Journal of Health Organization and Management

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Received 5 March 2016
Revised 20 May 2016
Accepted 28 May 2016

Abstract

Purpose – New hepatitis C medicines such as sofosbuvir underline the need to balance considerations of innovation, clinical evidence, budget impact and equity in health priority-setting. The purpose of this paper is to examine the role of public participation in addressing these considerations.

Design/methodology/approach – The paper employs a comparative case study approach. It explores the experience of four countries – Brazil, England, South Korea and the USA – in making coverage decisions about the antiviral sofosbuvir and involving the public and patients in these decision-making processes.

Findings – Issues emerging from public participation activities include the role of the universal right to health in Brazil, the balance between innovation and budget impact in England, the effect of unethical medical practices on public perception in South Korea and the legitimacy of priority-setting processes in the USA. Providing policymakers are receptive to these issues, public participation activities may be re-conceptualized as processes that illuminate policy problems relevant to a particular context, thereby promoting an agenda-setting role for the public.

Originality/value – The paper offers an empirical analysis of public involvement in the case of sofosbuvir, where the relevant considerations that bear on priority-setting decisions have been particularly stark. The perspectives that emerge suggest that public participation contributes to raising attention to issues that need to be addressed by policymakers. Public participation activities can thus contribute to setting policy agendas, even if that is not their explicit purpose. However, the actualization of this contribution is contingent on the receptiveness of policymakers.

Keywords Hepatitis C, PPI, Agenda-setting, Direct-acting antivirals, Priority-setting, Public and patient involvement, Sofosbuvir, DAAs

Paper type Case study

Introduction

In 2013, the Food and Drug Administration in the USA approved sofosbuvir and simeprevir for the treatment of chronic hepatitis C infections (US Food and Drug Administration, 2014). The regulatory agencies of other countries soon followed and the use of sofosbuvir was approved by the European Medicines Agency in January 2014 (European Medicines Agency, 2015). These medicines, along with a third called daclatasvir, were hailed as a breakthrough in the treatment of patients with chronic hepatitis C as they are considered to be highly effective antiviral agents that, for the first time, attack the hepatitis C virus (HCV) directly. These drugs are not only more effective in achieving sustained virological response (SVR) – effectively curing patients – but also have fewer side effects than previous treatments. Unsurprisingly, there has been high

Journal of Health Organization and Management
Vol. 30 No. 5, 2016
pp. 769-785

1477-7266
DOI 10.1108/JHOM-03-2016-0035

demand for these new "cures" for hepatitis C among patients – especially given the alternative prospects of deteriorating liver function and possible liver transplantation or death, alongside the psychological distress and social stigma attached to the disease (Vietri *et al.*, 2013; Younossi and Henry, 2015).

However, the new HCV medicines come at a price. It is a price that most countries struggle to afford, regardless of their wealth or the structure of their health system. The actual price of the regimen is hard to unveil because many health care systems engage in confidential negotiations with pharmaceutical manufacturers for discounted prices, but a 12-week treatment with sofosbuvir has been estimated to cost as much as $84,000 in the USA (McCarthy, 2015). Policymakers or insurers face difficult decisions on whether to cover these novel and costly medicines, weighing the benefits these drugs could offer against the opportunity costs of securing health benefits for the broader population. Such challenges raise questions about what role, if any, patients and the public have in priority-setting decisions for new and expensive drugs. This paper outlines how the highly innovative, but very expensive, new hepatitis C medicines have exacerbated the challenge of making prioritization decisions in health care and explores the role of patient and public involvement (PPI) in addressing this challenge.

The focus of the paper arises from deliberations held at a workshop at the Brocher Foundation in Switzerland in November 2015. The workshop was dedicated to exploring ways to improve equitable access to health care through increasing public and patient involvement in prioritization decisions. It brought together academic and policy experts in health priority-setting and public involvement from 12 countries. Its purpose was to exchange knowledge and observations about country experiences of PPI in priority-setting. One of the observations emerging from the deliberations was that the new HCV medicines seem to have exacerbated the challenge of making fair prioritization decisions because of the complex set of issues around innovation, clinical evidence and budget impact to which they give rise. This paper asks what role, if any, public involvement has played in alleviating some of these issues. How have countries involved the public and patients in addressing the question of how to secure equitable access to new hepatitis C medicines? What can we learn from this experience?

