Infrastructuring experience: what matters in Patient Reported Outcome data measurement?

Abstract:

Patient Reported Outcome (PRO) data are being mobilized widely as a means to implement clinical and governance decisions making systems that are based on measurements of "what matters to patients". Little is known however of *how* these – datified and calculative – versions of patients' embodied experiences become integrated in healthcare systems to achieve clinical, managerial and political goals. Drawing on ethnographic and documentary data collected on a Danish national initiative to establish a questionnaire bank and a technical infrastructure for PRO-data, this paper explores the epistemic and moral tensions of emerging infrastructures for patient reported data. Our data reveals that those involved in crafting and developing the Danish PRO system seek to encode 'patient experience' the Danish healthcare system by infrastructuring for the clinic, by infrastructuring for the organisation and by infrastructuring for participation. The infrastructuring efforts in each of these domains involves tensions as the emerging phenomenon of PRO rubs up against existing and concurrent ways of working clinically and of enhancing and evaluating the quality of clinical care. Thus, while we share critical social science concern about standardisation of patient experience, we here show how those concerns are already pragmatically present in the infrastructuring efforts that patients, clinicians and administrators engage in.

Introduction

Patient Reported Outcome data (PRO data) are being mobilized widely in Western healthcare systems to ensure that clinical and governance decisions are based on measurements of "what matters to patients" (Coulter 2017). Sometimes also referred to as PROMs (Patient Reported Outcome Measures), these are data on patients' experiences on

the effects of treatment as collected through standardized questionnaire tools[1]. This is evident in programmes linking health care quality assessment to PRO data in countries such as the US, UK or Sweden, in the past two decades (Black 2013; Nilsson et al. 2016).

The FDA defines PROMs as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" (US FDA 2009: 1). According to the NHS, "PROMs measure a patient's health status or health-related quality of life at a single point in time," (https://www.england.nhs.uk/statistics/statistical-work-areas/proms/). Generally administered to patients as online questionnaires to be filled out regularly – at home or at the clinic – during the course of treatment, PROs are seen to embody the goal of creating what Wachter (2015) labelled a 'learning health care system', where data is used to improve the organisation and delivery of health care. Moreover, PROs and the systems set up to collect them are promoted as participatory technologies, where data "coming directly from the patient", is given a central place in healthcare decision-making – clinical or otherwise. In the clinical encounter the promise is more personalized treatment, and at a managerial level, more quality and efficiency. Thus, in 2017, the OECD issued a ministerial statement arguing for the need for better and more widespread use in member states' health systems of "measures of patients' own experiences of medical care and health care outcomes" (OECD 2017: 5). Such measures would, it was suggested, "better equip countries with data that reflect what matters to patients" (ibid: 15).

Taking as point of departure Hogle's call for research on how data is made meaningful and is acted upon in interaction with "policies, technologies and social conditions" deploying novel infrastructures (Hogle 2016: 388), in this paper, we are concerned with the pragmatics of making 'patient's own experiences' usable for health care systems. The formalization of 'patient experience', reconfiguring the subjective into objective, standardized data and useful data flows is no simple task (Shapin 2012). How is this done in practice? How do these data become integrated in existing health care organisations and systems? And with what effects when it comes to the role of 'the patient' and 'experience' in the healthcare

[1] In this paper, we mainly use the abbreviation PRO even if there are regional differences and some scholarly debates of terminology and delineation of PRO versus PROM. Some of these issues will be elaborated on in the analysis. Until then, the reader should see both abbreviations as referring to the same phenomenon.

system? While part of larger 'datafication' efforts within national health systems (Hogle 2016; Hoeyer et al. 2019), we find the mobilization of PRO data particularly interesting because these efforts seemingly aim to align well-known expectations of increased efficiency and effectiveness with more normative aims of "incorporation of the patient's point of view into the assessment of the appropriateness and effectiveness of professional allopathic medicine" (Sullivan 2003: 1995). Patients are – through data on their subjective experience – enlisted as 'co-creators' of health services and medical innovation (Anderson & McCleary 2016). But turning personal experience into standardized data, which can be circulated and used for a multitude of purposes, is not without controversy. For example, Hausman (2015) has argued against aggregation and averaging of health states valuation because it makes equivalent conditions and situations, which are significantly different from an ethical point of view (life threatening vs minor conditions). Others have pointed to the tension between the rhetoric of personalisation in PROs and the reality that is brought to bear through aggregation of data (Prainsack 2017). This points to a further tension between the promise of personalization as a "deepening" of knowledge of the patient and the construction of standardized and versions of experience devoid of real "patient knowledge" (Pols 2014). While we share a concern for "the seduction of quantification" (Merry 2016) resulting in instrumentalized versions of patients' voices, here we interested in investigating the pragmatics of these tools (Moreira 2018). In the paper, we are focus thus on exploring the production of datafied, "thin" versions of patient experience through the negotiations and compromises involved in integrating it in existing, already data rich health care systems.

Our approach to these questions highlights the complex and partial process of making a socio-technical infrastructure for patient experiences. Using the notion of infrastructuring as a lens to analyse this process (Star & Bowker 2002), we focus on the relational, temporally emergent and performative dimensions of data and information systems (Karasti & Blomberg 2017). The concept helps us "theorize infrastructures as they develop" (Bowker 2018: 212), making it possible to identify and map the multiplicities and uncertainties that are involved in the making of PRO. Using this approach, we suggest that the Danish initiative provides a unique window for us to investigate the formation of PROs in its 'preparation' or pre-launch phase, a critical period that shapes future development. In this, Denmark may be seen as a critical case for theory development (Yin 2017) of datification of health care, both

due to the extent to which the relation between citizens and welfare institutions are already highly digitized and due to the country's long-term tradition for citizen involvement in policy and practice (Hoeyer 2016).

