bioethics.

General issues

The majority of respondents (N = 130; 93.1%) indicated that they had seen publications emanating from RUPD. Around half (N = 130; 54.3%) thought RUPD occurred 'often', with a third (N = 130; 31.5%) having personally undertaken it. A quarter of respondents (N = 130; 25.4%) disagreed that use of pre-collected HDSS data could be considered as research and more than two-thirds (N = 124, 71.3%) supported it as a valid alternative methodology.

[38] INDEPTH. 2015. *INDEPTH Scientific Conference*. Ghana: INDEPTH Network.
[39] Rothman KJ, Gallacher JEJ & Hatch EE. 2012. Why representativeness should be avoided. *Int. J. Epidemiol* 2012; 42 (4): *1012-1014*.
[40] Dawson B & Trapp RG. 2004. Basic and Clinical Biostatistics. 4ed. McGraw-Hill Companies. ISBN 0-07-141017-1
[41] Sim & Dawson, *op. cit.* note 10; H3A, *op. cit.* note 28.
[42] Capron et al., *op. cit.* note 30.
[43] Ibid.

Independent review and ethical governance of RUPD

About three-quarters of respondents (N = 111; 76.2%) thought RUPD should undergo REC review, but a minority either disagreed (9.2%) or declined to answer (14.6%). Nineteen respondents (N = 126; 15.1%) opted for RUPD without any ethical requirement while 7.5% (N = 120) would start RUPD without REC review until there was a publishable manuscript. Most respondents (N = 115, 83.5%) were not aware of any written rule, policy or regulation governing RUPD. When asked if there was a need for specific RUPD guidelines, 85.6% (N = 125) agreed with 73.8% of them choosing 'strongly agree'.

Respect for study participants and communities

Respondents' views on preferred stages for seeking permission and prior processes for conducting RUPD were sought (Table 2). Majority (N = 120, 95%) of them agreed to seeking prior permissions. Of six possibilities given, obtaining permission from the custodian and REC approval was the most preferred (41.7%). Six respondents would 'use only personal and professional discretion'.

Table 1. Socio-demographic characteristics (N = 130)

VARIABLE	*CATEGORY*	*N*	*(%)*
Regions	West Africa	65	(50.0)
	East Africa	41	(31.5)
	Southern Africa	4	(3.1)
	*Asia, Europe, and North America	5	(3.8)
	Unspecified	15	(11.5)
Age (years)	<30	16	(12.3)
	31-50	92	(70.8)
	>50	15	(11.5)
	Unspecified	7	(5.4)
Primary training	Public Health (including Medicine)	48	(36.9)
	Epidemiology	16	(12.3)
	Statistics & Information Systems	16	(12.3)
	Law and other fields	12	(9.2)
	Demography & Social Sciences	7	(5.4)
	Economics	5	(3.8)
	Bioethics	2	(1.5)
	Unspecified	24	(18.5)
Institution of work	Research institution	75	(57.7)
	Ministry of health	33	(25.4)
	International organization	6	(4.6)
	Academic	3	(2.3)
	Other	4	(3.1)
	Unspecified	9	(6.9)
Professional role	Researcher	59	(45.4)
	REC member or administrator	18	(13.8)
	Public health officer or clinician	18	(13.8)
	Data management	8	(6.2)
	Research center administrator	5	(3.8)
	Policy making	4	(3.1)
	Other	9	(6.9)
	Unspecified	9	(6.9)
Ethics Training	Yes	88	(67.7)
	No	31	(23.8)
	Unspecified	11	(8.5)

* Due to small numbers, the non-African respondents from Bangladesh, The Netherlands, Sweden, Switzerland and the Unites States are pooled.

Informed consent

Using Likert-scale responses, we assessed perceptions about practices associated with the principle of respect for persons. Obtaining individual consent was rejected by most respondents (70.1%), but when RUPD involving genetic data was made a possibility, the rate of rejection was only 14%. Table 3 presents the distribution of responses to practices that are argued against in the literature.

In the 'comment' section, six respondents stated that individual consent should be sought only at researchers' discretion. One respondent remarked that there was no question about participants' rights to individual consent in any research, but the problem with RUPD was one of feasibility.

