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Participatory Governance in Health Research

Patients and Publics as Stewards of Health Research Systems

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12.1 INTRODUCTION

This chapter discusses participatory governance as a conceptual framework for engaging patients and members of the public in health research governance, with particular emphasis on deliberative practices. We consider the involvement of patients and members of the public in institutional mechanisms to enhance responsibility and accountability in collective decision-making regarding health research. We illustrate key principles using discussion of precision medicine, as this demonstrates many of the challenges and tensions inherent in developing participatory governance in health research more generally. Precision medicine aims to advance healthcare and health research through the development of treatments that are more precisely targeted to patient characteristics.

Our central argument in this chapter is that patients and broader publics should be recognised as having a legitimate role in health research governance. As such, there need to be institutional mechanisms for patients and publics to be represented among stewards of health research systems, with a role in articulating vision, identifying research priorities, setting ethical standards, and evaluation. We begin by reviewing relevant scholarship on patient and public engagement in health research, particularly in the context of the development and use of Big Data for precision medicine. We then examine conceptualisations of participatory governance and outline stewardship as a key function of governance in a health research system. Thereafter, we propose the involvement of patients and publics as stewards who share leadership and oversight responsibilities in health research, and consider the challenges that may occur, most notably owing to professional resistance. Finally, we discuss the conditions and institutional design elements that enable participatory governance in health research.

12.2 PATIENT AND PUBLIC ENGAGEMENT IN HEALTH RESEARCH

Beresford identifies two broad approaches that have predominated in public engagement in health and social research since the 1990s.[1] *Consumerist approaches* reflect a broad interest in the market and seek consumer feedback to improve products or enhance services; in contrast, *democratic approaches* are concerned with people having more say in institutions or

[1] P. Beresford, 'User Involvement in Research and Evaluation: Liberation or Regulation?', (2002) *Social Policy & Society*, 1(2), 95–105.

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organisations that have an impact on their lives. Unlike consumerist approaches, democratic approaches are explicit about issues of power, the (re)distribution of power and a commitment to personal and collective empowerment. Well-known examples of democratic approaches include the social movements initiated by people living with disability and HIV/AIDS, where these communities demanded greater inclusion in the development of scientific knowledge and health policy decisions.[2] Moral and ethical reasons based on democratic notions of patient empowerment and redistribution of power, and consequentialist arguments that patient and public engagement can improve research credibility and social acceptance, are also offered by health researchers.[3] It should be noted that patient and public engagement does not, in and of itself, constitute an active role for members of the public in health research and policy decision-making. Conceptual models have often highlighted the multiple forms that engagement can take, which vary in the degree to which members of the public are empowered to participate in an active role (see Aitken and Cunningham-Burley, Chapter 11).

In recent years, the potential to link large data sources and harness the breadth and depth of such Big Data has been hailed as bringing 'a massive transformation' to healthcare.[4] Data sources include those collected for health services (e.g. electronic health records), health research (e.g. clinical trials, biobanks, genomic databases), public health (e.g. immunisation registries, vital statistics), and other innovative sources (e.g. social media). Achieving the aims of precision medicine relies on the creation of networks of diverse data sources and scientific disciplines to capture a more holistic understanding of health and disease.[5] Conducting research using such infrastructure represents a shift from individual and isolated projects to research enterprises that span multiple institutions and jurisdictions. While the challenges of doing patient and public engagement *well* have been widely recognised, the emergence of precision medicine highlights the stakes and urgency of involving patients and publics in meaningful ways.

Biomedical research initiatives that involve large, networked research infrastructure rely on public support and cooperation. Rhetorical appeals to democratising scientific research, empowerment and public benefits, have been employed in government-sponsored initiatives in the USA and UK in attempts to foster to public trust and cultivate a sense of collective investment and civic duty to participate, notably to agree to data collection and sharing.[6] Such appeals have been explicit in the US Precision Medicine Initiative (PMI)[7] since its inception, whereas they have been used post hoc in the NHS England care.data programme after public backlash. The failure of care.data illustrates the importance of effective and meaningful public engagement – rather than tokenistic appeals – to secure public trust and confidence in its oversight for large-scale, networked research. Established to be a centralised data sharing system that linked vast amounts of

[2] C. Barnes, 'What a Difference a Decade Makes: Reflections on Doing 'Emancipatory' Disability Research', (2003) *Disability & Society*, 18(1), 3–17; S. Epstein, 'The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials', (1995) *Science, Technology, & Human Values*, 20(4), 408–437.

