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Choosing treatments and the role of shared decision-making

FRANCE LÉGARÉ, MARTIN HÄRTER, ANNE M. STIGGELBOUT, RICHARD THOMSON, DAWN STACEY

Introduction

In 2015 people in OECD countries consulted a medical practitioner between two and sixteen times (OECD, 2015). These care-seekers were once expected to go along with whatever the doctor decided was best, but this has been slowly changing since the 1970s. As highlighted in Chapter 2 of this book, growing awareness of the limits of medical interventions and of the lack of control over decisions about one's own care (Illich, 1975) led to calls for equality between the patient and the health professional towards establishing a partnership for making decisions and determining the direction of care.

The notion of a more participatory approach to informed decision-making was first proposed by Robert Veatch in 1972, who suggested the idea of “sharing of decision-making” (Veatch, 1972). Evidence was accumulating that where doctors and patients agreed on the problem, outcomes were better (Starfield et al., 1979). In 1982 a US presidential commission noted that while health care systems were increasingly effective at addressing disease, there was a “diminished capacity and inclination to care for the patient in more human terms” (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982, p. 33). These observations came at a time when there was increasing recognition of practice variations (Wennberg & Gittelsohn, 1973) and of unnecessary surgery (Leape, 1989) across the USA. Neither of these could be explained by variation in the burden of disease or medical need, while evidence pointed to widespread overuse, underuse and misuse of tests and treatments. Policy-makers finally began to take note, and shared decision-making was proposed as one potential solution. The US Presidential Commission stated that “[p]ractitioners should seek not only to understand each

patient's needs and develop reasonable alternatives to meet those needs but also . . . present the alternatives in a way that enables patients to choose one they prefer. To participate in this process, patients must engage in a dialogue with the practitioner and make their views on well-being clear" (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982, p. 44). Shared decision-making (SDM) was seen to be especially appropriate with regard to 'preference-sensitive' conditions (Weinstein, 2000; Weinstein, Clay & Morgan, 2007). It began to take root as a core approach in primary care and to be considered the crux of person-centred care (Weston, 2001; Charles, Gafni & Whelan, 1997).

Along with supported self-management (Effing et al., 2007), SDM has now entered government policy and legislation in several countries. Since 1968 more than 6000 articles have been published about the theory and practice of SDM, and as of 2013 over 500 per year (Koster, 2016), indicating an exponential growth of scientific research in this area (Blanc et al., 2014). Much research has focused on studying the impacts of SDM tools (such as decision aids) but there remains a dearth of evidence that takes into account the full complexity of SDM and, more importantly, its implementation in clinical practice (Coulter, 2017), and physicians have been slow to adopt it (Couet et al., 2015).

With the notion of the relationship at its core, SDM can be defined as an interpersonal, interdependent process in which health professionals, patients and their caregivers relate to and influence each other as they collaborate in making decisions about a patient's health care (Légaré & Witteman, 2013). Together they consider the scientific evidence and the patient's preferences and values before making a treatment choice. The information transfer is two-way, and the health professional may not be the only, or even the main, source of information for patients. Patients' own unique experiences and preferences are equally important for informing the decision, acting as experts in their own right (Charles, Gafni & Whelan, 1997). It can involve the patient and their family and caregivers (Légaré, Stacey & Pouliot, 2011), along with one or more health professionals (often working in teams with patients who have chronic illnesses), as well as other health care workers, for example in the context of community-based primary care and home care (Légaré et al., 2015).

This chapter begins by setting out the challenges of arriving at a consensual definition of SDM. It discusses how SDM has entered policy debate and legislation and the possible drivers behind this. We examine

the empirical evidence for its impact on outcomes at the individual, organizational and system levels, and discuss barriers to its implementation. We discuss models of SDM and how it can be measured, as well as current research trends, and finally propose a framework for a way forward.

How do we define SDM?

SDM is thought to involve three main steps. First, the clinician and the patient recognize and acknowledge that a decision is required, such as making a choice about starting, continuing, stopping or postponing treatment for a given condition. This is called the decision point (Coulter, 2011), not to be confused with a single point in time, as decisions can be an ongoing event (Rapley, 2008). Second, both parties understand the best available evidence concerning the risks, benefits and consequences of available options, including the option of doing nothing (watchful waiting). Third, the treatment decision reflects the patient's informed values and preferences about the outcomes of options. For example, a woman with breast cancer may prefer to have conservative breast surgery rather than a mastectomy in the knowledge that survival rates are equivalent (Fisher et al., 2002). Or a patient may not want to be prescribed medication, preferring to cope with the condition rather than live with the side-effects of the medication (Weiss et al., 2015). Such decisions can be supported by specifically designed patient decision aids, such as leaflets, videos or web-based tools. Tailored to a person's health condition, decision aids present the evidence and help clinicians and patients clarify their preferences and values (Stacey et al., 2017). Collections of decision aids can be found at the A to Z Inventory of Decision Aids (Ottawa Hospital Research Institute, 2015) and at the Med-Decs database (Stalmeier, 2012).