In the extant literature, the importance of involving the public in health priority-setting is explained with reference to the complex and multiple relevant considerations that can bear on decisions. For example, to justify the model of "accountability for reasonableness," Daniels and Sabin (1997) argue that priority-setting institutions must ensure fair processes. Because more than one relevant consideration generally bears on priority-setting questions, relevant considerations often conflict and there is no consensus among decision-makers, commentators or the public at large as to how to trade them off against each other. Daniels and Sabin give PPI a role in ensuring fair process and many commentators argue that it should take center-stage (Emanuel, 2002; Friedman, 2008; Rid, 2009; Sabik and Lie, 2008).

This paper contributes to the existing debates by offering an empirical analysis of public involvement in the case of sofosbuvir, where the relevant considerations that bear on priority-setting decisions have been particularly stark. It examines how the public has been involved in decisions on new HCV medicines in four countries (Brazil, England, South Korea and the USA), thereby offering comparative insights on how different health systems involve the public in complex priority-setting problems, and on the perspectives that emerge. Perspectives that emerge include the role of the universal right to health in Brazil, the balance between innovation and budget impact in England, the effect of unethical medical practices on public perception in South Korea, and the legitimacy of

priority-setting processes in the USA. Although these issues are contextual and not necessarily novel in the individual contexts, they appear more pronounced in the case of sofosbuvir. If policymakers are aware of, and receptive to, these issues, public participation activities may be usefully re-conceptualized as processes that illuminate salient policy problems relevant to a particular context, thereby supporting an agenda-setting role for the public. The actualization of this role is highly contingent on policymakers being receptive to the issues. Given the important perspectives that emerged in the case of sofosbuvir, this paper concludes that further research is necessary on whether they have found traction in the public policy arenas of Brazil, England, South Korea and the USA.

The paper proceeds by providing a brief conceptual overview of health priority-setting and PPI, the methods and data for the case studies, the new HCV medicines generally, and of sofosbuvir particularly. These sections set the scene for the discussions of the country case studies and the conclusion in the latter parts of the paper.

Health priority-setting and PPI

Setting priorities in health care holds a prominent place on the policy agenda in countries around the world, particularly as countries seek to achieve universal health coverage. The advent of this agenda, including the creation of health technology assessment (HTA) organizations, has brought about an increased interest in the role of PPI in health prioritization (e.g. Martin *et al.*, 2002; Abelson *et al.*, 2007) because decisions involve making difficult choices that cannot be made solely on technical grounds and hence need to be justified and legitimized in the context of social values and procedural justice (Clark and Weale, 2012; Daniels and Sabin, 1997).

Regardless of where priority-setting takes place, it is concerned with making decisions that provide a good quality, and a fair, health service while ensuring that the health system is sustainable. The extant literature suggests that public input into the choices made should be included as one important criterion against which to assess the fairness of prioritization decisions (Sibbald *et al.*, 2009; Kapiriri and Martin, 2010; Sabik and Lie, 2008). However, barriers to public involvement exist (Goold *et al.*, 2005) and little empirical evidence is available on the effect of PPI generally, and different modes of PPI such as deliberative processes specifically (Mitton *et al.*, 2009; Abelson *et al.*, 2003).

This paper follows Weale *et al.*'s (2016, p. 5) definition of public participation in priority-setting as involving "[…] individuals or groups taking part in processes of policy making that shape the determination of priorities in health care and the conditions of access of different groups in society." It is collectively orientated and excludes forms of patient involvement such as involvement in research or shared decision-making as these forms of involvement are not aimed at bringing about a decision that affects public policy at large. This collectively orientated mode of public participation can come in different forms such as the inclusion of patient or public representatives in HTA bodies, mini-publics or consultative forums convened to garner public and patient views. Importantly, it also includes more unconventional forms of public participation such as protests, demonstrations, public campaigns and litigation. To include these forms of involvement is crucial because in some countries they have become a routinized mode of involvement that can affect priority-setting decisions (Weale *et al.*, 2016; Slutsky *et al.*, 2016).

Methods and data

The paper employs a comparative case study approach. Its main units of analysis are the country-specific processes of public participation in the case of sofosbuvir.

We focus on sofosbuvir because it has received substantial attention in media outlets worldwide. The country case selection was informed by the aim to include countries with conventional and unconventional modes of public participation in health prioritization (Weale *et al.*, 2016). For reasons of data availability, the selection was restricted to the countries represented at the Brocher Foundation workshop entitled "Improving equitable access to health care through patient and public involvement in prioritization decisions" in Switzerland in November 2015. The represented countries were Australia, Brazil, China, Colombia, Germany, New Zealand, South Africa, South Korea, Sri Lanka, Thailand, the UK and the USA.

