

Introduction: The Role of International Stakeholders in Genomics and Public Health

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INTRODUCTION

In today's world, genomics and public health advancements are dependent upon international collaboration. Scientists collaborating at an international level carry a significant share of genomics research. Moreover, funding agencies and private funders routinely fund international projects. The World Health Organization, UNESCO, and other international institutions are key actors in the development of public health policies and strategies. Finally, patients all around the world are ultimately the recipients of the benefits of such advancements. What is the role of these different stakeholders?

Stakeholder involvement raises both theoretical and practical challenges. The interconnected nature of scientific research and the global scale of the challenges that public health concerns raise are only likely to increase the international dimension of genomics and public health activities. Moreover, differences in the cultural values, legal frameworks and political goals of the various stakeholders may have a negative impact on future development. How do we acknowledge the international dimension of genomics research and develop strategies that aim to foster international dialogue among the key actors? What groups should be represented? Who can legitimately speak for each group? How to reconcile conflicting

interests? What process of involvement would ensure both efficiency and fairness?

Historically, decisions affecting the general public have been made with input from selected people—those with responsibility for the decisions or with applicable technical expertise. Increasingly, the broader public is demanding more direct involvement in decisions that will affect their lives. Other chapters in this book present a variety of points of view in order to offer insight into the role that some international stakeholders play in the complex arena of genomics and public health. In particular, these chapters describe the activities of international networks of scientists in promoting both genomics research and equitable access to its benefits, as well as the role that patients and, more generally, the public ought to play in debating the merits and justifications of conducting genomics research and its links to public health. This chapter explores the practical, ethical, and policy justifications for the role of international stakeholders in genomics and public health. It then discusses some principles and methods for a framework for stakeholder involvement in deliberations at an international level.

2. THE BASIS OF STAKEHOLDER INVOLVEMENT IN GENOMICS AND PUBLIC HEALTH

2.1 *Practical Justifications*

Genomics is a very promising field of research when it comes to improving the health of individuals. Although genomics knowledge is also likely to benefit public health, the book of genomics' contribution to public health still needs to be written, for the most part. The scale of the scientific, economic and political challenges imposed by genomic research requires efforts involving a plurality of actors on an international level. In fact, in order to translate the potential of genomics research, time, resources and the involvement of the research community worldwide are required. Moreover, a series of practical considerations—world-wide genetic variation, the

need for large-scale databases rich in data and other information from individuals with a variety of social and health backgrounds, the uncertainties surrounding the success of translating genomic research into treatments and pharmaceutical products that would enhance individuals' health, funding efforts that go beyond a single institution, and the uncertainties regarding the economic profitability of these efforts—all require coordinated and extensive efforts.

The interconnected nature of scientific research and the global scale of the challenges that public health concerns raise are only likely to increase the international dimension of genomics and public health activities. However, differences in the cultural values, legal frameworks and political goals of the various stakeholders may have a negative impact on future development. Consequently, it is important, from a practical point of view, that the international dimension of genomic research is acknowledged and that those strategies which aim to foster international dialogue among its key actors are developed.

2.2 *Ethical Justifications*

Although practical justifications based on the scale of the challenges imposed by the efforts to combine genomics and public health could alone justify involving stakeholders in discussing and deliberating genomics and public health issues, ethical reasons add support to recommending (if not requiring) stakeholder involvement at the international level. Ethical reasoning is an important step when reasoning about genomics and public health because health is a public good, and decisions concerning health can benefit and, more importantly, can harm humanity. Therefore, responsible persons ought to constantly reason about what is ethically required, permissible, or non-justifiable whenever discussing a possible course of action (policies, research programmes, or other initiatives) relating to genomics and public health. The ethical arguments that can be advanced to support this claim are based on concerns about trust, respect for the rights of the stakeholders and autonomy, with the related ideas of pluralism and deliberative democracy.