However, as noted, at its core SDM is about relationships and values, and as such it is difficult to define. Charles, Gafni & Whelan (1997) identified four key components: the patient and the clinician are involved in all phases; both parties share information; both parties take steps to build a consensus about the preferred treatment; and an agreement is reached about the treatment to be implemented. These components have since been renamed, further divided and redefined. However, most definitions still revolve around information exchange, deliberation, making the decision, and follow-up (Makoul & Clayman,

2006; Stacey et al., 2010; Elwyn et al., 2012; Stiggelbout, Pieterse & De Haes, 2015). The single defining feature of SDM remains what Ian McWhinney called the “exchange and synthesis of meanings” (Stewart, 2003) that take place in the clinical encounter.

When SDM entered clinical practice, it was typically in the context of ‘professional equipoise’ (Pauker & Kassirer, 1997; Elwyn et al., 2000), that is, in situations where the doctor had no clear preference about the best treatment choice. However, more recently SDM has been recognized as desirable in all situations where there is more than one reasonable approach to managing or treating a given condition (including watchful waiting). It is also seen to be useful for eliciting patients’ values, namely what matters to the patients or their family members about the decision, such as efficacy, side-effects and cost, as well as life philosophies, priorities and life circumstances (Weinstein, Clay & Morgan, 2007; Lee, Low & Ng, 2013). Even where probabilities of risks and benefits of a given treatment are known for the population as a whole, these do not automatically translate to the individual, and the importance attached to risks and benefits may differ among individual patients, depending on their values and preferences.

While SDM is widely seen to be core to person-centred care (Coulter, 2017), some authors have taken a more cautious approach. For example, some authors have noted that SDM has been used to make patients uniquely responsible for their health (care) choices, with health professionals no longer being held accountable for decisions (Tobias & Souhami, 1993; Buetow & Kenealy, 2007; Sandman, Gustavsson & Munthe, 2016). Others noted that patients do not necessarily want to involve clinicians in decisions (Degner & Sloan, 1992) or prefer that the clinician makes treatment decisions on their behalf (Woolf, 2001; Schattner, 2002). Yet others argued that SDM can make patients feel anxious and insecure (Levy et al., 1989; Caldon et al., 2011; West & West, 2002) and there have been concerns that SDM might inadvertently favour those with higher education and disadvantage those who are already marginalized, thus reinforcing health inequities (Thomson, Murtagh & Khaw, 2005). We shall come back to these concerns later.

How has SDM entered law and policy?

There is now increasing consensus that there is an ethical imperative for health professionals to share important decisions with patients

(Salzburg Global Seminar, 2011). In recognition, many countries in Europe, North America and Australia (Härter, van der Weijden & Elwyn, 2011) have put in place formal recognition of SDM in the form of policy and regulatory frameworks as part of a wider move towards more person-centred systems. Elsewhere, the importance of SDM is increasingly being considered, with a small number of countries in South America and south-east Asia slowly introducing related policies (Härter et al., 2017b). Their rationale ranges from respect for consumer and patient rights and democratic public engagement to more instrumental arguments such as that it might increase efficiency and help control health care costs (Gibson, Britten & Lynch, 2012).

Most European countries are legislating on informed consent and patients' right to information using civil law (e.g. the Netherlands) or public law (e.g. Finland) (*see* Chapter 13). Other countries have dedicated elements of their national or regional legislation specifically to their interpretations of SDM. These include France (2002 Act on Patients' Rights and Quality of Care) (République Française, 2002), Chile (2006 Law on Rights and Responsibilities of People when Engaging in their Healthcare) (Bravo et al., 2011), Norway (1999 Patients' Rights Act) (Ringard et al., 2013), Sweden (2015 Patient Act) (Riksdag, 2014) (Box 11.1), Germany (Patients' Rights Act) (Bundesministerium für Gesundheit, 2013), the UK (2012 Health and Social Care Act) (Government of the

Box 11.1 Excerpt from the 2015 Patient Act, Sweden

“Caregivers are required to provide you with all necessary information no matter who you are or what background you have . . . The information must be adapted to your particular circumstances and capabilities . . . You must always have the chance to explain what you want to happen – then it is up to you to decide how much you want to take advantage of that opportunity. Once you are familiar with the options that are available, you can give your consent or otherwise indicate your preferences. You are always entitled to turn down any care that is offered to you. You can also change your mind after you have approved a certain kind of care.”

Source: 1177 Vårdguiden, 2016

United Kingdom, 2012), and the United States (2010 Patient Protection and Affordable Care Act) (US Congress, 2010). Elsewhere, patients' rights to information and participation in their own care are recognized across a broad diversity of legislation, such as in Italy and Denmark (Tragakes et al., 2008; Dahl Steffensen, Hjelholt Baker & Vinter, 2017).