Following Slutsky *et al.*'s (2016) distinction between consensus, i.e. conventional, and contestatory participation, i.e. unconventional, modes of participation, Brazil, England, South Korea and the USA were selected as cases. England represents a system where contestatory participation is not routinized (Slutsky *et al.*, 2016), whereas Brazil and South Korea represent countries where it is routinized. The USA represent a unique case in that participation is neither clearly consensus nor contestatory-based because of a lack of federal prioritization decision-making in which the public participates in a routine fashion. Nevertheless, as we shall see, forums for participation do exist in the form of institutes such as the Institute for Clinical and Economic Review (ICER).

The paper draws on country data on PPI and health priority-setting that was presented at the Brocher Foundation workshop. This data were supplemented by data from secondary literature. At the workshop policy and academic experts presented the status quo of health priority-setting and PPI in their countries following a template of nine areas (see www.clahrc-southlondon.nihr.ac.uk/public-health for presentations):

(1) overview of health system and approaches to prioritization;

(2) degree and nature of PPI in prioritization;

(3) rationale for PPI;

(4) successes and challenges;

(5) a prioritization case study and impact of PPI in this case;

(6) issues highlighted by the case study;

(7) ethical or social values questions in relation to PPI;

(8) lessons learnt; and

(9) future plans for PPI in prioritization.

In its discussion of the country cases, this paper broadly follows the outlined template. Each case study begins with a brief overview of the health system and approaches to PPI in health prioritization. A discussion of the rationale as well as the successes and challenges of PPI is omitted because the focus is on the prioritization case study (sofosbuvir) and the issues, ethical questions and lessons learnt. Unless they emerge directly from PPI in the case of sofosbuvir, the category of future plans for PPI is also omitted for the purpose of this paper.

Due to the small number of cases included in this paper, the generalizability of the observations is limited. However, the purpose of this paper is not to bring forth generalizable claims, but to provide an insight into the role PPI has played in coverage decisions on new HCV medicines. This is to gain a better understanding of the contributions of PPI activities in complex prioritization decisions.

New HCV medicines

"Hepatitis C is a virus that can infect the liver" (NHS Choices, 2015). Long-term, and potentially life-threatening complications from chronic hepatitis C infection include liver cirrhosis and liver cancer. More than 185 million people are affected by hepatitis C and approximately 350,000 people die each year as a consequence (World Health Organization (WHO), 2014, p. 25). Hepatitis C is transmitted through contact with infected blood specimens (WHO, 2014). There are several types and subtypes of the infection, so-called genotypes.

In recent years a rapid development in treatments for chronic hepatitis C has taken place. In 2011 and 2012, the medicines telaprevir and boceprevir were introduced. Since 2013 additional medicines have been approved around the world, namely, sofosbuvir, simeprevir and daclatasvir. These medicines are direct-acting antivirals (DAAs) that target the HCV itself, an innovation over previous treatments that indirectly suppressed the virus through inhibiting its replication.

This paper focuses on sofosbuvir. The main clinical endpoint measured in randomized controlled trials on hepatitis C medicines is the SVR, that is the virus being undetectable in the blood three or six months after treatment (WHO, 2014). Sofosbuvir achieved a SVR in over 90 percent of the patients across different genotypes of hepatitis C (WHO, 2014). Clinical experts equate the achievement of a SVR to a cure (National Institute for Health and Care Excellence (NICE), 2015, p. 46). Arguably, providing a drug like sofosbuvir would not only yield benefits for patients, but also avert future high costs associated with liver transplants as well as generate public health benefits through reduced HCV transmission. However, there is still much uncertainty surrounding the potential of future (liver) complications for patients who have cleared the virus or the question of which patients would progress to more serious stages of liver disease if left untreated. Trials on sofosbuvir report fewer, and less severe, side effects as well as a potential reduction of the treatment cycle from 24-48 weeks to as little as 12 weeks (WHO, 2014). Additionally, sofosbuvir is administered orally in the form of a pill once a day for usually 12 weeks, whereas previous methods of administration were mostly through injections.

However, at an estimated price of $84,000 for a 12-week treatment in the USA, sofosbuvir has been labeled the $1,000 pill (McCarthy, 2015). The first WHO guidelines on the screening, care and treatment of patients with hepatitis C recommend access to the new medicines. In the absence of sufficient funds to treat the entire patient population, they recommend to treat the sickest patients first (WHO, 2014). This is the way a number of countries have approached the access, for example, guidelines in the USA and England recommend to treat patients with cirrhosis first (McCarthy, 2014; NICE, 2015).

