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Public Health Genomics (PHG) and Public Participation: Points to Consider

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Abstract

Large-scale population biobanks, which aim to collect biological tissues, personal health information, and genomic data, are being introduced worldwide with the promise of increasing knowledge on chronic diseases such as diabetes and heart disease. Experts recognize the need for public participation to address the many social, legal and ethical complexities raised by the introduction of biobanks for public health research. However many researchers and decision makers struggle with how to promote public participation. This paper presents six issues that public participation must address. These issues are then applied to three large scale genetic biobank projects: CARTaGENE, Generation Scotland, and the United Kingdom Biobank. Finally, the efforts of these biobanks will be compared to the British Columbia Biobank deliberation project, which implemented a deliberative public participation experiment on biobanking.

Keywords

Public participation, deliberative democracy, biobanks, population health, policy, ethics

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Authors

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Introduction

> "*Society needs biobanks because they can contribute greatly to health. But biobanks also need society in the form of generalized support, financial resources, the cooperation and trust of patients and healthy individuals*" (Yuille et al., 2008).

Public health genomics (PHG) is a field that combines genetics, medicine, lifestyle, behavior, and other environmental factors to better understand what makes people healthy. PHG is expected to lead to health promotion programmes and preventive public health strategies that will benefit society as a whole (Khoury, Burke, & Thomson, 2000). In turn, PHG has raised expectations for policymakers regarding the potential impact of genomic research on common diseases like cancer, diabetes, and heart disease (Gwinn & Khoury, 2006; World Health Organization, 2006; Centers for Disease Control and Prevention, 2007).

For the research community, biobanks are important resources to understand the contribution of genes to various commonly occurring diseases (McBride et al., 2008; Brand & Probst-Hensch, 2007; Greely, 2007; Centers for Disease Control and Prevention, 2007). "Biobank" is a term used to describe collections of biological tissues and health related information such as personal medical history data, clinical data from health records, lifestyle information from surveys, and genomic data (OECD, 2006). Biobanks can range from small collections of samples located in academic or hospital settings, to large-scale population-wide samples collected from participants with and without diseases (Cambon-Thomsen, Rial-Sebbag, & Knoppers, 2007; Cambon-Thomsen, 2004).

Large-scale population biobanks are being introduced worldwide, notably in Iceland, Estonia, Britain, Latvia, Japan, Sweden, Singapore, the United Kingdom, the United States and Canada (Swede, Stone, & Norwood, 2007). However, the creation of large-scale biobanks raises numerous social and ethical issues. Individual rights, trust, consent to the use of samples, access to samples, confidentiality, sharing of research findings, ownership, and potential commercialization are all examples of the controversial nature of biobanks (Tutton & Corrigan, 2004).

In a public health environment, balancing the needs of the individual with the broader collective good is challenging. Often, tension resides between protecting an individual's privacy and advancing science for a greater collective purpose (Yuille et al., 2008). For instance, there are concerns that the rules governing storage and access to biobanks will not protect the confidentiality of the

participants' medical data (Robling et al., 2004). Furthermore, without proper rules and regulations, biobanks could increase the risk of discrimination by reinforcing genetic exceptionalism or determinism (Secretary's Advisory Committee on Genetics, 2007). Also, the growing pressure to communicate research results to the participants, with some arguing for "no return" of result and others arguing for the "the return" of results, presents another challenge because of the lack of guidance for ensuring ethical practice (Knoppers, Joly, Simard, & Durocher, 2006). Furthermore, biobanks raise the concern of ownership (Tutton, 2007; Levitt & Weldon, 2005). For instance, who controls and decides the future research uses of the samples is important, especially when the exact future uses of the stored samples are not easily envisaged. To complicate matters further, new technologies such as high-throughput sequencing and/or genome wide association studies may broaden the scope of the original proposed research (Greely, 2007). Finally, the formation of biobanks for commercial ventures has sparked debates about whether public money invested in biobanks is appropriate, whether access to data and samples by the private sector is acceptable, and whether privatization or issuing patents based on data or samples is ethical (Busby, 2006; Weldon, 2004).

These socio-ethical issues should be considered carefully before population-wide biobanks are introduced (Akesson, Bjellerup, & Vahter, 1999; Tutton, 2007; Weldon, 2004). Biobanks are dependent on people's willingness to donate samples and information, hence public support and participation is fundamental for their continued success (Swede et al., 2007). The involvement of the public in large scale projects is increasingly recognized (Cambon-Thomsen et al., 2007), yet the implementation of public participation remains limited (Gauvin & Abelson, 2006; Abelson & Gauvin, 2004; Abelson & Eyles, 2002).