Communities' autonomy

The majority of respondents (N = 126; 65.9%) supported prior disclosure about RUPD to community leaders (N = 120; 62.5%), but 23% disagreed. Three respondents added that community advisory boards should be established; eight suggested local representation in RUPD discussions within the community; and three added that selected community representatives should inform themselves about RUPD and serve as REC members.

Asked about concerns communities might have about RUPD, respondents mentioned the following:

i conducting scientifically interesting but socially-undesirable studies
ii insensitive publications
iii discontent about data use
iv doubts about RUPD findings and legal battles
v exploitation and deception
vi absence of compensation for time and effort

Table 2. Preferred stages for seeking permissions to conduct RUPD (N = 120)

Step 1	*Step 2*	*Step 3*	*N (%)*
Custodian	REC	-	50 (41.7)
Custodian	REC	Regional or national health authorities	48 (40.0)
Custodian	Analyze data. If publishable take Step 3	REC	9 (7.5)
Use only personal and professional discretion	-	-	6 (5)
Custodian	-	-	5 (4.2)
Custodian	Regional/national health authorities	-	2 (1.7)

Table 3. Perspectives on informed consent

Practice	*Strongly Agree*	*Agree*	*Neutral*	*Disagree*	*Strongly Disagree*
Seek individual consent for every study (N = 127)	13 (10.2%)	9 (7.1%)	16 (12.6%)	25 (19.7%)	64 (50.4%)
Prohibit RUPD involving genetic records, if individual consent is not sought (N = 93)	60 (64.5%)	14 (15.1%)	6 (6.5%)	6 (6.5%)	7 (7.5%)
Seek one-time consent for future publications (N = 125)	36 (28.8%)	16 (12.8%)	21 (16.8%)	26 (20.8%)	26 (20.8%)
Grant individual rights to withdraw their own data from RUPD (N = 127)	46 (36.2%)	17 (13.4%)	21 (16.5%)	19 (15%)	24 18.9%)
Individual interests and consent could slow down RUPD (N = 126)	40 (31.7%)	29 (23%)	20 (15.9%)	15 (11.9%)	22 (17.5%)

Providing benefits

Only a quarter of respondents (N = 124; 24.9%) agreed to the notion of providing benefits to RUPD participants. More than half (55.7%) were against it and a fifth undecided (19.4%). To a proposal for result dissemination to communities before publications, 69% agreed, 14% disagreed, and 17% were undecided.

We sought examples of realistic benefits to provide in RUPD. Respondents suggested building custodians' data managing capacities to improve funding and employment (n = 15); using RUPD to support policy legislation (n = 7); prioritizing research that is of local interest (n = 5); access to interventions (n = 5); sustaining systems in which RUPD knowledge can be applied to improve health (n = 4); focusing on on-site data analyses to promote local leadership in RUPD, address local questions and speed result translation to relevant policies (n = 2); and providing policy briefs (n = 1). Six respondents suggested that HDSS communities should proactively state what benefits they expect from RUPD for researchers to comply.

Risks in RUPD and procedures for minimizing them

Table 4 documents respondents' opinions about risks that are suggested in the literature as well as risks they identified in their practice. Compromise of personal and family data following release to researchers was the most (59.5%) endorsed, but under a quarter of respondents (23%) thought that HDSS residents faced risks to confidentiality from RUPD publications.

Figure 1 shows respondents' attitudes to risk minimization procedures. Seventy four percent of respondents supported anonymizing data before release to researchers. The least preferred option for risk minimization was limiting RUPD to non-sensitive studies.

Fairness in assigning communities to RUPD

Respondents did not consider community perceptions of being over-researched or burdened relevant in RUPD (Table 4). The three most important conditions for RUPD to be considered acceptable were REC approval, potential to result in change in health policy, and local leaders' agreement (Table 5).