The challenge of providing access to these new medicines includes considerations of cost effectiveness, affordability, health equity, public health and the ethical implications of treating the sickest patients first. One of the biggest issues is how to resolve the perceived tension between cost effectiveness and affordability. The approach to prioritization in many tax-based health systems focuses on the assessment of cost effectiveness, with an assumption – explicit or implicit – that treatments should be made available to all patients for whom they deliver outcomes whose cost effectiveness exceeds a pre-determined threshold. But when the total budget impact of such a treatment is large, its adoption may require significant re-direction of resources, either from other areas of health spending, and/or from areas of non-health expenditure (Claxton *et al.*, 2015; Ward, 2015). A re-direction of resources raises questions of equity

with regard to the patient groups who lose out as a result. It therefore requires debate and resolution in the political space, which may or may not include the wider public.

The above issues are complicated by the fact that hepatitis C is already strongly associated with health inequities. It disproportionately affects populations in low and middle income countries (Graham and Swan, 2015), which to date have not had much access to available treatments due to the challenging screening and monitoring requirements. Moreover, sofosbuvir and other DAAs have been labeled a cure, a label that few other medical innovations achieve. Familiar issues of pricing and the current patent system are also surfacing. For example, Argentina, Brazil, China, Russia and the Ukraine are challenging the current patent for the new hepatitis C drugs (Bagcchi, 2015). Similarly, a non-governmental organization of doctors in France that provides health care for vulnerable populations worldwide, the Médecins du Monde, is challenging the patent at the European Patent Office (Boseley, 2015). Given this mix of complex issues, the question arises if PPI can help adjudicate between the different issues. What has the experience of involving the public and patients been in the case of sofosbuvir?

Public participation in the case of sofosbuvir

Brazil

The Brazilian Public Health System, better known by the acronym SUS (Sistema Único de Saúde; Unified Health System) was established under the Federal Constitution of Brazil in 1988. Enshrined in the Constitution is a right to health care and a governmental duty to guarantee universal and equal access to services and activities that promote, protect and restore health (Paim *et al.*, 2011). Brazil's forums for public participation include municipal and state health councils comprised of members of the public and patient representatives. Through these councils health care planners are held to account by the citizenry (Dall'Agnol Modesto *et al.*, 2007). Brazil's tradition of public involvement is also reflected in the way the public is involved in the SUS. The National Health Council, which consists of a mix of representatives of service user organizations (50 percent), health care worker representatives (25 percent), government and health service providers (25 percent), holds monthly meetings in which proposals are deliberated (Dall'Agnol Modesto *et al.*, 2007).

In the case of sofosbuvir, the National Commission on Technology Incorporation (CONITEC) in the National Health System (NHS), the HTA body in Brazil, decided unanimously to recommend the inclusion of sofosbuvir, daclatasvir and simeprevir for the treatment of chronic HCV (Comissão Nacional de Incorporação de Tecnologias no SUS (CONITEC), 2015a). The recommendation was preceded by a public consultation on HTA report. Public contributions were made through submissions to the CONITEC website.

During the process of assessing sofosbuvir, CONITEC also presented revised Clinical Protocol and Therapeutic Guidelines (PCDT) for the disease, with new guidance on treating the condition. The assessment process did not evoke as much public protest and engagement as did the revised PCDT. According to the revised protocol, the degree of fibrosis determines the group of patients who are eligible to be treated with the new antiviral agents under the SUS, excluding patients at fibrosis stages F1 and F2 (Comissão Nacional de Incorporação de Tecnologias no SUS (CONITEC), 2015b).

The Brazilian Movement of the Fight against Viral Hepatitis (2015) voiced its dissatisfaction with the protocol and invoked the constitutional universal right to health, claiming that the patient groups included in the protocol "represent less than 4% of the current need and means tearing the principle of universality of access to health"[1]. The official estimate is that 60,000 patients will be treated with sofosbuvir in

the next two years. To the Work Group of Intellectual Property (2015), "this is less than 1/3 of the related demand […]."