Incorporating the public into these discussion of biobanks, presents significant challenges. Scepticism of the methods of involving the public (Abelson et al., 2003), as well as a general lack of public understanding about basic genetic concepts (Lanie, Jayaratne, & Sheldon, 2004), limits the legitimacy of public input.

This paper begins with a framework of six pertinent issues concerning public participation: (1) the definition of public participation, (2) the explanation of the goals of public participation, (3) the definition of the public, (4) the timing of participation, (5) the tools to promote participation, and (6) the evaluation of public impact. Addressing each issue can help better understand the application of public participation to public health genomics and particularly biobanks. We have examined how three large scale genetic population database projects involved the

public in the setting up of a population biobank: CARTaGENE, Generation Scotland, and the United Kingdom Biobank (Table 1). The paper concludes by considering the contribution of a deliberative public participation model on the topic of biobanking in British Columbia.

Public Participation: what are the challenges?

Public participation is a controversial term that has generated considerable debate. The ambiguity of the term stems from differing understandings of the definition, the goals, the methodology, and the evaluation.

(1) Defining public participation

Public participation is difficult to define because terms like communication, consultation, involvement, engagement, collaboration, and partnership are often used synonymously. This complicates the understanding of public participation. While a comprehensive review of the term is beyond the scope of this paper, the classifications proposed by Health Canada, the OECD and the International Association for Public Participation (IAPP) will be used.

Health Canada describes public participation as a continuum that ranges from low levels of "communication, via mid levels "consultation," to high levels of "participation/engagement". At one end of the continuum, "communication" is a top-down approach, a one-way flow of information. "Consultation" on the other hand, provides opportunities for feedback from the public regarding policy options. At the other end of the continuum, 'participatory approaches' encourage active partnering, dialogue and involvement in the decision making process (Health Canada & Health Products & Food Branch, 2004). The OECD describes public participation in a similar manner to Health Canada. Citizen involvement ranges from recipients of information to active partners in policy development (OECD, 2001). Likewise, the International Association for Public Participation (IAPP) describes public participation along a continuum ranging from passive to active involvement (International Association for Public Participation, 2005).

These three models exemplify the crucial distinction between communication and participation. Communication is passive and entails the dissemination of information to the public (Rowe G., Marsh, & Frewer, 2004). In contrast, participation is an active process and entails feedback, exchange, and sharing of power between participants. In addition, a distinction is highlighted regarding the level of participation. Passive participation implies a one-way or indirect input where the views of the public are sought regarding a specific process or an idea.

In contrast, active participation invokes a two-way or direct process in which information circulates from the authorities to the public, and from the public to the authorities (Abelson et al., 2004).Two-way active dialogue also known as "deliberation", is seen as the most effective way to engage the public in discussions, and to partner with them in decision making and/or policy decision-making processes (Rowe & Frewer, 2005; Turnbull & Aucoin, 2006). The deliberative approach is favored over the other public engagement methods, as both stakeholders in the projects (the public and the health staff) are linked to the creation and results of the projects.

(2) Goals of public participation

There are many reasons to involve the public in decision making and policy-development. Generally, public participation in health research is expected to improve understanding of the health issues most important to the public, contribute to public accountability, increase capacity building, promote solidarity trust and tolerance (Boote, Telford, & Cooper, 2002; Abelson et al., 2002;Wynne, 2006;Abelson et al., 2003; Innes & Booher, 2004; Rowe et al., 2005).

The creation of population based biobanks raised much discussion and controversy around the world (Reilly, 2000; Godard, Marshall, Laberge, & Knoppers, 2004; Greely, 2007). For this reason, it is essential to involve the public to further good governance and accountability in decision making process, to assess public perception regarding the design and future usages of samples, to improve the relevance of the research (Yuille et al., 2008; Tallon, Chard, & Dieppe, 2000), to facilitate recruitment (Boote et al., 2002), and to address the issues of commercialization (Greely, 2007).

(3) Which public needs to be involved?