[3] J. Thompson et al., 'Health Researchers' Attitudes towards Public Involvement in Health Research', (2009) *Health Expectations*, 12(2), 209–220.

[4] E. Vayena and A. Blassimme, 'Health Research with Big Data: Time for Systemic Oversight', (2018) *Journal of Law, Medicine & Ethics*, 46(1), 119–129.

[5] Ibid., 120.

[6] J. P. Woolley et al., 'Citizen Science or Scientific Citizenship? Disentangling the Uses of Public Engagement Rhetoric in National Research Initiatives', (2016) *BMC Medical Ethics*, 17(33), 1–17.

[7] The US PMI was launched in 2015 with the aims of advancing precision medicine in health and healthcare. A cornerstone of the initiative is the All of Us Research Program, a longitudinal project aiming to enroll 1 million volunteers to contribute their genetic data, biospecimens and other health data to a centralised national database. 'National Institutes of Health', www.allofus.nih.gov/.

patient data including electronic health records from general practitioners, care.data was suspended and eventually closed in 2016 after widespread public and professional concerns, including around its 'opt-out' consent scheme, transparency, patient confidentiality and privacy, and potential for commercialisation.[8] See further, Burgess, Chapter 25, this volume.

Research using Big Data raises many unprecedented social, ethical, and legal challenges. Data are often collected without clear indication of their uses in research (e.g. electronic health records) or under vague terms regarding their future research uses (e.g. biobanks). Challenges arise with regard to informed consent about future research that may not yet be conceived; privacy and confidentiality; potential for harms from misuses; return of results and incidental findings; and ownership and benefit sharing, which have implications for social justice.[9] As cross-border sharing of data raises the challenges of marked differences in regulatory approaches and social norms to privacy, there have been calls for an international comparative analysis of how data privacy laws might have affected biobank practices and the development of a global privacy governance framework that could be used as foundational principles.[10] Arguments have been made that relying on informed consent – which was developed primarily for individual studies – is insufficient to resolve many of the social and ethical challenges in the context of large-scale, networked research; rather, the focus should be on the level of systemic oversight or governance.[11] Laurie proposes an 'Ethics+' governance approach that appraises biobank management in processual terms.[12] This approach focuses on the dynamics and interactions of stakeholders in deliberative processes towards the management of a biobank, and allows for adaptation to changes in circumstances, ways of thinking, and personnel.

12.3 PARTICIPATORY GOVERNANCE IN HEALTH RESEARCH SYSTEMS

The concept of governance has theoretical roots in diverse disciplines and has been used in a variety of ways, with a variety of meanings.[13] In the health sector, the concept of governance has been informed by a systems perspective, notably the World Health Organization's framework for health systems.[14] In their review, Barbazza and Tello claim that: 'Despite the complexities and multidimensionality inherent to governance, there does however appear to be general consensus that the governance function characterizes a set of processes (customs, policies or laws) that are formally or informally applied to distribute responsibility or accountability among actors of a

[8] S. Sterckx et al., '"You Hoped We Would Sleep Walk into Accepting the Collection of Our Data": Controversies Surrounding the UK care.data Scheme and Their Wider Relevance for Biomedical Research', (2016) *Medicine, Health Care, and Philosophy*, 19(2), 177–190.

[9] W. Burke et al., 'Informed Consent in Translational Genomics: Insufficient without Trustworthy Governance', (2018) *Journal of Law, Medicine & Ethics*, 46(1), 79–86; A. Cambon-Thomsen et al., 'Trends in the Ethical and Legal Frameworks for the Use of Human Biobanks', (2007) *European Respiratory Journal*, 30(2), 373–382; E. Wright Clayton and A. L. McGuire, 'The Legal Risks of Returning Results of Genomic Research', (2012) *Genetics in Medicine*, 14(4), 473–477

[10] E. S. Dove, 'Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework', (2015) *Journal of Law, Medicine & Ethics*, 43(4), 675–689.