The fact that the Brazilian Movement of the Fight against Viral Hepatitis invoked the constitutional universal right to health reflects a prominent feature of many health systems in Latin America where the right to health is enshrined in the Constitution. Reimbursement decisions on medicines are made through benefit plan assessments (BPA), following the principles of financial sustainability and of clinical efficiency. For a molecule to be considered for BPA, it generally has to overcome the HTA hurdle. In order to ensure financial sustainability some countries perform different degrees of budget impact analysis (e.g. Ministerio de Salud de Colombia, 2015). In this setting there is an inherent tension between the HTA results and the BPA results that may yield that a cost effective technology is unaffordable for the entire system, which is why CONITEC recommended restricting access to sofosbuvir according to fibrosis stage.

Given the constitutional protection of the right to health, Latin American individuals and campaign groups can resort to courts to challenge the results of the HTA and BPA. Every year thousands of Latin Americans resort to this unconventional form of PPI and more often than not judges rule in favor of the avalanche of plaintiffs (Cubillos *et al.*, 2012). The effect that easy litigation has on the incentives to participate in the more established PPI mechanisms is unclear. If one can almost certainly win a case in less than two weeks, why join a process that may take months or years and that may not lead to your desired outcome? Policymakers in Latin America continue to grapple with the constraining effects of the constitutional right to health on priority-setting decisions.

England

The NHS is a tax-based health system in which national and local structures share decision-making responsibility. At local level, 211 clinical commissioning groups (CCGs) are responsible for commissioning (Thorlby and Arora, 2015), i.e. buying, health services from public, private or non-profit health care providers. At the national level, NHS England (2016) oversees spending and allocation of resources. CCGs and NHS England are supported by the National Institute for Health and Care Excellence (NICE), an organization responsible for appraising the clinical and cost effectiveness of new medicines. If NICE makes a positive recommendation on a new drug, then commissioners are under a legal obligation to make the treatment available (National Institute for Health and Care Excellence, 2016a). NICE makes its appraisals on the basis of clinical and cost effectiveness considerations as well as social value judgments (Rid *et al.*, 2015).

NICE conducts a public consultation process for every treatment it appraises. In this process there are two groups that are allowed to participate, namely, consultees and commentators. Consultees include patient and professional organizations, the pharmaceutical manufacturer, government and NHS entities (National Institute for Health and Care Excellence, 2013, p. 4). Commentators include manufacturers of comparator technologies or research groups who are allowed to comment, but do not have a right to appeal the decision. The wider public can submit comments on NICE's website (National Institute for Health and Care Excellence, 2016b).

NICE (2015) made a positive recommendation for the use of sofosbuvir, although the use of sofosbuvir in genotypes 4, 5 and 6 was only recommended in patients whose infection had already progressed to liver cirrhosis. The contentious issues did not arise as a result of NICE's appraisal of sofosbuvir, but as a result of NICE's decision to grant NHS England an extension to the normal implementation period in which a NICE-recommended treatment has to be made available on the NHS. Usually NHS commissioners have to ensure that

patients receive access to the recommended treatment within three months after it has been recommended (National Institute for Health and Care Excellence, 2016a). In the case of sofosbuvir a waiver of this period was sought by NHS England (National Institute for Health and Care Excellence (NICE), 2014b). Four reasons were provided: first, NHS England argued that the health service had to be reworked in order to provide access to the new medicines through specialized treatment centers. Second, a substantial increase in demand for treatment could be expected, making it necessary for NHS England to ensure it could accommodate this demand. Third and fourth, networks for service provision would have to be created in order to guarantee that appropriate screening and monitoring structures were in place for hepatitis C patients (NICE, 2014b).

Although NHS England's request downplayed the expected budget impact of sofosbuvir as a reason for the request – because budget impact is not an eligible reason for such extensions under the legal framework set by the government – the ensuing protest suggests that stakeholders agreed that it was a veiled request based on concerns about budget impact (National Institute for Health and Care Excellence, 2014a). The submissions by NHS England suggest that such views were not far-fetched. According to NHS England's submission: "[…] at the prices proposed by the manufacturer in their NICE submission, this technology is not affordable at the quantum of new expenditure it would represent" (National Institute for Health and Care Excellence, 2014c, p. 8). Consultees were given the opportunity to comment on NHS England's request. One patient organization summarized the problems as follows:

> The Hepatitis C Trust objects in the strongest possible terms to any attempt to introduce budget as a factor. If we are going to change our health care resource allocation model to one based on arbitrary consideration of this year's budget, then this should be debated nationally, preferably through an election manifesto. Either NICE has a mandate to decide resource allocation or it doesn't (The Hepatitis C Trust, 2014, p. 6).