SDM legislation facilitates the appropriate application of the so-called 'reasonable patient standard'. The standard for informed consent is typically physician-based. This means that clinicians must provide patients with the information that a so-called 'responsible body of physicians' would consider appropriate under similar circumstances (Moulton et al., 2013). However, this is slowly changing, with for example approximately half of the states in the USA having adopted 'the reasonable patient standard' instead (Spatz, Krumholz & Moulton, 2016). This views the informed consent communication process from the patient's perspective, that is, clinicians must provide patients with all the information that a 'reasonable patient' would want under similar circumstances. Case law based on this standard has also been applied in Australia, Canada, the Netherlands and the United Kingdom (Box 11.2), whereas elsewhere

Box 11.2 A reasonable patient

Montgomery v Lanarkshire Health Board, 2015, UK. A woman with insulin-dependent diabetes claimed that her obstetrician failed to communicate the risk of shoulder dystocia during vaginal delivery (a complication associated with foetal macrosomia) that ultimately resulted in severe foetal brain anoxia. She claimed that had she received full information about the risks, she would have opted for a caesarean delivery. Yet the treating obstetrician (and other expert physicians called to trial) claimed that the ensuing risk was very small and thus appropriately not communicated, because a caesarean delivery is not in the maternal interest. The UK Supreme Court ruled that the standard for what physicians should inform patients about the risks, benefits and alternatives of treatment '*will no longer be determined by what a responsible body of physicians deems important but rather by what a reasonable patient deems important*'.

Source: Spatz, Krumholz & Moulton, 2016

in Europe the notion of the ‘reasonable body of physicians’ standard prevails. The importance of establishing the ‘reasonable patient’ as the standard in the context of SDM can be illustrated by Washington State in the USA. Washington State is among the US states where informed consent has been patient-based since a key court case in 1999 (King & Moulton, 2006). In 2007 it introduced legislation that supports the use of SDM and it also provided that if a clinician uses a ‘certified decision aid’ as part of the informed consent process, there is a presumption that informed consent has been given (Washington State Health Care Authority, 2016). Thus, the context of the ‘reasonable patient’ as the norm facilitated the introduction of explicit SDM legislation. This suggests that a similar move would be necessary in Europe if SDM is to be implemented on a large scale.

However, available evidence suggests that while countries in Europe are engaging in a variety of activities conducive to the wider implementation of SDM, system-wide approaches to translating SDM into routine practice are as yet lacking. Coulter et al. (2015) assessed the readiness for SDM in five European countries by examining clinical policies and the availability of various SDM support services in France, Germany, the Netherlands, Spain and the UK in 2015. They found that while SDM was receiving growing attention, it was not yet as high on the policy agenda as it was in the USA at the time. There was evidence of research activity around SDM, increasing advocacy by patient groups on patient rights and SDM, and the incorporation of SDM in ethical and professional standards. But there was a lack of professional leadership and of institutional support. Furthermore, countries varied greatly with regard to the development and availability of SDM tools. Some had been developed and tested with patients locally but mostly in the context of research, with little institutional support or strategic planning for wider dissemination.

Coulter et al. (2015) further highlighted that the training infrastructure necessary for clinical staff to acquire SDM skills was patchy in the countries studied. While SDM was beginning to be included in basic communication skills training, it was not yet implemented as a core component of health professional education and training. This situation is now changing in some countries, such as in the Netherlands and Germany, where SDM is taught and examined in most medical schools, although on a limited scale (van der Weijden et al., 2017; Härter et al., 2017a). In Switzerland, all five medical schools (Basel, Bern, Geneva,

Lausanne and Zürich) have formally integrated SDM into both undergraduate and postgraduate training (general internal medicine) (Selby, Auer & Cornuz, 2017).

SDM is a fast-moving field and, in addition to educational progress, efforts to develop strategic policy frameworks for SDM are under way across Europe. Thus the Netherlands has seen a range of policy moves to a more systematic implementation of SDM at the national level, as exemplified by a 2015 letter to Parliament from the Minister of Health (Rijksoverheid, 2015). The Ministry of Health is introducing a specific registration code to finance additional time needed for SDM, and forthcoming amendments to the Medical Treatment Agreement Act will require physicians to inform the patient about risks and benefits and discuss treatment options (van der Weijden et al., 2017). In addition, the national associations of medical specialists and of patients and consumers are campaigning together to promote nationwide implementation of SDM (Federatie Medisch Specialisten, 2015).

Similarly, SDM is now firmly on the policy agenda in the UK, with policy-makers, professional regulators and societies, and patient organizations, as well as the courts, committed to ensuring that SDM becomes the norm throughout the National Health Service (NHS) (Coulter et al., 2017). A key challenge has been the coordination of various activities and initiatives and in 2015 over 40 organizations came together to form the SDM Collaborative, led by the National Institute for Health and Care Excellence (NICE). The Collaborative has published an SDM consensus statement and an action plan which sets out actions taken by individual partners in the short- and medium term (National Institute for Health and Care Excellence, 2016).

Progress has been somewhat slower in France, despite having the legal foundations in place for system-wide strengthening of SDM, in particular through the aforementioned 2002 Act on Patients' Rights and Quality of Care. The 2016 health reform provided for the introduction of a public information service which seeks to disseminate information on health, and especially on treatment, care and support offered to the public (Moumjid et al., 2017). Under the responsibility of the Minister for Health, the information should be in simple language and accessible for people with disabilities.