[11] Burke et al., 'Informed Consent', 83–85; K. C. O'Doherty et al., 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks', (2011) *Social Science & Medicine*, 73(3), 367–374; Vayena and Blasimme, 'Health Research with Big Data', 123–127.

[12] G. Laurie, 'What Does It Mean to Take an Ethics+ Approach to Global Biobank Governance?', (2017) *Asian Bioethics Review*, 9(4), 285–300.

[13] G. Stoker, 'Governance as Theory: Five Propositions', (1998) *International Social Science Journal*, 50(155), 17–28.

[14] E. Barbazza and J. E. Tello, 'A Review of Health Governance: Definitions, Dimensions and Tools to Govern', (2014) *Health Policy*, 116(1), 1–11; F. A. Miller et al., 'Public Involvement in Health Research Systems: A Governance Framework', (2018) *Health Research Policy and Systems*, 16(1), 1–15.

given [health] system'.[15] Common values, such as 'good' or 'democratic,' and descriptions of the type of accountability arrangement, such as 'hierarchical' or 'networked,' may be used to denote how governance should be defined. The notion of distributed responsibility or accountability relates to the assertion that governance is about collective decision-making and involves various forms of partnership and self-governing networks of actors.[16]

A systems perspective allows for a more integrated and coordinated view of health research activities that may be highly fragmented, specialised and competitive.[17] Strengthening the coordination of research activities promotes more effective use of resources and dissemination of scientific knowledge in the advancement of healthcare. The vision of a learning healthcare system, which was first proposed by the US Institute of Medicine (IOM), illustrates a cycle of continuous learning and care improvement that bridges research and clinical practice.[18] The engagement of patients, their families and other relevant stakeholders is identified as a fundamental element of a learning healthcare system.[19] Engaging patients as active partners in the cycle is argued to both secure the materials required for research (i.e. data and samples) and enhance patient trust.[20]

Pang and colleagues propose stewardship as a key function within a health research system that has four components: defining a vision for the health research system; identifying research priorities and coordinating adherence to them; setting and monitoring ethical standards; and monitoring and evaluating the system.[21] Other key functions of a health research system include: financing, which involves securing and allocating research funds accountably; creating and sustaining resources including human and physical capacity; and producing and using research. An important question is therefore how to engage and incorporate the perspectives and values of patients and publics in governance, particularly in terms of stewardship.

Internationally, participatory governance has been explored in multiple reforms in social, economic, and environmental planning and development that varied in design, issue areas and scope.[22] Fung and Wright use the term 'empowered participatory governance' to describe how such reforms are 'participatory because they rely upon the commitment and capacities of ordinary people to make sensible decisions through reasoned deliberation and empowered because they attempt to tie action to discussion'.[23] They outline three general principles: (1) a focus on solving practical problems that creates situations for participants to cooperate and build congenial relationships; (2) bottom-up participation, with laypeople being engaged in decision-making while experts facilitate the process by leveraging professional and citizen insights; and (3) deliberative solution generation, wherein participants listen to and consider each other's

[15] Barbazza and Tello, 'Health Governance', 3.
[16] Stoker, 'Governance as Theory', 21–24.
[17] T. Pang et al., 'Knowledge for Better Health – A Conceptual Framework and Foundation for Health Research Systems', (2003) *Bulletin of the World Health Organization*, 81(11), 815–820.
[18] Institute of Medicine, *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America* (Washington, DC: National Academies Press, 2013).
[19] K. H. Chuong et al., 'Human Microbiome and Learning Healthcare Systems: Integrating Research and Precision Medicine for Inflammatory Bowel Disease', (2018) *OMICS: A Journal of Integrative Biology*, 22(20), 119–126; S. M. Greene et al., 'Implementing the Learning Health System: From Concept to Action', (2012) *Annals of Internal Medicine*, 157(3), 207–210; W. Psek et al., 'Operationalizing the Learning Health Care System in an Integrated Delivery System', (2015) *eGEMs*, 3(1), 1–11.
[20] Psek et al., 'Learning Health Care System'.
[21] Pang et al., 'Health Research Systems', 816–818.
[22] A. Fung and E. O. Wright (eds), *Deepening Democracy: Institutional Innovations in Empowered Participatory Governance* (New York, NY: Verso, 2003).
[23] Ibid., p. 5.

