

Mode 2 Knowledge Production in the Context of Medical Research: A Call for Further Clarifications

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Abstract The traditional researcher-driven environment of medical knowledge production is losing its dominance with the expansion of, for instance, community-based participatory or participant-led medical research. Over the past few decades, sociologists of science have debated a shift in the production of knowledge from traditional discipline-based (Mode 1) to more socially embedded and transdisciplinary frameworks (Mode 2). Recently, scholars have tried to show the relevance of Mode 2 knowledge production to medical research. However, the existing literature lacks detailed clarifications on how a model of Mode 2 knowledge production can be constructed in the context of medical research. This paper calls for such further clarifications. As a heuristic means, the advocacy for a controversial experimental stem cell therapy (Stamina) is examined. It is discussed that the example cannot be considered a step towards Mode 2 medical knowledge production. Nonetheless, the example brings to the fore some complexities of medical knowledge production that need to be further examined including: (1) the shifting landscape of defining and addressing vulnerability of research participants, (2) the emerging overlap between research and practice, and (3) public health implications of revising the standard notions of quality control and accountability.

Keywords Mode 2 knowledge production · Medical research · Stamina · Bioethics

Introduction

The traditional researcher-driven environment of medical knowledge production is losing its dominance by the expansion of more participatory and participant-oriented approaches. Community-based participatory research (Smikowski et al. 2009; Wallerstein and Duran 2010) or participant-led medical research (Vayena et al. 2015) are some examples of this emerging trend.

More broadly, over the last decades, some sociologists of science have developed a novel account of the relation between science and society (Gibbons et al. 1994; Nowotny, Scott, and Gibbons 2001, 2003). Gibbons et al. (1994) suggest that a new model of knowledge production (KP) is gaining ground with a different social agenda. The new model of KP, produced in “broader, transdisciplinary social and economic contexts”, is described as “Mode 2” in contrast to “Mode 1” that is traditionally produced “within a disciplinary, primarily cognitive” context (Gibbons et al. 1994, 1).

Recently, some scholars have emphasized the relevance of applying the notion of Mode 2 KP to the medical context, for example, the contribution of lay people and patients to the orphan drug development (Crompton 2007) and post-genomic personalized medicine projects (Özdemir et al. 2012). However, the existing literature lacks detailed examinations of how a clear account of Mode 2 KP can be developed in the medical

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context. This paper is a call for such further examinations. It also aims to call for further clarifications on how to address the specific complexities of medical research and their ethical implications. The paper begins by providing a brief background to the historical and conceptual development of the notion of Mode 2 KP. Then, as a heuristic means, a recent controversy over advocacy for access to an experimental stem cell therapy (Stamina) will be introduced. This example will be analysed to clarify its similarities and differences with Mode 2 KP. It will be discussed that the example fails to meet the criteria to be considered as a step forward to Mode 2 medical KP. Nonetheless, the example brings to the fore some complexities of medical KP that need to be taken into account in further explorations for developing a detailed account of Mode 2 medical KP.

Mode 2 KP: A Historical and Conceptual Background

In their pioneering book, *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies*, Gibbons et al. (1994) differentiate between traditional discipline-based KP (Mode 1) and the emerging transdisciplinary arrangements of KP (Mode 2). The former is committed to an “operational” division between pure and applied science (Gibbons et al. 1994, 19). In the first phase of the development of the modern science, Newtonian physics through the pursuit of “an abstract mathematical formulation of the rules governing the motion of matter in space and time” exemplified the perceived norms of scientific inquiry (Gibbons et al. 1994, 43). In Mode 1 KP, a specific set of “cognitive and social norms” mandates “what shall count as significant problems, who shall be allowed to practise science and what constitutes good science” (Gibbons et al. 1994, 3). On the contrary, Mode 2 KP implies a two-way relation between pure, theoretical sciences and practical, applied sciences. The traditional pursuit of fundamental principles is being abandoned “towards modes of enquiry oriented towards contextualized results” (Gibbons et al. 1994, 19). Furthermore, the applied sciences are not only involved with discovering but also some elements of design and fabrication can be integrated to produce the knowledge in the context of application (Gibbons et al. 1994).

The debate on Mode 2 KP gained further depth with *Re-thinking Science: Knowledge and the Public in an*

Age of Uncertainty, in which Nowotny, Scott, and Gibbons (2001) explain that there is a range of weak to strong contextualization. Strong forms of contextualization imply a robust reflexive interaction between science and society. Further, they emphasize the importance of opening public forum as *Agora* (the public space in ancient Greek city-states) to clarify the social preconditions of Mode 2 KP. *Agora* provides a public forum “in which ‘science meets the public’, and in which the public ‘speaks back’ to science” (Nowotny, Scott and, Gibbons 2001, 247). They also underline the importance of a Mode 2 society that is in a “reflexive and interactive” relationship with Mode 2 KP (Nowotny, Scott and, Gibbons 2001, 50).

