

**Shared Decision Making:
Where Evidence Based Medicine Meets Patient-Centered Care**

By

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Abstract

Shared Decision Making bridges patient-centered care with evidence based medicine, while at the same time highlighting the tensions between them. Shared decision making, a structured form of patient-centered communication, includes information exchange, deliberation and consensus building and is advocated in clinical situations where the evidence leaves room for more than one medically reasonable choice. Based on the ethical principal of patient autonomy, the central tenants of shared decision making are: understanding the patient from a bio-psychosocial perspective, empowering the patient to be an active participant in the decision making process, and incorporating patients' values and preferences into the decision. In the context of chronic disease care the provider patient relationship becomes a paramount. Shared decision making has been shown to increase patient knowledge, decrease consultation time, improve patient satisfaction, and reduce decisional conflict. However translating shared decision making into clinical practice remains difficult. A complex intervention, implementation requires provider behavior change as well as skills training for the competencies of shared decision making which includes patient-centered communication and conveyance of risk. Decision support interventions, especially through the use of decision aids, assist the process of shared decision making.

Assessing quality in patient-centered decision making remains a challenging task. Quality monitoring programs using current performance measures fail to account for patient-centered care and are even at odds with it. Clear definitions of high quality decision making and patient-centered measures need to be developed and operationalized for use in quality monitoring in clinical practice in order to including patient centered decision making in measurement of quality care. Financial incentives such as pay for performance need to be realigned to support patient-centered care and to encourage patient-centered decision making. Practice guidelines need to be made more patient-centered by making preference sensitive decision points explicit and including tools of shared decision making, such as decision aids, directly into their content. Broader systemic changes are needed to create a system that values and rewards patient-centered care and shared decision making.

The good physician treats the disease; the great physician treats the patient who has the disease.

~ Sir William Osler

Medicine is a science of uncertainty and an art of probability.

~ Sir William Osler

Part 1:

Nowhere is the art of medicine more pronounced than in the provider patient relationship, especially when difficult medical decisions need to be made. The art of medicine is constantly balanced with evidence based practice, even in the mundane decisions of day to day medical practice, such as choosing a specific medication or determining which diagnostic or screening test to order. Provider style, patient cultural backgrounds, socioeconomic concerns all enter into the provider patient relationship, influencing decision making with each decision to be made. Traditionally medical decisions were most often physician directed, executed in a paternalist decision making style. The provider, as the possessor of medical knowledge, ascertained the best option for the clinical situation and instructed the patient as to the plan of care. This paternalistic style has become less prominent with the emergence of more patient-centered care grounded in a stronger emphasis on the importance of patient autonomy.¹ Patient-centered decisions are made in a collaborative manner with the provider and patient engaging together in information exchange and deliberation and with the patient's values and perspectives informing the final decision. This decision making style, called shared decision making, is imbued with the art of medicine as it depends upon skilled communication while bringing the patient and his or her context to the forefront. Shared decision making uniquely intersects patient-centered care with evidence based medicine (often thought of as the antithesis of the art of medicine) through

its charge of eliciting and incorporating the patient's perspectives, values and context into medical care while being firmly rooted in medical evidence.

Evidence Based Medicine

Since the 1990s evidence based medicine has become a central tenant to providing high quality medical care. A shift from anecdotal medicine, evidenced based medicine systematically applies medical knowledge attained through clinical research to medical practice. With the goal of improving quality and reducing practice variation through standardization, evidenced based medicine is implemented through clinical practice guidelines, protocols and best practices.² Its touted benefits include improvement in the quality of care through the provision of objective scientifically based care, improved outcomes, increased efficiency, decreased practice variation, and the provision of a scientific basis for health care policy.³ The impact of evidence based medicine reaches beyond the provider patient encounter to quality monitoring, payer reimbursement, and influencing research and policy direction.

Critics of evidence based medicine are concerned about over generalization with a one size fits all or 'cookbook' approach to medical care. Another area of concern is about the evidence itself that is used to inform the development of guidelines and protocols. Clinical trials are often population-based studies where subgroups of patients such as minorities and women are frequently under represented.³ Both of these criticisms reflect the concern that evidenced based medicine does not accommodate an individual patient's distinct features and circumstances. To counter these concerns, proponents of evidence based medicine argue that the evidence must be taken within the context of the individual patient and guidelines should provide a framework for medical care but should not be the sole dictating force.⁴ However, tension

remains between implementation and evaluation of the quality of evidenced based medical care and the unique needs of individual patients.