To do this, we draw on ethnographic and documentary data collected on a programme in the Danish Health System aimed at establishing a national questionnaire bank and technical infrastructure for PROs, tightly coupled with a more general national focus on health digitalization. Between 2015 and 2019, the first author participated in eight public meetings on PRO, conducted more than 40 hours participant observation in a PRO project on heart rehabilitation, and interviewed 15 stakeholders related to the national PRO initiative. The observations involved participation in workshops, some involving heart patients, some primarily clinicians in the area of heart disease and rehabilitation. Extensive fieldnotes were made during and after these workshops, complemented with documentation provided at the meetings. Informants for the interviews were selected through a snowballing approach to identify key actors in the Danish PRO arena. Semi-structured interviews were transcribed in full and anonymized. Online and print documents on the national PRO initiative and related activities were collected.

In the following, we first offer a brief genealogy of PROs. Our aim in this is to explore the political and epistemic investments of such standardised measurements of 'patient experience'. This provides a useful background against which to understand the tensions experienced by promoters of PROs in Denmark. We then explore how they are reflexively addressed in the Danish case. Here we identify three domains of infrastructring – the clinic, the organization and participatory arenas – each with its own set of tensions shaping what the inclusion of patient experiences as PRO data might entail in practice. We end by discussing the implications of our findings for how we may understand attempts of datafying the patient voice.

A brief genealogy of PROMs

As suggested above, the establishment of PROs as central tools in the international agenda for health care reform was sealed with the OECD recommendation in 2017. This drew on the work of the OECD High Level Reflection Group (HLRG) on Health Statistics, which argued that PROM programmes represented the best path for "countries [to become] well-

equipped to meet the challenges presented by ageing populations and the accompanying rise in chronic disease and multiple morbidities, [making] it essential that data collected are relevant and actionable, and correspond to what matters most to patients" (HLRGHS, 2017: 15). In a commentary to the report co-authored by economist Michael Porter and OECD's Secretary-General Angel Gurría, it is argued that the change "requires asking patients themselves" their own assessment of health, quality of life in highly standardised way so as to make results comparable across time points, providers and across countries (Gurria & Porter 2017).

Porter himself is one of the founders of the International Consortium for Health Outcomes Measurement (ICHOM), an organization dedicated to providing standardized sets of outcome measures, many of which are to be reported by patients (ICHOM 2018). In this vision and with reference to an ideal of "putting people at the centre", patients are granted a central role in healthcare management: by providing information about their health, patients not only inform decisions regarding their own treatment, but also provide the means for governing healthcare on their behalf. This can be seen as the realisation of Michael Porter's highly influential work on Value Based Health Care, where value is defined as "the patient health outcomes achieved per dollar spent." (Porter 2010: 2477).

The linking of more efficient health care to market competition underpinned by standardised measurement of health is not new. Indeed, it has been a consistent orientation in attempts to reform health care for at least 40 years (Moreira 2012). Nowhere is this linkage more clear than in the proposals attached to US health reforms in the 1980s. One of its key proponents, Paul Elwood argued that the transition from a centralised administration of health care to a distributed, networked structure would have to rely on a shared information infrastructure focused on outcomes. Outcomes management, he argued, would provide the infrastructure for "rational decision making" in health care, orienting insurers, providers and users towards common goals (Elwood 1988). In this, he argued that *experience* played a key role:

The intricate machinery of our health care system can no longer grasp the threads of experience. […] our common interest is the patient but we represent that interest from such divergent even conflicting viewpoints [that we now] need a central nervous system. […] I

propose that we adopt a technology of collaborative action [...] Outcomes management is a ***technology of patient experience*** *designed to help patients, payers and provider make rational choices"* (Ellwood 1988: 1550-51; our emphasis)

Specialization, the different perspectives and interests of healthcare actors and patients' lack of information on quality to inform their choices on a health market, thus called for a 'central nervous system' based on "measurements of the effects of choices of patients, payers, and physicians on the patient's aspirations for a better quality of life" (ibid). Such measures should become "a new universal language of hurting, functioning, working, interacting, and living" (ibid: 1551).

Market rankings and preferences thus relied on establishing a 'universal language', a form of rendering equivalent health care providers across context, conditions, specialities, organisations and patients. That language was not to be found on doctor's assessments, insurers' valuations or patients' individual opinion. What was required was a form of measuring outcomes based on an objective assessment of 'patient experience', an operation that would encode a stable qualification of wellbeing and function across individuals and context. Developing and using a measure of health would be what Thevenot (1984) described as an 'investment in form', embedding a stable form of qualification of objects or persons, facilitating its quantification, and enforcing a specific mode of political co-ordination that enacts efficiency.

Interestingly, Elwood, suggested that the exemplar route for this future 'technology of patient experience' was the Medical Outcomes Study's (MOS) search for "practical instruments for measuring outcomes" (Elwood 1988: 1552). Aiming to develop a measurement of health to quantify the effects of different health approaches within the RAND' Health Insurance Experiment, MOS investigators drew on the WHO 1948 definition of health to propose a model that "take(s) into account the cognitive processes underlying the *evaluation*" that participants made about the functional, mental and social aspects of their health, (Ware et al 1980: 12; our emphasis). Enacting this evaluation as a 'cognitive process' was pivotal because it made health amenable to be investigated through psychometric methods. Thus, it became one of the key aims of the health status measurement team at the MOS to systematically perform "psychometric evaluations" of the ratings used in health

questionnaires. From this work, it would eventually emerge one of the most commonly used health outcomes measurement instruments – the 36-Item Short-Form Health Survey (Ware and Sherbourne 1992) – which remains a point of reference for those proposing the implementation of PRO data collection and analysis in health systems, such as the OECD High Level Reflection Group (HLRG) on Health Statistics (see above).

