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Starting on the right foot:
Public consultation to inform issue definition in genome policy

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Abstract

This paper reports the first phase of a project to evaluate how different methods of applied ethics assess public interests in governing genomics and biotechnology. The objective was to select three topics and issues for further research in order to provide a practical context for a diverse range of public interests. Ten focus groups with and without direct interests in genetics and genomics were asked to characterize the field of genomics, their hopes and their concerns. Thematic analysis identified the range of topics, which were categorized into types of interests and their relation to human health, environment and food. The nature and scope of these concerns were further assessed, and three topic areas were proposed.

The preliminary version of the analysis was critiqued by an interdisciplinary group of academics on-line and at an international workshop held in January 2003. The topic "governance of genomics" replaced an earlier suggestion, reflecting the concerns of the workshop participants and supported by analysis of the focus groups. In addition to providing a representative approach to defining the issues for ethical analysis, the project stimulated participants' interest in learning more about genomics and being more involved in discussions about the related public goods and governance.

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1. Introduction

Genomic research (and its eventual products) is a high technology sector supported by large amounts of public and private resources[i,ii]. This sector is commonly promoted on the basis of potential "public benefits." For example, Genome Canada's glossary[iii] defines "genomics" as a study "of genes and their function" that is:

> *...bringing about a revolution in our understanding of the molecular mechanisms of disease, including the complex interplay of genetic and environmental factors.... stimulating the discovery of breakthrough healthcare products by revealing thousands of new biological targets for the development of drugs, and by giving scientists innovative ways to design new drugs, vaccines and DNA diagnostics.*

Initiated in April 2002 with a grant from Genome Canada[1], *Democracy, Ethics and Genomics: Consultation, Deliberation and Modelling* is a project designed to compare different ethical approaches to public involvement in governing genomics and biotechnology. We believe that pursuing a methodological framework, as well as processes and criteria in this conceptually rich, complex and high profile area will contribute significantly to appropriately incorporating the interests of the public in all areas of policy development.

The project has two objectives.
1. **To develop a defensible methodological framework within which government, industry and other parties interested in the area of genomic research, its commercialization, application and regulation, can conduct policy development processes that meet the democratic values of representation, transparency and accountability.** We intend to achieve this objective by bringing together three research streams—consultation, democratic deliberation and computer-based modelling—to test alternative approaches to meeting these democratic values.

2. **To make recommendations for determining appropriate processes and criteria for the democratic governance of genomics in relation to environmental, ethical, legal and social issues[2].**

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[1] "Genome Canada is the primary funding and information resource relating to genomics and proteomics in Canada." (http://www.genomecanada.ca/fsTemp.asp?l=e, captured 12/05/2002)

[2] The project should also provide an evidence-based evaluation of the relevance of various methods of applied ethics to the democratic management of genomic research.

The first stages of this project (completed between fall 2002 and winter 2003) were taken up with conducting and analyzing the results of *issue definition focus groups*. Based on that work, this paper considers:

- the advantages of defining issues for consultation and policy analysis according to a diversity of interests assessed through focus group research; and
- how this process can serve to define policy issues in a manner that is more representative of the "public interest."

"Experts" and the people

Governance in this document is understood to include:

- policy, law and all other forms of regulation;
- the apparatus or structures used to design and implement regulations;
- market mechanisms that are not, strictly speaking regulations; and
- other social behaviour that serves a regulating function, such as cultural norms.

Governance necessarily embodies explicit or implicit judgements about the relative weight of the interests and concerns expressed by various groups, including the public[iv]. That said, there is a tendency in most industrialized countries to depend on "experts" to describe and assess the benefits, risks and merits of research and development, particularly in areas of high technology. Consequently, governments typically look to:

- researchers within a given field to define the potential scope of a particular technology;
- industry representatives to identify opportunities for finance, manufacture and distribution; and
- lawyers, policy analysts, economists and ethicists to suggest or create frameworks for managing this range of opportunities.

The presumption often appears to be that government itself adequately represents public interests. If and when the public is consulted, it is (generally) to identify where they will use a technology—rather than whether to use the technology—to identify concerns with its use, or to reduce the influence of "interest groups." This attitude and risk perception research sees public interest as a phenomenon to be described, evaluated and moved, but not engaged.

The motivation behind this reliance on experts is complex. Even a cursory analysis quickly identifies a web of relationships that increasingly underlie corporate, political and university strategies, the growth in universities and corporations of professional risk/benefit expertise, the difficulty inherent in identifying the public interest and a persistent belief that the public is ignorant of and uninterested in science[v].

Unlike genomics, which is a relatively new area of study, environmental consultation has a long history of public consultation and risk assessment. In *Ten propositions for untangling descriptive and prescriptive lessons in risk perception findings*[vi] T. McDaniels explains that while there is merit in having technical specialists make some judgements, their expertise does not extend to objective identification of what risks are important, or why.

There is no such thing as an objective characterization of risk. All risk characterizations and all analysis are subjective and value-laden, including lay and expert views. . .When technical specialists call for a more "objective" characterization of risk, they are simply asking for a greater role. . . selecting what risks are important, and why, are not solely technical judgements.

These (and other) factors mean that governance regimes, including public policy and licensing, often rely on analysis that moves beyond "solely technical judgements" of risks and benefits. It is in this realm that dominant ideologies, as well as powerful economic and political interests influence governance. It is also the realm where the public can bring substantial pressure to bear.