Patient-Centered Medicine

Patient-centered care, another emerging principle for the provision of medical care, has been identified as a pillar of high quality of care by the Institute of Medicine.⁵ Placing patients at the focal point of medical care, patient-centered care shifts the system away from a provider-focused or a disease-focused framework to one where a patient's individual characteristics, perspectives, values, and context become integral to his or her medical care. Patient-centered care means giving patients a voice and a role in their own care and understanding the patient from a bio-psychosocial perspective. Partnership and communication become paramount to the provider patient relationship.⁶ Beyond improving quality, it has been argued that there is a moral imperative for providing patient-centered care.⁷ While many different definitions of patient-centered care exist, Moira Stewart has eloquently laid out six defining features: (1) exploring the patient's disease and patient's illness experience; (2) understanding the whole person; (3) finding common ground; (4) incorporating prevention and health promotion; (5) enhancing the provider-patient relationship; (6) being realistic.⁸ Robinson et al. further distills patient-centered care into two key concepts: promotion of patient involvement and individualization of care.⁹

The ascendancy of patient-centered care as a primary organizing principle for medical care necessitates shifts in the structure and delivery of medical care. The patient-centered medical home has emerged as the manifestation of the care structure for implementing patient-centered care, with major provider organizations including the American College of Physicians, American Academy of Family Physician, and the American Academy of Pediatrics declaring

patient-centered care as a fundamental goal for the organization of care and creating efforts within each of their disciplines to study and implement the medical home model.¹⁰ The central tenants of the patient-centered medical home include: access, care delivery, care management, population management, team based care and evidence based medicine. An informed empowered patient interacts with a prepared proactive care team resulting in high quality care with the aim of generating improved outcomes.¹¹ Patient education and activation is emphasized in the patient centered medical home. The patient is encouraged to seek knowledge and understanding about his or her own medical circumstance and is supported and taught skills for self-management of chronic diseases. A key shift in patient centered care is that an activated and empowered patient can become an invested participant in the medical decision making process. Both providers and patients will require new attitudes, skills, and tools to successfully adopt this type of patient-centered communication.

It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has.
~ Sir William Osler

Shared Decision Making

Shared decision making, the manifestation of patient-centered communication, grounds the clinical encounter in evidence while bringing the patient to the center of the decision making process. Through the process of shared decision making, providers and patients make medical decisions jointly by examining the current medical knowledge, reviewing options, outcomes and risk, and exploring patients' beliefs and perspective. Patients' values are incorporated into a consensus and together providers and patients determine the best course of action. In the seminal 1999 article, Charles et al. outlined the three elements essential to shared decision making: 1) two way exchange of information, 2) discussion and deliberation of possible options and

outcomes, and 3) consensus building.¹² A distinct shift from a paternalism, both provider and patient take on new roles in patient-centered decision making. The provider no longer acts as the central decision making agent and holder of all medical knowledge. The patient becomes an active participant, central to the clinical consultation, with his or her values and perspectives influencing the best course of action.

For this discussion shared decision making will be limited to the context of the provider and patient making a joint decision. However it is important to note that within new structures of care this paradigm will need to be expanded to include others in the decision making process, including members of a multidisciplinary health care team and patients' family members and surrogate decision makers.¹³ In the setting of the patient centered medical home members of the medical team have expanded roles and can become involved in many aspects of the decision making process through patient education and health coaching.¹⁴ The roles and influences of these other participants and how they are involved in patient centered decision making deserve further exploration and study beyond the scope of this paper.

Shared decision making provides structure to the deliberative process enabling medical care to be patient-centered while staying true to the tenants of evidence based medicine. By incorporating the known risks and benefits of a given medical decision, it helps providers and patients balance medical knowledge (i.e. evidence based medicine) with an individual's belief system and feelings about their personal health. The patient's perspective becomes integral to the decision at hand while being placed in the context of current medical knowledge. Patient-centered communication should activate patients, engaging them in their own healthcare, leading to an empowered patient who will feel ownership of the decided plan of care. Patient activation is truly the crux of patient-centered communication. An activated patient is more likely to ask

questions and engaged in the decision making process increasing the likelihood that the resultant decision will be concordant with the patients' beliefs and values which will facilitate adherence.

^{15, 2} The hope is that shared decision making will lead to improved quality in health care by increasing patient satisfaction, generating more cost effective care, and improving health outcomes ² while placing the patient at the center of their own medical care.

In contrast to a paternalist decision making style, shared decision making interjects the concept of uncertainty into the deliberative processes.¹⁶ An assessment of personal risk acceptance becomes imperative as evidence is reviewed and the concept of risk explored, making the limitations of medical knowledge explicit. In situations of 'clinical equipoise', when several reasonable options exist or when the risks and benefits of the decision must be weighed, the patient's perspective becomes essential to the decision making process.¹⁷ It is exactly these 'preference sensitive decisions' where the structured process of shared decision making becomes the most useful in providing the scaffolding to explore and integrate the patient's perspective and help balance the medical evidence to attain a consensus decision.¹⁸

Patients bring a wide variety of perspectives, cultural backgrounds, religious beliefs, and levels of education to the clinical encounter. Every patient will have her or his own belief structure, biases, information or misinformation. In the age of the internet, many patients come to come to their medical appointments having sought out information about medical issues from a myriad of sources of varying credibility. Likewise providers will often have their own set of assumptions and biases that will influence the encounter. Ideally shared decision making provides a process to explore and acknowledge these differing perspectives and biases. Acknowledging these biases and actively addressing them should allow for medical decisions that are concordant with patients' values.