Which public can participate? Which public should be consulted in policy making? Which public is allowed to receive, use, or access the information gathered? The term "public" connotes a diversity of meanings both in scientific literature and in public discourse. Health Canada describes the public as individuals or groups of individuals who may be interested in, or affected by, the health policies. However, sometimes the public is referred to in passing as the general public, consumers, patients, health care providers and professionals, or representatives of academia and industry (Health Canada et al., 2004). Considering that public health touches many communities, another approach is to consider the public on a continuum ranging from individuals, to stakeholders, to "the general public" (Boote et al., 2002). This classification includes lay citizens,

research subjects, patients, healthy individuals, stakeholders and people living in a specific geographical neighborhood. In public health genomics, the term stakeholder may include interest groups, funding institutions, regulatory bodies, and professionals such as geneticists, policy makers, lawyers and ethicists.

Alongside the issue of defining "the public" there is the question of who represents the public? The heterogeneity of populations means that differences in age, language, ethnicity, disability, gender, sex, religion, education, literacy, income levels, and lifestyle factors need to be represented in the discussions (Secretary's Advisory Committee on Genetics, 2007). The diversity of the public should be accurately represented in order to ensure the results are widely accepted, to enhance respect between diverse groups with varying opinions, and to respond to differing needs and concerns of public groups (Turnbull et al., 2006).

(4) Timing of involvement

The timing of public participation affects the intensity of influence the public can offer. Public participation that occurs early on when an initiative is being planned generally allows for greater public input and raises the possibility of successfully implementing the ideas. However, if public participation occurs after the decision making process has been completed this has less impact on future changes (Gramberger, 2001). This principle draws on Arnstein's ladder of citizen participation (Arnstein, 1969), which describes the levels of public influence ranging from informing, to involving, to empowering the public.

(5) Tools to promote public participation

An abundance of tools exists to inform, consult, and engage the public. For example, newsletters and websites serve to inform the public while surveys and opinion polls seek to consult the public. Other tools such as focus groups foster participant interactions and citizen juries promote discussion, deliberations and many other participation tools have been described by Rowe and Gramberger (Rowe et al., 2005; Gramberger, 2001).

Involving the public in health research has become increasingly common (Saunders, Crossing, Girgis, Butow, & Penman, 2007; Abelson et al., 2002). The deliberative approach wherein participants interact in open discussions is considered the most dynamic approach to exercise significant influence on decision making and/or other recommendations relating to health research and policy (International Association for Public Participation, 2005).

(6) Evaluation of public participation

Despite a growing recognition of the utility of public participation in health research, there has been surprisingly little systematic evaluation to assess the success of this process. Most evaluations to date have been either descriptive or anecdotal. This lack of evaluation stems partly from the disagreement on how to measure public involvement and its impact.

Generally, the evaluation criteria proposed in the deliberation literature focuses more on the process than on the individual factors influencing the success of participation (Rowe & Frewer, 2000). Nevertheless, individual factors such as feasibility, quantity of information obtained, and the representation of the public have been recommended to complement process oriented evaluations. Criteria still need to be elaborated in a manner to broaden its application. Rowe and colleagues provide a useful framework by listing several criteria levels that should be taken together to capture the process and outcome of public participation (Rowe G. et al., 2004; Rowe & Frewer, 2004).

Important to acknowledge is that public health genomics is still in its infancy. Due to the diverging opinions about how biobanking information can be integrated into prevention programs and health services, there is still a need to clarify what data will be used to measure success (Brand et al., 2007).

Although not an exhaustive list, we have identified six essential issues that provide academic and policy makers with tools to guide their approach when embarking on a public participation process. Despite the willingness of the participating public to be involved, numerous challenges remain to enable the public to participate in the development of biobanks. Amongst the three principal levels of participation, active participation is preferred because it allows an exchange of information that directly involves the public. We realize that the "public" is not limited to the participating individuals, but rather encompasses a wider public that could be interested in the research results.

The Experience with Public Participation in Large Scale Population-wide Genomics Biobanks: Three Case Studies

To illustrate public participation in practice and to demonstrate the key issues that emerged in the literature, we will review the public participation strategies of three large scale genomic databases using publicly available information. We will compare how the selected public participation criteria have been applied to the three population-wide biobanks in Canada, England, and Scotland. These large-

scale biobanks are being developed to integrate genome-based knowledge into epidemiological and public health research policies and health services. By linking genetic, lifestyle, and personal factors, these biobanks are thought to hold many promises for society (Brand et al., 2007). The term public participation will be defined as the process of strengthening public input into governmental initiatives on the topic of genomic biobanks. The issues selected are reported in Table 1.