From a science studies point of view, psychometrics is one of most established techniques through which psychology enacts its object of inquiry (Igo 2007; Young 2017). By enabling the mapping of personal qualities in mathematical, structured measurement, psychometrics facilitate the generation of inscriptions – distribution curves, etc – that can be compared, correlated, subsumed and integrated (Latour and Woolgar 1986). The transformative capacity of psychometric procedures is thus epitomised in the reconfiguration of a fuzzy, deeply subjective thing such as 'experience' into a tractable object enacted as a psychological operation of 'valuation' of information.

This brief genealogical exploration, enables us to understand how PROs are layered on a complex sociotechnical assemblage that configures experience through the application of psychological techniques, which themselves elicit subjectively experienced phenomena and convert them into objective, quantifiable data. This is explicitly justified as a means to ascribe value to health care interventions or programmes that are seen as competing for a limited pool of resources. As we will see in the case below, however, deciding what matters in infrastructuring experience with PROs in health care systems is not a simple implementation of this proposal or ideal, and is laced with uncertainty.

The Danish Case: Infrastructuring experience in a data-intensive healthcare system

Denmark is a critical case study to understand the dynamics of infrastructuring experience. As a nation undergoing overall an overall transformation of infrastructure defined by Hoeyer (2016) as "intensified datasourcing", Denmark has recently made comprehensive investments toward using extensive patient reported data across the health care system (Ministry of Health 2018:p.27). As a result, Denmark has a highly developed digital health infrastructure with patients in the national health system accustomed to have their health data shared digitally among various health providers and generally said to have trust in health authorities. Nevertheless, recent intensification of data sourcing have spun some

public controversy (Wadmann & Høyer 2018) and revealed the many, partially contradictory aims and stakes involved (Høyer 2016). Neither public nor local legitimacy of new data sourcing practices and infrastructure can be taken for granted. And so is the case with its national PRO infrastructure.

The specific political aim to nationally introduce PRO has been brought to bear by two different, partly overlapping initiatives: a Value Based Healthcare initiative led by regional authorities (Danske Regioner 2015; Pedersen 2017), and an initiative promoting PRO data as means of patient empowerment and clinical quality – Program PRO.

Inspired by Porter and experiences in other countries, in 2014-15, the Regional authorities set out to test if principles from VBH approach could provide alternative, less activity-focused and more patient-centred forms of healthcare governance. In this, PROs featured as central tools to enable change. According to an analysis of the initiative made by Bonde et al. (2018) the concept of VBH was locally translated by connecting with "existing practices, agendas and commitments" (Ibid: p. 1119). Patient experience was not, as intended, stitched into the attempts to build an alternative governance infrastructure (KORA 2016). Nevertheless, funding was secured for supporting widespread, cross-sectorial use of PROs (Finansministeriet 2016: 33).

In parallel with the VBH-projects, a different initiative was instigated in 2016 by a broad coalition of healthcare actors, aiming towards building an expansive, continuous and cross-sectional collection of patient reported data. It grew from a project – Program PRO – initiated by a large patient association - Danish Patients - involving 29 experts across different fields and institutions, who in a 2016 report provided recommendations for the use of what was here termed "PRO-data" throughout the Danish health sector (VIBIS 2016). The definition used in the report of PRO-data is more closely related to the FDA definition mentioned above, with a focus on data reported directly from the patients on their experience of their state of health. The aim of using PRO-data is suggested to be at both the individual level, for the clinical dialogue and "involvement" in decision making, and at an aggregate level, for research, clinical databases and as a quality indicator/metric. Throughout the report the main focus, however, is on making the patient "a partner" in the Danish health care system so that decisions both at the clinical and the managerial level

should be based on “the perspective of the patient”, tying this data intensification practice to the rhetoric of patient empowerment (Armstrong 2014). Interestingly, there is in the report only one reference to Porter and the concept of Value Based Healthcare is not mentioned at all, which could have been expected given the widespread and international influence of both the author and the concept.

The report was greeted with enthusiasm by policy makers, and a National PRO office was established in 2017 under the auspices of the Ministry of Health, drawing on a cross-sectorial steering group (Langstrup 2018). The National PRO office has as its primary task to support the widespread use of PRO-data and to select and or develop the specific questionnaires to be put in a national PRO-bank, setting a national standard for relevant “crown-marked” PRO-tools in a number of clinical, cross-sectional treatment areas (pro-danmark.dk). Central to its task is also to make the national IT-infrastructure suitable for sharing PRO tools and PRO data across sectors. The work is highly collaborative, whereby questionnaires are selected and/or developed with the involvement of patients, health professionals, patient associations and those responsible for existing national clinical quality databases in what is termed “clinical coordination groups”(CCGs).

As of August 2019, six CCGs were completed. The groups were organized with a parallel track for patient involvement and one primarily for clinicians with representation of a patient from the patient track – an organization that again underlines the investment as one in patient empowerment. The clinicians attending clinician groups were to represent all relevant clinical contacts that a patient in the specific treatment pathway might have across sectors and professions. The clinicians were appointed by their local region, municipality or professional association. The goal of the meetings was to describe a cross-sectorial patient pathway, find points at which patients should be asked to provide PRO-data, choose what the purpose of the data should be in the clinical context and decide which specific questionnaire tools and items should be included into the national PRO-bank for this area. In the end, the ‘package’ is to be piloted in clinical practice and then made available in local record systems via a national IT-infrastructure. At the end of the fieldwork period (September 2019), the results from five of the six groups were in different stages of piloting in clinical practice.