Trust is an important justification. Given that public health policies are important to various stakeholders and that public health policies often need to balance—and sometimes sacrifice—some interests against other interests, stakeholders' ability to trust policymakers to make the best possible decision is necessary for the future viability of policies affecting genomics and public health. Thus, a consequentialist perspective supports stakeholder involvement: if stakeholders trust the policymaking process, they are likely to accept its outcome even if it limits some of their interests, and genomics and public health initiatives are likely to benefit from that, as will the health of individuals. Trust is certainly fostered by stakeholder involvement, which offers opportunities for communication between policymakers and stakeholders and the possibility for the latter to express their views in the policymaking process.

Stakeholder involvement may also offer an opportunity to protect the rights of those affected by public health policies. Involving stakeholders from the community that will be affected by the public health programmes or by genomic research is certainly ethically desirable. Along these lines, the American Public Health Association's Public Health Code of Ethics, which is concerned with respecting the rights of the individuals in the community, provides that "2) Public health should achieve community health in a way that respects the rights of individuals in the community" and that "3) Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members."¹

Autonomy is also an important ethical consideration. Granting ethical consideration to autonomy reflects the idea that each individual is the best judge of his or her own interests. As a consequence, individuals should be in the position of self-determination, of deciding their destiny for themselves. Autonomy, however, has very strong individualistic features as it has been traditionally construed as a space that ought to be protected against influences from state authority or, more generally, from collective power. Genomics and public health are areas where an individualist

approach to autonomy is challenged. How to reconcile autonomy and the protection of common goods?

Expressing preferences and acting in conformity with our value system deserves ethical consideration. When dealing with public goods such as health and knowledge, collective actions must reflect individuals' desires and values. Stakeholder involvement is certainly a challenge to individualist autonomy, but it is also an opportunity for reinforcing individuals' "self ruling" prerogatives in at least two dimensions: pluralism and deliberative democracy.

First, stakeholder involvement should be seen as a means to include and mediate between diverse, culturally and value-based points of view. When dealing with research on a global scale that connects stakeholders in different parts of the world, differences in cultural values may be challenging. One strategy to cope with this challenge is to adopt a top-down approach in which principles are decided by actors—international institutions, major funding bodies, and large research institutions—in a position to impose their views on other stakeholders. A different and preferable strategy is to establish a process, that involves a plurality of stakeholders and that brings together the points of view of actors with different values, both from the centre and the periphery of genomic research. Although apparently less efficient, the latter approach seems to be ethically preferable because respect for the different value systems of the various international stakeholders is an important part of managing public goods such as health and biomedical research.

Second, stakeholder involvement allows individuals, directly or through their representatives, to participate in decisions affecting public goods so that the outcomes of deliberation reflect, to some extent, their values and desires. Indeed, democracy is often considered the best political arrangement whenever decisions affecting public goods are necessary. Deliberative democracy theories translate the too general ideal of democracy into a viable framework for democratic collective actions and decisions.² Emphasizing a shared process of discussion, following rules of rational argument and non-coercive exchange of views, Joshua Cohen, a prominent

deliberative democracy scholar, argues that “to justify the exercise of collective political power is to proceed on the basis of a free public reasoning among equals.”³ In other words, “free public reasoning among equals” is required when health and other public goods are at stake. Within this conceptual framework, involving stakeholders in discussions and deliberations is certainly a particularly attractive strategy for discharging the duty to justify the exercise of collective political power.

The interaction between deliberative democracy and genomics and public health will be the main theme of the rest of this chapter. Different ethical considerations are in favour of the view that strategies which aim to foster international dialogue among key actors ought to be supported and implemented. Before proposing a working definition of “stakeholder” and delineating a stakeholder involvement process, this chapter will discuss the policy justifications for involving stakeholders in deliberations on genomics and public health.