Respondents' general recommendations

Respondents recommended the following for RUPD ethics: (A) custodians should collaborate and create awareness about RUPD to enable residents know what their data is or should be used for, its importance to science, and what benefit communities stand to gain from being participants; (B) promote a working link between the community via its representative team and the respective REC; (C) develop institutional regulations and ensure adherence to them; (D) build capacity in use of analytical tools to improve funding and employment; (E) prioritize research that is of local interest; (F) negotiate access to health interventions; (G) sustain systems in which RUPD knowledge gained can be applied to improve health; (H) publish in ways that are culturally and socially appropriate; and (I) maintain community dialogue.

DISCUSSION

This survey assessed perspectives of stakeholders experienced or knowledgeable about RUPD in relation to research ethics principles. Each question attracted a high (> 70%) response rate which is suggestive of practitioners' acknowledgement of the relevance of the selected issues and their own awareness about the implied principles. RUPD practitioners support the literature which recommends data use beyond the narrower purposes for which they are collected,[44] but differ in perspectives on what, how, and when research ethics principles and governing regulations are needed. The issues discussed are common to health research, but have dimensions peculiar to HDSSs. To our knowledge, available empirical literature[45] on the closest methodologies to RUPD, such as bio-banks[46] and epidemiological research[47] have structural and

[44] CIOMS, *op. cit.* note 10; Bull et al., *op. cit.* note 11; Public Health Ontario, *op. cit.* note 17.
[45] Capron et al., *op. cit.* note 34.
[46] Elger, *op. cit.* note 10; Capron et al., *op. cit.* note 34.
[47] Sim & Dawson, *op. cit.* note 10; CIOMS, *op. cit.* note 10.

Table 4. Perceptions about identified risks

A. Risks	*Strongly Agree*	*Agree*	*Neutral*	*Disagree*	*Strongly Disagree*
Risk to confidentiality in publications (N = 126)	14 (11.1%)	15 (11.9%)	32 (25.4%)	31 (24.6%)	34 (27%)
Rights to control use of personal and family data may be compromised (N = 121)	53 (43.8%)	19 (15.7%)	13 (10.7%)	20 (16.5%)	16 (13.2%)
Stigma and stereotyping, if results are negative (N = 126)	28 (22.2%)	26 (20.6%)	19 (15.1%)	22 (17.5%)	31 (24.6%)
Communal rights of control on data storage, use and publication (N = 121)	36 (29.8%)	29 (24%)	18 (14.9%)	19 (15.7%)	19 (15.7%)
Feelings of being over researched (N = 126)	13 (10.3%)	12 (9.5%)	25 (19.8%)	29 (23%)	47 (37.3%)
Loss of trust in custodian for allowing RUPD (N = 120)	17 (14.2%)	21 (17.5%)	27 (22.5%)	30 (25%)	25 (20.8%)

B. Additional risks identified by respondents

- Disregard for community dignity
- Social embarrassment
- Communal fear of being under international scrutiny
- Unresolved issues after long years of research could cause local rage
- Misuse of data
- Data access by parties unknown to the community
- Lack of opt-out opportunities
- Mismatch between research goals and local interests
- Non awareness of RUPD by community

paradigmatic differences that do not enable effective comparisons with this survey. Indeed, the evolution of health research through changes to the various landscapes including technology generate new opportunities and challenges that renders available ethical provisions inadequate.[48] Ongoing updates to guidelines as relevant and authoritative as the 'Common Rule'[49] and the CIOMS Guidelines[50] attest to this fact and justify this survey for RUPD.

Independent review and ethical governance of RUPD

The international requirement for the ethical review of health research[51] is clearly supported for RUPD. However, the perception that RUPD is not 'research' is substantial and can reduce practitioners' adherence with seeking prior REC review. To date, developments in ethical research have been largely based on compliance with guidelines, policies on best practices, and frameworks.[52] Low levels of awareness of the relevant provisions for RUPD and the high endorsement of the need for a RUPD-specific framework are suggestive of a gap in ethical RUPD. Calls for the development of institutional regulations and adherence to them are justified and urgent. We recommend that because scientists may rarely pay attention to the philosophical reasons for which ethical RUPD conduct should be or is the way it is prescribed,[53] including REC review, providing a specific ethical guidance framework for RUPD will improve ethical conduct.

