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Pragmatic evidence and textual arrangements: A case study of French clinical cancer guidelines

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ABSTRACT

Both critics and supporters of evidence-based medicine view clinical practice guidelines as an important component of this self-defined "new paradigm" whose goal is to rationalize medicine by grounding clinical decision-making in a careful assessment of the medical literature. We present an analysis of the debates within a guideline development group (GDG) that led to the drafting, revision and publication of a French cancer guideline. Our ethnographic approach focuses on the various aspects of the *dispositif* (or apparatus) that defines the nature and roles of participants, procedures, topics and resources within the GDG. Debates between GDG members are framed (but not dictated) by procedural and methodological rules as well as by the reflexive critical contributions of the GDG members themselves, who justify their (tentative) recommendations by relating to its (possible or intended) audiences. Guideline production work cannot be reduced to an exchange of arguments and to consensus-seeking between pre-defined professional interests. It is about the production of a text in the material sense of the term, i.e. as a set of sentences, paragraphs, statements and formulations that GDG members constantly readjust and rearrange until closure is achieved. As such, guidelines partake in the emergence and stabilization of a new configuration of biomedical knowledge and practices grounded in the establishment of mutually constitutive links between two processes: on the one hand, the re-formatting of clinical trials into a device for producing carefully monitored evidence statements targeting specific populations and clinical indications and, on the other hand, the increasingly pervasive role of regulatory processes.

Introduction

Clinical practice guidelines (CPGs) are key components of evidence-based medicine (EBM), the self-styled "new paradigm" which "de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision-making", and argues for "using the medical literature [especially results from randomized clinical trials] more effectively in guiding medical practice" (EBM Working Group, 1992, p. 2420). Medical reformers and administrators consider CPGs "the tool of choice to weed out unwarranted variation in diagnostic or therapeutic practice and to enhance the scientific nature of medical care delivered" (Berg, Horstman, Plass, & van Heusden, 2000, p. 766). Thousands of CPGs have been produced in the past decades by a great variety of institutions and associations in many different countries (Weisz et al., 2007).

Unsurprisingly, CPGs have attracted the attention of many commentators. A substantial part of the social science literature on this topic (e.g. Castel & Merle, 2002; Timmermans & Berg, 2003) focuses on the *use* of guidelines as distinct from their *production*. This distinction, however, may be challenged for, as we will see, guideline producers often openly discuss its potential use and users; as noted, more in general, by science studies scholars (Akrich, 1992), technical devices contain built-in *scripts* of their expected deployment: examining those scripts can deepen our understanding of future uses. Most articles on the production of guidelines have been published in medical journals and usually consist of methodological recommendations and suggestions on how to improve the process (e.g. Eccles et al., 1996; Eddy, 1990). Among the social science studies that investigate guideline production, a number have resorted to an experimental or a retrospective design to correlate the professional characteristics of guideline group members with their decisions (e.g. Hutchings & Raine, 2006). Yet, as analysts of procedural rationality would argue (e.g. Reynaud & Richebé, 2007, p. 8), guideline development

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cannot be equated simply to a decision about a preset number of choices, but often leads to novel, unexpected solutions. Only ethnographic investigations of guideline development can account for the dynamics and peculiarities of processes that take place in time.

Pagliari and Grimshaw (2002) observed interactions among group members, focusing on the effect of professional role and status on group discussions. However, by implying that decisions were constrained or even pre-determined by pre-existing social variables such as professional status, their study foreclosed any consideration of their emergent nature as predicated upon interactions between group members. In contrast, Moreira's (2005) ethnographic study of guideline development more subtly portrays the debates taking place during group meetings. Borrowing from Boltanski and Thévenot's (1999) "pragmatic sociology", Moreira focused on the actors' own critical capacity, identifying five types of "repertoires" used by the participants to justify the guideline's content by reference to the *actions* to which the guideline would presumably lead in the "external world". While participants from different professional groups made preferential use of specific repertoires, Moreira attributed this fact less to the presence of *a priori* interests than to the observation that group members envisioned different (future) practices and users.