2.3 *Policy Justifications*

In addition to practical and ethical considerations, involving stakeholders in deliberations on genomics and public health is also defensible based on two policy justifications. First, stakeholder involvement can be instrumental to a better analysis of the issues. In fact, discussing public issues helps stakeholders form opinions when they might otherwise have none or to refine and revise their views according to the views proposed by other stakeholders. The quality of decision-making should improve if it must stand up to public examination of its appropriateness and coherence. Second, stakeholder involvement usually leads participating stakeholders to commit to the deliberation process that leads to a decision and to uphold its outcomes. Thus, it increases the authoritative power of any policy outcome. As the World Health Organization recently pointed out, “The political feasibility of policy depends on: the power of the players; their position; the intensity of their commitment; and their numbers.”⁴ Thus, the stakeholder’s “voice” of acceptance is widely

perceived to add legitimacy to the decision-making process. Norman Daniels nicely summarizes the policy benefits of involving stakeholders as follows:

“[Stakeholders] improve deliberation about relevant reasons, potentially adding to the range of considerations and the perspectives from which they are evaluated. By being involved, they take some ownership of the results, and through their potential roles as public critics or advocates, they can help explain and defend decisions they have come to take ownership for.”⁵

3 THE RELEVANT STAKEHOLDERS: A WORKING DEFINITION

Until this point, this chapter has made a case for stakeholder involvement without defining the term “stakeholder.” Very simply put, the American Heritage Dictionary of the English Language defines a “stakeholder” as “One who has a share or an interest, as in an enterprise.”⁶ Similarly, the World Health Organization tells us that a “stakeholder” is “Any party to a transaction which has particular interests in its outcome”⁷ or, alternatively, “who stands to win or lose by a line of policy.”⁸ Consequently, the notion of stakeholder is built around the concept of interest and policy outcome. “Interest” is defined both in terms of “right, claim, or legal share,”⁹ and in terms of “participation in advantage and responsibility.”¹⁰ “Policy outcome” is synonymous with the “end result...consequence [or] effect” of a given policy.¹¹ In sum, this semantic excursus shows that the notion of shareholder entails the consideration of three elements: (1) a stake or interest in the outcome of a certain course of actions, (2) participation in the deliberations involving that course of actions, and (3) responsibilities towards other stakeholders.

Three implications follow from this working definition of “stakeholder.” First, only actors who have an interest in the outcome of genomics research and public health policies and programmes can be listed among the relevant stakeholders. Second, if having a vested interest is the discriminating factor when it comes to including potential stakeholders among those who ought to be involved in deliberations, it also plays a critical role in the stakeholder

involvement process. Stakeholders must declare what their stake is, articulate their interest in relation to the genomics and public health issue to be deliberated, and be accountable for their actions based on a declared interest to the other stakeholders. Third, rights and responsibilities follow from their inclusion among relevant stakeholders. If these individuals are entitled to be involved in deliberations which have outcomes that may affect them, they are also responsible for representing, or failing to represent, specific interests and for failing to act reasonably. Accountability is simply the reserve side of the right to be included.