The submissions in response to NHS England's request to delay the date by which sofosbuvir has to be made accessible highlights complex questions about the how the ability of NICE's decision-making framework to accommodate cost effectiveness and affordability is perceived by stakeholders. The patient representatives raised the issue that if budget impact is an implicit consideration in cases such as sofosbuvir, then this has to be made explicit and deserves debate in the wider public and political policy-making arena.

South Korea

The Republic of Korea has a National Health Insurance Service (NHIS) that covers 96.6 percent of the population (Organisation for Economic Co-operation and Development, 2012). The rest of the population is covered "[…] by a medical aid plan which is directly funded by […] the national and local governments […]" (Ahn *et al.*, 2012, p. 344). While the NHIS is known for its population-based universal coverage, the benefits that are covered are limited and out-of-pocket payments were at 36.9 percent in 2013 (Organisation for Economic Co-operation and Development, 2015) even though the benefit coverage has expanded since the 1990s.

In 2012, the NHIS set up a lay citizen's council, the Citizen Committee for Participation, made up of lay members of the public who are selected following an application process. Although still in its early years, the decision-making mechanism of the committee, and its influence on the final decisions by the Health Insurance Policy Committee, are considered significant. In its first year 69 percent of newly covered services were originally chosen and recommended by the Citizen Committee

(Oh *et al.*, 2015). However, except for the Citizen Committee, PPI is not prominent in Korea unless a nationwide interest develops that puts pressures on adopting new health technologies, especially pharmaceuticals. Such was the case with sofosbuvir.

The case of sofosbuvir reached the public agenda not through the Citizen Committee, but through a scandal that rocked a clinic in Seoul in November 2015. Sofosbuvir was approved by the regulatory authority in September 2015 (The Korean Ministry of Food and Drug Safety Online Pharmaceutical Library, 2015). A scandal arose in a neighborhood in Seoul when an outbreak of HCV was tied to the re-use of disposable needles at a local clinic specializing in intravenous (IV) injection services (Ah-young, 2015a). According to *The Korea Times* (Ah-young, 2015b), a total of 78 HCV infections were confirmed until the December 4, 2015 and 55 out of 78 patients were found to have type 1a, which is usually prevalent in less than 1 percent of the hepatitis C patients in Korea (Seong *et al.*, 2013). Many Koreans learned about the disease and the treatment option of sofosbuvir and its combination drug from news reporting on a massive scale and they were sympathetic to the victims of unethical medical practices. The incident elevated the issue of sofosbuvir to the national political arena, with public and advocacy groups campaigning for access to the new medicines. The coincidence of this event and the reimbursement review process of these drugs finally resulted in the Ministry of Health and Welfare asking for a faster review of sofosbuvir (The Daily Pharm, 2015).

The Korean experience highlights additional ethical issues that characterize the debate on new hepatitis C drugs, namely, issues of fairness, government accountability and public responsibility when infections occur due to unsafe medical practices. This is the case in the recent scandal in Korea, but similar examples can be found in other countries, for example, in the UK where contaminated blood transfusions in the 1980s led to increased HCV infections. Even though this issue did not emerge as a result of formalized PPI processes, the public outcry in Korea underlines the effectiveness of public campaigns in the face of such scandals. The final reimbursement decision is outstanding at the time of writing, but given the scandal and the ensuing public reaction, it is unlikely that the formalized PPI process, if pursued by the decision-making authorities, will lead to any recommendation other than to reimburse sofosbuvir.

The USA: the Institute for Clinical and Economic Review

Due to the fragmented nature of the American health care system there is no one government-mandated institution for health priority-setting. Following the introduction of the Patient Protection and Affordable Care Act in 2010, the health care system remains a predominantly private system but the percentage of uninsured continues to drop (The Commonwealth Fund, 2015). There are two publicly subsidized and federally managed health care programs, namely, Medicare for the elderly population over 65 and Medicaid for families meeting low-income eligibility criteria (The Commonwealth Fund, 2015). Given the lack of institutionalized priority-setting, this section examines the experience of an independent research body, the Institute for Clinical and Economic Review[2], that produces evidence reports on new medicines, on which payer organizations such as insurers draw.