Later, Nowotny, Scott, and Gibbons (2003, 2006) provide a summary of both pivotal books. They list five characteristics of Mode 2 KP as (1) production of the knowledge in the context of application, (2) transdisciplinary through mobilization of a wide range of potential contributors, (3) increasing diversification of loci of knowledge production, (4) revision of the traditional notions of accountability through reflection, and (5) new notions of quality control in order to create space for new definitions beyond the mere “scientific excellence” (Nowotny, Scott and, Gibbons 2003, 2006).

In the first seminal book, Gibbons et al. (1994, 1) state that the distinction between Mode 1 and Mode 2 is essentially heuristic. By the same token, a recent, controversial example of advocacy for an experimental stem cell therapy will be heuristically examined to explore the implications of Mode 2 in the medical context.

Stamina: The Controversies of *Hope and Healing*

Davide Vannoni, an Italian professor of psychology, tried to start an enterprise on the fringe of modern medicine. He was the founder of Stamina Foundation that offered the patients suffering from neurodegenerative disorders an unproven and experimental stem cell “treatment” (MacGregor, Petersen, and Munsie 2015). His technique, called Stamina method, was based on altering mesenchymal stem cells (MSC) taken from the patients’ bone marrows into “healing” neural stem cells (MacGregor, Petersen, and Munsie 2015).

Soon after expanding the technique across the country, the regulatory bodies suspended Stamina method due to lack of sufficient evidence of safety and efficacy (MacGregor, Petersen, and Munsie 2015). Faced with

massive negative publicity and media coverage, on May 2013 the Italian health minister shocked the scientists by providing legal support for allowing limited access to the experimental therapy (Fрати et al. 2013). Further, the Italian Parliament approved the use of the technique on a small scale and allocated three million Euros for putting the Stamina method to the test (Margottini 2013).

Then, in May 2014, the European Court of Human Rights refused to grant a patient the right to access to the unproven Stamina method (Rial-Sebbag and Blasimme 2014). The patients continued to resort to Stamina Foundation for “magical” treatment until March 2015, when Vannoni was declared to be guilty and negotiated with the Torino court to revoke his punishment contingent on not offering the patients the controversial “treatment” (MacGregor, Petersen, and Munsie 2015).

Stamina and Mode 2 KP: Similarities and Differences

Taken at face value, one might draw a parallel between Stamina and aforementioned features of Mode 2 KP. Though initially, it was a campaign for access to the experimental therapy, it later became a drive for putting Stamina to the test. This direction might seem to be in the context of application (patients’ urgent need for any alternative treatment). Also, a wide range of activists and patients’ advocates were supporting access to and development of Stamina (mobilization of different stakeholders). Further, the primary locus of knowledge production in the case of Stamina was a non-academic setting i.e. private clinics. The activists were also pushing the deal through to make Stamina Foundation less accountable to the existing regulatory bodies. Moreover, the pro-Stamina “right to life” (sì a Stamina, sì alla vita: yes to Stamina, yes to life) ethos tried to go beyond standard interpretations of quality control based on scientific excellence (MacGregor, Petersen, and Munsie 2015), though the Italian scientific community opposed it because of insufficient evidence of efficacy and safety.

However, advocacy for Stamina cannot be considered a step forward to Mode 2 medical KP. It fails to meet the deeper promises and features of Mode 2 KP (Table 1). The form of contextualization in the case of Stamina was extremely weak. There was not much reflection about how Stamina should be put to the test and what might be the implications for regulation of future experimental therapies. This weak contextualization shows the

Table 1 Characteristics of Mode 2 KP and the main reasons why Stamina cannot be considered a step forward to Mode 2 medical KP

Mode 2 KP characteristics	How does Stamina differ from Mode 2 KP?
Production of knowledge in the context of application	Extremely weak contextualization Absence of an active <i>Agora</i>
Transdisciplinary framework of KP	Very limited scope of collaboration Lack of involvement with the scientific community
Diversification of the loci of knowledge production	Very limited scope of communication
Revision of the traditional notions of accountability through reflection	Implicitly and not through sufficient reflection
New notions of quality control	Implicitly and not through sufficient reflection

importance of creating a public forum as *Agora* that did not emerge in Stamina case. Further, in the case of Stamina, the mainstream researchers and the scientific community did not contribute much to the development of the campaign. There was, then, a very limited scope for what has been referred to earlier as the transdisciplinary framework of KP. Further, Stamina cannot be considered a case of diversifying the loci of knowledge production.