In approaching patient-centered communication, it is important to understand that patients will desire variable approaches to decision making. Research has shown that many patients desire more information about their own health and want to actively participate in their health care.¹⁹ However, some patients also clearly prefer a provider directed decision making process.²⁰ Importantly, employing shared decision making does not obligate all patients to participate in joint consensus building. Patient-centeredness dictates that patients should be able to choose whether or not to participate and the degree to which they want to be involved.²¹ While not all patients want shared decision making, taking the time to assess how a patient wants to be involved in the decision making process is inherently patient-centered because patients' values about how their medical decisions should be made are accounted for.²²

Likewise, a patient's perspective on medical choices would be expected to change with different situations, likely even shifting during the course of an illness, be it acute or chronic.²³ Recognizing that decision making styles will vary depending on the clinical scenario, Kon describes 'the shared decision making continuum' in a recent JAMA editorial.²⁴ He proposes five decision making styles/approaches along this continuum: patient or agent driven, physician recommendation, equal partners, informed non dissent, and physician driven. When employing shared decision making, providers will need to assess the patient's perspective about being involved in the decision and will need to take the requisite time to determine a patient's 'autonomy preference'²² and where a patient falls on this decision making continuum.

Patient centered decision making raising important questions about how to reconcile when a decision made through shared decision making does not coincide with best practices or current evidence as understood through the lens of evidence based medicine. Shared decision making is advocated in situations of clinical equipoise, when the evidence leaves room for more

than one clinically appropriate choice. However, inherent to patient centered care is the acceptance that patient's context, and their values and perspectives deserve to be heard, acknowledged and incorporated into medical decisions, even when this results in decisions different from those that providers would have made independently. Such decisions require new ways of understanding success in decision making where the process of decision making is valued as well as the medical outcome. This will be explored further in part 2 of this paper.

Shared Decision Making in the Context of Chronic Disease

The seminal model of shared decision making put forth by Charles et al. discusses shared decision making in the context of acute decisions, specifically in the setting of breast cancer treatment. However, there are unique factors to consider for decision making in the chronic disease setting when compared to acute medical decisions including the urgency and timing of decisions, as well as the timeframe and location of implementation. Chronic disease decisions, such as medication choice, rarely have the same temporal urgency as acute decisions. For example, when deciding between surgical options for cancer treatment, there is an understandably relatively urgent need to make a timely decision. Once the acute decision is made, i.e. when a certain surgical option chosen, the course of care moves on from that juncture. That decision does not need to be revisited. On the other hand, chronic disease decisions are revisited overtime, modified and adjusted. Glycemic or blood pressure control remains ongoing concerns for someone with diabetes, as will lifestyle modification and medication adherence. These issues can and will be addressed again at subsequent follow up visits. For the acute decision, implementation is often a one time, short term event that is often executed by the clinician, as would be the case in a surgical intervention. Conversely, the implementation of

decisions in chronic disease most often lies in the hands of the patient, requiring independent follow through and takes place outside the clinical setting, as when a patient chooses whether or not to take the prescribed medication. Treatment adherence in chronic disease involves daily choices on the part of the patient and continued commitment to the plan of action.

Taking into account these important distinctions of chronic disease care shared decision making aims to shift the locality and timing of when the actual decision is made. In a paternalist provider-patient encounter the true decision about treatment options, the one where the patient is fully empowered as to his or her choice, occurs once the patient has left the office. This is especially true in the context of chronic disease and medication adherence.²⁵ In such a scenario the crucial decision comes outside of the clinical encounter when the patient must decide whether or not to follow through and actually take the prescribed medication. Many factors may influence whether or not a patient will adhere to the plan of care.²⁶ A patient may decide not to take the medication if they feel that it is too expensive, if there is concern about side effects, or simply that the effort of taking a pill everyday outweighs any perceived benefit. Shared decision making aims to shift this crucial decision point to occur during the structured process of the clinical consultation by exploring the patient's perspective about taking medication and empowering the patient to make a decision that aligns with his or her personal values and the medical circumstances.²⁷ If the patient has gained a realistic understanding of the clinical situation, weighed the risks and benefits and come to a consensus decision with the guidance of the provider then it would follow that the patient will leave the encounter empowered and feeling concordant with the decision and would more likely follow through with the decision, thus increasing medication adherence.²⁸

Noting these differences between acute medical decisions and the decisions of chronic disease care, the Charles et al. model has been expanded to fit the needs of chronic disease care. Noting that the steps of shared decision making are iterative as decisions are revisited in chronic disease care, the provider patient relationship, identified as a crucial component of patient-centered communication, takes on enhanced prominence. Continuity of care and clinical rapport are indispensable to decisions made over time, just as communication and trust are fundamental in exploring the patients' perspective and facilitating the integration of patient values into the decision.

A strong provider patient relationship, together with the original three steps of shared decision making: information exchange, deliberation, and consensus building, make up the requisite components of successful shared decision making in chronic disease care.²⁹ Each step takes on additional dimensions when successfully implementing patient-centered chronic disease care, where understanding the patient from a bio-psychosocial perspective becomes crucial. Beyond the simple exchange of medical knowledge and the review of risks and benefits, truly patient-centered disease management necessitates a two way dialogue that explores patient specific factors such as the socioeconomic circumstances and cultural influences which will inform the patient's decision and frame the patient's facility to implement the plan. Eliciting a patient's personal risk acceptance and incorporating his or her risk tolerance into the decision is central to the shared decision making process.³⁰ In chronic disease care, factors such as the capacity for medication adherence, the motivation and capability to implement lifestyle changes, and a patient's ability to carry out self-management, are inherently intertwined with socioeconomic and cultural factors which need to be actively explored during the decision making process.