In the next section, we will focus or analysis on Program PRO and the CCGs, emphasising how this initiative was explicitly set up to distinguish itself from VBH-projects, both in Denmark and internationally – something which also makes the Danish case stand out. By aiming to link PROs to clinical practice, the everyday clinical encounter and patient empowerment, the initiative provides a unique window into the tension inherent to personalisation-through-standardisation that lay at the core of visions of data-driven health systems. It is to these tension that we now turn.

Infrastructuring for clinical work: Making PRO clinically meaningful?

In setting up Program PRO, its leaders were mindful of the market efficiency connotations associated with standardised metrics. As such, the definition of PRO-data agreed upon in the initial Program PRO excluded the M for measurement, setting it apart from the VBS-initiative and international initiatives more often referring to "PROMs". As one of the experts involved in the initial reports and the national initiative suggested, they chose to take out the M because they did not want to indicate a close relation to the use of these tools as part of population-based aims and targets, the primary application of PROMs in the US and UK (Interview and fieldnotes). In particular, in the UK, challenges had been pervasive in motivating patient and clinicians to collect the data as it was only used at an aggregated level for management, not at the clinical level - with resulting low reply rates. While these reduce the usefulness of data at the aggregate level, more importantly they indicate lack of ownership of the process among clinicians. Moreover, concerns of PRO data being associated with the negative connotations of increasing paper work taking up clinicians time – something that had been publically debated over a number of years – made the enrolment of clinicians a particularly pertinent issue (Langstrup 2018:p. 572). Consequently, the Danish protagonists were focused on establishing a close, positive association between PRO and clinical practice. As one health services experts put it in one of our interviews,

PRO needs to be generated in the clinical meeting between the health professional and the patient. That makes it meaningful for the patient and for the health professional" (Interview health services expert 2017).

The insistence on "clinical meaningfulness" translated into a much-used differentiation in the Danish arena between "active PRO" and "passive PRO", where the first denote the preferred practice in which data is collected for immediate use in the clinical encounter,

with possibility for secondary use for quality monitoring and research. In contrast, the "passive PRO" is equated with the collection of the same data, with no immediate clinical relevance or action taken. Thus, in the "Values" section of Program PRO, it is stated that "PRO-data should support relevant dialogue between patient and health professional" and "should be meaningful for patients, health professionals and management", while also contributing "to improve the outcome of patient pathways and thereby contribute to visible value for the patient" (VIBIS 2016: p.38).

"Clinical meaningfulness" and "active PRO" can thus be seen as a strategy of enrolling clinicians as central actors in the infrastructuring of experience. This focus also justifies the composition of the CCGs, mainly consisting of physicians and nurses from the clinical area for which PRO tools should be selected. In the CCG workshops – often more than 4 whole day meetings spanning up to 6 months – it was continuously stressed that the goal primarily is to facilitate the use of PRO-data in a clinically relevant way – to inform clinical dialogue, screening based on patient needs or clinical decision-making – only secondarily for quality management or research. For instance, a powerpoint slide shown at several of the CCG workshops on heart rehabilitation, under that heading "Why is PRO a good idea?", pictured a person with different light sources illuminating the figure: "the record", "test results", "the consultation" and finally "PRO data". On the same slide, different "perspectives" of PROs relevance was listed with benefits for "patient" and "health professional" at the top and for "process" and "development" below and in semi-transparent colours, signifying that these benefits were secondary.

One difficulty that arises from the emphasis on clinical relevance, however, and on differentiating the initiative from other data-driven efficiency efforts, is that the measures or data at the centre of the groups' deliberations are standardized measures such as QoL, ADL and similar health related information, also used in VHB programmes. Many clinicians involved in the groups we observed, knew the English terms from using the measures in clinical research or from working with clinical quality databases. This made the terminological monitoring around the use of "active PROs" extremely challenging when promoting the national initiative to clinicians at public meetings and when working in the CCGs, as we illustrate below. Moreover, several of the participants in the CCGs were also

already engaged in the national VBH-projects where initially the concept of PROMs was used, and where the primary target was value as understood in economic terms.

In the CCG on heart rehabilitation, for example, this tension between "clinically meaningful" and "active" PROs and the argument that "passive PROs" could be equally meaningful for clinicians work, played out at several occasions. A key discussion concerned whether or not it was meaningful to ask patients to fill out a PRO-questionnaires for "baseline data" even if it would not inform any immediate clinical action, for instance just before undergoing heart surgery. The clinical meaningfulness of this consultation was not clear, or as one consultant phrased it, "It is important that we don't invent *data collection consultations* with no clinical purpose!" (Cardiologist heading the CCG, fieldnotes). Some of the clinicians further argued that the stress induced by the questionnaire filling would be an undue burden for patients:

"When discussing whether sexual issues could be part of a baseline questionnaire, one clinician bursts out "But isn't that totally irrelevant when you are in shock after your ticker just stopped?! Should I then have to consider if I have a satisfying sex life? I have just written my testament!" (Fieldnotes).

This assessment was challenged by the view, usually voiced by clinicians engaged in VBH or clinical registries, that such baseline data would enable measurement of aggregated outcomes of interventions, and thus to value the treatment provided: "Now it is a black box! We want to know if they are getting better!" (Cardiologist engaged in VBH-initiatives, fieldnotes).