Respect for study participants and communities

Consistent with relevant literature,[54] individualized informed consent was not supported for RUPD. Cost and impracticality,[55] communal cultures of the collective against individualistic views,[56] and the fact that relevant guidelines support general public health data use or research without informed consent[57] may account for this. Nonetheless, individualized consent becomes necessary when research questions are sensitive. Researcher discretion is important.

The importance of 'community' values was dominant in the survey findings. Support for actively involving community leaders in RUPD exceeded the traditionally acclaimed importance of requiring institutional permission from custodians for similar methodologies.[58] These findings are suggestive of preferences for decision making that involve

[48] Largent, *op. cit.* note 1.
[49] DHHS. *op. cit.* note 7.
[50] Largent, *op. cit.* note 1.
[51] SAMRC, *op. cit.* note 7; CIOMS, *op. cit.* note 10; CIOMS, *op. cit.* note 29; Nuffield Council on Bioethics. 2013. *Open Consultation: The linking and Use of Biological and Health Data. London.* Available at: http://ico.org.uk/~/media/documents/consultationresponses/nuffield-council-on-bioethics-consultation.pdf [Accessed 14 Nov 2016]; World Health Organization. 2011. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva; European Commission. 2013. Ethics for Researchers. Luxembourg: *Publications Office of the European Union*.
[52] Bull et al., *op. cit.* note 11; Emanuel et al., *op. cit.* note 13; Marckmann G et al. Putting public health ethics into practice: a systematic framework. *Frontiers in Public Health* 2015;3:23; Kass, *op. cit.* note 32.
[53] Sim & Dawson, *op. cit.* note 10.
[54] Ibid.; Largent, *op. cit.* note 1; CIOMS, *op. cit.* note 10; Elger, *op. cit.* note 10 ; H3A, *op. cit.* note 28; Capron et al., *op. cit.* note 30.
[55] DHHS. *op. cit.* note 7; Sim & Dawson, *op. cit.* note 10; CIOMS, *op. cit.* note 10 ;
[56] Metz, *op. cit.* note 27.
[57] CIOMS, *op. cit.* note 10; Public Health Ontario, *op. cit.* note 20; H3A, *op. cit.* note 28; European commission, *op. cit.* note 51.
[58] Bull et al., *op. cit.* note 11; Elger, *op. cit.* note 10; H3A, *op. cit.* note 28.

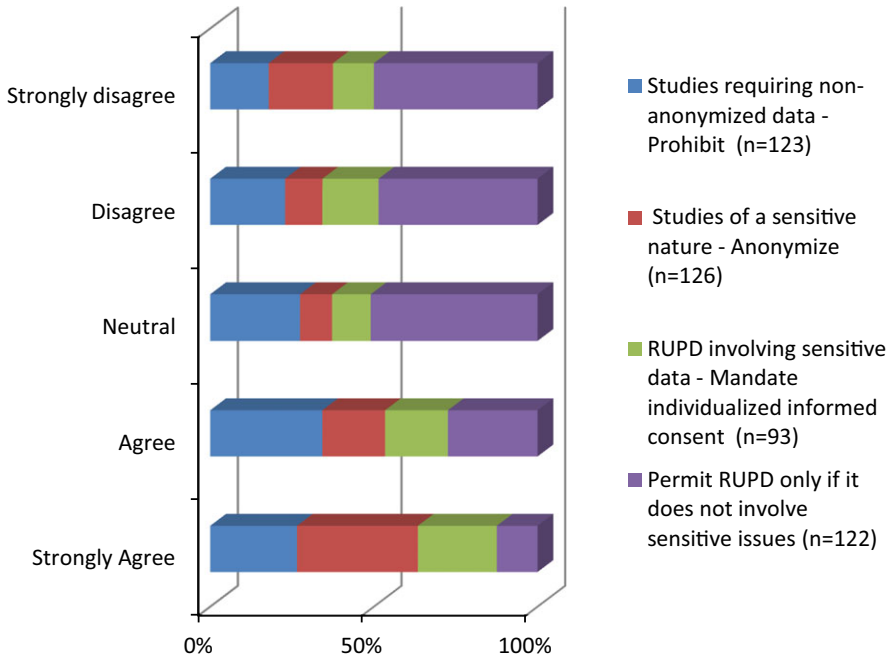

Figure 1. Attitudes to risk minimization procedures [Colour figure can be viewed at wileyonlinelibrary.com]

