

SETTING HEALTH PRIORITIES IN RESEARCH: AN AFRICAN PERSPECTIVE

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Abstract: There is much biomedical and epidemiological research taking place in Africa today. This research is both *horizontal* (involving local researchers and regional research institutions) and *vertical* (involving international research sponsors and collaborators). Research is the necessary pathway for any biomedical innovation designed to improve health and, in most cases, such research requires the use of human beings as research participants. Research participants cannot however, be viewed in isolation; they live in *communities*. This begs the question: how do communities benefit from research activities taking place within their own locales? It has become almost a mantra in the research ethics world to say that *communities must benefit from positive research outcomes*. This ethical rule is important; however, my paper will focus on community involvement *prior* to the actual research being carried out. Using African examples as case studies, I will examine the extent to which communities are involved in setting the health research agenda for their members and whether or not they are included in priority setting activities. Research being undertaken in several African communities may indeed address health problems in that community; however, how high are those problems in the list of health priorities for that particular community? Are other important health problems being neglected? While much has been said about provision of treatment shown to be successful *after* research to the wider community, not enough has been said about who decides what research is important for the community *before* such research is carried out.

Key Words: Ethics, research, health priorities, community benefits

ESTABLECIMIENTO DE PRIORIDADES DE SALUD EN INVESTIGACIÓN: UNA PERSPECTIVA AFRICANA

Resumen: Hoy día, en África, se realiza mucha investigación biomédica y epidemiológica, que es tanto horizontal (involucra a investigadores locales y a instituciones regionales de investigación) como vertical (involucra patrocinadores y colaboradores internacionales). La investigación es el camino necesario para lograr innovaciones biomédicas diseñadas para mejorar la salud y, en la mayoría de los casos, requiere participación de seres humanos como sujetos de investigación. Éstos no pueden, sin embargo, verse en aislamiento; son parte de una comunidad, lo que implica una pregunta: ¿cómo se benefician las comunidades con la investigación que tiene lugar en ellas? En el mundo de la ética de la investigación se ha convertido en un *mantra* decir que las comunidades deben beneficiarse con los resultados positivos de la investigación. Esta norma ética es importante; sin embargo, mi artículo se enfoca en la participación de la comunidad antes de que se realice la investigación. Usando ejemplos de África como casos, examinaré hasta qué punto se incluye a las comunidades al establecer la agenda de investigación en salud, y si se les consulta al fijar prioridades. Puede que la investigación que se realiza en varias comunidades africanas responda a sus necesidades de salud; sin embargo, ¿cuán prioritarios son estos problemas para cada comunidad? ¿Son postergadas otras necesidades importantes de salud? Mientras que se ha dicho mucho sobre proveer tratamiento para la comunidad entera después de que la investigación ha demostrado ser eficaz, no se ha dicho lo suficiente sobre quién decide cuál investigación es importante para la comunidad antes de que se realice.

Palabras Clave: Ética, investigación, prioridades de salud, beneficios para la comunidad

ESTABELECIMENTO DE PRIORIDADES DE SAÚDE NA PESQUISA: UMA PERSPECTIVA AFRICANA

Resumo: Atualmente se realiza muita pesquisa biomédica e epidemiológica na África que é tanto horizontal (envolvendo pesquisadores locais e instituições regionais de pesquisa) como vertical (envolvendo patrocinadores e colaboradores internacionais). A pesquisa é o caminho necessário para se conquistar inovações biomédicas para melhorar a saúde e, na maioria dos casos, exige a participação de seres humanos como sujeitos de pesquisa. Estes não podem ser vistos isoladamente, são parte de uma comunidade, o que implica um questionamento: que benefícios a pesquisa traz para a comunidade? No mundo da ética da pesquisa se transformou um *mantra* dizer que as comunidades devem se beneficiar com os resultados positivos da pesquisa. Esta norma ética é importante, contudo, meu artigo enfoca a participação da comunidade antes que se realize a pesquisa. Utilizando exemplos da África como casos, examinarei até que ponto as comunidades são incluídas ao se estabelecer a agenda da pesquisa em saúde, e se são consultadas ao se estabelecer as prioridades. Pode ser que a pesquisa que se realiza em muitas comunidades africanas responda às suas necessidades de saúde, contudo, o quanto são prioritários estes problemas para cada comunidade? Outras necessidades importantes de saúde são postergadas? Embora muito se falou sobre a provisão de tratamento para a comunidade inteira após ter-se demonstrado que a pesquisa é eficaz, não se falou o suficiente em relação a quem decide antes que seja realizada, qual é a pesquisa é a mais importante para a comunidade.