The tension between the personalised care vs the standardised measurement was nowhere more visible that in relation to issues of validity. When choosing questionnaires in the CCGs, there is often a choice to be made between a number of either disease specific or generic tools, such as the SF-36 (see above). The PRO office is responsible for providing participants in the CCGs with an overview of possible tools and a literature review covering evidence of their use and validity. Usually, participating clinicians may have had experience of working with or routinely use one or more of the tools, as mentioned. There is among the involved actors a general trust in the ability of questionnaires to collect important data on patients' experiences of their own health to support clinical care. However, this trust has been criticised as methodologically naïve, with some experts being concerned with how CCGs

engage in selecting PRO-tools, and the basic methodological assumptions of the national PRO initiative (Interviews with questionnaire experts).

For example, in the CCG on early detection of depression, clinical psychologists expressed concerns regarding the way particular questionnaire tools were selected for the national PRO-bank (interview with participants). These participants had previously been involved in the National Health Authorities development of evidence-based clinical guidelines for early detection of depression. The psychologists argued that the clinical guidelines on the area were not taken adequately into account at these workshops (interview with participant). The idea that the same generic PRO-tool could be used to screen for depression in different somatic treatment trajectories were for them highly problematic: "We were just told, it has to be generic. Where did that come from? What is the argument for that?"(Interview with psychologists). They referred to existing evidence on screening for depression within particular somatic areas, and suggested that the correct way would be to use the screening tools validated nationally for the specific disease area, or at least for those to be taken as a starting point, rather than trying to find a generic tool. As one of them put it to us later, "the quality of the new [tool set] they wanted to deliver was worse than what was already there – in terms of its validity..." (Interview with psychologists). What they experienced was that the production of comparable data was prioritized.

Indeed, a consistent critique raised by researchers with expertise in questionnaires, statistics and quality of life hinged on how questionnaire tools have been developed and validated for purposes that significantly differ from the (multilevel) application in the national PRO initiative (Interview with questionnaire expert). Many PRO tools were initially developed and validated for application in research at a population level. Now the same tools would be used at the level of the individual for clinical purposes. This critique goes to the heart of Program PRO's aim to make measures 'clinical meaningful'. How can they be meaningful if they are not valid? And what counts as validity in a clinical and personalized context? Such issues remained unsettled in the negotiations to infrastructure patient experience.

This critique also pertain to the proliferation of PRO-tools being developed ad hoc, to the editing of existing validated tools being for clinical purposes or to encompass wishes of

patient representatives. Little is known about the effects of these changes to the validity of results and thus their impact on clinical decisions and outcomes. Again, how important this lack of information is, depends on whether the tools are to be mainly used to raise awareness of issues to address in a person-centred, and support personalised dialogue, or they are to become build into an evidence-based algorithm to support prioritization or clinical decision-making. Within the latter, using un-validated tools renders results incomparable and hence problematic to use at an aggregate level – whether for clinical decision making, research or quality management.

The agenda of the national initiative is that only validated tools should be included in the PRO bank. However, as the example above shows there is not necessarily agreement on what constitutes methodological rigor, or what the validation is for. In an interview with one manager from the national PRO office, she suggested that it is necessary to be inclusive in relation to already established clinical practices that use PRO tools, which are not necessarily validated scientifically, but only "tested": "What if they [clinicians, ed.] in Region North have been using a questionnaire for a hundred years and have tested it and everything. Then what?!" (Interview, PRO office 2017)

The key to the interviewee's reasoning lies in the difference between validation and test. In her view, the questionnaires and algorithms that might be used by clinicians are "tested", but not necessarily to the high standards of formal questionnaire validation demanded by statisticians and methodologist. The test, then, is here a pragmatic form of validation, provided by the habitual use of a tool over a number of years, rather than by experimental procedure (Marres & Stark 2020). A recognition of the relational and potentially unsettling character of PRO infrastructure, the preference for continuity of use of 'tried and tested' tools denotes also an attempt to align the PRO programme with existing clinical practices. It is from this perspective that we can understand another interviewee's view that the national PRO approach is following an "implementation logic", rather than a scientific logic, wanting to ensure speedy diffusion of PRO tools rather than a sound basis of evidence: "For them [proponents of the national initiative, ed.] a questionnaire is a questionnaire and we just have to get started and push ahead" (Interview with questionnaire expert).

The pragmatist focus on implementation is buttressed by the optimist agenda surrounding the use of 'big data' in health and healthcare (Prainsack 2015). In this, technological promises associated with generating new kinds of data blur established boundaries between valid and invalid data. This is not to say that the protagonists are indifferent to the kinds of data collected. Rather, they explicitly address this issue as requiring balance or compromise. As a physician and health services professor put in at an international seminar given by the National PRO office, "this is about data and standardization, but it also about dialogue and everyday life" (Fieldnotes). Balancing evidence concerns with a focus on ensuring meaningfulness for clinicians is key requirement of the PRO infrastructure. Tools chosen with reference only to scientific rigor, but without adequate involvement of the stakeholders might hamper the implementation the national PRO bank in and across practices, and thus decrease the reach of data driven health services.

Infrastructuring for the organization – balancing efficiency, actionability and control

In the previous section, when analysing the work of making PRO data clinical meaningful, we also touched upon the relational character of infrastructure, and in particular on how it relates to "the installed base" (Star 1999: 382) of clinical work already entangled with research and governance practices and specific measures of patients' experiences. While the focus of much of the PRO initiative lays on its clinical use, downplaying its economic efficiency aims, better prioritization, planning and cross-sectorial coordination remains a central aim of the initiative. Making patient flows "data driven" rather than "calendar driven" is particularly promoted as a necessary step to avoid wasteful care in a context of increasing demand from raising numbers of chronic patients. Monitoring patients with PRO data will enable, it is argued, the use of algorithms to calculate and plan appointments, in a needs-based and efficient manner.