The Institute for Clinical and Economic Review is an independent research institute funded largely by non-profit foundations. It produces evidence reports on medical technologies to help guide the application of evidence to clinical practice and insurance coverage policy (Institute for Clinical and Economic Review (ICER), 2014b). The Institute has created regional committees of independent clinicians and public representatives, called Comparative Effectiveness Public Advisory Councils (CEPAC),

who are convened to deliberate on evidence reports in meetings open to the public (Institute for Clinical and Economic Review, 2016). The meetings are spent debating the evidence, after which the CEPAC votes on whether the evidence is adequate to demonstrate that a new technology is as good or better than other options available to patients. The reports include evidence on cost effectiveness and potential budget impact and the Institute asks the CEPAC groups to vote on the "value" of new interventions.

The Institute's draft evidence report on the HCV medicines received criticism from patient advocacy groups focused predominantly on the results of the economic analyses that found that these drugs would not reduce long-term costs in the health care system while presenting huge potential short-term costs that could overwhelm health care budgets (Institute for Clinical and Economic Review, 2014c). At the public CEPAC meeting, the CEPAC voted that the evidence was adequate to demonstrate the clinical superiority of the new drugs but that they represented a "low" value to the health care system[3] (Institute for Clinical and Economic Review, 2014a). The voting stage of the meeting was followed by a so-called policy roundtable, an invited group composed of representatives from insurers, manufacturers, clinical experts and patients. The roundtable included the leader of one of the patient groups. This representative criticized the vote of the CEPAC and sought to cast aspersions on the clinical expertise, primary motives and financial interests of all involved (Institute for Clinical and Economic Review (ICER), 2014d). The clinical experts responded by expressing their belief that, for clinical and economic reasons, the most reasonable path forward was to prioritize patients for treatment, with sicker patients receiving treatment first (ICER, 2014d). They felt this was reasonable not only because the short-term clinical risks were minimal, but because there was inadequate infrastructure to treat all patients immediately and because the financial repercussions of immediate treatment for all eligible patients was unrealistic (ICER, 2014d).

The recommendation to use severity of initial liver damage as a method of prioritizing patients was the recommendation that was included in the final CEPAC report (ICER, 2014b). The patient advocacy organizations did not accept this recommendation and opposed it in the press (Clary, 2015). But private and public health insurers felt empowered to establish their initial coverage recommendations to mirror this approach, and many cited the CEPAC report as justification (e.g. United Healthcare, 2014). Anecdotally, many insurers informed the Institute that having a transparent, independent process for evidence review was important to their decision-making. Even if patient advocacy groups disagreed with the result, insurers felt that the overall process had enough legitimacy to serve as a cornerstone of their coverage policies.

The case underlines complex questions about the purpose of PPI and the legitimacy of prioritization decisions. While insurers found the Institute's process helpful, the protests by patient advocacy groups suggest that they did not view the CEPAC vote as a fair outcome of a legitimate process. The extant literature on the legitimacy of decision-making processes in health priority-setting converges on the idea that outcomes of decisions are more legitimate if the public has been involved (Daniels and Sabin, 1997; Abelson *et al.*, 2007; Parkinson, 2003). However, the experience of the ICER in the case of HCV medicines suggests that enhancing the legitimacy of decision-making processes of independent review bodies in the eyes of public and patient representatives remains a challenging issue.

Discussion and conclusion

Examining PPI in the case of sofosbuvir across multiple and diverse settings highlights that none of the countries included in this paper diverted from their established modes of involving the public and patients. These modes need to be viewed in the political and

historical contexts of the respective countries. They led to different, yet very important, questions that need to be addressed. In England, stakeholders stressed the controversies that arise when cost effective medicines are not covered within the statutory timeframe due to budget impact concerns, even though such a delay is statutorily permitted in certain circumstances. This suggests that the methodological approach employed by NICE does not sit easily with stakeholders. The public consultation process highlighted this issue, but it cannot be resolved in the currently available PPI forums. It is a political question that needs to be addressed in the wider public space.

In South Korea, a scandal pre-empted potential deliberations by the established Citizen Committee of Participation. The Korean example brings to the forefront the importance of what Slutsky *et al.* (2016) label "contestatory participation" and of the significant pressure that media campaigns can exert on decision-making in health priority-setting. It remains to be seen how the story unfolds, but it seems likely that the established forums of PPI will not deviate from the public perception that the novel HCV medicines should be made available in the light of unethical medical practices. The Korean example is as much a story of successful pressure exerted through media spaces as it is an example of how an issue can reach the policy agenda and exacerbate the challenges faced by policymakers.