CARTaGENE

In Canada, the Province of Quebec has developed the CARTaGENE project to better understand the role of genetics and the environment on the health of a heterogeneous population. CARTaGENE is a population based project that plans to recruit a random sample of 50,000 individuals aged 25 to 75. CARTaGENE is designed to produce a map of genomic variations in health determinants as well as a DNA bank for researchers. The project is based at the University of Montreal and is funded by the governmental research agencies Genome Canada and Genome Quebec. Over the last four years, CARTaGENE has engaged the general public, policy experts, and researchers in a public participation process.

Goals of public participation

In 2003, the public participation project was initiated to identify policy concerns surrounding biobanking, to build legitimacy, and to thereby gain public trust for the CARTaGENE project (Godard et al., 2004; Racine, 2003). Due to the magnitude of the project, CARTaGENE's inclusion of public participation is critically important to the project's success. CARTaGENE has sought to evaluate the public's perceptions and knowledge of genetics, address their interest and fears, and to identify the most effective communication tools (Godard et al., 2004).

Forms of public participation and who is the public?

The research team of CARTaGENE introduced an information plan as well as a public engagement plan to identify public opinion on the project. Consultation mechanisms enabling exchanges between researchers and citizens took place. For example, the CARTaGENE team organized town hall meetings in the participating regions of Quebec six months prior to the recruitment of the participants as a means to promote the open exchange of opinions, ideas, and policies about the CARTaGENE project. The CARTaGENE researchers also met with leaders in various multicultural districts of Montreal to provide them with

opportunities to learn about the project, to examine the ethical and social aspects, and to discuss any concerns. These consultations allowed citizens to provide input into the project.

Tools to promote public participation

Several tools were used to promote public participation, the approaches differing depending on the public targeted: stakeholders and/or the general public (See Table 1). In addition to information sessions, the organizers brought together ethics, law, and policy experts to discuss innovative strategies to gather community input. To meet the increasing demand for information, the CARTaGENE team developed a website, produced a newsletter, and issued press releases. Moreover, in the fall of 2003, nineteen focus groups were held to further assess the public's ethical and social concerns. The topics addressed by the focus groups included privacy and confidentiality, the anonymity of DNA samples, and consent forms.

Evaluation

Qualitative public participation results show that the research project is generally perceived favourably. At the same time, the data suggests that before embarking on such a large study, the organizers will need to reassure potential participants about confidentiality, transparency, and access to research results (Godard, Marshall, & Laberge, 2007).

Other issues

Cultural, religious and linguistic values have greatly impacted the CARTaGENE project. This is mainly because the project involves the collection of genetic data from French and English Canadians located in the province of Quebec. The province has a rich history that stems from the French and British colonial legacy and the later influence of the Catholic Church. These cultural, religious, and linguistic values have withstood the changing times and have posed a challenge to the creation of a genetic database in the province of Quebec.

UK BIOBANK

In 1998, the UK Biobank project funded by the Medical Research Council, the Wellcome Trust (Britain's largest research charity) and the UK Department of Health, combined forces to develop a genetic biobank. The project aimed to recruit a large scale cohort of 500,000 people between the ages of 45-69 within

primary care settings. The overall goal of this biobank was to explore the interaction of environmental and genetic factors for common diseases and to additionally serve as a resource for the biomedical research community. The UK Biobank is run by a charitable, non-profit company, and will be an academic enterprise but with commercial access (UK Biobank 2003).

Goals of public participation

From its creation, (Cragg Ross Dawson, 2000), the UK Biobank included the public in the development of the biobank to increase credibility, to build public trust, and to identify and address public concerns about ethical and governance issues (People Science & Policy Ltd, 2002). An important component of the public participation activity was to assess stakeholder concerns (Swede et al., 2007). The stakeholder consultations were designed to assess public attitudes toward consent, confidentiality, security of data, commercialization, governance, recruitment and the communication of genetic information as well as propose a name for the initiative. This information helps inform policy makers about potential safeguards that would be most acceptable to the public when establishing a large population cohort.

Forms of public participation and who is the public?