In this, it is significant that protagonists draw on the example of "telePRO": a system already in use in a number of different specialized treatment pathways such as epilepsy, asthma, diabetes, where patient regularly log PRO questionnaires. Data is then processed by an algorithm to determine thresholds for clinical action such as automated appointment cancelling or the triggering of a phone call by a nurse checking on the patient. The system is well aligned with policy calls for using digital tools and data to curb increasing demands, the

Danish Ministry of Health arguing that "there is really no alternative to increased digital collaboration" to ensure a "sustainable development of our healthcare system" (Ministry of Health 2018: p.8-9). CCGs are mindful of the political risk associated with using efficiency as a policy aim and often stress that the Ministry of Health is not promoting PROs simply as a way to cut funds, but rather to "prioritize" and "set resources free", focusing on the possibility of putting the data to use in particular clinical trajectories.

However, the question of using PRO data for a more efficient and data driven organization of clinical encounters rubs up against other organizational and professional concerns. While there is very little opposition, on a general level, to the idea of using PRO-data on issues such as QoL or mental distress, clinicians raise reservations about the actionability of the data that will be obtained through these means:

"Sleep! But what the hell am I to do about that with my cardiology expertise? […] We should not ask about things that we just leave unattended, then patients will be very disappointed" (Cardiologist in clinical coordination group, Fieldnotes).

How, the clinicians ask, should they deal with the possibility of new demands for managing issues that they neither have the expertise to manage themselves nor (knowledge of) services to refer the patient to? Several times such questions are raised as ethical, organisational and professional challenges for clinicians not used to dealing with issues ranging from sleep, as in the quote above, to sexual health or loneliness. This also challenges the argument of PRO data as a means for more efficient care. The head of the CCG addressed this at a meeting:

"When some chief physician says to me, "I don't want to ask about loneliness, because I can't do anything about it!", I tell him, that the patient want to be asked anyway. They want a referral. You will just have to refer the patient to a specialist". (fieldnotes).

So the argument is, that clinicians are not to handle these issues, rather they are just obliged to help the patient navigate toward the places and people that can help them – be it elsewhere in the health system or in voluntary and patient organization. Actively guiding the patient through the health system is justified not only by its individual benefit to how it might reveal priorities to be pursued. As one clinician put it in a CCG meeting, "If it is what is important to our patients, then that is what we should develop our health system toward" (fieldnotes).

The organizational aim of the national PRO initiative is thus that PRO data should be used for coordinating patient trajectories, by directing focus on needs and outcome of treatment. In this, health care professionals are to be enrolled as organisational experts, translating data into shaping patient's pathways in the health care system. Patient pathways are another complex organizational infrastructure into which PRO data are to be weaved (Allen 2014). Purposefully actors across all relevant sectors involved in the particular treatment area are therefore invited to participate in the CCG. At the CCG workshops a lot of work goes into articulating – for instance by drawing exercises – what might constitute a common patient pathway along which PRO data can be produced and used, notwithstanding the variability of locally ways of organizing activities.

However, the challenges related to mobilising all relevant actors and sectors along specific treatment trajectories are not trivial. Who should be included? More importantly, who can be included? In the group working on heart rehabilitation, for example, the group comprised heart surgeons, heart nurses, physiotherapists, nutritionists, psychologists, patients and representatives from the patient association, but did not include general practitioners. This is because the General Practitioners Association has generally been averse to appoint representatives: only in two of the six CCGs there has been a GP representative. Their aversion has roots in controversies about their professional autonomy and role as the patients' privacy protector in an increasingly data-intensive health system (Wadman & Høyer 2018).

While acknowledging that PRO-data might have some potential for ensuring a patient-centred health system, the national association of GPs (DSAM), in its policy paper on the issue, stressed that there was lack of evidence on the effectiveness of PRO to bring about such system (DSAM 2017). This is compounded by a significant burden of data work on patients and clinicians, with the risk of diverging their attention away from clinical relevant information toward irrelevant data "polluting" the record (ibid). For the DSAM, PRO data is a challenge to the central role of GPs in health care systems such as the Danish, where their work as the systems' gate keepers is supported by a pragmatic focus on the 'whole person', and by patient records and data curated for that purpose. In this regard, GPs role in data collection, curation and processing is not solely contributing but should be seen as "a filter, which minimizes the risk, that the overview of the record is hampered by excessive or

unwanted PRO-data" (DSAM 2017: PP). Instead, Danish GPs appear to be saying, CCGs aim to plan the 'overview' from above, by committee, away from the clinical situation.

It is not surprising that the absence of GP representatives in CCGs produces frustration within the groups, as they are recognised as a key component of health care system and in managing patient pathways. Participating patients, in particular, are bewildered by their nonattendance, which they see as undermining the potential PRO data has to transform patient trajectories:

"In the patients drawing of their shared experience of an illness trajectory the GP figures twice – both at the beginning and at the end of the trajectory. When reviewing the drawing at the second workshop, one patient says "It doesn't make sense that the GPs isn't here (in the CCG, ed.) when they are in the drawing!"" (fieldnote).

For the promise of PRO to be brought to bear, it is necessary that all actors are aligned through the standard patient pathway. Misalignment, or lack of buy-in, from a strategic group of actors opens up the uncertainties inherent to implementing a new data infrastructure. As temporally emergent character of PRO data becomes publicly visible, as the sociotechnical vision it embeds reveals its partiality, the value it aimed to brings forth is downhearted, and its costs emphasised.