Nowotny, Scott, and Gibbons (2003) emphasize that this feature of Mode 2 is the result of a broader scope of communication between scientists and other stakeholders. In the Stamina case, the level of communication between the scientific community and the Stamina Foundation was extremely limited. Further, putting Stamina to the test in private clinics was secondary to the fact that the main method of access to Stamina was through private clinics. The revision of traditional notions of accountability and quality control in the case of Stamina lacked the reflective features of Mode 2 KP. Part of the reason for this lack of reflection is because the activists aimed primarily to campaign for access to the Stamina method and not necessarily to put the experimental therapy to the test.

Mode 2 KP in the Medical Context: Specific Modalities and Ethical Issues

As mentioned above, the case of Stamina fails to meet the criteria for being considered a case of Mode 2 medical KP. Nonetheless, the controversy over Stamina brings to the fore some issues of KP that are more relevant or have important implications in the context of medical research. In what follows, some aspects of the advocacy and

development of Stamina will be highlighted to show some of the complexities and particularities of KP in the medical context. It should be noted, however, that there are many other specific issues in the context of medical research that need to be further addressed.

Changing Landscape of Defining and Addressing Vulnerability

Patients who sought the Stamina method were in a position that has been described as “medical vulnerability” (Kipnis 2001). Their vulnerability stems from “having run out of options” (Kipnis 2001) that might expose them to “ineliminable therapeutic misconception” (Kipnis 2001). A regulatory response to this high level of vulnerability, as supported by the international scientific community (Frati et al. 2013), was to protect patients pursuing Stamina from potentially dangerous therapies and exploitation by private clinics. When patients took agency, they forced the existing regulatory bodies to accommodate their needs; they did not want to be perceived as vulnerable and frail research subjects to be overprotected. In the wider picture, the traditional preventive stance of regulatory bodies on vulnerable participants is being revisited (Welch et al. 2015). Any compelling account of medical KP, then, needs to address this changing ethical and regulatory landscape of defining and addressing vulnerability in the context of medical research. For example, what role should the regulatory bodies play in defining vulnerability of research participants who proactively shape the direction of medical research?

Emerging Overlap Between Research and Practice

It has been recently argued that the sharp boundary between medical research and clinical practice can be desirably blurred to systematically facilitate the expansion of evidence-based medicine and yield “socially valuable research” (Largent, Joffe, and Miller 2011). This view seems similar to what has been referred to earlier as the production of knowledge in the context of the application. The Stamina controversy, albeit negatively, points to the possible blend of clinical practice and the research. Stamina was an experimental therapy i.e. neither a research initiative nor an established practice. If the emerging trend of integrating research and practice gains

ground, as it has been shown recently (Lowe et al. 2016), production of medical knowledge also need to be considered in connection with the clinical practice. This raises questions such as whether new interpretations of quality control of medical research, as a feature of Mode 2 KP, should extend to clinical practice. What are the implications of Mode 2 medical KP for clinical practice? Do we also need a *Mode 2 clinical practice*?

Public Health Implications of Revised Notions of Quality Control and Accountability

In 2009, a Torino magistrate disapproved the Stamina method because of its danger to the public health (MacGregor, Petersen, and Munsie 2015). The magistrate’s rule, though, was about access to the experimental therapy and highlights the potential direct risks associated with cutting-edge medical research for the wider public. Moreover, there is also a potential indirect risk to public health. The Stamina case showed that there might be “room for science policy decisions that contradict the established regulatory framework” (Blasimme and Rial-Sebbag 2013, 18). This burden of public health concerns reveals another twist of applying the notion of Mode 2 in the context of medical KP. For instance, how to maintain a consistent perception of public health risk while undermining the centralized, conventional oversight authorities? How does the process of revising the standards of quality control and accountability affect the institutional authority of regulatory bodies?

Conclusion

Mode 2 knowledge production has been conceptualized as an emerging model of knowledge production that reshapes scientific discoveries in more socially embedded ways. Some scholars have recently debated the notion of Mode 2 KP in the context of medical research. This paper aimed to call for further clarifications on applying the notion of Mode 2 in the context of medical research. The case of Stamina, a controversial experimental stem cell therapy, was heuristically examined to highlight the deeper aspects of Mode 2 KP. These aspects include the importance of public forum as *Agora* and contextualization through reflection, which have not been at play in advocacy and development of Stamina. Nonetheless, the controversy over Stamina brings to the fore

some complexities of KP that are more relevant or have important implications in the context of medical research. Three preliminary sources of complexity have been highlighted: (1) the changing landscape of defining vulnerability, (2) the emerging overlap between research and practice, and (3) public health implications of revised notions of quality control and accountability. There are, however, many other specific issues in the context of medical research that need to be further explored.

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