Table 5. Perceived conditions for fairness

Condition of RUPD	*Strongly Agree*	*Agree*	*Undecided*	*Disagree*	*Strongly Disagree*
(a) receives local REC permission (N = 120)	79 (65.8%)	24 (20%)	8 (6.7%)	2 (1.7%)	7 (5.8%)
(b) can result in change of health policy (N = 117)	59 (50.4%)	31 (26.5%)	13 (11.1%)	7 (6%)	7 (6%)
(c) has the agreement of the community leadership (N = 120)	41 (34.2%)	34 (28.3%)	18 (15.0%)	17 (14.2%)	10 (8.3%)
(d) is in line with local or national health priorities (N = 117)	41 (35.0%)	32 (27.4%)	23 (19.7%)	11 (9.4%)	10 (8.5%)
(e) conforms to the custodian's mission (N = 118)	40 (33.9%)	30 (25.4%)	22 (18.6%)	15 (12.7%)	11 (9.3%)
(f) receives permission from head of the custodian (N = 118)	38 (32.2%)	25 (21.2%)	22 (18.6%)	20 (16.9%)	13 (11%)
(g) does not involve sensitive questions (N = 117)	32 (27.4%)	19 (16.2%)	18 (15.4%)	28 (23.9)	20 (17.1)
(h) proposing team was involved in HDSS data collection (N = 119)	10 (8.4%)	11 (9.2%)	22 (18.5%)	29 (24.4%)	47 (39.5%)

local leaders' permission (group autonomy).[59] Our endorsement mirrors attitudes in many cultures of the South, particularly Africa where seeking elders' permissions for important activities are common.[60] We recommend the following: responsibility towards RUPD should be entrusted to a recognized community team;[61] a working link among the community team, custodian, and REC would enable effective engagement of the community team to lead in creating local awareness about RUPD, its governance, conduct, and implications of RUPD results to promote ethics. The community representative team becomes the practical unit for decision making and communal determination in RUPD.

Another important dimension of the principle of respect for persons in RUPD, at least for traditional setups in Africa where humaneness and rightness are generally constituted by positive relation to others,[62] is that what is right is defined in its harmonious relation to and contribution to one's community. Opt-out options which influential literature support as safeguards of voluntariness in database studies[63] may thus not be considered practical in these communal systems. Since one-time consent[64] was also not a decisive option in the survey, the search for an ideal solution should consider alternatives to opt-out options. We suggest optimizing the unique feature of re-contact

[59] Capron et al., *op. cit.* note 30.
[60] H3A, *op. cit.* note 28; Metz, *op. cit.* note 27.
[61] Jao I et al., *op. cit.* note 33; Jao I et al. Involving Research Stakeholders in Developing Policy on Sharing Public Health Research Data in Kenya. *J Empir Res Hum Res Ethics* 2015; 10(3):264–77; P. Tindana et al. Community engagement strategies for genomic studies in Africa: a review of the literature. *BMC Medical Ethics* 2015.
[62] Metz, *op. cit.* note 27.
[63] Largent, *op. cit.* note 1 ; CIOMS, *op. cit.* note 10 ; Elger, *op. cit.* note 10 ; Bull et al., *op. cit.* note 11 ; H3A, *op. cit.* note 28.
[64] CIOMS, *op. cit.* note 10 ; Elger, *op. cit.* note 10.

with residents via the HDSS rounds. The following mix of procedural processes will also be helpful.

First, essential information about RUPD should be shared with the custodian and community representative team for prior permissions. REC review and approval should then be sought. Second, brief information about RUPD should be provided orally or as an addendum to the routine HDSS document used during the house-to-house visits preceding or following the start of RUPD. Tick boxes may be provided for options to the following issues: (1) Sunset agreements[65] stating how often and how long residents may wish to be re-consented, for instance 5 years, 10 years or a lifetime; (2) what should happen with data upon death or emigration; and (3) broad topics a resident might wish to be informed about before RUPD or have their data excluded from. Where societal pressures against opt-out are strong for communal reasons,[66] dialogue and researchers' assurance of the worth of individual rights both to consent or dissent to participation should be prioritized. If paper-based activities may render these recommendations unbearably costly, documentation may be substituted with oral consent, but the remaining elements of informed consent expressed in disclosure, comprehension, voluntariness, and self-determination[67] can be upheld.