Evidence for Shared Decision Making

Employing shared decision making is intuitively right on several levels, since it conforms to the ethical principle of patient autonomy,³¹ supports patient-centeredness, and patients desire it.³² However, evidence surrounding its use and implementation is still evolving. The study of patient-centered communication is a young but burgeoning field with certain emergent themes. The theoretical underpinnings of patient-centered decision making are being developed, explored, and evaluated.^{15, 33, 34} Ongoing implementation research is exploring how to increase provider capacity and evaluating various approaches to decision support interventions and decision aids.³⁵ Studies point to increased patient knowledge, decreased consultation time,² improved patient satisfaction, and reduced decisional conflict with the use of shared decision making.³⁶ Other purported benefits include decreased practice variation through systematic application of a decision making process that includes review of the evidence.³⁷ Shared decision making has shown to increase use of recommended risk factor screening tests.³⁸ The hope is that shared decision making will promote more efficient use of medical resources by leading to choices that result in a decrease use of options that do not have clear benefits, as can be the case with some screening tests, and the increase use of options with clearer benefits such as cardiovascular risk modification.³⁸ It has been postulated that shared decision making can even reduce litigiousness, although supporting evidence is lacking.¹⁷ Importantly, patients who have been involved in shared decision making show increased activation³⁹ and increased adherence to the treatment plan.²⁷ Although impact on outcomes remains inconclusive, emerging data shows improvement in intermediate clinical markers such as glycemic control and decreased lipid levels.³⁹

Translating Shared Decision Making into Practice

Despite successes in the settings of clinical trials, shared decision making remains difficult to achieve in clinical practice and has not been broadly adopted.^{40,41} Provider specific factors impact incorporation of shared decision making into practice, as explored in a 2006 review article entitled, “**Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions**” by Gravel et al.⁴² Providers concerns about time constraints were the most commonly cited perceived barrier to implementing shared decision making. Other identified barriers include concerns about lack of applicability to their patient’s characteristics and lack of applicability to the clinical situation and well as concerns over the role of the patient in the decision making process, such as assumptions that patients desire other decision making styles and disagreement with asking the patient about their role the decision making process. On the other hand, several facilitators to implementing shared decision making were also identified including: perception of positive clinical impact, hope for improved patient outcomes, perceived patient preference, and characteristics of the patient. Notably, provider motivation was also a key facilitator. Understanding the above barriers and facilitators can help direct the implementation of shared decision making, future study design, and health policy.

Providers must foremost be willing to accept this patient-centered communication style which represents a distinct shift from provider driven, paternalist medicine. Beyond motivation, the steps of shared decision making are complex tasks and providers will require communication training and specifically designed aids to support the deliberative process. Several conditions have been identified as essential to integrating shared decision making into practice: 1) ease of access to medical evidence 2) assistance with discussion of risk and the balance the various

options, and 3) a supportive clinical culture which promotes and encourages patient activation and involvement.¹⁷ Competencies for shared decision making have been outlined (see table 1)⁴³ and studies have shown that they can be operationalized and taught.⁴⁴ While best practices for teaching and disseminating these skills to providers remains to be clarified,³⁵ it is clear that the implementation of shared decision making necessitates a complex intervention⁴⁵ with multiple intertwined components acting independently.²⁷ Ongoing research continues to examine effective approaches to operationalize these skills, train providers, and develop quality decision aids.^{33, 46}

Table 1: The competencies of shared decision making

| |
|--|
| Problem definition — clear specification of the problem that requires a decision. |
| Portray equipoise — that professionals may not have a clear preference about which treatment option is the best in the context. |
| Portray options — one or more treatment options and the option of no treatment if relevant. |
| Provide information in preferred format —identify patients’ preferences if they are to be useful to the decision-making process. |
| Check understanding —of the range of options and information provided about them. Explore ideas, concerns and expectations about the clinical condition, possible treatment options and outcomes. |
| Checking role preference — that patients accept the process and identify their decision-making role preference. |
| Decision making —involving the patient to the extent they desire to be involved. |
| Deferment if necessary —reviewing treatment needs and preferences after time for further consideration, including with friends or family members, if the patient requires. |
| Review arrangements —a specified time period to review the decision. |

Fundamentally, implementing patient-centered communication requires behavior change on the part of providers.^{47,48} With this understanding some implementation interventions explicitly apply the constructs behavior change theory to facilitate incorporation of shared decision making into the clinical encounter.³⁵ For example, interventions target attitude change through educational interventions or deliver training to providers aimed at improving provider self-efficacy, a key component to successful implementation of a new learned behavior or skill. However there are concerns that shared decision making research may not always be explicitly

grounded in theory and therefore lack transparency. Although no single theory can inform the entire shared decision making process, interventions should be grounded in decisional theory which address the deliberative process as well as theories which address behavior change.¹⁸

Communication skills for effective deliberation and shared decision making are multifaceted. Providers must be able to assess where a patient falls on the decision autonomy preference spectrum for a particular decision. They must engage patients and listen to them. They must elicit their values and perspective and incorporate them into the resultant decision. Providers are generally comfortable conveying the medical evidence to patients. However, ensuring it is done in an accessible manner often remains difficult. An even more challenging task is interpreting population based evidence for an individual and explaining its application to the patient sitting in exam room.² Risk communication, a central component to effective shared decision making, requires its own skillset. Explaining uncertainty and depicting risk in a manner patients can understand is a sophisticated and complex task.