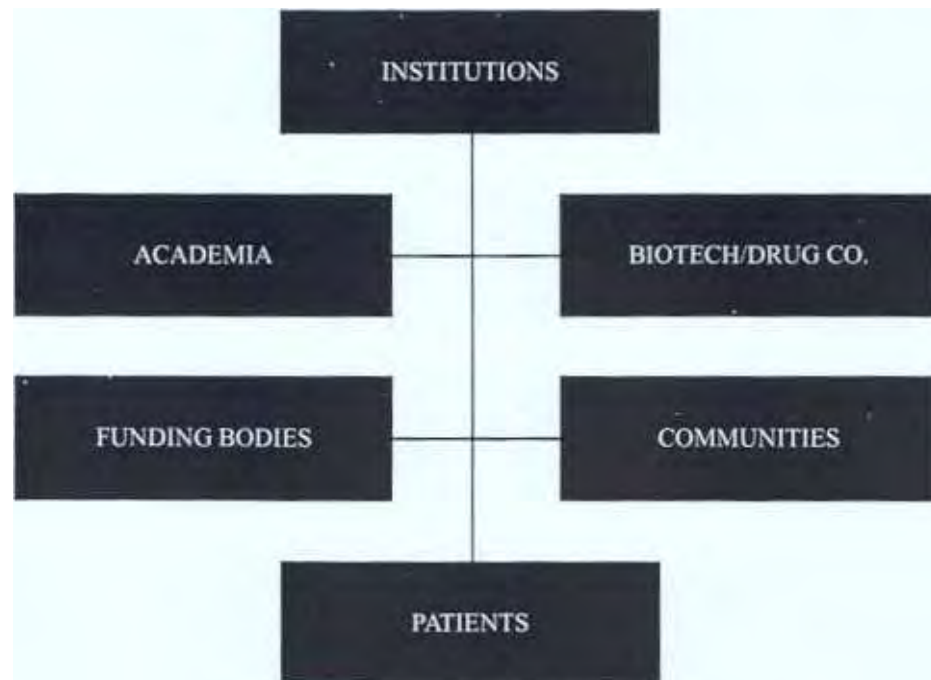
4. A LIST OF RELEVANT STAKEHOLDERS IN GENOMICS AND PUBLIC HEALTH

Based on the proposed working definition, it is possible to reason about stakeholders in genomics and public health in terms of individual and collective actors who have a stake in the outcome of genomics and public health policies and programmes. Among them, one could first name international organizations—the World Health Organization, the World Intellectual Property Organization, the World Trade Organization, UNESCO and others—that are, albeit with different powers and competencies, responsible for promoting and implementing policies in this area. Other institutional actors, at the national and international level, are also included in the category of policymakers: the US National Institutes of Health is an example of a national, governmental institution that is in the position to influence policies with international ramifications. Funding bodies should also be included in the list. The UK Medical Research Council, the Gates Foundation, and the NIH once again, have certain rights and responsibilities that follow from their involvement in funding projects on a global scale. Academics are also stakeholders because, on one hand, they contribute the most in terms of research to the field of genomics and public health and, on the other hand, they are greatly affected by policies in this area. Private companies—primarily biotech and pharmaceutical companies—have a vested, commercial interest, flowing from their investments in research and development, linked to the outcome of the research itself but also

dependent upon the legal framework and the economic environment in which genomics and public health actions take place. Of course, patients are key stakeholders because, ultimately, they are the real recipients of the efforts to translate genomic knowledge into treatments and products that benefit their health. Finally, communities are important stakeholders because they are certainly affected by public health policies and programmes and also because they provide the economic (mostly through taxation) and political support for the design and implementation of genomic research and public health policies and programmes.

The interests of the listed stakeholders, however, sometimes overlap, as highlighted by Diagram 1. An example of how the line separating these categories of stakeholders is blurred is an academic who might be funded by a private company, a policymaker who could be linked to patients with specific conditions, or an institution that is inclined to favour academics doing research in its country as opposed to more qualified or better funded researchers from other countries.

DIAGRAM THE STAKEHOLDERS IN PUBLIC HEALTH GENOMICS



5 THE STAKEHOLDER INVOLVEMENT PROCESS: PRINCIPLES

The final two sections of this chapter will discuss a framework for the involvement of stakeholders in deliberations concerning genomics and public health policies and programmes at an international level. The design of such a framework is challenging. On an international level, efficiency, fairness, and accountability are arguably the principles that provide the strongest foundations for the process of involving stakeholders in deliberations.

5 *Efficiency*

Efficiency must be construed as a function of *time* and *quality*. First, time is a critical element when goods of primary importance, such as healthcare, are at stake. Indeed, the potential benefits of genomics and the pressure imposed by public health challenges require that decisions concerning policies and programmes be reached within a reasonable delay from the time policy actions are sought. A process that requires an excessive amount of time would fail to achieve its goal, notwithstanding the merits of the policy outcomes. Second, the outcome of the deliberation process must lead to the design and implementation of policies and programmes that will effectively foster advancements in genomic research and ultimately gather information that will lead to improvement in public health measures.

5.2 *Fairness*

In this context, fairness must be intended both in its substantive and its procedural dimensions. The most important substantive trait of fairness is that stakeholder involvement improves the outcomes of the deliberation process by making them more fair. As already discussed, genomics and public health deliberations affect health outcomes, and health is a public good. Moreover, these deliberations are likely to involve certain interests. However, if more views are taken into account and more rationales are brought to the discussion in order to

justify a course of action, the outcomes will likely be more fair, being grounded on a broad information base and assessed through pluralistic scrutiny.