This issue is further exemplified by the enhanced visibility of possible tensions between the new data infrastructure being proposed and the 'installed base' of different patient record systems used in different regions and different sectors, already mentioned in the previous section. Decisions on which systems to use have long been delegated to regional authorities, municipalities and general practitioners. Although a number of inter-operability solutions have been put into place, there are still challenges and uncertainties. As a recent, problem ridden, attempt to implement an electronic patient record and management system across two regional authorities – Sundhedsplatformen – makes clear, the aim to uniformise the types and amounts of data that should be included in patient records, across regions, goes against the practice of autonomy within a pluralistic administration. Indeed, regional authorities have insisted on being free to choose the supplier of the specific PRO module tasked with distributing questionnaires, collecting answers, calculating and displaying results.

CCGs are acutely aware of this issue. The heart rehabilitation CCG, in particular, has voiced its concerns to the national PRO office, asking if the technical, inter-operability infrastructure would be in place. The answers suggested optimism at best but also expose the limited control national data authorities have to impose new standards. Enacting a 'digitally-led', patient-centred, efficient health care system taunts existing health data infrastructures and their embeddedness in political structures. As the tensions between 'old' and 'new' ways of organising health care become visible, the neutral character of PRO data infrastructure is dented. While leaders of the programmes have put much emphasis on distinguishing PRO data from the economist vision apparent in VBH, CCG's work of assembling PRO data architecture deploys a different form of politics, asking some health care practitioners to take on new duties and identities, and others such as GPs to forego existing ones. PRO data potentially destabilises not only the professional order of the health care system but also administrative procedures and institutions. Paradoxically, it claims to make health care more responsive to patients by denting the capacity to curate data and adjust data architectures to local authorities and local practices. Circling this conundrum requires evidencing investment in making data tools directly linked to patient participation and involvement.

Infrastructuring for participation – how to make PRO data matter to patients

A final domain of infrastructuring patient experience in our case of PRO data in Denmark concerns the ways in which the mobilization of these measures involves enrolment of actual patients in CCGs. This is the key means through which CCG aims to ensure that PRO infrastructure enables patient participation in data collection and use. In this respect, once again, Program PRO positions itself as an ambitious programme, aiming to bring together two forms of participation. On the one hand, PRO data is seen to enable individual participation in health care, supporting 'clinically meaningful' and personalised care. Qualitative research of patients' experiences of PRO/PROM supports the argument that the collection of PRO data in itself should not be seen as participatory, only becoming so when used to facilitate dialogue or learning (Boyce et al. 2014; Mejdahl et al. 2016). Others, taking a more political stance, have argued that PROs can only count as genuinely participatory if the measures themselves have been developed through meaningful involvement of patients

in their construction (Kirwan et al. 2017). This latter position is more focused on what could be labelled “collective participation” as a form of democratic representation.

The aim to bring together these two forms of participation appears to have been reinforced by the extraordinary engagement of patient associations in the initial mobilization of PRO in Denmark. The national PRO initiative has involved patients and patient associations in the process of choosing PRO tools for the national PRO bank. This was done in two ways: by including patients and/or their representatives in CCGs, and by organising parallel patient workshops which feed their deliberations to CCGs. The key challenge faced in the parallel workshops, in particular, was finding the adequate frame of the situation: what were these forums for? Should they be organised as consultative meetings, where patients are asked for their views and preferences, or should they have deliberative capacities? What might be the right tools and formats for teasing out what true and relevant patient experience is? Rather than a simple policy decision, this required crafting and qualification of the interaction between group members. The meeting followed a set structure. First, staff and consultants from the PRO office would introduce the concept of PRO. Second, patients discussed and mapped their experiences of disease pathway across sectorial borders. These maps would then be linked to specific PRO areas and measures chosen by clinicians, and a discussion followed about their usability and relative importance. The main conclusions of the workshops would subsequently be communicated to the CCG, who would make the final decisions on which PRO tools to choose. This procedure, however, raised the risk of patient involvement being deployed as consultation. To mitigate this risk CCG chairs were committed to amplifying the role of patient input in CCGs. As one the chairperson of the CCG on heath rehabilitation put it: “We may think that we already know what [questionnaires, ed.] to use. But that is not how it is going to be here. We cannot take the tools right off the shelf. We need to start from scratch” (fieldnotes).

The differentiation between ‘how it’s going to be here’ and a situation where PRO tools are ‘taken off the shelves’ is intended to mark an epistemic and political boundary. The knowledge process that supports the choice of PRO tools is robust insofar as patients’ contributory role is recognized and one can explicitly trace the views expressed by patients to the outcome of the CCGs. For such views to be adequately equipped, all patients involved in the workshops had to be ‘educated’ on the purposes of PRO data, and the variety of

questionnaire tools through which the data is obtained. In fieldwork in the workshops, patients consistently found all the possible PRO areas suggested to them (physical functioning, social functioning, quality of life, coping, pain, self-management, diet, sleep) relevant, and related many of the themes to experiences they had had as part of living with a heart disease:

"Sitting reviewing the questionnaire themes presented, a spouse whispers to her husband, a heart patient: "I think all of it is relevant! Don't you think?". He responds in low voice: "Yes". The patient next to them agrees and continues, "but we don't have to deselect anything"" (fieldnotes).

However, they also clearly suggested that they were not interested in answering questions if their answers were not addressed and acted on by a clinician. As HL noted in her fieldnotes, "everytime the patients discuss a questionnaire theme they talk about how the answer will help them talk to the clinician about important issues" (Fieldnotes). While this position was aligned with the "active PRO" vision, it also fuelled clinicians concerns about guaranteeing actionability of data, as discussed above. Taking patients' views seriously would mean committing to this pledge, so as to ensure individual and collective participation. Rather than providing a new start of how and why tools should be chosen, patient involvement resulted primarily in heightening the political stakes of the initiative. But making such politics visible threatens the stability of the consensus that deliberative processes are supposed to bring forth.