According to a recent work on public opinion and genetics by C. Condit:

...in a democratic society [where] the lay public can exert substantial influence on the progress of science and the use of science-based technologies... It is not surprising... that all parties involved—including scientists, legislators, physicians and ethicists—are quick to make assertions of what the public believes...[vii]

Condit goes on to note that the literature on lay attitudes in the area of genetics has a consumer orientation. The focus is on "relatively small groups of people who use genetic information and technologies in clinical or research settings." According to Condit, this could lead to individual consumers "who are pursuing their own private advantages and interests" being mistaken for the public, their necessarily narrow self-interests being misidentified as the public's interests. The fact that "the public" is a collective that is difficult to accurately describe or survey, increases the likelihood of this happening.

Mistaking consumers for the public—rather than recognizing that consumer interests are only one component of a public's interest—affects governance in a number of ways, most obviously by supporting the presumption that identifying and evaluating interests is governed by market system competition[viii]. Equating consumers and the public also reinforces a belief among many researchers and decision makers that the public simply needs educating about the safety and benefits of research to alleviate concerns and deflate controversy.[ix,x,xi]

In a paper prepared for the Stewardship Standing Committee of the Canadian Biotechnology Advisory Committee, S. Sherwin emphasized the importance of "justly arbitrating among competing interests by establishing fair procedures that are responsive to the full range of interests at stake," as well as putting in place "an open and responsive process that will allow input from those whose interests might often be overlooked or misunderstood."[xii] Similar to Condit, Sherwin is careful to distinguish product consumers (*i.e.*, stakeholders who need safe, reliable, affordable products, accurate information and protection from exploitation) from citizens concerned with the broader social, cultural or environmental effect of developing or distributing those products.[xiii]

Sherwin is also among those who make important distinctions between protecting natural rights (the fair arbitration of competing interests), common goods (things of interest to all members of a society) and collective goods (things achievable only through collective

action).[xiv] These distinctions present a theoretical richness important for ethical reflection and analysis of policy options on governance in the public interest.

In *From Chance to Choice: Genetics and Justice*,[xv] a volume arising from a project sponsored by the U.S. Program on Ethical, Social and Legal Implications of the Human Genome Project (ELSI), A. Buchanan, D.W. Brock, N. Daniels, and D. Wikler discuss the importance in society of the "cooperative framework" within which competing interests (*e.g.*, interests held by the public, consumers, corporations, researchers and government agencies) need to be balanced. The authors point out that representing diverse public or citizen interests may require a more inclusive framework than is provided by the market or elected officials.

> *Theorists of justice have not only failed to supply a principled account of how… conflicting interests ought to be balanced; they have almost without exception failed to identify the problem as one of justice. Instead, they have framed the first problem of justice as that of how to determine the fair distribution of the burdens and benefits of social cooperation, proceeding on the assumption that the basic characteristics of the cooperative scheme is given, and that most or all individuals to whom distributive justice is owed are participants in that cooperative scheme. There is a prior problem of justice, however… that of choosing the cooperative framework itself.*

These justice theorists[xvi,xvii], as well as public interest groups in a number of areas (*e.g.*, disability, environment, and animal welfare) emphasize the importance of procedural approaches to priority setting in a democratic society. Fairly representing the public in processes that establish regulatory frameworks and define the investment of public funds is essential to procedural approaches to justice.

Restricting discussions about the governance of genomic research, its commercialization or application to (for example) consumers and researchers does not meet the test of fairness in a democratic society. If inadequate or inappropriately weighted representation tends to favour specific groups or individuals to the exclusion of others, if the only contribution to debate is through the expression of market place preferences, if the hopes and concerns of self-interested parties are used to define "objective" interests, then the democratic values of representation, transparency and accountability cease to exist.

2. Methodology: starting on the right foot

Defining interests – the focus group model

This project distinguishes *interests*—things in which people perceive themselves to have a right or a share, *e.g.*, common goods—from *issues*—disputes about perceived *interests*—and *topics*—in this case, groupings of issues. Governance issues tend to be disputes about how to assess, balance, trade-off and regulate particular interests.

Defining issues inevitably rules particular interests "in" or "out." Consequently, issue definition is where expert-based approaches to policy development typically begin to bias deliberations and/or consultations. This means that the initial, and possibly most important, challenge to non-expert-based policy discussions in technical areas is the

creation of a framework that recognizes citizen interests and ensures representative participation. Simply identifying an issue (*e.g.*, labelling GMOs) by fiat and relevant stakeholders (*e.g.*, environmental groups) according to the issue is inadequate; the range of interests, which includes both hopes (*e.g.*, a reduction in pesticide use) and concerns (*e.g.*, unintended environmental harm), will be incomplete. Participants will be engaged from, and limited to, the perspective of particular roles (*e.g.*, consumers) rather than as citizens with interests based on citizenship and rooted in the particularities of their lives.

Asking people about issues related to genomic research tends to stimulate complex positional responses replete with assumptions about how to assess interests and govern situations. However, asking people to identify their interests makes it possible to select *topics* related to genomic governance on the basis that they provide a fruitful context for assessing a diversity of relevant interests.

The focus group model of consultation presents a useful tool for identifying a diversity of interests within a particular field. In focus groups, participants have an opportunity to shape discussion, as well as reflect on and respond to comments by group members.[xviii] The shared understandings of aspects of life experiences that result from these conversations enhance participants' abilities to learn from each other.[xix] Consequently, focus groups provide an opportunity to expand the breadth and depth of discussion,[xx] producing knowledge by and for study participants, as well as researchers[3].

Recent work in the United Kingdom has used focus groups to understand lay and professional accounts of genetic practice and policy[xxi, xxii]. In particular, this research critiques the deficit model of lay expertise[4], suggesting instead that focus groups can provide a context in which participants demonstrate considerable sophistication in their knowledge and understanding of complex issues.[xxiii]

In *Democracy, Ethics and Genomics*, identifying interests through focus groups was facilitated by particular decisions about method. For example, each focus group session included only participants recruited into to one of three segments according to their self-described relationship to an area of interest.