Finally, a number of countries, including the UK, the Netherlands, Germany and Norway, have invested in initiatives to make patient decision aids available to some extent (Coulter et al., 2017; van der Weijden

et al., 2017; Härter et al., 2017a; Ringard et al., 2013). For example, in the UK NICE hosts 27 (as of August 2017) short-form patient decision aids to help patients have informed conversations about their condition with their health care provider (NHS RightCare, 2017; NHS England, n/d). In the Netherlands, the national associations of medical specialists and of patients host publicly available patient decision aids on national patient portals (van der Weijden et al., 2017). In Germany, the Institute for Quality and Efficiency in Health Care (IQWiG) recently developed three decision aids for the national breast, colon and cervical cancer screening programmes in response to requests from the Federal Joint Committee, the highest decision-making body in the German statutory health insurance system (Härter et al., 2017a).

Despite this progress in implementing SDM in European countries, considerable barriers remain. For SDM to become a standard approach in the clinical encounter, there is a need for professional organizations to incorporate patient decision support tools in clinical practice guidelines and, more broadly, for policy-makers and institutions to support local clinicians in the routine implementation of SDM (Coulter et al., 2015). We will return to the issue of what needs to be done later.

What does SDM achieve?

Shared decision-making has been associated with a number of expectations, ranging from improving population health outcomes, reducing health inequalities, optimizing health care costs, improving patient experiences, and increasing patient knowledge or engagement in their own care, to reducing litigation. Whether SDM is likely to achieve any of these expected outcomes depends on a range of factors, which we review here.

Overall, the principal conviction underlying SDM is that clinicians must both honour the patient's self-determination and offer a relationship of support, that is, SDM recognizes both autonomy and interdependence as key motivators. It also recognizes the importance of sharing the probabilistic nature of evidence and it recognizes that both emotional and cognitive factors play a role. These 'dualities' are reflected in many studies of SDM. Early evidence found that a relationship of mutual respect or equality between the patient and doctor during the decision-making process increases patient satisfaction (Menzel, Coleman & Katz, 1959). These early findings have been replicated elsewhere,

with recent systematic review evidence demonstrating that SDM may have a positive impact on affective-cognitive patient outcomes, such as knowledge, satisfaction with care, and concerns/anxieties about the illness (Shay & Lafata, 2015). Compared to patients who did not reach agreement with their health professionals on certain key components of the clinical encounter, those who did reach an agreement felt more satisfied with the clinical encounter (Krupat et al., 2001).

These kinds of outcome are important. Research on decision-making has shown that personal decision-making involves a negotiation process with the 'outside world' which encompasses more than cognition. However, much SDM work has focused on cognition (e.g. knowledge, understanding) rather than emotion. Emotional factors such as trust, reassurance and comfort influence intermediate outcomes including adherence (Sewitch et al., 2003) and self-care skills, which in turn influence health outcomes (Street et al., 2009). These factors could also, in part, explain differences between decisions made in natural contexts and those made in experimental contexts (Rapley et al., 2006).

There is a fundamental ethical argument for involving patients in decisions about their own care and treatment, since it is their body and their illness, and so it is their aspirations, values and preferences that should be addressed. Evidence suggests that patients generally want more information about their health condition and would like to take an active role in decisions about their care (Alston et al., 2012; Kiesler & Auerbach, 2006). However, the degree to which a decision is shared varies widely in terms of the underlying health problem, the treatment or care options and the actors involved, including the patients themselves (Hagbager, Salsali & Ahmadi, 2004; Joseph-Williams, Edwards & Elwyn, 2014).

In terms of reducing health inequalities, systematic review evidence suggests that SDM significantly increases knowledge among disadvantaged groups, as well as their clarity about their values and preferences, although evidence is less clear on impacts on adherence levels, anxiety and health outcomes, as well as on screening/treatment preferences, intentions or uptake (Durand et al., 2014). Others observed that reducing the patient/clinician power differential is essential before most patients feel comfortable or competent to engage in SDM (Joseph-Williams, Edwards & Elwyn, 2014).

In some countries litigation is a major concern, and Durand et al. (2015) found that poor communication is strongly correlated with

medical malpractice litigation. However, based on a synthesis of five studies, they concluded that there is insufficient evidence to determine whether SDM reduces medical malpractice litigation. Nevertheless, effective decision support can lead to decreased decisional conflict (i.e. personal uncertainty regarding one's choice) and some evidence suggests that if SDM is applied, patients appear to be more satisfied and more compliant with the treatment they have agreed upon, which is likely to reduce the risk of litigation (Ubbink, Santema & Lapid, 2016).

Among health professionals in particular, there is widespread concern about the time required for implementing SDM in routine clinical care (Légaré et al., 2008). The belief that it will lengthen consultations is so pervasive that the Dutch government proposes to compensate clinicians for the additional time they perceive they would need to implement it, as noted above. Yet although consultation lengths vary depending on the context, there is no definitive evidence that SDM systematically requires more time than usual care (Légaré et al., 2012b; Légaré et al., 2018) except in palliative care contexts (Stacey et al., 2017). Furthermore, any additional time spent on SDM may be recouped if patients return less frequently.