In 2000, several focus groups were held with representatives from the disabled community, from religious groups, and with the general public who had direct involvement or experience with human genetics research or services. In 2002, workshops were held to assess the ethical and management issues of the targeted age groups (45-69) in Hertfordshire, the West Midlands and the Glasgow area. Primary care professionals were invited to the workshops to further inform the participants (The Wellcome Trust and MRC, 2000; Barbour, 2003).

Tools to promote public participation

A range of consultative methods including interviews, surveys, workshops, and focus groups were used extensively in early stages of the project. Results from the consultation were posted on the internet. Focus groups were given a leaflet that had been produced by the UK Biobank. Group meetings took place where individuals were invited to discuss values, their willingness to take part, and what would influence their views about ownership, commercial exploitation and governance issues (Tutton, 2007).

Evaluation issues

Results from the People, Science and Social Policy Report (People Science & Policy Ltd, 2002) suggest that the research period (five weeks) had been insufficient to adequately represent two social groups: the semi skilled and those dependent on State benefits. The report recommended further consultation to address regional and socio-economic representation and suggested that the six groups involved in the consultation should be followed in the developing stages of UK Biobank. No assessment was made as to whether the selection of citizens during the consultative period was an accurate representation of the UK population, and the limitations of such a large project were not acknowledged (Petersen, 2005a).

Generation Scotland

During the same period, a collaborative project involving several universities of Scotland, the MRC Human Genetics Unit, the National e-Science Centre, the Scottish School of Primary Care, and National Health Scotland (NHS) launched Generation Scotland (Smith et al., 2006). The project aimed to establish a large family-based cohort study with detailed phenotypic information of up to 50,000 individuals, including siblings, parents, and offspring. The rationale behind the project was that many common diseases have a heritable component. As a result, a family study design would permit researches to measure family traits associated with these diseases. A public consultation was implemented to allow the public to shape the goals of the biobanking, to raise concerns regarding recruitment, withdrawal, access, consent, feedback, confidentiality, public engagement as well as to suggest research priorities (Haddow, Cunningham-Burley, Bruce, & Parry, 2004).

Goals of public participation

Generation Scotland aimed to explore the ethical, legal and social issues relating to the family-based population DNA bank design. The key components examined were consent, withdrawal, confidentiality, access, ownership, and commercialization. The public participation also aimed to assess the approval of the recruitment methods, clinical feedback, informational tools, media promotion, and possible future research to be conducted with the information (Haddow et al., 2004).

Forms of public participation and who is the public?

From the outset, a significant public consultation component was present in the Generation Scotland project. The first phase involved interviews with 'experts' including geneticists, lawyers and theologians, and focus groups with the broader public. Focus groups were constructed in order to reflect a variety of demographics, interest and involvement in the biobank, (Haddow et al., 2004). According to observers, positive feelings were present among the participants in the consultation. This was attributed to the 'common good' sentiment designed in the creation of the study. However, concerns arose around private interests and potential stigmatization of particular illnesses. Controversial issues included the content of feedback and the potential future consequences of that information.

Tools to promote public participation

A range of consultative methods including interviews, surveys, workshops, and focus groups were used extensively in the early stages of the project.

Evaluation issues

Reactions to the idea of open-consent were fairly positive among the specialists but divided among the 'lay' participants in the focus groups. This was apparently related to a 'common good' sentiment to the creation of the study (Haddow, 2004). However, there is no declared intention to assess or evaluate the public participation exercise. This could presumably be done in the last of the 3 stages of the public consultation. However, this phase as with the previous keeps the focus on issues of participation and acceptance of the Generation Scotland Study itself. The aims for this phase as stated on the website are interviews with non-participants and hard to reach groups and re-interview of scientists involved in Generation Scotland.

Deliberative Democracy and Biobanks

So far our review of public participation has been limited to informing and consulting the public when setting up population-wide biobanks. Actively seeking input from citizens is a meaningful way to promote two-way participation or "active partnerships" between researchers and the public. It is argued that these active partnerships can improve the relevance of the questions, enhance the democratization process, ensure public accountability as well as protect public interest (Abelson et al., 2002). Deliberative processes, including deliberative

forums and polling citizen juries, seek public participation where citizens can reflect on the issues at hand.

Based on the potential societal impact of biobanking and the numerous socio-ethical issues, a deliberative model that drew on the theory of deliberative democracy was initiated in British Columbia (Burgess, O'Doherty, & Secko, 2008). The British Columbia Biobank Deliberation project conceptualised public participation as a way for the public to discuss their hopes and concerns about biobanks. Furthermore, the deliberation project informed the public of the technical and social issues regarding databanks, and facilitated their input into policy making. In particular, the public participation project provided an opportunity for participants to work towards a communal consensus on many of the controversial issues pertaining to biobanks.