Unlike paternalist medicine where the provider is perceived as omnipotent, shared decision making interjects of the idea of uncertainty into the decision making process, an unsettling concept for both providers and patients. This discomfort with uncertainty may be an unspoken impediment to the wider adoption of shared decision making.⁴⁵ The concept of uncertainty is difficult to define and no consensus exists as to the best way to communicate and present in the clinical setting. Risk, a complex yet subtle concept, is similarly perplexing for providers and patients to conceptualize. Risk communication presents a particularly challenge as it deals with nuanced, potentially confusing, and often emotionally charged issues. The manner in which risk is communicated and presented will greatly influence the interpretation of the balance of benefit and harm.¹⁶ For example, presenting risk as relative risk reduction can over

emphasize the benefit of a treatment when a small number of individuals are impacted and will minimize the potential harm. Absolute risk reduction better conveys the magnitude of such an impact and can influence both provider and patient's interpretation of the risk and preference for treatment options.⁴⁹ There have been calls for risk to consistently be presented in absolute risk reduction to minimize bias.^{16, 49} Because of the intricacies inherent to risk communication many providers require support in assessing and communicating uncertainty and risk. Tools which display the concepts of risk in accessible formats, such as graphical depictions, weighted scales, or numerical scales may assist the process of risk communication.²

Decision Support Interventions

As exemplified by risk communication, more is needed beyond specific communication skills training to support the decision making process. Decision support interventions, as defined by Elywn et al., are a broad category of interventions designed to support the shared decision making process:

“Decision support interventions help people think about choices they face: they describe where and why choice exists; they provide information about options, including, where reasonable, the option of taking no action. These interventions help people to deliberate, independently or in collaboration with others, about options, by considering relevant attributes; they support people to forecast how they might feel about short, intermediate and long-term outcomes which have relevant consequences, in ways which help the process of constructing preferences and eventual decision making, appropriate to their individual situation.”^{18 p.705}

For decision support interventions to be successful the decision support must be acceptable to clinicians, easily integrated into clinical practice, and be supported by evidence showing that the interventions improve the decision making process and patient specific outcomes. As complex interventions, decision support interventions must assimilate multiple domains: clinical

knowledge to inform the issue at hand; decision science/ communication theory to apply the underpinnings for requisite skills, medical informatics to integrate technologies into the decision making process; and organizational learning to create system level changes to incorporate new processes of care.³⁰

Decision support interventions can be divided into three general categories: (1) those for use during the clinical encounter by clinicians, (2) those that are to be used outside the clinical encounter by the patient, and (3) those using social media, the internet or other interactive technologies, often independently from the health care field.¹⁸ Each of these types of decision support are important for a patient-centered decision making processes because they offer opportunities to educate and empower the patient.

Decision support used outside the encounter, whether independently or in conjunction with the medical system, helps transform the clinical encounter by educating and empowering the patient. A prepared proactive patient comes to the clinical consultation ready to actively participate in the decision making process and ideally will be more prepared to participate in shared decision making. Such decision support interventions take many forms. Websites such as Health Dialog⁵⁰ and the Dartmouth Center for Shared Decision Making⁵¹ provide forums where patient can independently explore decision support tools or even get consultative services via health decision coaches. Patient based forums such as consumer advocacy sites, chat rooms, web sites, social media, and other online forums offer means for patients explore these issues independent from the medical system. From a consumer advocacy standpoint there is value to an empowered patient in enhancing provider readiness for shared decision making.² A knowledgeable informed patient who asks questions forces providers to be prepared with evidence based answers.

Decision Aids

Decision aids, the decision support intervention designed for use during the clinical encounter, primarily support the processes of shared decision making.¹⁸ Decision aids concisely guide the provider and patient through the steps of shared decision making by condensing the necessary information and integrating patient preferences into the deliberative process. For a decision aid to be effective it must fit easily into the clinical work flow and be easy for both provider and patient to use. These tools can take many forms but most often are handouts, booklets or computer based tools to be used during the clinical encounter. While the topics they cover vary widely they are most useful in situations of clinical equipoise where risks and benefits need to be weighed and more than one reasonable option exists.⁴³ It is exactly these preference sensitive decisions where decision aids so valuable in making patient preferences explicit.