Procedural traits of fairness encompass a variety of traits. First, fairness requires that stakeholder involvement leads to a discussion where the “majority rule does not make right.” Although dissent and disagreement are likely to colour any stakeholder involvement process, the goal of such process is not to reach a consensus of more than half of the stakeholders in order for the deliberation to end, but rather through a dialogic assessment of the strength of the various interests, rationales and positions. Sometimes, an agreement is not required, and the opportunity for increasing the understanding of the various positions is a superior goal to be achieved through stakeholder involvement. Other times, formal decision-making rules apply to a specific deliberation. This is the case, for instance, in international organizations’ drafting of guidelines. Specific rules regulate the process that leads to the approval of the guidelines. However, even if the process is regulated, it is important that decisions are taken not simply because “the majority says so” but rather because the proposed outcome is superior from a political, technical and ethical perspective. Stakeholder involvement must foster the contribution of all points of view, and deliberation shall not ignore minority views: as long as they are rooted in reason, disagreement and dissent should be given some weight.

This leads to the second trait of procedural fairness: the non-exclusion rule. Stakeholders ought not to be excluded based on discriminatory criteria or because of socio-economic barriers (lack of funding, linguistic barriers, lack of political representation.). This rule will be relevant to the discussion of selection criteria below.

Finally, unless in its purely informal forms, stakeholder involvement must be structured around certain procedural rules that participants must agree upon. In fact, it is crucial that ground rules are set and that the selected stakeholders agree to respect them. Aiming to provide a clear framework for fair participation, the ground rules must encourage stakeholders to express reasoned perspectives on the issues

being debated, balance differences in stakeholders' power and ability to influence the discussion and deliberation, indicate the scope of stakeholder involvement, and finally, indicate what decision-making process will be adopted, if decisions are required.

5.3 *Accountability*

As a corollary of the requirements of efficiency and fairness, involved stakeholders must be held accountable for their participation, in case they act unreasonably or non-cooperatively. Several strategies may contribute to implement accountability.¹²

The publicity requirement—information regarding the stakeholder involvement process must be publicly available, understandable by non-participating stakeholders, and aim to render the process as transparent as possible—offers the opportunity for scrutinizing the stakeholders and therefore for their accountability. By offering the possibility for the public or other stakeholders—especially those who have not been selected to participate in the process—to scrutinize the actions of the selected stakeholders, the publicity and transparency of the process lead to greater accountability. The full rationale of any recommendation or decision should also be publicly accessible.

Moreover, accountability may also be enhanced by requiring, at the outset of the process, that selected stakeholders declare and articulate the stake they have in genomics and public health, and state who they represent and their authority to do so. Such statements will set the scope of their involvement and limit the range of rationales that are permitted to serve as basis for advocating certain measures. Consequently, they will be accountable based on the declared stakes they aim to represent should they adopt an unreasonable or non-cooperative attitude.

Finally, although certainly not easy to implement, a third possible accountability strategy is the exclusion of unreasonable or non-cooperative stakeholders from deliberative processes in the future. Peer pressure is often a powerful accountability strategy. However,



this strategy is easier to implement whenever stakeholders are selected by invitation, and a law or other binding regulations do not formally regulate the stakeholder involvement process.

6. THE STAKEHOLDER INVOLVEMENT PROCESS: METHODS AND ILLUSTRATIONS

Efficiency, fairness, and accountability are principles that both inform and shape the stakeholder involvement process at an international level. The following sections describe some methods that can be used to design and implement such a process.

6.1 *Stakeholder Selection*

If efficiency is construed as a function of time and quality and is thought to be a primary concern in reasoning about genomics and public health, the stakeholder involvement process must reflect these assumptions. When it comes to the selection of stakeholders, should all stakeholders or only major stakeholders be involved? Ideally, all stakeholders would be involved. However, efficiency concerns may justify restricting involvement to stakeholders who either other, higher stakes connect to the outcome of the deliberation or to stakeholders with a wider basis of representation (for instance, a representative of a trade association rather than individual representatives from a number of companies that also belong that that trade association.)