positions and offer reasons for their own positions. A similar concept is collaborative governance, which is defined by Ansell and Gash as 'a governing arrangement where one or more public agencies directly engage non-state stakeholders in a collective decision-making process that is formal, consensus-oriented, and deliberative and that aims to make or implement public policy or manage public programs or assets'.[24] The criterion of formal collaboration implies established arrangements to engage publics. Participatory governance is advocated to contribute to citizen empowerment, build local communities' capacity, address the gap in political representation and power distribution, and increase the efficiency and equity of public services. Unfortunately, however, successful implementation of participatory governance ideals is 'a story of mixed outcomes' with the failures still outnumbering the successful cases.[25]

Yishai argues that the health sector has remained impervious to the practice of participatory governance: patients have not had a substantial voice in health policy decisions, even though they may enjoy the power to choose from different health services and providers as consumers.[26] Professional resistance to non-expert views and marginalisation of public interests by commercial interests are cited as some of the reasons for the limited involvement of patients. Similarly, there are concerns that public voices are not given the same weight as those of professionals in health research decision-making. Tokenism, engaging patients as merely a 'tick-box exercise' – for funding or regulatory requirements – and devaluing patient input in comparison to expert input are common concerns.[27] Furthermore, most engagement efforts are limited to preliminary activities and not sustained across the research cycle; the vast majority of biomedical research initiatives do not engage publics beyond informed consent for data collection and sharing.[28]

Deliberative practices, such as community advisory boards and citizens' forums, have been suggested as mechanisms to allow public input in the governance of research with Big Data.[29] Public deliberation has been used to engage diverse members of the public to explore, discuss and reach collective decisions regarding the institutional practices and governance of biobanks, and the use and sharing of linked data for research.[30] However, in many instances, public input is limited to the point in time at which the deliberative forum is convened. One example of ongoing input is provided by the Mayo Clinic Biobank deliberation, which was used as a seeding mechanism for the establishment of a standing Community Advisory Board. To address

[24] C. Ansell and A. Gash, 'Collaborative Governance in Theory and Practice', (2008) *Journal of Public Administration Research and Theory*, 18(4), 543–571, 544.

[25] F. Fischer, 'Participatory Governance: From Theory to Practice' in D. Levi-Faur (ed.), *The Oxford Handbook of Governance* (New York, NY: Oxford University Press, 2012), pp. 458–471.

[26] Y. Yishai, 'Participatory Governance in Public Health: Choice, but No Voice' in D. Levi-Faur (ed.), *The Oxford Handbook of Governance* (New York, NY: Oxford University Press, 2012), pp. 527–539.

[27] J. P. Domecq et al., 'Patient Engagement in Research: A Systematic Review', (2014) *Health Services Research*, 14(89), 1–9; G. Green, 'Power to the People: To What Extent has Public Involvement in Applied Health Research Achieved This?', (2016) *Research Involvement and Engagement*, 2(28), 1–13; P. R. Ward et al., 'Critical Perspectives on 'Consumer Involvement' in Health Research: Epistemological Dissonance and the Know-Do Gap', (2009) *Journal of Sociology*, 46(1), 63–82.

[28] E. Manafo et al., 'Patient Engagement in Canada: A Scoping Review of the 'How' and 'What' of Patient Engagement in Health Research', (2018) *Health Research Policy and Systems*, 16(1), 1–11; Woolley et al., 'Citizen Science', 5.

[29] Burke et al., 'Translational Genomics', 84; Vayena and Blasimme, 'Health Research with Big Data', 125.