As tools to be used during the clinical encounter, decision aids fulfill the conditions previously described as indispensable to integrating shared decision making into practice by: (1) providing easy access to evidence, (2) assisting in risk communication, and (3) creating a supportive clinical culture. Decision aids review and synthesize the pertinent medical evidence presenting it in a succinct and accessible format as well as presenting the complex concepts of risk in a manner which patients can readily understand, facilitating risk communication.²⁷ They create a format whereby patient's preferences and values are explored and incorporated into the consensus.⁵² Decision aids can be tailored to a patient's distinct risk profile presenting individualized risk information.²⁸ Moreover, a decision aid can actually change the physical relationship between provider and patient by shifting body position and creating a shared body language, strengthening the partnership in the deliberative process.¹⁸ Arguably the very presence

of decision aids and their use in medical practice transforms the clinical culture towards one where patient involvement in decision making is nurtured and encouraged.

Studies of decision aids show that they are readily accepted by both patients and providers and successfully facilitate the shared decision making process. Their use not only reduces patients' decisional conflict but also generates increased patient participation in the decision making process without leading to increased anxiety.³⁶ Decision aids have been shown to increase patients' knowledge of the medical evidence, improve understanding of risk,⁵³ help create more realistic expectations, and create increased concordance between providers' preferences and the clinical options patients choose.⁵⁴ Importantly they also correlate with improved quality of life for patients.³³ Decision aids engage and empower patients in the decision making process leading to increased patient activation⁵⁵ which in turn correlates with increased adherence with the medical decision.³⁹

Decision aids exist for a myriad of diagnoses, from choosing breast cancer treatment options³⁶ to medication choice for diabetes management.⁵² Many of these decision aids have been systematically developed using both provider and patient input²⁸ and have been validated and evaluated in clinical trials.³⁶ Recognizing the importance of standards and quality in decision aid development and evaluation, guides have been developed to help structure this process²⁷ and models define the components of decision support interventions.³⁰ The International Patient Decision Aids Collaboration (IPDAS) has created a set of quality standards to assist in the development and evaluation of decision aids. These standards are based on a check list which can generate a quality score.⁵⁶

Figure 1: Example of Decision Aid – The Statin Choice Tool⁵³

Prepared exclusively for patient

1 What is your risk of having a heart attack in the next 10 years?

Using information about your health we've estimated that you have a 15-30% chance of having a heart attack sometime in the next 10 years. This table shows you how we estimated this risk.

In addition you are lowering your cardiovascular risk by regularly using metformin and gemfibrozil (Lopid).

| Your risk | <15% | 15-30% | >30% |
|-----------------------|------------------|------------------|----------------|
| Gender | woman | man | man |
| Age | 60 or younger | 60-75 | 75 or older |
| Had diabetes for | less than 10 yrs | less than 10 yrs | 10 or more yrs |
| Have protein in urine | no | no | yes |
| Latent A1c | <5% | 6-7% | >7% |
| Usual blood pressure | <120 | 120-140 | >140 |
| Total HDL cholesterol | <4 | 4-6 | >6 |
| Smoking | non-smoker | ex-smoker | smoker |

WHAT DOES THIS ESTIMATE MEAN?
It means that out of 100 people like you, about 20 will have a heart attack in the next 10 years, and about 80 will not.

Keep in mind that we do not know what will happen to you; if you were to have a heart attack we cannot tell when this will happen.

2 What benefit can you expect from taking statins compared to not taking statins?

NO STATIN
Our guess of what will happen to 100 people like you if they were to decide NOT to take statins; out of 100 people like you, about 20 will have a heart attack in the next 10 years, and about 80 will not.

YES STATIN
Our guess of what will happen to 100 people like you if they were to decide to take statins; out of 100 people like you, about 15 will have a heart attack in the next 10 years and about 85 will not. About 5 people will avoid a heart attack by taking statins; about 95 did not change their outcome by taking statins.

3 What downsides can you expect from taking statins compared to not taking statins?

- Statins need to be taken daily for years.
- Some statins may cost less to you depending on your drug plan.
- Common side effects: nausea, diarrhea, constipation (most patients can tolerate)
- Muscle aching/stiffness: 5 in 100 patients (some need to stop statins because of this)
- Liver enzymes go up (no pain, no permanent liver damage): 2 in 100 patients (some need to stop statins because of this)
- Muscle and kidney damage: 1 in 20,000 patients (requires patients to stop statins)

4 What do you want to do now?

- Take (or continue to take) statins
- Not take (or stop taking) statins
- Discuss with your clinician today
- Discuss with your clinician in the future
- Discuss with others _____
- Who? _____
- _____

ATTENTION!
If you were to decide to take statins, we will not know if you would be among those who would not benefit (either by having a heart attack or by having one despite taking statins regularly) or those who would benefit (by avoiding a heart attack by taking a statin.)

© Mayo Foundation 2005. This information reflects the accuracy of your medical record and the best available research studies. It was prepared by Clinic researchers without funding from the makers of statins.

Shared decision making, a multifaceted and complex task, requires a motivated clinician who possesses good communication skills and decision support tools to assist in the process. While questions persist as how to best translate shared decision making and decision support into clinical practice, it also remains to be elucidated how to measure and define quality in shared decision making and patient-centered communication.