Among policy-makers another prime concern is the effective use of scarce resources. There are inherent challenges in assessing the cost-effectiveness of SDM, and robust evidence that SDM may lead to system-wide savings is lacking (Walsh et al., 2014; Trenaman, Bryan & Bansback, 2014). A systematic review of the effects of decision aids for people facing treatment or screening decisions found that patients who were better informed and had been given an opportunity to weigh up the risks of treatment options tended to choose more conservative options (Stacey et al., 2017). Based on such observations, there is an expectation among policy-makers that decision support tools can reduce overuse of costly services and treatments (Elwyn, Tilburt & Montori, 2013). There is indeed a persuasive argument that providing care that is informed and consistent with people's values can lead to more appropriate use of resources (Mulley, Trimble & Elwyn, 2012). However, if SDM is an ethical imperative (Box 11.3), and patients value being involved in the decision-making process, the promise of significant savings should not be a condition for its implementation, and indeed could jeopardize implementation efforts (Walsh et al., 2014; Sandman, Gustavsson & Munthe, 2016).

Box 11.3 The ethical imperative for shared decision-making

“The benefits of shared decision-making to Society will accrue by the accumulated trust that the profession engenders through daily interactions that demonstrate unequivocal fidelity to the dignity and values of informed patients. We do not advocate the abrogation of professional roles: it will remain necessary for physicians to disagree, even argue, respectfully, with patients, provided patients’ views are taken seriously. But, as clinicians invite and welcome patient involvement, it is also essential to share in the work of making difficult decisions, not to abandon patients at the fork in the road.”

Source: Elwyn, Tilburt & Montori, 2013

What practical tools support SDM?

Patient decision aids are the principal tool used to support SDM. In a review of 105 studies involving 31 043 patients, Stacey et al. (2017) showed that those who engaged in SDM and received a decision aid (either written, electronic, audio-visual or web-based tool formats) had greater knowledge of the evidence, felt clearer about what mattered to them, had more accurate expectations about the risks and benefits, and participated more in the decision-making process compared to those receiving usual care. Yet as noted earlier in this chapter, while there has been tremendous progress in the development of patient decision aids, including a generic decision aid (Ottawa Hospital Research Institute, 2015) that can be adapted to any health-related or social decision (Arimori, 2006; Saarimaki, 2013), it is unlikely that decision aids will be created for every decision and in every language. Also, their implementation remains challenging, in particular where the process is disconnected from the routine workflow or from the wider system context (Elwyn, Frosch & Kobrin, 2016). The fundamental need is still for skilled clinicians to have the right conversations with patients (Kunneman & Montori, 2016). Patient decision aids and other tools can facilitate the conversation, but they cannot replace it.

A significant body of work has focused on training health professionals in SDM. While there remains lack of consensus on the precise components of SDM (Shay & Lafata, 2014; Légaré et al., 2013; Légaré

& Witteman, 2013), there is agreement that risk communication skills can be learned by clinicians, both in their professional training and continuing professional education. Such training programmes for practitioners are becoming increasingly common (Diouf et al., 2016), with their effectiveness often measured in terms of changes in clinicians' behaviours and patient experiences (Al-Janabi, Flynn & Coast, 2012).

A 2018 Cochrane review of the effectiveness of interventions to improve health professionals' adoption of SDM found the overall evidence to be of low quality, with uncertainty about what type of intervention works best or what their key components should be (Légaré et al., 2018). It did suggest that interventions that simultaneously target both the health professional (e.g. training) and the patient (e.g. decision aids) are likely to be more effective than each on their own. Légaré et al. (2013) identified the range of core competencies clinicians should acquire for effectively involving patients in health-related decisions. These include being aware of patients' information needs, knowing how to communicate relevant information, nondirective interviewing, risk communication, eliciting patients' preferences, personalized care planning, and self-management support. They also include learning to use patient decision aids (Stacey et al., 2013) or clinical tools such as SURE to screen for decisional comfort (Légaré et al., 2010).

In summary, while promising, the existing evidence base on the effectiveness of SDM remains somewhat ambiguous or, with respect to certain outcomes such as cost savings, in need of more research. Evidence points to positive outcomes at the individual level but there are large gaps in the evidence about outcomes at the clinical, organizational and systems level, largely because of a lack of implementation at these levels (Elwyn, Frosch & Kobrin, 2016). Existing measures are still under development, as we discuss below. Perhaps a more fundamental and still unresolved question is what and who defines a 'good decision', and how to evaluate it (Hamilton et al., 2017), an issue discussed in some detail in Chapter 4 of this book.

What are the barriers to implementing SDM?

We established earlier that SDM is recognized as the core of person-centred care and is increasingly present in health care policy and legislation worldwide. Yet widespread implementation of SDM in routine practice (Couet et al., 2015) or at a system level (Elwyn et al., 2013)

remains the exception. We have also noted that patient decision aids are a helpful tool in SDM, and numerous accredited patient decision aids are available (Volk et al., 2013). Yet patient decision aids are not widely used in clinical practice and few people are even aware they exist (Lepine et al., 2016).