1. People uninvolved in genomics with no specific interest in genomic research.
2. People uninvolved in genomics who have an interest in genomic research (*e.g.*, people who: are at risk of a specific illness; are members of environmental non-governmental organizations; take a strong stance on specific aspects of genomic research).
3. People directly involved in some aspect of genomic research (*e.g.*, researchers, regulators, public and private funders).

This increased commonality among members within groups allowing the product of each segment to be analyzed without distinguishing different social and cultural locations[5].

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[3] A survey would have been a better approach for identifying which issues the participants thought were most important. However, a survey would have merely collected the superficial recollection of media coverage, marketing and personal experiences of those participants without a direct interest, and the established positions or vested interests of activists, funders, regulators or researchers.

[4] The view that the public must be "educated" before they can discuss issues and contribute to policy.

[5] This crude filter was applied at this level recognizing that the purpose of the focus groups was to provide a diversity of interests to inform Phase Two of this project and not to produce an exhaustive listing of comparable interests based on a cross-section of social and cultural locations found within Canadian society. Phase Two processes will recruit from a broader selection of interested populations.

Segment 1 and most segment 2 members were recruited by random digit dialing; one group of segment 2 members was identified through contacting NGOs. Potential participants were screened on the telephone using an interview schedule developed by M. Burgess, S. Cox and members of Praxis Inc.[6]. Segment 3 participants were recruited through referral and direct contact with agencies and companies known to have an interest in genomic research, its funding, regulation and application. All potential participants were asked to attend a two hour meeting in their community. Participants in segments 1 and 2 met in the evening and were paid $50 to off-set expenses; segment 3 participants attended meetings at mid-day and received lunch in lieu of financial compensation.

The intent was to recruit four segment 1 groups and three segment 2 groups with one set from each segment recruited from rural postal codes. However, analysis of data from the first meetings revealed no meaningful difference in the range of interests described by segments 1 and 2, therefore the rural segment was reformed to include both 1 and 2. One segment 2 group was composed of members of NGOs.

Another important methodological decision was to establish the scope of the focus groups without introducing technical or authoritarian barriers to the discussion. Accordingly, *genomics* was defined as "the study of the genome of humans, animals and plants," the *genome* as "all the DNA in an organism, including its genes," and the importance of genomics as:

> *How an organism looks, how well it fights disease, even how it behaves,*
> *are all influenced by its genetic makeup in combination with*
> *environmental factors.*

Once the scope of genomics was defined by each focus group—the moderator ensuring that (at a minimum) plant, animal and human genomics were considered—the structure of the focus groups moved participants to a) identify hopes related to genomics, and b) identify concerns related to genomics.

Introductions, identifying the scope of the subject, and identifying hopes related to genomics generally took half of the available time, the remainder being used to identify concerns. Discussions about what was possible or realistic were not encouraged to reduce the influence of technical authority on each group's ability to identify its interests.

To reduce the possibility of strong individuals dominating groups, all participants were asked to first write down their hopes, referring to examples from earlier in the discussion if that was helpful. Participants were then invited to describe their hopes, as well as affirm their agreement with previously mentioned hopes. After all hopes had been identified the moderator repeated the process for concerns.

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[6] Praxis Inc. (www.praxis.ca) provided research support to the project team in a number of areas, including data gathering and analysis and communications, primarily in connection with issue identification and group consultation. Praxis brings over two decades of experience working with all levels of civil society, the general public, government and the private sector. Blending academic training with real-world experience, Praxis staff have held or currently hold appointments as adjunct professors and research associates at universities in Canada and the United States. Praxis also shares its skills through post-graduate lectures, capacity building programs and training manuals at the local, national and international levels.

All of the discussions were recorded by a notetaker supported by audiotape; each example of the range of genomics or its application, as well as participants interests (hopes and concerns) was noted on flip charts. One-way mirrors were not used and observers were kept to a minimum: one co-investigator attended three sessions and met with the moderator and notetaker to debrief following the sessions. The notetakers did not record names and all of the transcripts were cleaned of identifiers before analysis.

Limitations

These 10 focus groups are not representative of the public. Rather they present a range of diversity of interests that are among the interests that should be considered in developing public policy.

The focus groups are also limited in terms of inter-group comparability by the variability of inter-group influences, such as personalities, and context, such as media events that occur between groups. While focus group discussions can generate detailed understanding and a diversity of views, there is a tendency in groups to work toward agreement that might undermine broader diversity.

Almost any recruitment to focus groups will fail to provide a representative sample of a population. Consequently, the extent to which results reflect attitudes or beliefs in the general population cannot be determined. In addition, a requirement of justice is that public consultations pay particular attention to groups who bear the greatest risks and those who are already disadvantaged.[xxiv, xxv] However, since the range of groups generally disadvantaged is too diverse to represent in a general consultation, we elected to delay identifying and involving disadvantaged and risk-bearing groups until we had completed issue selection.

Finally, two assumptions underlie this project. One is that people might make different choices or weigh risks and benefits differently for genomic research applied to medical as opposed to agricultural technologies. The other is that this study would ensure that both individual and population health benefits are represented within human genomics. While the research team resisted any finer definition of the interests, issues or topics prior to conducting and analyzing the results of the focus groups, these assumptions affect the design and analysis.

3. Analysis

The focus groups were not intended to, and did not provide sufficient direction to identify topics for the remainder of the project. Rather, the manner in which interests were identified provided a range of interests present in many areas of genome research or policy considerations.

The analysis of the focus group data was concerned with understanding the widest range of the diversity of interests expressed in the groups. These interests establish accountability at a project level in two ways.
1. The most dominant interests must be considered in the selection of key issues within specific topic areas.
2. The entire list of interests must be used to establish the range of interests and identify stakeholders for each key issue.