Part 2: Defining and Measuring Quality in Patient Centered Decision Making

Variability is the law of life; and as no two faces are the same, so no two bodies are alike, and no two individuals react alike and behave alike under the abnormal conditions which we know as disease.

~ Sir William Osler

Patient-centered care and shared decision making are accepted ideals for the delivery of health care and are put forth as a goal of high quality care.⁵⁷ Yet even as shared decision making bridges evidence based medicine and patient-centered care, it also highlights the tension between them. The constituents of high quality care are generally defined through the lens of evidence based medicine with it goal that medical practice should reflect best knowledge and practices about screening, diagnosis, and treatment as determined by current research. Guidelines, protocols, and best practices, the tools of evidence based medicine, delineate and set performance measures for measuring the quality of care. These current care delivery systems and quality monitoring programs, predicated on population based clinical trials and applied to broad categories of patients, often pit patient-centered goals against the current definition of high quality care.

An inherent contradiction exists between the goal of evidence based medicine to reduce unnecessary variation in practice and the goal of patient centered care to account for the needs of the individual patient. Performance measures, guidelines and quality benchmarks generally do not account for cultural differences, individual situations, and patient preference.^{3, 58} At times, decisions made through patient-centered communication will run counter to clinical guidelines because shared decision making is designed to account for patients' values and not an a priori treatment goal. Consequently, a conflict exists between the drive for the individualized decisions attained by patient-centered communication and the pressure for clinicians to meet prescribed disease-oriented, outcomes based performance measures.

Take for example the illustrative case of colon cancer screening and quality monitoring. In my medical practice I have personally experienced some well-informed patients who

understand the evidence, guideline recommendations, and the risks and benefits of screening who still personally opt not to partake in colon cancer screening. My patients cite a myriad of reasons as to why they are unwilling to undergo the screening: fear of the test, burdens of the test including the time or discomfort involved, fear of cancer, and the desire to take what life has in store and face it when it comes. Paradoxically, when I apply evidence based medicine and shared decision making, if my patient chooses not to undergo the guideline recommended screening then this patient interaction is not considered to conform to ‘high quality care’. My provider profile would show deficiencies in the area of colon cancer screening with such patients ‘falling out’ on my proficiency report. From afar it appears that I have provided substandard care based on current quality monitoring programs even though I have implemented quality care infused with evidence and patient-centered decision making.

Another question raised by this scenario is how to reconcile that patient centered care may result in a patient choosing care that may be considered ‘substandard’ by current evidence based standards and may even pose potential harm to the patient, such as a missed colon cancer diagnosis. A patient who opts not to undergo colon cancer screening may be forgoing a potentially lifesaving intervention. However based on the patient’s belief structure or values this may be a preferred choice for that individual. In such a situation the balance of the medical ethics of non-malevolence and beneficence versus patient autonomy is at play. When patient autonomy is given preeminence in patient centered care, clinicians will need to accept that decisions made with an empowered, informed, and activated patient will at times lead to outcomes that go against medical evidence which might have led to perceived better outcomes.

It is important to recognize that despite concerns about the limitations of current performance measures for clinical practice, especially in terms of accounting for the

individualized needs of patients, when carefully constructed performance measures remain a useful tool to assess population level quality of care.⁵⁹ There have been proposals to ensure performance measure are designed to meet certain standards to help address some of their deficiencies⁶⁰ and to exclude patients to whom general guidelines may not apply (i.e. the elderly, or patients with multiple co-morbidities).⁵⁸ While a critique of performance measure as a construct for quality assurance is beyond the discussion here, the fact remains that for the present time they are a well-established feature of quality monitoring programs that are likely here to stay for the near future. The pertinent question then becomes how to reconcile providing patient-centered decision making in the context of evidence based medicine while accounting for quality delivery of care.

No consensus for measuring patient centered quality has yet to emerge even with the push to implement patient-centered care and patient-centered medical homes. An important first step in reconciling this dilemma begins with establishing clear definitions of patient-centered communication and delineating how ‘high quality’ decisions are measured. Next, practical concrete patient-centered quality measures must be established. And finally, systemic changes must be made to incorporate patient-centeredness into care delivery structures and to align incentives and reimbursement with the goal of patient-centered care.

Defining Patient-Centered Communication

Defining patient-centered communication is a prerequisite for operationalizing and evaluating the important concepts of shared decision making. Patient-centered communication has been defined to include the following qualities:

1. Eliciting patients values and perspectives

2. Understanding the patient from a psychosocial perspective
3. Reaching a mutual decision concordant with the patients beliefs and attitudes
4. Empowering patients to participate to the degree that the patient desires.⁶

While this definition encompasses shared decision making, for clarity and measurement purposes the concepts need further expansion to elucidate what constitutes a high quality decision. A great deal of debate has occurred around this topic with many definitions offered. Foremost, quality patient centered decisions result in an adequate transfer of knowledge where the patient acquires a clear understanding of the choices and decision to be made. Secondly, the chosen course of action should reflect the patient's values and perspectives. Sepucha et al. offer this definition: *"The quality of a clinical decision, or its patient-centeredness, is the extent to which it reflects the considered needs, values, and expressed preferences of a well-informed patient and is thus implemented."*^{61p.57} Glyn Elwyn et al. recently argued that this definition is inadequate because it lacks clear delineation of the two major components of decision making, deliberation and determination.⁶² A useful definition of decision quality needs to delineate both the process of coming to a decision (deliberation) and the decision chosen (determination), so that these attributes can be evaluated and measured distinctly. It is especially important in situations where the decision may seem at odds with outcome based performance measures that there is a clear distinction between the process of decision making and the resultant decision. Exactly how to operationalize these constructs for measurement and reporting in general practice remains to be clarified and is the topic of ongoing investigation.^{61, 62} It is the key to incorporating patient centered endpoints into quality improvement programs and allow for the inclusion of decision making processes in the definition of quality.