Providing value and benefits

The obligation for researchers to provide value and benefit[68] often necessitates providing concrete gains on the basis of reciprocity and justice.[69] The principle itself is not questionable, but simply challenging to apply in RUPD given the general large numbers of individuals involved. Practitioners' several attempts to suggest realistic alternatives to individual benefit highlights their agreement in principle as well as their challenge, based on cost. In line with the literature,[70] they settled on knowledge dissemination as the most practical benefit for RUPD. However, there are problems even with this possibility, especially in Africa. With only 16% of internet access in Africa and 90% of households not connected to the internet,[71] assuring even this minimal benefit is a challenge. Further, many cultures have vernacular languages that are spoken and often not read.[72] This necessitates oral forms of communicating results. With 89% of people in these regions using mobile phones,[73] exploring mobile technological knowledge sharing opportunities would better assure that benefit is possible in RUPD. As some practitioners suggested, dialogue with community teams will also uncover other culturally and socially appropriate avenues including durbars and local radio stations for reaching the most inaccessible groups with RUPD knowledge. Lastly, the opportunity of re-contact through the routine house-to-house visits should be utilized to share RUPD results.

At the custodian and regulatory levels, practitioners' suggestions for capacity building to improve funding and employment; use of RUPD to contribute to health policy developments,[74] and legislation of policies; prioritizing research that is of local interest; negotiating access to health interventions; and sustaining public health systems in which new RUPD knowledge can be applied to improve health ought to be considered. Additionally, HDSS communities are a good source of knowing and aiming for relevant benefits in RUPD.

Risks and procedures to minimize them

Much of the emphasis in the literature has been on issues of confidentiality and privacy,[75] but our study reveals significant ambivalence about these issues in RUPD. The practitioners' attitudes may be linked to characteristics unique to INDEPTH HDSSs. We suspect that knowledge about ongoing processes of anonymization that are being introduced by INDEPTH's *iShare2* Program[76] and the solidarity of member HDSSs may have influenced respondents to think that anonymization is already a norm for HDSS data and RUPD. The communal nature of the contexts may also explain part of this. Practitioners were more clearly concerned about negative reporting of studies that contribute to stigmatization, discrimination, and stereotyping of communities.[77] Recognition of the commonality of HDSS communities in collectively facing risks led to much emphasis being placed on publishing in culturally and socially sensitive ways. Aligning RUPD's goals to issues that are relevant to host communities also helps balance risks. A helpful list of data protection and security measures are available internationally.[78] It is also expected

[65] Elger, *op. cit.* note 10.
[66] Metz, *op. cit.* note 27.
[67] Beauchamp & Childress, *op. cit.* note 8.
[68] Ibid.; Emanuel et al., *op. cit.* note 13.
[69] Kass, *op. cit.* note 32; Vayena et al., *op. cit.* note 31; Marckmann et al., *op. cit.* note 52.
[70] CIOMS, *op. cit.* note 10; Bull et al., *op. cit.* note 11; Emanuel et al., *op. cit.* note 13; Kass, *op. cit.* note 32.
[71] International Telecommunication Union (ITU). 2013. *The World in 2013. ICT Facts and Figures*. Available at: https://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2013-e.pdf [Accessed 14 Nov 2016].
[72] H3A, *op. cit.* note 28.
[73] ITU, *op. cit.* note 71.
[74] Capron et al., *op. cit.* note 30.
[75] CIOMS, *op. cit.* note 10; Capron et al., *op. cit.* note 30; Elger, *op. cit.* note 10; Bull et al., *op. cit.* note 11; European commission, *op. cit.* note 33.
[76] INDEPTH Network. *iShare2*. Available at: http://www.indepth-network.org/projects/ishare2 [Accessed 14 Nov 2016].
[77] Mduluza et al., *op. cit.* note 29.
[78] CIOMS, *op. cit.* note 10 ; European Commission, *op. cit.* note 33; European Commission, *op. cit.* note 51.

that the upcoming updated CIOMS guidelines will, like its preceding ones, be a useful resource to RUPD and Africa.