To complete the analysis, the moderators for the focus groups (P. Howie and J. Hewson, Praxis Inc.) compiled session notes for each of the ten focus groups from the notetaker's notes, the flip charts and nine audiotapes[7]. These compiled notes described in point form supported through illustrative quotes the scope of genomics identified in the sessions, as well as the hopes and concerns. The author (Burgess) reviewed the session analysis and compared it to the session notes, making very minor modifications. Hewson then constructed summary charts for groups with similar constituencies[8], which Burgess reviewed for consistency and to add increased detail to the categories.

Spreadsheets were created using categories from the revised summary charts and data from the session analyses. The spreadsheets were used to construct the list of hopes and concerns and to count the number of groups that raised each interest, comparing segments 1 and 2 collectively (seven groups) to segment 3 (three groups), and grouping the issues into types of interests (*e.g.*, hopes for cures, prevention and xenotransplantation were characterized as hopes for "advances in human health"). The number of groups raising new categories of interests was noted.

The three categories of information—types of genome research, hopes and concerns– were assessed as follows.

Types of genome research were addressed first by the focus groups. This initial exercise provided assurance that a major component of genomics was not neglected within any group[9].

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[7] One audiotape failed.

[8] I.e., Four groups: randomly recruited with no declared interest (3); randomly recruited with declared interest (2); randomly recruited from rural postal code, with and without declared interest (1); direct recruitment from NGOs and referrals (1); and direct recruitment from funders, researchers and regulators (3);

[9] The # sign indicates the number of groups identifying a particular topic.

Table 1: Types of Genome Research

Human	#	Plant	#
Stem cell research	4	Genetic modification of plants	3
Human genome project - mapping, identifying specific genomes, sequencing, expression	7	Marrying plants	1
		Genetically modified food	4
		Food production and preservation	3
Cures, treatment, prevention of disease	7	Biotechnology	1
Diagnostics, screening, profiling	5	Grow non plant proteins	1
Genetic links to disease	1	Cross species	1
Genetic counselling	1	Marketing biotechnology & GM foods	1
Gene assessment and evaluation	1		
Identifying gene that are carriers of disease	1	Escaped GMOs - alien species, invasive GMOs	1
Switching genes off/on to prevent or cure disease, gene therapy, manipulation, germ line	4	Animals	
		Genetically modified animals	3
		Fish farms	1
Birth defects	1	Crossbreeding	1
Human cloning	5	Create medicine	1
Reproduction	4	Cloning	2
Social programming - isolate genes for specific traits	1	Animal donors: growing human tissue & transplanting to humans	3
Re-grow tissue and body parts	1	Genetically modified insects e.g., for pest control, combat disease	2
Human augmentation	1		
Forensics	2	Species preservation	1
Miscellaneous		Growing animals	1
Biological warfare	1	Types of genomics	
Production of drugs by plants or animals	1	Pharmaco genomics	1
School demonstrations	1	Functional genomics (e.g., bioinfomatics)	1
Archaeology and palaeontology	1		
Computer modelling	1	Pathogenomics	1
Ethical issues	1	Agricultural genomics	2
Proteomics	1	Environmental genomics	1
Transgenics	2	Forestry genomics	1
Intragenics	1	Comparative genomics	1
		Bacteria genomics	1

Hopes were addressed after scope to avoid the risk that addressing concerns early might prevent some participants from listing possible benefits of genomics. The hopes expressed readily divided into human health, food production and the environment, categories of research and products widely identified in media, regulation and marketing. The hopes also seem particularly consumer-oriented, focusing on the kind of products and services that individual participants might hope would result from genomic research.

Whenever the discussion turned to concerns or qualifications, participants were encouraged to save those interests for discussion later, perhaps further discouraging reflection on collective interests or public goods. Nevertheless, population health, population control, increased food production, and environment are areas of hopes raised by the participants that reflect on common interests and stewardship of shared resources.

Table 2: Hopes

Human disease	#	Food	#
Cures for disease including detection, prevention, elimination	8	Food Production: fewer pesticides, eliminate pests, pest resistant	9
New/advanced treatments for disease: (e.g., plant or animal hosts for drug production, less invasive, personalized)	7	Food Production: increase nutritional value and quality	5
		Food production: optimizing and expanding environments	7
Growing organs, tissue, body parts and xenotransplantation	7	Food Production: increase yield and access (e.g., Third World)	9
Diagnostics/screening: early detection and manipulation	7	Food: increase shelf life	1
		Plants	
Gene identification	1	Plants: increased protection from unintended GM transfer	1
Fertility and reproduction	2		
Stem cell research	2	Increasing biodiversity in plants and humans for survival	1
Improved general human health	2		
Human enhancement/social		**Animals**	
Longevity	3	Animals: save endangered species	4
Human augmentation	3	Animals as models	1
Cosmetics	1	Animal efficiency	1
Defeat biological and chemical warfare	2	Cloning: animals	2
Population control	1	**Science**	
Forensics and crime	2	Research: further understanding/science	4
Forensics and paternity	1		
Environment		Research process: precautionary principle, government involvement	1
Environment: repair damage	3		
Environment: green energy sources	2		
Environment: holistic perspective	1	Research: broaden focus	1
Environment: sustainability-more efficient use, reduce depletion	5	Research: to inform decision making	1
Public		**Governance**	
Informing the public: right to know, balanced perspective	1	New industry: popular genomics to increase funding	1
Public involvement	2	Patents vs. gifts to humanity	1
Broad Benefits		New business model for pharmaceutical companies (e.g., boutique therapy)	1
Creating Utopia	1		
Solving world problems	1	Improved regulatory practices	1
Salvation	1		

Concerns were addressed last in the focus groups and the groups often revisited the hopes or types of genome research and considered what concerns they raised, making this the most nuanced discussion. The concerns identified were in some instances individual concerns about issues related to product safety and privacy of information. That said, the range of interests identified was generally more diverse, numerous and more focused on the broader public interest than was found in the discussion on hopes. Many of the concerns were expressed as issues related to governance, where identifying a concern

was something to be considered, but not necessarily the basis for a prohibition. There was also skepticism expressed about the ability of any governance regime to restrict or resist dominant market forces.