Palavras chave: Ética, pesquisa, prioridades de saúde, benefícios para a comunidade

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Introduction

There are several ways of classifying health research, however, for purposes of this paper, health research in Africa may be described as:

- a. Research that **is responsive** to a health need of the community **and** that need falls within the health research priorities of the community.
- b. Research that **is responsive** to a health need of the community, but that need **does not** fall within the health research priorities of the community.
- c. Research that is **not responsive** to a health need of the community, and does **not** fall within the health research priorities of the community.

It has become almost an ethical imperative in the research ethics arena that in order for health research to be ethical and of benefit to a community, it has to be **responsive** to the health needs of that community. This ethical requirement has been articulated in various international ethics guidelines and documents, for example:

Guideline 3 of the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects states that: “The health authorities of the host country, as well as a national or local ethical review committee, should ensure that the proposed research is responsive to the health needs and **priorities** of the host country and meets the requisite ethical standards”¹. *Guideline 10* also deals with responsiveness of researchers and states in part: “...Before undertaking research in a population or community with limited re-

sources, the sponsor and the investigator must make every effort to ensure that: The research is responsive to the health needs and the **priorities** of the population or community in which it is to be carried out; and any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community”².

The Declaration of Helsinki states in *paragraph 19*, that “medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research”³.

The United States National Bioethics Advisory Commission in its report entitled *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, recommended that “clinical trials conducted in developing countries should be limited to those studies that are responsive to the health needs of the host country (Recommendation 1.3)⁴.

The British Nuffield Council in its report *The Ethics of Research related to Healthcare in Developing Countries* also addresses the issue of responsiveness of research in its recommendations. It states, in chapter 10, note 10.9, that “to enable effective collaboration with external sponsors, developing countries should have a mechanism allowing them **to set priorities** for research into healthcare, together with a robust mechanism for scientific review and ethical review of any proposed research”⁵.

² Ibid.

³ World Medical Association (WMA). *The Declaration of Helsinki, Revised by the 52nd WMA General Assembly*, Edinburgh, Scotland, October 2000; accessed at www.wma.net on October 26, 2003.

⁴ National Bioethics Advisory Commission (United States of America). *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries volume 1*. Bethesda: US Dept of Commerce, Technology Administration, National Technical Information Service; 2001.

⁵ Nuffield Council on Bioethics. *The Ethics of Research Related to Healthcare in Developing Countries*. London: Nuffield Council of Bioethics; 1999.

¹ Council for International Organizations of Medical Sciences. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: CIOMS; 2002.

The ethical requirement that research that takes place in the community must be responsive to the health needs of that community was crafted as a guard against the possibility of exploitation of vulnerable populations by research sponsors and researchers from rich countries:

- A. Research that **is responsive** to a health need of the community **and** that need falls within the health research priorities of the community

For research in African countries, this category represents the optimal scenario and one which all researchers, given the limited resources available for health research in Africa, should strive towards; namely: that research should not only be responsive to the needs of the population, but should also fall within the health research priorities of the African country. Most of the international ethical guidelines require that the research must address a health need that is of **priority** to the community.

This raises a host of questions and issues; for example, do African countries have clearly stated health research priorities? If so, how have these priorities been determined? If not, how should researchers know whether the research falls within the priorities of the host community/country? Should all externally funded research fall within nationally defined priorities? Do these rules also apply to locally funded research as well? But first, why is it so important that health research be directed to issues of national or community priority?

The statistic that is often cited today is that 90% of all health research is undertaken on those diseases that cause 10% of the global burden of disease⁶. In order for poor countries to bridge this research division they have to clearly define their

health priorities and seek and/or set aside resources for health research infrastructure and funding (both local and international) for research on the identified areas. Health equity must be adopted as a core value in setting priorities for research⁷.

Today, many African countries are developing priority setting strategies in health research. Much of the priority setting activities in Africa have been influenced by the WHO recommendations and the *Commission on Health Research for Development (COHRED)*. COHRED is an international non-governmental organization that aims to support, broaden and strengthen the health research linkages and competencies of various stakeholders in countries and at the international level⁸. In 1990, COHRED urged countries to undertake essential national health research (ENHR) in order to help correct imbalances in global health and development⁹. Under the ENHR plan, priority setting is one of 7 elements and it has to be driven by demand, focusing on an analysis of health needs, people's expectations and societal trends¹⁰. Further, the involvement of different stakeholders has to be multi-level with input from the grass-roots to the national level, and it has to be multi-dimensional (qualitative, quantitative and take into account socio-economic and political considerations)¹¹.

⁶ Global Forum for Health Research. *The 10/90 Report on Health Research 2000*. Geneva: Global Forum for Health Research; 2000.