Goals of public participation

The pilot study based on principles of deliberative democracy was initiated to assess whether the active partnership approach could reach beyond the mere collection of data about public perceptions and instead lead to informed deliberative input in biobank governance. The design was founded on the assumption that current policy approaches inadequately represent input from informed citizens. The goal of public participation was thus to foster greater representation of citizens who, after informed deliberation with each other, could challenge whether appropriate values were being taken into account during policies formation.

Who is the public?

In order to allow citizens to help shape the governance of the British Columbia biobank, a stratified sample of twenty-one people participated in a two-weekend event. This event was based on the deliberative approach, and sought not only to inform citizens, but to obtain their input. The deliberation process required that the participants first understood the issues at hand so that they could later appropriately debate with the final goal of forming consensus where feasible. To minimize selection biases, the recruitment of participants was guided by the demographic categories of the 2001 Canadian Census to ensure diversity of ethnicity, religion, occupation, and sex. In addition, participants were randomly digit dialed and selected from five provincial health regions to ensure diversity of experience with health care providers. It is important to note that citizens were informed by stakeholders (such as disability advocates and researchers who would utilize biobanks), who gave presentations about the technical aspects of

biobanking. However, these stakeholders were not permitted to engage with participants during group discussions to ensure that the process of deliberation was not captured by vested interests.

Timing of participation

The leader of a proposed British Columbia BioLibrary made the commitment to consider and include the suggestions from the deliberations. The biobanks and federal agencies that funded this project and that were related to governance of research were also notified of the public participation. This combination of factors seemed to have stimulated participants' dedication as measured by the return rate, the evaluation forms, and the intensity of discussion.

Tools to promote public participation

Prior to the meeting, participants received an 18 page booklet and glossary. The booklet "Biobanking in British Columbia: a deliberative public consultation," was developed by the research group and was based on a wide review of the literature. The first weekend meeting began with presentations and discussions from five experts and stakeholders. Additional articles and summaries were provided to the participants. A website monitored by the researchers was created to encourage participant "blogging" as an additional support system. All the online discussions were then printed for participants attending the second weekend meeting. Attending two non-contiguous weekends enabled the participants to leave the intensity of the weekend discussions and reflect with their friends, family, and community. In addition, professional moderators and trained small group facilitators ensured the quality of the deliberation in discussions. Group deliberation was guided by the task of creating recommendations for a biobank in British Columbia. Deliberants were asked to document whether, for each issue they chose to discuss, they reached consensus, had persistent disagreement, or required more information. The participants were all compensated $100 per day, and for out of town participants, travel, food, and accommodation were paid for.

Evaluation issues

Public participation has been evaluated quantitatively using pre/post surveys and qualitatively through content and discourse analyses of audio recorded sessions. Participants began and finished the event with a Q-sort survey in which they ranked 8 policy statements and then 38 valued based statements, arranging them into a forced distribution (Burgess & O'Doherty, 2007). Much of the post-

evaluation analyses focused on whether public participation in the creation process of a genetic databank in British Columbia was a useful tool for guiding public policy. Some of the group's initial observations show that the small group discussions were successful in stimulating participant engagement, even pertaining to individuals who were reluctant at first (Longstaff, Burgess, & Lewis, 2006). The study also found that the diverse members of the public were able to engage in moderated, informed, and deliberative discussions about the complex topic of biobanks (Longstaff et al., 2006). One potential limitation of the process was that it was based on a relatively small sample of 21 participants (out of a target of 25). The sample size was limited because of the high costs associated with conducting a public deliberation of this type.

Although the sample did not satisfy the formal criteria for statistical representativeness of the province of British Columbia, the sampling method detailed above did ensure diversity. Factor analysis of participants' views before and after the event verified that diversity in demographic factors (filtered for in recruitment) was associated with diversity in participants' values and positions on ethical and social dimensions of biobanking. The research team concluded that the recommendations presented by deliberants were sufficient to inform biobanking policy on some broad ethical and social issues. In particular, it was found that all participants supported biobanking in principle (consensus among all 21 participants), given consideration of certain issues logged in deliberation. A deliberative event planned for 2009 will encourage biomedical researchers, policy makers and social scientists to work closely to design and rigorously evaluate a public engagement approach to biobanking.