Table 3 Concerns

Power	#	Outcomes	#
Control and access: e.g., class, wealth, power, developing world, US dominance or difference	7	Unintended outcomes: unpredictable risks, accidents, interconnectedness of good and bad, new diseases, resistance	8
Relationship between science and governance	1	Interfering with Mother Nature: complexity and unpredictability	1
Religion: e.g., problem to genomics, influences decision making, juxtaposing faith and science	7	Longevity: e.g., overpopulation, financial burden of longer life, stress on social system and environment	7
Control and regulations: who, how, speed of, global	8	Future generations - Our children are at risk?	1
Patents and control	7	Funding	5
Screening: confidentiality, discrimination	6	Negative intentions	6
		Biological warfare	8
Lack of an advisory council	1	Creating new problems	3
Moral/Ethical Issues		Instant evolution	1
Ideological gap: moral disagreement	1	Environmental impact: e.g., cross contamination, endangered wildlife, genetic pollution, reduced biodiversity	2
Playing God: e.g., soul in clones, animal cross-overs, natural order	3		
Screening and trait selection: Who has the right to make decisions? Threshold/draw the line?	4	Economic impact: e.g., countries refusing GM food, unnecessary industries	2
Cloning: spare parts, soldiers, rights	3	Quality and nutrition of GM food	3
Cloning: right to choose or refuse	1	Safety of GM foods	4
Stem cell research: human being, viable vs. aborted	2	Loss of individuality, diversity, adversity, good balance	5
Xenotransplants: concerns about crossing animals and humans	1	Less regard for human life, human drive	4
Genetic modifications and augmentation: social programming, definitions of good and bad	4	Discrimination e.g., toward diseased, disabled, "refusers" (re: children, GM foods) as minority, based on DNA	5
Standards of care: doctor's duty, parents' right to refuse, choice	2	Research Process	
		Irreversible: can't stop genomics	5
Public Knowledge		Lack of holistic approach	2
Public consults: representation and manipulation	2	Vision: e.g., why, way of thinking about genomics	4
Public interested in genomics?	2	Moving too fast	3
Marketing or promoting genomics: media, Hollywood	5	Distrust of motives and conflicts of interest	8
Fear and ignorance as a problem	5	Secrecy	3
Informing the public: general lack of information about genomics, need labels, lack of informed decision making	10	Rights, exploitation of research subjects, testing products - animals and humans	3

4. Initial results: dominant interests

Hopes

Hopes were first used to identify areas of genomic research that might best capture a numerically well represented range of interests. These areas of genome research present the hopes articulated in many of the focus groups, and form the background against which the concerns were identified. Selection of the dominant hopes does not presume that these are hopes to be pursued at the expense of all concerns or alternative hopes[10].

Advances in human health were, in one form or another, a significant part of the discussion of hopes in all 10 focus groups. Three components of advances in human health–health care services for individuals, a reduction of disease and health promotion for the population—were discussed in seven to eight focus groups.

The three distinct components identified were:
- cures, diagnostics, and prevention of disease;
- xenotransplantation and replacement tissues or organs; and
- screening and early detection.

Improvements in food production were also discussed as a hope in all 10 focus groups. Seven to nine focus groups discussed one of three discrete components of improvements in considerable detail. These were:
- reducing pesticide use and pests;
- increasing yield and access to foods; and
- expanding productive agricultural area.

Environmental hopes were discussed in six or seven focus groups, including:
- protection from loss of biodiversity; and
- environmental repair and sustainability of energy sources.

Concerns

Concerns identified by participants in most of the focus groups were broader in nature than hopes and less easily characterized as predominantly human health, food production or environment. This may be partially an artefact of the analysis, which characterized interests under a descriptive label. That said, the dominant concerns can collectively be referred to as problems of governance under uncertainty, diversity and injustice. Certainly the categories combining the interests into governance related issues could be conceptualized differently, but these categories are proposed as adequate for the purpose of selecting areas of genome research that represent these concerns and identifying governance issues within topic areas.

The following types of concerns were discussed in seven or more focus groups[11]:

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[10] Some members of the research team expressed concern that these hopes were dictated or heavily influenced by industry and other dominant interest groups through such things as marketing. Others suggested that the focus groups might reflect consumer-oriented responses of the public that guide industry and media in their communications.

[11] The first number refers to the number of focus groups in segments 1 and 2 (maximum 7 groups) that discussed the concern. The second number refers to the number of segment 3 focus groups (maximum 3 groups) that discussed the concern.

Managing complexity and unpredictability (7/3) includes concerns related to the effect of overpopulation and longer life on social systems and the environmental effects of genomic technologies.

Public information/mis-information (7/3) includes the need for public education, concerns about lack of available information about research or products, the misleading nature of media and other representation, and the lack of interest or involvement of the public in governance.

Equitable distribution of benefits (6/3) includes concerns about patents and costs of innovations, existing problems of distribution and access to food by developing countries, the development of technologies that will be used by the wealthy and confer further advantage, widening economic disparities within and between countries, and the dominance of U.S. and multinational companies.

Effective regulation (6/2) includes concern about the dominance of U.S. and multinational companies, the extent to which policy was scientifically informed, whether the right people were involved in the decisions, and how policy could be both timely and up-to-date.