[30] S. M. Dry et al., 'Community Recommendations on Biobank Governance: Results from a Deliberative Community Engagement in California', (2017) *PLoS ONE*, 12(2), e0172582; K. C. O'Doherty et al., 'Involving Citizens in the Ethics of Biobank Research: Informing Institutional Policy through Structured Public Deliberation', (2012) *Social Science & Medicine*, 75(9), 1604–1611; J. E. Olson and others, 'The Mayo Clinic Biobank: A Building Block for Individualized Medicine', (2013) *Mayo Clinic Proceedings*, 88(9), 952–962; J. Teng et al., 'Sharing Linked Data Sets for Research: Results from A Deliberative Public Engagement Event in British Columbia, Canada', (2019) *International Journal of Population Data Science*, 4(1), 13.

the challenge of moving from one-time input to ongoing, institutionalised public engagement, O'Doherty and colleagues propose four principles to guide adaptive biobank governance: (1) recognition of participants as a collective body, as opposed to just an aggregation of individuals; (2) trustworthiness of the biobank, with a reflexive focus of biobank leaders and managers on its practices and governance arrangements, as opposed to a focus on the trust of participants divorced from considerations of how such trust is earned; (3) adaptive management that is capable of drawing on appropriate public input for decisions that substantively affect collective patient or public expectations and relationships; and (4) fit between the particular biobank and specific structural elements of governance that are implemented.[31]

A few cases of multi-agency research networks that engage patients or research participants in governance are also available. For instance, the Patient-Centered Outcomes Research Institute (PCORI) in the USA established multiple patient-powered research networks, each focusing on a particular health condition (www.pcori.org). In the UK, the Managing Ethico-social, Technical and Administrative issues in Data ACcess (METADAC) was established as a multi-study governance infrastructure to provide ethics and policy oversight to data and sample access for multiple major population cohort studies. Murtagh and colleagues identify three key structural features: (1) independence and transparency, with an independent governing body that promotes fair, consistent and transparent practices; (2) interdisciplinarity, with the METADAC Access Committee comprising individuals with social, biomedical, ethical, legal and clinical expertise, and individuals with personal experience participating in cohort studies; and (3) patient-centred decision-making, which means respecting study participants' expectations, involving them in decision-making roles and communicating in a format that is clear and accessible.[32]

12.4 ENABLING CONDITIONS AND INSTITUTIONAL DESIGNS

12.4.1 *Enabling Conditions: Power/Resource Imbalances and Representativeness*

Fung and Wright propose that an enabling condition to facilitate participatory governance is 'a rough equality of power, for the purposes of deliberative decision-making, between participants'.[33] Nonetheless, power and resource imbalances are a common problem in many cases of patient and public engagement. Patients and publics bring different forms of knowledge that could be seen as challenging traditional scientific knowledge production and the legitimacy of professional skills and knowledge. Such knowledge could be constructed positively by researchers, but it could also be constructed in ways that question its validity compared to professional/academic knowledge.[34] Furthermore, patients and publics may not always be capable of articulating their needs as researchable questions, which limits the uptake of their ideas in research prioritisation, or a perceived mismatch may lead to resistance from researchers to act upon priorities identified by patients and publics.[35]

Articulating a vision for advancing patient and public engagement in a health research system is important, whether it is at an organisational or broader level.[36] We further propose recognition

[31] O'Doherty et al., 'Adaptive Governance', 368.
[32] M. J. Murtagh et al., 'Better Governance, Better Access: Practising Responsible Data Sharing in the METADAC Governance Infrastructure', (2018) *Human Genomics*, 12(1), 1–12.
[33] Fung and Wright, *Deepening Democracy*, p. 24.
[34] Thompson et al., 'Health Researchers' Attitudes'; Ward et al., 'Critical Perspectives'.
[35] F. A. Miller et al., 'Public Involvement and Health Research System Governance: Qualitative Study', (2018) *Health Research Policy and Systems*, 16(1), 1–15.
[36] Miller et al., 'Health Research Systems', 4–5.