Fairness in the assignment of communities to RUPD

Apart from selecting RUPD populations to ensure scientific validity and reduce risks, enabling community teams to contribute to RUPD decision making is an important approach to justice. The survey revealed that careful assignment of communities' data to different RUPD is important: communities with poor indices need not disproportionately be assigned to studies which stigmatize them for scientific benefit. The values of trust, transparency, and accountability[79] in these assignments are supported by practitioners and need to be integral to sustain the long term commitments, gains, and scientific growth that RUPD promises.

It is distinctive to note that contrary to the literature,[80] practitioners thought that communities would not feel 'over-researched' over time. Only HDSS communities could confirm or challenge this view. In line with the literature[81] nonetheless, practitioners' concerns about stigma, discrimination, and discontent make it prudent to recommend that community inclusion in RUPD be driven both by scientific and socio-cultural considerations. The level of engagement needed to exercise self-determination may sometimes be questioned because of low literacy rates and knowledge gaps. However, collaborative efforts from custodians, community teams, and RECs via workshops, training, and education will help overcome these challenges for the benefit of science and the people.

Limitations

Information provided in the vignette may have influenced some responses or discouraged respondents' own reasoning based on their experiences. The choice of distributing the survey at the conference limited access of participation largely to delegates. Because participants who returned the questionnaires were mainly based in African HDSSs, we missed cultural differences and operational diversities from the Asian and Oceanian regions of the South. The study does not claim to be representative. To the best of our knowledge however, this is the first survey of practitioners about the ethics of RUPD which can contribute to its future prospects. Empirical research involving HDSS residents' perspectives on the subject would further advance the understanding and reflections we have started.

[79] Vayena et al., *op. cit.* note 31.
[80] Yazoume, *op. cit.* note 16.
[81] Mduluza et al., *op. cit.* note 29.

CONCLUDING THOUGHTS

This survey has revealed some differing attitudes to the literature and current guidelines that are indicative of a need for education and re-examination of the extant ethical provisions that are relevant for RUPD. For RUPD ethics to be robust, the following will be important: empowering communities to proactively contribute to planning, review, conduct, and dissemination of findings from RUPD; seeking appropriate permission from custodians; and undergoing REC review. Where knowledge dissemination is the only realistic potential benefit, researchers' obligations to provide it should be raised to assume the status that medical ethics, for instance places on doctors towards their patients. Collective risks need to be considered seriously. Although practitioners' interests in completing most questions is suggestive of receptiveness to the idealistic possibilities of implementing research ethics principles in RUPD, RUPD ethics need not be left to individual or even institutional changes alone. It needs a higher motivation which, from historical evidence and the progress made in health research, rests in raising standards through the development of a specific RUPD guidance framework. The new CIOMS Guidelines are expected to be particularly useful to the South, but the presence of a specific framework for RUPD, gleaned from it and adapted to the South will be ideal.

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APPENDIX 1

APPLICATION OF ETHICAL PRINCIPLES TO RESEARCH USING PUBLIC HEALTH DATA IN THE GLOBAL SOUTH

VIGNETTE FOR STUDY QUESTIONNAIRE

Please read the following scenario to answer the questions below

The Tanghu Center (a fictitious health research center) was established in 2000. It has a population of 99000 under its surveillance. It has received local community support and significant funding to invest in modern facilities for health and demographic data collection and storage. Researchers at the center now suggest that this surveillance data should be explored and analyzed for scientific publications. Many topics are immediately proposed. Dr Ghutan for instance wishes to use the data gathered between 2005 and 2012 to compare issues between old and new residents after tuberculosis infection. It is agreed by many members present that such a coordinated effort to re-use existing data for publications could increase scientific capacity, enable young and new researchers to gain analytical skills, and ensure the fullest use of the hard earned data. Others note that the evidence from such publications will impact health policy and result in new ideas and research questions. Some members however, think that there could be ethical issues to consider.