Weighing absolute moral objections (6/1) includes concerns that anti-abortionist style terrorism would be a source of increased conflict and limit research and the benefits available to society. Some discussions also reflected a concern to be respectful of the beliefs of others, but not to necessarily have social policy directed by them.

Accountability to public interest and scientific integrity (6/3) includes concerns about the secrecy of regulatory decisions and research, the shaping of research by funding sources, the shaping of regulation by industry, and narrow conceptualizations of genomics.

Limit the use of technologies (6/2) includes the concerns that genomics and biotechnology is unstoppable, and that the technological imperative makes it difficult to slow or stop the development of technologies. This includes use of biotechnologies and genomics for warfare, as well as evaluating food and health applications.

Social conformity (5/3) includes concerns about the loss of diversity in nature and society, pressure to accept food and screening technologies, and increased discrimination toward persons with disabilities or any difference that can be characterized in terms of genomic traits or risks. There was also a discussion about how the ability to replace limbs and organs and reduce suffering associated with the human condition could be a loss in terms of our social and personal development.

5. Defining issues and topic areas

Dominant concerns identified in the focus groups (*e.g.*, property rights, confidentiality, discrimination, unintended consequences) cut across all topic areas, while dominant hopes are more specific and can easily be excluded. Accountability to hopes therefore requires that the dominant hopes are represented within the three topic areas.

That said, combining the dominant hopes and concerns from the focus groups highlights the complementary and conflicting interests that must be addressed in the decision making process. This raises the following types of questions.

Managing complexity and unpredictability: How can the risks associated with a topic area be assessed and weighed?

Public information/misinformation: How can informed yet unmanipulated public participation in determining public interests be achieved?

Equitable distribution of benefits: How can research nd the benefits (or burdens) of research and technology development be most fairly distributed?

Effective regulation: How can any governance regime be effective in this area?

Weighing moral objections: How can "in-principle" objections to genome research (*i.e.*, violation of organism integrity) be assessed and given appropriate representation?

Public interest and scientific integrity: How can the area of genomic research be governed to assure that the research is not unduly influenced by industrial or economic considerations, and that public interest is the primary objective?

Limiting the use of technologies: How can acceptable limits to technology be defined and enforced?

Social conformity: How can individual choice related to food production and consumption or differing views of health, appropriate health interventions and alternatives be preserved?

Topic area: Non-human genomics - Atlantic salmon

Salmon (or aquaculture) did not constitute a major discussion point in the focus groups; however, food production and the environment are dominant interests (see above). Some of these interests are clearly reflected in the Genome British Columbia supported *Genomics Research in the Atlantic Salmon Project* (GRASP), while all but the last (*i.e.*, environmental repair and sustainability of energy sources[12]) are possible considerations within salmon genomics and aquaculture. GRASP is a basic science research project in genomics intended to:

- lead to a reduction in fungal, bacterial and viral disease; and
- provide an understanding of how natural biological and biochemical systems work, which may be useful for:
  - increasing yield; and
  - optimizing and expanding environments for aquaculture.

Seed crops (*e.g.*, canola), were considered as a non-human topic area; issues affecting seed production meet all of the dominant interests and are (probably) more immediately relevant to interests such as increased food production. However, we are more likely to make a significant contribution by conducting research in the area of genomics and salmon because GRASP is located in British Columbia where salmon and salmon habitat have a special significance expressed in a variety of rich community perspectives (*e.g.*, First Nations, coastal fishing communities).

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[12] Addressing this hope requires establishing a fourth topic area. However, it is crucial for budgetary and other reasons that the next phase of research be limited to three key issues. We will return to this hope later in the project.

Combining the dominant hopes and concerns from the focus groups highlights the complementary and conflicting interests that must be addressed in the decision making process. The full list of interests expressed in the focus groups suggests that food production and environmental questions must also be formulated.

The following questions are an initial attempt to capture the non-human genomic interests expressed in the focus groups within a governance framework that addresses issues relevant to the topic area of Atlantic salmon.

a. How can the environmental and food production effects of genomically modified salmon be assessed and balanced?
b. How can the public be meaningfully and fairly involved in determining the public interest in salmon genomics and aquaculture?
c. How can the range of permissible genomic modifications of Atlantic salmon and related fish be determined and regulated?
d. What genomic research, modification, biotechnology or distribution should be encouraged to assure widespread or equitable benefits?
e. How (or to what extent) can the preservation of individual or community choice in fish production and consumption be protected or balanced?

Topic area: Human genomics - xenotransplantation and stem cell research

Unlike Atlantic salmon, which was not a discussion point among focus group members, discussions of the dominant public hopes in the area of individual human health (as distinguished from population health) included increased prevention and cures of illness and injury through transplantation, xenotransplantation, regeneration of body parts, gene screening and early detection.

Xenotransplantation is the transplantation of animal tissues or organs into humans; stem cell research focuses on the study and eventually use of human stem cells to produce tissues and organs that can be used therapeutically. Stem cell research also has applications in human and animal reproduction. This very active topic area raises issues of the fair distribution of benefits of research, as well as engaging in-principle objections to stem cell research, and NGOs supporting enhanced transplantation opportunities.

Combining the dominant hopes and concerns from the focus groups highlights the complementary and conflicting interests that must be addressed in the decision making process. The dominant concerns intersect with the hopes for xenotransplantation and stem cell research to raise general governance questions.