The experiences of the USA and Brazil countries underline the importance of national context. The deliberative meetings held by the ICER fill a void in a fragmented health system in which insurers, the public and patient advocacy groups have little guidance on which to draw when making tough decisions or engaging with each other. The Institute's experience accentuates the role that deliberative processes can play in evaluating evidence. However, it also shows how challenging it is for these processes to be viewed as legitimate by all those involved (Kieslich and Littlejohns, 2015), and failing to establish legitimacy is a real barrier to the contribution that public participation activities can make. In Latin America, PPI takes places in the context of NHSs that guarantee a right to health. The public and the patients insist on their right to health and policymakers are faced with the constraints that this system puts on policies that seek to introduce efficiency savings.

In conclusion, has the PPI experience in Brazil, England, South Korea and the USA helped address some of the difficult challenges that arise in the case of sofosbuvir? The short answer is no. The country experiences are as much a tale of challenges that arise when making difficult prioritization decisions as they are a tale of agenda-setting. With regard to the unconventional modes of participation such as protests and litigation, this observation is not surprising as they tend to receive much attention in the media. However, with regard to the more conventional modes of participation through consultation and deliberation, this observation is interesting as it may suggest an agenda-setting role for the public even when this is not the explicit purpose of these modes of participation. PPI on sofosbuvir has brought a number of issues to, or back on, the policy agenda. In England, policymakers need to address what NICE's cost effective paradigm implies for a cash-strapped NHS. The American experience suggests it may be time for policymakers to think about how they can help insurers and providers establish decision-making processes that are perceived as legitimate by the public. In South Korea, the importance of combining ethical and budgetary considerations has been underlined, especially when patients are infected with HCV through no fault of their own. In Latin America policymakers are having to strike the balance between realizing the right to health and the necessity to ensure the sustainability of health care systems (Ferraz, 2011). Of course, whether these issues find traction on the policy agenda depends on the receptiveness and willingness of policymakers to engage with them, and this question is an area for further research.

The possible role of issue characteristics (Lowi, 1964; Burgin, 1995) also merits attention in future research. Lowi (1964) argues that variations in policy-making processes can be explained with reference to the character and type of issues that are being addressed. In the case of pharmaceutical products issue characteristics include the disease area, the population affected, cost effectiveness, budget impact and questions of equity. The question that demands further exploration is whether certain characteristics of issues brought forth by cases such as the new HCV medicines call for a stronger, or a particular mode of public involvement. Given its large budget impact, views from the wider public could be gained on the kind of trade-offs they would be willing to make if access to the new hepatitis C medicines is to be provided. However, constructing a case for a stronger, or a particular mode of public involvement, will rest on the resolution of at least three arguments against it.

First, the discussed issues are not new or unique to HCV medicines. They are simply more pronounced in this case. The novel HCV drugs have brought to light the challenging issues that have long concerned policymakers, practitioners and academics. To use these challenges as an argument for going beyond existing modes of PPI would run the risk of establishing a case of exceptionality that may not be justified. Second, existing modes of involvement or participation all come with their own advantages, disadvantages and risks (Weale *et al.*, 2016). Regardless of how carefully a particular mode of involvement is chosen, chances are that none of them can address the entire breadth of issues. Third, isolating the situations in which issue characteristics exacerbate the challenges of decision-making to such an extent that warrants for taking the issues to the public at large would be difficult. Nevertheless, the complex trade-offs emerging in priority-setting decisions on HCV medicines suggest that the normative and empirical role of issue characteristics is worth exploring.

Acknowledgment

This work was generously supported by the Brocher Foundation in Geneva, Switzerland, where the workshop on "Improving equitable access to health care through increasing patient and public involvement in prioritisation decisions" was held in November 2015. The authors thank the Brocher Foundation for hosting and funding this workshop. Katharina Kieslich and Peter Littlejohns are supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) South London at King's College Hospital NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health. Gabriele Badano is supported by funding from the Independent Social Research Foundation. Renata Curi Hauegen is supported by the National Institute for Science and Technology on Neglected Diseases (INCT/IDN). The authors are grateful to the reviewers for their comments and suggestions on the manuscript.

Notes

1. Translated by one of the authors of this paper.
2. In order to avoid confusion between the incremental cost effectiveness ratio (ICER) and the Institute for Clinical and Economic Review (also ICER), this paper does not use the "ICER" abbreviation for the institute, but refers to it as the "Institute" or spells out its full name.
3. Please note that this section is an account from one of the co-authors who is the Director of the Institute and was present in the deliberations. The full summary of the proceedings can be found on the Institute's website (Institute for Clinical and Economic Review, 2015).

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