The evidence points to a number of barriers that hamper the routine implementation of SDM in clinical practice. We have highlighted the many real or perceived barriers noted by health care providers, such as time constraints to actively engage in SDM, or attitudes, such as the belief that patients want decisions made for them, or not being in the habit of engaging their patients in SDM (Légaré et al., 2006; Godolphin, Towle & McKendry, 2001; Makoul, Arntson & Schofield, 1995). Perhaps clinicians are reluctant because they were trained to relieve and protect patients from anxiety-provoking information (Tudiver et al., 2002). Further, patients might ask for a treatment option that the clinician does not consider beneficial and the clinician may be concerned about potential malpractice litigation (Zikmund-Fisher et al., 2016), although there is no conclusive evidence about the latter, as noted earlier (Durand et al., 2015).

There are also barriers on the part of the patient, who may not want to engage in SDM. The evidence on patient preferences about participating in decision-making is very mixed, for reasons we do not yet fully understand (Chewning et al., 2012). The role patients wish to play in the decision may depend on the type of health problem, on personal characteristics (Thompson, 2007), or on the level of trust between the patient and the physician: the lower the trust, the less the patient feels comfortable in engaging in the process (Kraetschmer et al., 2004). Also, attitudes and behaviours are slow to change. Thus even where clinicians wish to implement SDM, their communication skills may be inadequate (Stiggelbout, Pieterse & De Haes, 2015). In addition, patients are often reluctant to question their doctors because they worry this will be perceived as challenging the clinician's expertise ('being difficult'), which might, in turn, negatively impact the quality of care the patient will receive in the future (Adams et al., 2012; Frosch et al., 2012).

The inconsistent evidence base about the benefits and risks of SDM and consequent lack of confidence in SDM interventions might also reduce decision-makers' support for relevant strategies, as might the overlap in terminology between patient engagement and SDM and

the conceptual vagueness surrounding its key concepts (Légaré et al., 2013; Légaré & Witteman, 2013). Moreover, a set of best practices for SDM has yet to be agreed upon, and many of the underlying barriers themselves, such as clinician indifference, remain under-investigated (Elwyn et al., 2013).

Perhaps a more fundamental challenge relates to the issue of power, a challenge highlighted elsewhere in this volume (*see* Chapters 4, 5, 6 and 12). SDM requires an explicit sharing of power and knowledge in a relationship that has traditionally been characterized by an imbalance of power in favour of the clinician (Joseph-Williams, Edwards & Elwyn, 2014). In many cultures there is a strong hierarchy of authority which is not openly challenged, at personal, institutional or political levels (Rahimi, Alizadeh & Légaré, 2017), and this also applies to significant subcultures in western liberal societies (Coleman-Brueckheimer, Spitzer & Koffman, 2009; Mead et al., 2013). There is a need for researchers to develop patient decision aids and models that are flexible enough to be adapted to a variety of cultures, involving stakeholders from diverse backgrounds and paying particular attention to categories of patients who find risk–benefit information challenging. SDM training should also include considerations of health literacy and cultural competencies, and should increase awareness of variation in patient preferences (Hawley & Morris, 2016; Alden et al., 2014).

Much of the work on SDM has focused on patients' and clinicians' attitudes to and engagement in SDM. Conversely, little is known about policy-makers' views on and understanding of SDM, despite their key role in developing strategies necessary for its widespread implementation. Little is known, too, about the views of health care organizations, which might be reluctant to invest in SDM as it may involve changing established work patterns or provider tasks (Elwyn, Frosch & Kobrin, 2016). Some countries have changed financial incentives for providers towards value-based payment methods that seek to optimize health outcomes for the patient per dollar spent (Porter, 2010). There is increasing experimentation with, for example, pay-for-performance schemes, capitation and bundled payment arrangements or accountable care organizations to strengthen care coordination and hold health care providers to account for delivering high quality care (Anell & Glenngård, 2014; Nolte, Knai & Saltman, 2014; Kronick, Casalino & Bindman, 2015), and SDM could at least theoretically be built into such payment systems. However, such approaches are highly complex,

requiring careful design, relevant measures and indicators, and consideration of the context in which the payment system is introduced. The risk is that such systems can be distorted by uncontrollable factors such as patients' socioeconomic status, or measures that are inadequate for the task. For example, attribution (which doctors are responsible for which patient outcomes?) must factor in risk-adjustment and randomness or else physicians will be incentivized to avoid patients with multi-morbidities, who are exceptionally high users of hospital services (Anell & Glengård, 2014). Without institutional consensus on what constitutes value and quality in health care, measurement might simply reflect what physicians, politicians or accountants value, rather than what patients value (Mannion & Braithwaite, 2012).

How should we measure SDM?

Many reviews have shown that SDM processes and outcomes are difficult to quantify (Elwyn et al., 2001; Dy, 2007; Légaré et al., 2007; Simon, Loh & Harter, 2007; Kryworuchko et al., 2008; Scholl et al., 2011; Sepucha & Scholl, 2014). Identifying relevant theoretical models for SDM, evaluating interventions in clinical practice and measuring their impact (including cost-effectiveness) remain the subject of ongoing research in this relatively young field.