The following questions are an initial attempt to capture the human genomic interests expressed in the focus groups within a governance framework that addresses issues relevant to in the topic area of xenotransplantation and stem cell research:

a. How can the concerns about the unpredictable effects of xenotransplantation and stem cell research be balanced with the possible benefits?
b. How can respect for moral concerns about stem cell research be assessed and balanced with the interests of those who wish to pursue the research, develop the technologies or benefit from them?
c. How should the influence of industry and other powerful institutions on the development of xenotransplantation and stem cell research be assessed and governed?

d. What are the threats to diversity, well-being and individual freedom posed by developing xenotransplantation and stem cell research, and what governance models could provide appropriate protection?
e. What uses of xenotransplantation or stem cell technology are inappropriate, and how can they be effectively regulated in the public interest?

Topic Area: Human genomics - DNA banking and population health

Dominant hopes such as prevention, screening and early detection, and the equitable distribution of the benefits of genomics strongly recommend DNA banking or sampling and bioinformatics (computer assisted quantitative analytical techniques in modeling biological systems) as a topic area[13]. Developing the capacity to collect, assess, and compare massive amounts of human, animal and plant genome sequences and related data promises to develop the ability to understand the role of genomics in population health making it possible to devise screens to identify high risk individuals, families or groups with a common founder population, and perhaps to recommend prevention strategies or increased health surveillance. This provides an opportunity to study community and population health as dimensions of genome research.

The special populations that this area engages are diverse. But since many of the populations have an ethno-cultural identity that might become associated with genomic knowledge or phenotypic predispositions, this area will be fruitful for discussions with groups that share a founder population, or which can be characterized by a phenotypic expression, such as some disability. The area also provides this project with a human health context for dialogue with First Nations people.

Combining dominant hopes and concerns from the focus groups highlights the complementary and conflicting interests that must be addressed in the decision making process. Analysis of the full list of hopes and concerns (interests) expressed in the focus groups (see Tables 2 and 3) suggests the following questions as an initial attempt to capture the interests expressed in the area of DNA banking and population health within a governance framework.

The following questions are an initial attempt to capture the human genomic interests expressed in the focus groups within a governance framework that addresses issues relevant to in the topic area of DNA banking or sampling and bioinformatics:
a. How can individual health interests (e.g., privacy) and population health interests be assessed and balanced in the governance of DNA sampling and population health research?
a. How can the general public be educated and involved in the determination of research in the public interest, particularly since this research will reflect and create controversial notions of normalcy, health and disease?
b. How can governance best support the development of benefits of banking and related population-health research for the least well-off?
c. What constitutes misuse of banked data or tissues and how can it be effectively regulated?

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[13] Although DNA banking or sampling and bioinformatics can support individual interventions (*e.g.*, pharmacogenomics), individual-related issues were, at this point, thought to be better addressed under xenotransplantation and stem cell research, but see later discussion from workshop and peer review.

d. How can the diversity of opinion about using banked materials and data, and the risks and benefits to groups, be identified, evaluated and mitigated?

e. How can appropriate individual autonomy in matters of screening, population health and choice of patients, parents and public be established and protected?

6. Critical peer review and refining the issues

A preliminary version of the analysis described in this paper was presented to an interdisciplinary group of academics via a private website[14]. Their critical commentaries were posted to the same website and these documents were used to initiate discussions at an international workshop held in January 2003.

The objective of presenting the analysis and suggested issues to this group was to improve the analysis and ensure that the selection of issues was as sensitive as possible to the interests identified in the analysis of the focus groups.

Some participants strongly criticized specific constructions of governance concerns and groups. The following points were particularly contentious:

- labeling principle objections to certain kinds of research as "moral," as if other positions were more substantive;
- the difficulty and necessity of "skilling up without skewing" for public consultations and ethical analysis;
- characterizing any group as a minority when it is not clear there is a majority on these issues;
- using "stakeholder" to identify groups who had direct interests, as if broader society did not have direct interests;
- identifying groups as disadvantaged who in fact have legal entitlements related to the issues (*e.g.*, First Nations' people and salmon);
- referring to "the general public" as if this group had unified interests[15];
- suggesting that any single method of public consultation could be appropriate to the diverse groups relevant to these issues;
- avoiding false legitimacy of public consultations and their conclusions;
- being clear how public consultations and this research might influence governance and communicating that information to the participants;
- avoiding strategic behaviour in the public consultations that will be difficult to analyze because their purpose is not obvious;
- exercising caution in defining what uses of genomic research can be of benefit to population health as opposed to individualized health care and risk; and
- recognizing that the issues as defined are not, strictly speaking, genome research, but the applications and extensions of genomics[16].

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[14] The project's public website can be found at http://gels.ethics.ubc.ca.

[15] For the purpose of referring to the legitimate role of all citizens in the governance of society, the phrase "civil society" will be used to refer collectively to the various formulations of publics, consumers, and communities within society, including but distinguishing the role of technical experts from their participation as members of society.

[16] The scope of the issues could not be restricted to the narrow definition of genome research and still be accountable to the interests identified in the focus groups.

Other critical comments will be considered in the design of the public consultations.[17]

Explicit regulation (*i.e.*, law), often enforces a cultural norm on those who would not stay within the norm, such as proposed laws against sex-selection. Some policies are criticized because they undermine more effective incentives that are built into the market, such as trade tariffs or subsidies to farmers. Groups holding critical perspectives on genomic research often do not want to participate in discussions of regulating genome research because such an activity presumes that all such research will proceed and can be controlled through explicit policy and governing bodies, rather than being able to include considerations of whether or not to fund or even prohibit certain forms of genome research.

The role of technical experts and civil society in governance will vary depending on the form of governance considered—consumer choice, organized opposition, facilitated input into policy, or participation on advisory boards are very different activities.[18] It is important to put the issue of governance into a specific context so that the scope is limited and the questions of appropriate governance can be based on what is effective in a particular situation to achieve a particular goal, or determining what is an appropriate goal in a particular area of genomics. For that reason, the initial description of the issues and topic areas presumed that governance would be considered in the context of the issues.