Fairness concerns also play an important role in selecting the stakeholders to be involved. Since stakeholder involvement provides support to policy outcomes that potentially limit or sacrifice the interests of some categories of stakeholders, the opportunity to participate in public deliberation and scrutiny of the proposed policies is essential. But what does the requirement for fairness in electing participants entail? First, stakeholders should not be excluded on discriminatory criteria such as political views or membership in certain groups (religious groups, ethnic minorities). Second,

stakeholders should not be excluded because of socio-economic barriers such as inability to travel due to lack of funding, inability to participate in deliberations due to linguistic barriers, or lack of political representation because a specific community is not a formal member of the UN or an identifiable nation under international law. Technological advances have made it possible to involve stakeholders in remote or poor areas of the world (for instance, by holding conferences over the internet), and therefore, alternative strategies must be explored before excluding stakeholders when socio-economic barriers prevent them from actively engaging in the discussion.

Moreover, the relevant stakeholders vary depending on the level of decision-making. If the genomics and public health deliberation involves international organizations, the representation of various geographical regions is a key factor because wider representation leads to the inclusion of stakeholders with diverse cultural and professional backgrounds, from areas with various levels of economic developmental and societal arrangements. On the other hand, if discussions concern a project affecting a specific community, representatives of community groups must take part in the process. Special consideration should be given to vulnerable groups that are potentially affected by the project. If the same project also aims to translate research in treatment, the involvement of representatives from industry and from the local ministry of health seems particularly appropriate.

6.2 *Setting Ground Rules*

Efficiency, fairness, and accountability also require setting ground rules that regulate the stakeholder involvement process. Efficiency requires a clear framework that limits stakeholders' actions without impeding their participation. Ground rules may include provisions regarding the timing and means of communication, the means that ensure the publicity of the process, the decision-making rules on any given issue (if required), the rules on dissent and disagreement, and finally, the rules on how to monitor and revise the policy or programme in the aftermath of the stakeholder involvement process.

Fairness requires that the ground rules favour equal participation and fair outcomes. Finally, accountability requires that participating stakeholders commit to the process, and cannot withdraw from it unless exceptional circumstances intervene.

6.3 *Publicity and Transparency*

Adequate publicity or transparency of the stakeholder involvement process is an important requirement. Deliberations concerning genomics and public health involve decisions affecting a public good, health. Therefore, securing adequate publicity or transparency of the stakeholder involvement process is certainly an important yet ambitious goal. The rationale seems even more compelling whenever international organizations or national governments are involved in the process or whenever public money is used to fund research or public health initiatives.

Ideally, the publicity requirement requires that the information be both widely accessible to the public and comprehensible by all stakeholders. If international organizations are involved, consultation organized through a form of publicly accessible hearings, including the presentation of evidence and arguments, is the primary avenue for facilitating direct participation in the process. Broadcasting or making those hearings available over the internet is an effective alternative to direct participation. Making meeting notes—including an indication of the invited parties along with their statement of interests—available for comment is also an important tool. Whenever recommendations are present, it is crucial that the rationale for the grounds of the recommendations is publicly available. Publishing in open-source journals is also an important tool that favours the involvement of stakeholders who face economic barriers to participating directly in the debate.

7 CONCLUSIONS

Human welfare depends in part upon advancements in genomic knowledge. Consequently, genomics is strategic to public health improvement in the future. However, the challenges that genomics and public health raise are immense, and require efforts that are coordinated worldwide and that involve a variety of stakeholders. Practical, ethical and policy considerations support this claim.

Involving stakeholders in reasoning about genomics and public health is in itself challenging. Stakeholders may have interests that are economically, culturally and politically incompatible. However, the arguments in favour of opening debates and deliberation concerning an important public good such as health are compelling. The challenge is to design a framework that supports this vision. On an international level, efficiency, fairness and accountability are principles that provide the strongest foundations for the process involving stakeholders in deliberations. Those principles also provide practical guidance on how to implement stakeholder involvement with regard to the selection of stakeholders, setting ground rules that govern such a process, and its publicity and transparency. Involving all relevant actors in debates over genomics and public health is a book that, for the most part, has yet to be written. However, although the involvement of all relevant stakeholders is proving to be challenging, the lack of it would be a loss for humanity.

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