of patients and publics as having legitimate representation as stewards or governors, with a role in articulating vision, identifying research priorities, setting ethical standards, and evaluation. Moreover, we suggest that formal arrangements are required to enable patients and publics in their role as stewards and governors within institutional architecture. A range of innovative mechanisms have been explored and implemented. For instance, ArthritisPower, which is a patient-powered research network within PCORI, established a governance structure in which patients have representation and overlapping membership across the Executive Board, Patient Governor Group and Research Advisory Board. Clear communication of expectations, provision of well-prepared tools for engagement (e.g. work groups organised around particular tasks or topics, online platform for patient governors to connect) and regular assessments of patient governors' viewpoints are found to be necessary to support and build patients' capacity within a multi-stakeholder governance structure.[37]

It should be recognised that members of the public vary in their capacity to participate, deliberate and influence decision-making. Those who are advantaged in terms of education, wealth or membership in dominant racial/ethnic groups often participate more frequently and effectively in deliberative decision-making.[38] Power and resource imbalances can result in the problem of co-optation whereby stronger stakeholders are able to generate support for their own agendas. The lack of representation of certain groups – i.e. youth, Indigenous, Black and ethnic minority groups – has been noted in many efforts of patient and public engagement in health research,[39] which reflects structural barriers and/or historical discrimination and mistrust due to past ethical violations. This raises challenges of how to promote and support inclusion and equity in decision-making. This also serves as a valuable counterpoint on power dynamics as discussed by Brassington, chapter 9.

There are also concerns that patients may risk becoming less able to represent broader patient perspectives as they become more trained and educated in research and more involved in the governance of research activities. For instance, Epstein documented the use of 'credibility tactics', such as the acquisition of the language of biomedical science by HIV/AIDS activists to gain acceptance in the scientific community, and Thompson and colleagues identified the emergence of professionalised lay experts who demonstrated considerable support for dominant scientific paradigms and privileged professional or certified forms of expertise among patients and caregiver participants in cancer research settings in England.[40] To guard against this, the governance structure of ArthritisPower maintains a mix of veteran and new members by limiting patient governors' memberships to three years.[41]

12.4.2 *Institutional Designs: Relationships, Trust and Leadership Support*

Fung and Wright outline three institutional design elements that are necessary for participatory governance: (1) devolution of decision-making power to local units that are charged and held accountable with implementing solutions; (2) centralised supervision and coordination to

[37] W. B. Nowell et al., 'Patient Governance in a Patient-Powered Research Network for Adult Rheumatologic Conditions', (2018) *Medical Care*, 56(10 Suppl 1), S16–S21.

[38] Fung and Wright, *Deepening Democracy*, p. 34.

[39] Miller et al., 'Health Research System Governance', 7; Green, 'Power to the People', 10.

[40] Epstein, 'The Construction of Lay Expertise', 417–426; J. Thompson et al., 'Credibility and the 'Professionalized' Lay Expert: Reflections on the Dilemmas and Opportunities of Public Involvement in Health Research', (2012) *Health*, 16 (6), 602–618.

[41] Nowell et al., 'Patient Governance', S21.

connect the local units, coordinate and distribute resources, reinforce quality of local decision-making, and diffuse learning and innovation; and (3) transformation of formal governance procedures to institutionalise the ongoing participation of laypeople.[42] At a national level, devolution of power implies that the state solicits local units, such as community organisations and local councils, to devise and implement solutions. Members of the public are engaged at a local level through these organisations as stakeholders who are affected by the targeted problems. Within a health research system, network or organisation, patients and publics may serve on advisory boards and committees as members within a multi-stakeholder governance structure.

In this section, we discuss factors that may facilitate or impede the participation of patients and publics in the governance structures of health research systems, networks or organisations. It is important to consider multilevel engagement strategies for matching participation opportunities to varying interests, capacities and goals of patients and publics.[43] These strategies may range from patients and publics having one-time input into a targeted issue, to serving in leadership roles as members of a research team or governing body. Involving patients and publics in governance structures in an ongoing manner requires relationship building over much longer periods of time.