Discussion

In this article, we examined six essential issues central to public participation in the development of large-scale genomic biobanks. Three case studies were presented: CARTaGENE in Canada; UK BIOBANK and Generation Scotland in the UK, to illustrate a range of participatory approaches adopted. In addition, we presented the case study of a smaller public engagement process based on the principles of deliberative democracy to highlight the added values of a deliberative approach.

The comparison reveals that public participation as described in the three case studies can be characterized as follows: i) the participation is important when assessing a variety of goals including but not limited to: improving relationships with the public, and increasing public confidence in biobanking projects ii) the public that was invited to participate included a wide range participants from

urban and rural areas, members from organized groups, users of services, and marginalized populations; iii) the type of participation mainly focused on informing or educating the public, and on gathering information to help shape the development of the biobank; iv) different designs and tools were used to facilitate public participation including newsletters and websites to inform the public, questionnaires and opinion polls to take the pulse of the public, and workshops or focus groups to give the public the opportunity to inform the experts; v) the public participation was conducted in the early stages when the biobanking projects were still being defined; and vi) there was a lack of knowledge on the effects of public participation and on how the public input was incorporated into the development of the long range plans of these biobanks. (See Table 1)

While there is a growing acceptance of the need for public input in large scale projects like biobanks (Cambon-Thomsen et al., 2007), it remains difficult to ensure that this public input is an accurate representation of the diverse public, and not just a narrow range of interested individuals. The case of the British Columbia Biobank deliberation is perhaps an exception as it was conducted by an independent academic research group who specifically excluded identified stakeholders with a vested interest from deliberations. Adopting deliberative methods to shape biobanks enhances the understanding for non-academics partners, increases the relevance of the research products, enhances the credibility, and potentially generates additional resources for the development and functioning of the biobanks.

Although deliberative approaches promise to increase public input, it is important to understand the goals for which public input is sought. Just as researchers must carefully consider the “right public” needed, and the “right tools” to be used, the purpose of public participation must be identified. Given the lack of evaluations of public participation strategies, careful attention to evaluating all public participation approaches is highly recommended. (Petersen, 2005b; Abelson & Gauvin, 2006). In this regard, evaluation studies are needed to confirm the feasibility, the quality of information obtained, the accuracy of the representation of the public, the satisfaction of participants, and the degree and efficiency of the participation.

Table 1: Comparing Public Participation: CARTaGENE, Generation Scotland and UK Biobank projects

	CARTaGENE	Generation Scotland	UK Biobank
Goals	address policy concerns surrounding biobanking; address the socio-ethical implications and the social perceptions of the CARTaGENE project	address policy concerns about ELSI, recruitment, consent, access, ownership, future research	address policy concerns regarding the biobank; increase awareness, establish priorities, governance issues, recruitment issues
Forms of Public Participation	informing; consulting	consulting	consulting on issues like recruitment, consent, feedback of health information, ongoing dialogue, right to withdraw, relationship with researchers
Who is the public?	individuals aged 25 to 75 ; random sample stakeholders; 18 regions of the province	reflect different publics, citizen groups, families who volunteer, demographics, interest, geographic, involvement	lay people between ages 45-69, cross section of population of interest, rural and urban
Tools to Promote Public Participation	focus groups, surveys, workshops, public consultation, opinion poll, website for information	interviews, focus groups, citizen jury, survey, exit questionnaire	two-hour sessions at a local venue at least two weeks in advance of the meeting, meeting took place in the evening , invited to comment on the report, telephone interviews, pamphlet & FAQs, website
Timing of Participation	during planning stage; agenda setting stage	early in the development	early in the development of the biobank, comment will be passed on to the Wellcome trust
Evaluation Issues	difficult to assess policy implications at this stage, questionnaire survey to validate results from focus group	consultative, more weighted towards informing the public	used results to develop recommendations re biobanks
Other Barriers	religious; cultural linguistic	not mentioned	not mentioned

In conclusion, one of the most important challenges to overcome in order to facilitate public input in public health policies is to define specifically public participation. The ambiguity of the current terminology at the international and national levels has led to confusions between the distinction of informing the public about health policy and eliciting public input in the formation of policy. Due to the difficulty in precisely defining "public participation", there continue to be different understandings of what participation entails.

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