Although there is considerable methodological overlap between Moreira's approach and ours, there are also several differences. Firstly, we have chosen to focus on a different empirical domain, oncology. All medical professionals attending our guideline group meetings were specialists, albeit from different disciplines. This probably accounts, in part, for the absence of a structuring effect of professional parameters on group dynamics. Oncology, moreover, has a long multidisciplinary tradition, which, in the French case we studied, is entrenched both in the institutional nature of comprehensive cancer centres and in state regulations. Secondly, the role of material and textual artifacts in the shaping of judgments and actions is a key element of pragmatic sociology, but this is notably absent in Moreira's analysis. In line with science & technology studies' longstanding focus on textual inscriptions and translations (e.g. Latour, 1990), and following up on Mykhalovskiy and Weir's (2004) programmatic suggestion to investigate the textual dimension of EBM, we pay special attention to textual practices. Guideline group meetings cannot be reduced to an exchange of arguments to select a winning position, after which the actual writing of the guideline would amount to a mere formality. Textual activities do not happen *after* consensus has been reached, they are *part* of the debate. Closure of debate does not necessarily imply that participants share the same opinion or interpretation. The collective production of a text — i.e. of a specific sequence of sentences and paragraphs that group members constantly readjust and rearrange until a final version is agreed upon — signals the end of debate. Thirdly, we have borrowed from the sociology of organizations with respect to procedures and organizational routines. One of the most striking features of the dynamics of a guideline development group lies in the role of (local) procedures, rules and distinctions, as set by the guideline developing institution and flexibly enforced, interpreted, adapted and modified by group members. Our analysis will focus precisely on this "apparatus" (or *dispositif*, to use Foucault's notion (1994)) and, in particular, on the organizational and methodological routines that are deployed in the course of group activities.

Our focus on *dispositif* and texts has led us to an additional point. Clinical trials do not test substances nor do agencies such as the FDA approve them; both institutions test and process specific *claims* about substances. Amounting to carefully crafted textual statements about the scope and results of a clinical trial (e.g. substance X works against condition Y affecting patient population Z), claims are excerpted from publications, submitted for drug market approval and embedded in guidelines. As we will see, this is far from a mechanical transposition, but this process presupposes and depends on the upstream production of specifically formatted textual claims. As a result, guidelines no longer appear as self-contained evidence-based tools targeting individual clinician's behavior; they are elements of a chain of textual *translations* linking knowledge production about therapeutic substances and pathological processes, drug marketing and the regulation of medical practices. In other words, they partake in the emergence and stabilization of a new biomedical configuration grounded in the establishment of mutually constitutive links between two processes: on the one hand, the re-formatting of clinical trials into a device for producing carefully monitored evidence statements targeting specific markets (Greene, 2007) and, on the other hand, the increasingly pervasive role of regulatory processes within biomedicine (Cambrosio, Keating, Schlich, & Weisz, 2006).

Material and methods

Our ethnographic analysis centres on an oncology guideline development group convened by a French program called "Standards, Options, Recommandations" (SOR). Established in 1993 by the National Federation of the French comprehensive cancer centres (FNCLCC), with additional financial support from a national charity, the French National League against Cancer, and the government's Health General Directorate (HAS), the SOR program was given the mandate to develop and update oncology guidelines in order to harmonize "clinical practices between cancer centres concerning diagnostic, classification, treatment and follow-up procedures" (Fédération Nationale des Centres de Lutte Contre le Cancer, 1994, p. 50; our translation). The FNCLCC is the umbrella organization of the 20 regional comprehensive cancer centres, whose origin goes back to the 1930s (Pinell, 2002) and which combine clinical research and treatments within a multidisciplinary framework. In 2008, the French National Cancer Institute (INCa, established in 2004) took legal responsibility for the SOR program. The program relies on a distinctive framework for the production of guidelines that emphasizes the need to follow the tenets of evidence-based medicine by producing recommendations resting on the best available scientific evidence or on expert consensus when adequate evidence appears to be lacking (Fervers, Hardy, & Philip, 2001). Between 1993 and 2006, SOR published 81 guidelines, i.e. 54% of the 148 published French clinical practice guidelines (Castel, 2009). Professional and public bodies have formally endorsed the SOR programme and medical audits conducted by Social Insurance use them as reference. The SOR guidelines have been diffused outside France, namely in the *British Journal of Cancer*, and the SOR program was one of the founding members of international initiatives such as the Guidelines International Network.

Our research strategy was to follow the development of a particular guideline from the initial stages to the final drafting and circulation of the guideline document, a process that in our case took place in 2007–2008 over a period of 21 months. We selected a therapeutic guideline centered on a trans-disciplinary medical condition that affects patients with different forms of cancer. The study was approved by McGill University's Research Ethics Board I. For confidentiality reasons, we have removed any information that could allow readers to identify the specific topic of the guideline and thus individual group members. The group included clinicians from the two core medical specialties treating that particular condition, as well as medical oncologists, pathology/laboratory specialists, academic researchers investigating the condition, anesthesiologists, and two SOR methodologists, for a total of 22