⁷ Siithi-amorn C, Somrongthong R. Strengthening health research capacity in developing countries: a critical element for achieving health equity. *British Medical Journal* 2000; 321: 813-5.

⁸ Information about COHRED may be obtained from their website: www.cohred.ch

⁹ Commission on Health Research and Development. *Health Research: Essential Link to Equity in Development*. New York: Oxford University Press; 1990.

¹⁰ The other elements are promotion and advocacy, ENHR mechanism, capacity building, financing, evaluation and networking.

¹¹ Council on Health Research for Development (COHRED). Priority Setting for Health Research: Lessons from Developing Countries. *Health and Policy Planning* 2000; 14 (2): 130-6.

Over 27 developing countries have started experimenting and implementing health research priority setting as a logical component in their essential national health research strategies. In Africa, several countries have been holding regular meetings to discuss ENHR progress in their various countries. At these meetings, experts share information on developments in their own countries—as well as challenges and lessons learned.

As a result of this and other initiatives, national health research priorities are being or have been drawn up in several African countries. These priorities have not been developed only using technocratic approaches, but they have been drawn up as part of a comprehensive, participatory, interactive and iterative process. The input of researchers, decision-makers at various levels, health service providers and communities have factored into priority setting decisions. Examples of countries in Africa which have drawn or are in the process of drawing research priority plans include Tanzania, Uganda, Kenya, Ethiopia, Guinea, Zimbabwe, Mali, South Africa, Senegal, Malawi and Sudan, Cameroon, Burkina Faso. These countries have recognized that prioritization is also a **political process** that involves dialogue and debate as well as an underlying value system.

The ENHR Program has its share of problems: progress in implementing the strategies has been slow due to ineffective communication strategies, weak national funding arrangements, influences of international organizations involved in health research. However, in many countries in Africa, efforts have been made to set national and community level health research prioritization plans and these efforts should be encouraged by researchers.

Researchers and research sponsors who would like to carry out health research in Afri-

can countries have to take the extra steps to find out what health research priorities exist in those particular countries, and ask themselves whether their proposed research fits within the country's health research agenda. They have to ensure that the research plan will not simply be a duplication of existing research efforts—all too often you find the same research question being conducted by different research groups in a single country without any coordination or interaction amongst them. This is a waste of resources and should not be allowed to happen.

Again, if researchers (both local and international) are serious about bridging the research division then it is imperative that they find out which institutions are responsible for setting research priorities in that country¹², pay attention to the country specific national/community research plans (in development or already developed) and explain how their own research plans will **enhance** and not retard, the national/community agenda and benefit the community involved.

If it has been established that the host African country does not have any set policies on health research priorities, then the researcher must take additional steps to engage with stakeholders in the country including community members, government officials, local researchers and local health providers in that country to determine the importance of the proposed research and how the community will stand to benefit from the results of study.

An interesting piece of information: In an National Bioethics Advisory Commission sur-

¹² These institutions vary from country to country. In countries like South Africa, Malawi and Sudan, the relevant institution is the Ministry of Health; in Kenya and Tanzania, the government has delegated this duty to parastatals: The National Center for Health Research Development and the National Institute for Medical Research respectively. In other countries like Bangladesh, the national research priority setting process has been initiated by non-governmental agencies.

vey of US researchers working in a developing countries, 73% of them said that their interest in addressing global inequalities in health, motivated them to work in a developing country, however, 40% of them said that the research priorities of their funding agencies were inconsistent with the top priorities of the developing country in which they were conducting research¹³. I believe that researchers who are genuinely interested in diseases of the developing world need to be able to lobby funding agencies (in collaboration with other health development and civil society organizations) to pay more attention to the 90-10% division.

In order for this to happen, however, developing countries themselves must have well defined health research priorities. The EHNR initiative has therefore been instrumental in this regard and international researchers should engage to the extent possible with this process in order to become familiar with the health priorities in the countries in which they propose to work in and in so doing, enhance the set agenda.

B. Research that is responsive to a health need of the community, but that need does not fall within the health research priorities of the community.

This category is more problematic than the first. What happens when the research question is responsive to a certain health need in an African country, but that need does not fall under the list of health research priorities identified by that particular country or community?

Should such research be allowed? If so, under what conditions? If not, why?

I do not think that *all* research that is externally funded but that does not fall within the nationally defined list of priorities should be excluded; however, I think there should be some caveats put in place. The Nuffield Council report stated that since all research has the potential to contribute to the development of local skills and expertise quite apart from the inherent value in diversity of research, such studies should be allowed to take place.