Including "governance" as a topic instead of one of the proposed areas was raised as a possible way to approach the dominant concerns from the focus groups. This suggestion gained significance as it became apparent that considerations of governance would likely be implicit within discussion and difficult to analyze within particular topics.[19] Focusing on whether something is an appropriate practice tends to presume that once appropriate practice is defined, governance can and should ensure the practice. However, governance in an area where science changes faster than law and the dependence of governing bodies on expert knowledge implicitly draws the values of experts and funders into the regulating activities (*i.e.*, genomic research) is extremely challenging. This is further complicated by the expense of involving the public in governing activities through policy development.

That said, given a basic outline of how genome research and biotechnology is currently governed, technical experts and civil society could be asked to consider what they think an appropriate governance structure should achieve in the area of genomics, and by what methods. This would directly engage many of the dominant concerns articulated in the focus groups (*i.e.*, managing complexity and unpredictability, public information/mis-information, equitable distribution of benefits, effective regulation, assessing in-principle

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[17] The design of the overall project requires another peer review following completion of the public consultation and other streams of ethical research.

[18] Participants in the workshop made clear the relevance of political philosophy, including the critical literature in deliberative democracy, to defining and understanding civil society, governance, and public participation exercises. One stream of this research will apply this scholarly area to the design and analysis of the consultations and project recommendations.

[19] Workshop participants were particularly helpful on this point, proposing that governance should replace on of the genome research topics as an issue for public consultation in its own right, and that in public consultations the general discussion of governance could follow consideration of two particular areas of genome research.

objections, accountability to public interest and scientific integrity, limiting the use of technologies, and problems of social conformity).

This peer group discussion directly influenced issue definition and scope, enhancing the investigators' analysis of the focus groups and leading to the replacement of "xenotransplantation/therapeutic stem cell research" with "governance of genomics."

It is interesting to note that many non-dominant hopes expressed by the groups relate to governance (see Table 2). For instance, one interest identified in a focus group composed of regulators was expressed this way:

> *V5 - To better inform the policies, programs and legislation that government, industry, etc., would use to appropriately manage or direct the application of genomic research. . . I hope the research itself feeds into the process and informs the process in terms of policy making, decision making and legislation.*

In a focus group of rural participants recruited by telephone, one of the participants expressed concern about public manipulation:

> *. . .my fear is, bottom-line, that large corporations will use their ethics money or whatever to just do little token, you know, groups like this and go thanks, thanks, and now I'll do what I really want to do. I don't know how much power. . . this type of group actually has in decision-making. You know, we give our opinions, we talk and discuss stuff, and then take their little data . . . But will it make any difference? Are they actually going to listen to the concerns of even 100 people or is it just like those are interesting, we'll have to just kind of tweak it . . . maybe I'm cynical.*

7. Conclusion

This project models how policy decision making can be directed by ensuring representation of interests from civil society. This paper began with the assertion that defining issues (and scope) for ethical analysis can exclude relevant interests, and that beginning policy development with public participation will lead to a different definition of issues and better accountability to the range of relevant interests. A set of issues for comparison were not identified prior to the consultations; however, it is reasonable to observe that the public consultation resisted the practical and scientific tendencies to narrow the scope to consider genome science as building an understanding of entire genomes. Such a narrowing would have excluded most of the interests identified in the focus groups as relevant to genomics. Consequently, this public consultation on issue definition has demonstrated the importance of having the scope of an issue large enough to encompass the effects of downstream technologies on environment and society; what populations benefit and how to preserve individual choice; positive and negative effects on the environment of use of genomic knowledge.

The peer review noted the importance of governance issues *per se* to the interests identified in the focus groups. This highlighted the issue of governance itself as a topic for discussion that could address such things as how to govern in the face of

incommensurable interests, how to manage complexity and how to inform but not manipulate "public" involvement.

While this discussion was initiated at the workshop, it was stimulated in part by the nature of the dominant concerns identified in the analysis of the focus groups. For example, the issues of governance raised in the areas of salmon genomics and aquaculture applications, as well as DNA and data sampling and use for human health, will be intertwined with the particular politics and interests relevant to those fields. Some insights into appropriate governance will arise from comparing genome research and its application in a human health field to a non-human health field, but governance of genomics is itself a topic that deserves ethical analysis. Identifying the issues such as managing complexity and unpredictability, public information/mis-information, equitable distribution of benefits, effective regulation, assessing in-principle objections, accountability to public interest and scientific integrity, limiting the use of technologies, and problems of social conformity also make it possible to compare the issues related to genomic research and applications to other fields that have managed these issues of governance. Governance in the public interest, defining the public interest, public consultation and managing risks to particular populations for the benefit of a broader population are all considered in the literature on the environment.[xxvi] Ethical analysis of governance in genomics must also engage these other literatures, a point that might have been missed by a narrow focus on genome research and policy.

Finally, this research project does not claim that the interests described through this focus group process are representative of civil society. However, using focus groups as a basis for identifying issues (and their scope) does begin to establish accountability and legitimacy related to procedural justice: All subsequent analyses and consultations carried out by this project will be based on the issues developed in response to the interests identified by this (limited) cross section of civil society.

One test of accountability is how well the topics and issues selected for further research satisfy the participants that their interest are encompassed in those topics and issues. A second test is how well subsequent ethical analyses satisfy concerned individuals and groups that the analysis and recommendations fairly assess and represent the identified interests. Or, on a less accommodating approach, how well the analysis establishes the basis for informed critique of the recommendations and for further debate and reform. These additional evaluations form part of the next phase of this research.

Finally, the effect on many participants should be noted. According to one participant:

> *...when I was contacted about this group and asked if I had any interest in genetic research, I said 'no'. If asked tomorrow, I would respond differently.*

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