Clarity of roles and purposes of patient and public engagement is needed for relationship building, as well as for developing and maintaining trust. Participatory forms of governance are more feasible when stakeholders have opportunities to identify mutual gains in collaboration. However, pre-existing relationships can discourage stakeholders from seeing the value of collaboration. In health research that spans multiple sites, approaches and willingness to engage patients and publics may differ considerably across the participating sites.[44] Establishing new relationships with patients as partners may be considered too risky and jeopardising to current relationships by some sites.

Additionally, engagement activities that focus on 'patients', 'citizens' or 'members of a community', may each carry different sets of assumptions. Patients often have a personal connection to the health issue in question, whereas community members are selected to represent a collective experience and perspective. In national biomedical research initiatives, engagement as 'citizens' may lead to the exclusion of certain groups, such as advocacy groups and charities, from governing committees to avoid 'special interests'.[45] While people may be able to navigate and draw on different aspects of their lives to inform research and policy, further exploration is needed to understand the common and distinctive aspects between different types of roles that people occupy.[46] In any case, clarity regarding roles and responsibilities, and transparency in the aims of engagement are necessary for relationship and trust building.

Fung and Wright assert that centralised supervision and coordination is needed to stabilise and deepen the practice of participatory governance among local units.[47] At a national level, centralised coordination is a component of leadership capacity to ensure accountability, distribute resources, and facilitate communication and information sharing across local units. According to Ansell and Gash, facilitative leadership is important for bringing together stakeholders, promoting the representation of disadvantaged groups, and facilitating dialogue and

[42] Fung and Wright, *Deepening Democracy*, pp. 20–24.
[43] For an example, see A. P. Boyer et al., 'Multilevel Approach to Stakeholder Engagement in the Formulation of a Clinical Data Research Network', (2018) *Medical Care*, 56(10 Suppl 1), S22–S26.
[44] K. S. Kimminau et al., 'Patient vs. Community Engagement: Emerging Issues', (2018) *Medical Care*, 56(10 Suppl 1), S53–S57.
[45] Woolley et al., 'Citizen Science or Scientific Citizenship', 11.
[46] See Kimminau et al., 'Patient vs. Community Engagement', for a comparison of the two.
[47] Fung and Wright, *Deepening Democracy*, pp. 21–22.

trust-building in the collaborative processes.[48] Trust-building requires commitment and mutual recognition of interdependence, shared understanding of the problem in question and common values, and face-to-face dialogue. Senior leadership and supportive policy and infrastructure are recognised as building blocks for embedding patient and public engagement in a health research system.[49]

12.5 CONCLUSION

In this chapter, we have discussed the potentials and challenges of involving patients and publics as stewards or governors of health research, whether within a broad health system, a research network, or a specific organisation. We have also outlined some of the conditions and institutional design elements that may impede or facilitate the engagement of patients and publics in governance structures, focusing on issues of power/resource imbalances, representativeness, relationships, trust and leadership support. Some conditions and institutional design elements are necessary for the implementation of participatory governance, but our discussion is not intended to be comprehensive or prescriptive. In particular, we are not proposing a specific governance structure or body as an ideal. Governance structures can vary in their purposes and constituencies. With rapid scientific advances and potential for unanticipated ethical and social issues, a multi-stakeholder governance structure needs to contain an element of reflexivity and adaptivity to evolve in ways that are respectful of diverse needs and interests while responding to changes. Moreover, the literature on patient and public engagement has documented the need for rigorous evaluation of the impact of engagement on healthcare and health research, especially given the problems of inconsistent terminology and lack of validated frameworks and tools to evaluate patient and public engagement.[50] Stronger evidence of the impact and outcomes, both intended and unintended, of patient and public engagement may help normalise the role of patients and publics as partners in health research regulation.

[48] Ansell and Gash, 'Collaborative Governance', 554–555.
[49] Miller et al., 'Health Research System Governance', 6–7.
[50] Manafo et al., 'Patient Engagement', 4–7. Also, Aitken and Cunningham-Burley, Chapter 11, this volume.