Where patient where willing to provide views on the tools themselves, their main concern was that PRO questions were difficult to understand or phrased in an out-dated way. For instance, in the heart rehabilitation CCG, patients expressed a negative opinion of the format and content of PHQ9 – a questionnaire for screening for depression that was considered in the heart rehabilitation group – which the chairperson half-jokingly said annoyed her: "Unfortunately it is one of those that we would really like to use for research" because of its high internal consistency in statistical terms" (fieldnotes). So here, including patients also implies to trade-off scientific rigor, and introduce potential challenges of measurement inertia, if measures are already organizationally embedded in clinical or research practices. While there has been and continues to be an extraordinary support for the introduction of PRO data among patient associations and individual patients involved in

the national initiative and attention from clinicians to the inputs from patient workshops, tensions are also experienced in this domain.

Another potential tension that arise pertains to the feasibility of making durable connections to the broad section of patients' everyday life and concerns – also those patients not directly represented among the highly engaged patient representatives. Both patient representatives and clinicians in the CCG on heart rehabilitation were very concerned about the representativeness of the patients involved:

"One of the clinicians asks: "How were they selected? It is always the active patients who participate in things like this". The head of the CCG says, that they come from all walks of life" (fieldnotes).

Both clinicians and patients themselves questioned if they could reasonably be seen as legitimate spokespersons for all heart patients and were concerned for passive, "weak patients" and their abilities to engage meaningfully with PRO. In particular, clinicians expressed concern that some patients might experience PRO as yet another burden of treatment and paternalistic or moralizing surveillance. One nurse called for increased reflection among the clinicians:

"Have we really considered what it is we are doing, asking all these questions? Maybe the patient just wants to get home and drink a lot of beer? Should we dictate what constitute quality of life for the individual? No we shouldn't! We should not be moralizin".

Obviously not everything that patients may experience and value in their lives – like drinking beer – will be represented through the questionnaire tools and what is represented will be privileged accordingly. However, a widespread, systematized, standardized and continuous form of participation as it is envisioned with the Danish PRO initiative needs individual patients for whom answering questionnaires is seen as meaningful, and it needs patient representatives to provide input and legitimacy to the very process of infrastructuring for experience.

Discussion

In this paper, we have asked: What matters in infrastructuring experience within health care systems? Our approach to this question was focused on understanding the pragmatics of making a socio-technical infrastructure for patient experiences in a specific health care setting. Recognising technologies of patient experience as specific types of 'investment in form' with historical roots was our point of departure to explore the normative and epistemic tensions involved in establishing a national PRO database.

Our data reveals that those involved in crafting and developing the Danish PRO system seek to encode 'patient experience' in the Danish healthcare system by infrastructuring for the clinic, by infrastructuring for the organisation and by infrastructuring for participation. The infrastructuring efforts in each of these domains involves tensions as the emerging phenomenon of PRO rubs up against existing and concurrent ways of working clinically and of enhancing and evaluating the quality of clinical care. In infrastructuring for the clinic protagonists seek to ensure that PRO as a clinically meaningful tool is prioritized over managerial aims. This however rubs against the embeddedness of research and quality management as part of clinical practice. Also, what is useful clinically may involve trade-offs in terms of scientific rigor equally creating tensions. Infrastructuring PRO also involves relating to organisational concerns such as the need to make care trajectories more efficient and better coordinated across sectors. But redirecting resources and expertise to issues that matter to patients also raises concerns as to the actionability of PRO data and the capacity of organisations and clinicians to respond. The installed base of sectorial powers and boundaries and existing data infrastructures provides extra challenges that bring to the fore the political and relational nature of PRO. Finally, infrastructuring PRO for and through patient participation is seen as central to the overall legitimacy of the endeavour, but in its own right introduces dilemmas when considering if PRO is truly a participatory and patient-centred tool. Further, compromises reached in any of these domains are also not necessarily aligned with each other, adding to the complexity of the work of infrastructuring PROs.

Literature on data infrastructures for personalised health care has focused on the implication of datafication and surveillance for practice. Looking at emergent infrastructures of personalized medicine, Barbara Prainsack (2017) has used the notion of a "surveillance assemblage" (p. 51-55) to point to arrangements in which certain technologies and human practices together operate by abstracting individuals into data flows to be reassembled for various purposes at different times and in different places as "data doubles". More widely, scholar also points towards how the conversion of experience into a standardised set of data simplifies the meaning and significance of patient experience as a form of knowledge (Pols 2014).

While we share these scholars' concerns about the consequences of infrastructuring personal data and intensified data sourcing at large, our research highlights the challenges

and balancing act that such infrastructuring requires understanding the forms of normative and practical reasoning developed by those who are directly involved in collective negotiation about what constitutes 'experience' for specific purposes in specific contexts. For them, 'patient experience' is above all an epistemologically and morally unstable figure. Ellwood's dream of "a new universal language of hurting, functioning, working, interacting, and living" is not within reach. It is a key finding of our paper, that while it might be a powerful trope in gathering actors and resources, it is not easy to decide and to settle upon "what matters to patients". In this regard, CGCs negotiating how to infrastructure experience could be seen as an instructive experiment in practically handling the 'ontological politics' of patient experience. Whether the PRO infrastructures enabling the circulation of more 'thin' versions of patients' 'data doubles' will push out or transform other ways of knowing patients and engaging with such knowledge in health care are pertinent questions for further research in the application of PROs in practice.

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