However, the Council recommended that a careful balance has to be drawn to ensure that particular care is taken to restrain any tendency on the part of the sponsor to pursue their interests to the detriment of those of the host country. The Council suggested that when research funded by external sponsors is proposed which falls outside the national priorities for research into health care set by a host country, those proposing the research should be required to justify the choice of the research topic to the appropriate research ethics committees in both the host and sponsoring countries¹⁴.

I think that researchers and research sponsors can go further than simply justifying the choice of research topic. Even though the research topic may not be on the list of research priorities, the research itself can attract other benefits to the community which may be of priority. After all, the research will use up time and resources of the host country, trained personnel will also most likely be employed in the study. In order to determine what these other benefits are, researchers should engage with stakeholders in the community to the extent possible from health officials to policy mak-

¹³ Kass N, Hyder A. Attitudes and Experiences of US and Developing Country Investigators Regarding US Human Subjects Regulations. In: National Bioethics Advisory Commission (United States of America). *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*. Bethesda: US Dept. of Commerce, Technology Administration, National Technical Information Service; 2001.

¹⁴ Nuffield Council on Bioethics. *The Ethics of Research related to Healthcare in Developing Countries*. London: Nuffield Council of Bioethics; 1999: Paragraph. 2.32.

ers, to members of the public. The entire research process can then be seen in a more global sense as a negotiation process where the community identifies needs outside of the research topic itself, which are of importance, and from which the community will benefit. The needs themselves might be quite diverse and may include facilities like a new community health clinic, a series of wells to provide clean water or even the establishment of a vaccination program; the point being that the community should be empowered enough to negotiate the conditions under which such research will take place. This empowerment of the community to negotiate terms of the research is not exclusive to only this category of research.

I am aware that many communities may not have the power to “engage”. Rich research sponsors can wield a lot of influence from the top all the way down, developing world governments may not have adequate infrastructure to monitor research; the potential research subjects are often poor and cannot read or write with the result that the bargaining power is unequal. This is why there is need for more caution and caveats when such research is proposed. Questions will arise as to who is the community and how does one define “benefit” should it be a health benefit? An economic benefit? Should the benefits be directed to the individuals in the study? To the community involved? To the country at large? These are not easy issues to resolve and therefore there needs to be much investment and commitment from all the parties in order to reach well-balanced solutions.

- C. Research that is **not responsive** to a health need of the community, and does **not** fall within the health research priorities of the community.

The third category has been the subject of much debate and I will not discuss it at length.

Most, if not all of the international ethics guidelines have tried to prevent this type of research from occurring due to the potential for exploitation. Having said that, there may be communities that might be willing to assume the risks of the certain types of research (depending of course on degree of risk) for which they will not benefit directly from, in exchange for other types of benefits which they consider to be of greater importance to them. This may sound plausible in theory, but, unfortunately, in reality, many resources poor communities do not have the negotiating or bargaining power that is necessary to make such deals with rich sponsors and there is a great danger or exploitation-and a strong argument can be made as to why such research has to be avoided all together.

Conclusion

Whereas we hear a lot about the fact that community input is important in the drafting of protocols for research and that local researchers and stakeholders should be involved in the design of research studies, I think that we should also focus on the involvement of communities in determining what type of research should occur in the first place, and what conditions, if any, should be attached to such research. I have given three broad classifications under which these discussions can take place. The first one is the optimal situation where the interests of the researchers/research sponsors coincide with the interests of the host community and the research is of priority and benefit to the community. This is the goal towards which researchers (both local and international) should strive if the research gap between poor and rich countries is going to be narrowed. I should also mention that results from such research stand a better chance of being translated into national policies since they fit into the wider national research plan.

The second situation describes a scenario where the research question itself may be of some relevance to the community, but it does not feature high or at all on the list of health research priorities in that particular community. In that case, I do not think such research should be abandoned entirely **IF** the research sponsors are willing to engage with the community to determine the conditions under which such research should take place. This could be a discussion on the benefits that research sponsors can provide, which are of importance to the health and wellbeing of that community. The caveat being that the community must have the upper hand in the negotiations. Not always an easy task.

The third category is to be approached with great caution, if at all, because of the great po-

tential for exploitation of vulnerable research participants due to the unequal bargaining power between the parties involved. The levels of risks that a community is willing to endure in a clinical trial that has no relevance to them is also a contentious issue and the problem is further compounded by the difficulties in obtaining informed consent from such communities.

In all these categories however, there is an underlying factor; that is, researchers and research sponsors must make serious attempts to engage with host countries or host communities from the earliest stage possible; and that is not in the designing of protocols, but rather, in deciding what protocols to develop in the first place that will provide maximum benefit to the health and wellbeing of the community.