The kinds of outcome researchers seek primarily reflect the expectations of those assessing SDM. Where patient engagement is built into legislation (such as the Affordable Care Act in the USA), health care administrators seek reliable and valid system level measures that allow conclusions about the impacts of SDM strategies on population health. A major impediment to the more rapid spread of SDM may be that there are not yet enough system measures that can be effectively and efficiently tracked by health care organizations. Much research has explored more process-oriented outcomes, for example measures of the patient's role in decision-making (Conway, Mostashari & Clancy, 2013).

Those who are interested in clinical practice may focus their research on the creation of brief tools, such as the three-question CollaboRATE (Box 11.4), which measures efforts made by the clinical team to engage them in decision-making as reported by patients (Barr et al., 2014).

Several conceptual frameworks have been proposed for measuring SDM. The most comprehensive and commonly used model was designed

Box 11.4 The CollaboRATE tool: a three-item patient-reported measure of SDM

The CollaboRATE tool consists of three items.

Thinking about the appointment you have just had:

1. How much effort was made to help you understand your health issues?
2. How much effort was made to listen to the things that matter most to you about your health issues?
3. How much effort was made to include what matters most to you in choosing what to do next?

Responses to each item can range from 0 (No effort was made) to 9 (Every effort was made) for a maximum total of 27.

Source: Barr et al., 2017

by Makoul & Clayman, and it identifies nine essential constructs that describe the observable features of SDM in a consultation (Makoul & Clayman, 2006; Clayman et al., 2012). Using this framework, Bouniols, Leclère & Moret (2016) reviewed and mapped validated SDM measurement tools and found that none of the identified tools mapped on all the nine elements described by Makoul & Clayman, although all measured three of the elements ('define/explain problem', 'patient values/preferences', and 'check/clarify understanding'). The MAPPIN' SDM instrument and SDM'Mass developed by Kasper and colleagues (Kasper et al., 2012; Geiger & Kasper, 2012) cover eight of the components.

Elwyn, Frosch & Kobrin (2016) developed a conceptual framework that hypothesizes a set of outcomes of SDM (or 'collaborative deliberation') that considers the 'reach' of its consequences. Proximal effects are immediate, for example informed preferences; distal effects are more enduring, such as modified relationships; and distant effects may change service utilization or institutional norms. A different approach was taken by Sepucha and colleagues, whose model for decision-making distinguishes three general constructs across the continuum of the decision-making process (Sepucha & Mulley, 2009; Sepucha & Scholl, 2014):

- Decision antecedents, or the features of the patient, provider or organization that may influence the decision-making process;

- Decision-making process or behaviour in the consultation, such as patient involvement in the decision, decisional conflict or the use of patient decision aids; and
- Decision outcomes, including knowledge, decision regret, decision quality and patient's experience of care.

Tools to measure decision antecedents at the patient level include the Control Preferences Scale, which evaluates the preferred role of a patient in decision-making (Degner & Sloan, 1992); the Autonomy Preference Index, which measures patient preferences about their role in decision-making and their desire to be informed; and tools that assess broader patient characteristics such as health literacy (Aboumatar et al., 2013) and the culture and history of the physician/patient power imbalance. Each of these instruments has its strengths and weaknesses.

Decision-making processes are commonly assessed using the Observing Patient Involvement Scale, or OPTION (Elwyn et al., 2005); two 9-item SDM questionnaires (patient and clinician versions) (Kriston et al., 2010; Scholl et al., 2012); or the Decisional Conflict Scale (DCS) (O'Connor, 1995). Few process measures adequately capture implementation, and different stakeholders have different perceptions as to whether SDM has occurred (Rodenburg-Vandenbussche et al., 2015; Shay & Lafata, 2014). Interestingly, only studies in which the patient reported that SDM had occurred (rather than reported by the doctor, or a third observer) found a significant association with improved patient outcomes (Stewart, 2001). This finding suggests that the patient's perspective is critical to the science of measuring SDM.

Decision outcomes are assessed by measuring decision quality, decision satisfaction or decision regret (Sepucha, Fowler & Mulley, 2004; Brehaut et al., 2003). Many of these scales have good reliability statistics, but the validity of most tools remains undetermined, especially as far as diverse populations are concerned. In addition, there are important ceiling effects (high-level scores with little variability in both patient-reported outcomes and other process measures). Very few measures are sensitive to changes in outcomes over time (Kirwan et al., 2016; Barr & Elwyn, 2015). Finally, there is still a gap between measuring SDM for research purposes and measurement for clinical and policy-oriented purposes.

Some researchers use measurement frameworks to explain the mechanisms underlying SDM behaviours and explore the relationships between the different constructs of sociocognitive models. Many such

models posit that behaviour is driven by intention, and that intention has measurable and modifiable determinants (Frosch et al., 2009; Desroches et al., 2011).

New theoretical frameworks are expanding our understanding of decision-making but they have yet to demonstrate their applicability. Measures need to be practical, valid and reliable, and developed in consultation with patients. There is a need for wider testing with both exploratory and confirmatory factor analyses, and for revising existing instruments. Scales should be tested for responsiveness before being used in intervention studies. Further work on discriminant validity would enable us to assess if a scale can distinguish between a decision-making process that is unilateral and one that is truly shared. In the best of all possible worlds, a standardization of outcome measures would allow more meaningful cross-study comparisons (Scholl et al., 2011; Decary et al., 2017).

What are the research trends in SDM?

Research on SDM has gone beyond decisions about medical diagnostics and treatments. For example, in the era of personalized medicine SDM is clearly called for concerning decisions about, and follow-up of, genetic tests for predispositions for which data and treatments are not yet available (Katz, Kurian & Morrow, 2015). Dyadic SDM research now takes into account the mutual influence of the patient and the physician in the consultation (Melbourne et al., 2011; Couet et al., 2015; Légaré et al., 2012a; LeBlanc et al., 2009). Research has also moved beyond conceptualizing SDM as a single encounter to broadening research beyond the consultation (Rapley, 2008). SDM has been incorporated into many more decision contexts, such as around loss of functional autonomy (Hanson et al., 2011), palliative care (Belanger, Rodriguez & Groleau, 2011) and mental illness (Coffey et al., 2016).

A key development has been the involvement of a wider range of actors in SDM research, such as family caregivers who are closely involved in decisions about the care of relatives, and a wider group of health professionals and social care workers (Garvelink et al., 2016; DeKeyser Ganz et al., 2016). Researchers are developing models, assessment tools, interventions and decision support tools that take into account decisions shared between all these actors (Laidsaar-Powell et al., 2013; Stacey et al., 2010; Garvelink et al., 2016). A growing team

consciousness of SDM could improve resource use and other group-level performance scores (Sorbero et al., 2008), as well as bringing about change in the cultural norms of health care organizations and systems (Elwyn, Frosch & Kobrin, 2016), with an increasing volume of work looking specifically at the impact of SDM at the meso and macro levels (Ballard-Barbash, 2012).

Identifying better measures for SDM remains a core research area, as demonstrated by the recent application call for measures of SDM by the US-based Agency for Healthcare Research and Quality (Agency for Healthcare Research and Quality, 2016). Much research has been devoted to exploring the relationships between the constructs of various behavioural models and proposing tools that are sensitive to the less rational and more affective aspects of behaviour change (Sniehotta, 2009; Kelders et al., 2016). Considerable research is also being devoted to developing and measuring the impact of patient decision aids (Volk et al., 2016). Lastly, the contribution of SDM to reducing waste in health care is gaining attention as most industrialized countries face increasing financial constraints (Morgan et al., 2016).

How can we move SDM forward?

Frosch & Carman (2016) propose a framework of ‘patient and family engagement’ for moving ahead with interventions and policies to implement SDM. Their model envisages a continuum of patient engagement that is applicable to direct patient care, organizational governance and policy development, and yet remains flexible enough to match the capabilities, interests and goals of individual patients (Dy & Purnell, 2012). It posits that patient values influence not only clinical decisions but also decisions about hospital design, recruitment, quality improvement strategies and policy priorities. The continuum structure of this framework is also responsive to the accumulation of evidence about what works and what does not.

Facilitators for developing such a culture of engagement at the policy level are social and cultural norms that are open to public influence, as well as institutions that are open to public participation, as demonstrated, for example, by state policies responding to public pressure to control the tobacco market (World Health Organization, 2017). The organization, financing and governance of health care systems play a key role (Korda & Eldridge, 2011). Legislation can also facilitate patient

engagement by, for example, mandating public advisory councils in hospitals (Carman et al., 2013).

SDM is only one of the many facets of greater engagement of patients and the wider public in health care at the different tiers of the system. As several contributions to this volume have shown, fostering an engagement culture at all levels and including civil society is essential if equal partnerships and effective relationships between patients and professionals are to be translated into a reality. SDM is mostly applicable at the clinical level (Carman et al., 2013), and its effective translation into routine practice will require a change in the status quo, which in turn will require greater investment in educating the public about health and health care, and the acquisition of skills and competencies to ask questions, express values and preferences, and understand risks. This transformation is necessary more than ever, at both the individual and system level, for ethical, financial, social, political and legal (in some countries) reasons. Finally, it forms a core element of health care quality, with more responsive services likely to lead to better outcomes, improved patient experiences and more effective self-management.

Conclusion

In summary, health care decisions that will lead to improved population health, patient experience and cost-effectiveness depend on an understanding of the best available scientific evidence and on patients' informed values and preferences. SDM is an approach that has the potential to improve population health by reducing harms of treatments that are not beneficial for all and increasing the benefits of those that are. It also has the potential to improve patient experience by engaging them in the decision-making process. In addition, although the evidence remains patchy, it has the potential to ensure a more appropriate use of limited resources and thus increase the cost-effectiveness and sustainability of health systems. There are effective interventions for facilitating SDM, including training health care professionals and patient decision aids. However, SDM is not yet widely implemented in routine clinical practice, with various barriers obstructing its adoption at the individual patient and provider level and, more importantly perhaps, at organizational and system levels. These barriers can be overcome by establishing a culture of patient engagement at all levels of the health care system, from individual decisions and programme development to research and health policy.

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