Achieving Individualization: Patient-Centered Communication Quality Measures

Patient-centeredness is currently being measured and reported by national quality monitoring programs. In its report, **The National Healthcare Quality Report (NHQR)**, the Agency for Healthcare Research and Quality includes patient-centeredness among the four reported pillars of quality along with effectiveness, patient safety, and timeliness. The outpatient patient-centered measures are composites based on surveys of patient experience looking at patient perception of providers' listening, clear explanations, respect of patients' viewpoints and time spent with patients.⁵⁷ Additionally, the National Committee for Quality Assurance (NCQA) has established recognition standards for patient-centered medical homes. These standards are evolving and the NCQA acknowledges current limitations in assessing patient-centeredness and patient experience.⁶³ The new 2011 standards expand evaluations of patient-centeredness using a new standardized patient experience survey. However this tool lacks clinical experience and national benchmarking data, so its true usefulness remains to be seen. Also these current reports of patient-centeredness based on patient experience do not focus specifically on patient centered communication and decision making.

Patient-centered care is a multifaceted concept; hence no single approach or method for measuring quality will be comprehensive enough to capture all its essential characteristics. When evaluating patient-centered communication the definitions and constructs should be grounded in theory, making an overt connection between the proposed measure, its theoretical grounding, and the construct it is evaluating. Measures need to be bidirectional to account for the communication of both participants (patients and providers). Because patient-centered communication is based upon eliciting and incorporating patient preference, measures must address the 'informed flexibility' that results from communication that accounts for the context

of individual patients.⁶ Once again it is the process of decision making, not the outcome of the decision that must be measured. Additionally, measures need to employ validated instruments which can assess concordance between patient and physician. Measures that rely on patient self-report should be employed with an awareness of their potential confounding and bias until ongoing research provides better tools that overtly address these issues. Regardless of what measurement or definition is applied, it is the patient who is ultimately the only one able to determine whether or not patient-centeredness has been achieved.⁹

No single clinical indicator can measure patient-centered communication in a simple and satisfying way. Due to the complex nature of the interactions being studied, both implementation and evaluation require the application of complexity theory to provide a framework for evaluating patient-centered communication. Complex interventions necessitate utilization of multi-modal/ mix-method evaluation techniques that employ both qualitative and quantitative analysis.^{27, 64} Validated tools to measure aspects of patient-centered communication have been developed and are being used in research such as: the OPTION scale for measuring the extent which providers involve patients in the decision making process,³² the Lorig communication scale which examines patient activation,³⁸ the COMRADE tool for evaluating risk communication,⁴⁶ or the Ambulatory Care Experiences Survey (ACES) which assesses patient experience with care.⁶⁵ However, these tools were designed to evaluate patient-centered communication during clinical research and cannot be easily adapted for use as quality measurement tools in practice. Measurements of patient-centeredness and decision quality used in research are often too cumbersome to translate for clinical use. They typically involve labor and time intensive methods such as direct observation or detailed pre and post consultation surveys.

Measuring Decision Quality

Developing appropriate clinical patient centered quality measures remains difficult beyond establishing a clear definition or adapting current research methods. Disease oriented outcome performance measures, such as measures of glycemic control or cholesterol levels, do not satisfactorily reflect successfully implemented decision making processes and do not adequately address patient-centered issues. Outcome measures are more relevant on a population level than for individual patients or individual decisions. Distinct measures of patient-centeredness, measures that matter to patients, are needed. Heralding back to the ethical principal of patient autonomy, patient-centered communication can be taken as an end of its own and high quality decision making should be measured independent from the outcome.⁶⁶ The act itself of measuring decision quality draws attention to the importance of patient-centered communication. Measuring decision quality can, in and of itself, actually improve the process of decision making.⁶⁷

Proposed endpoints for measuring patient-centered communication include looking at decision making outcomes such as knowledge, decisional conflict, and patient activation or involvement.⁶⁶ With patients as the key determinants of whether or not care is patient-centered some form of patient self-report is crucial in evaluating patient-centered care.⁶⁸ One suggested format for measuring patient centeredness is a numeric rating scale to assess patient self-report of patient-centeredness similar to scales typically used for patients to report pain levels. This scale would ask patients to rate their perception of the patient-centeredness of care provided on a scale from one to five.⁹ However while numeric scales are useful tools for assessing pain levels, a concept that is relatively straight forward and familiar to patients, the concepts of patient-

centered care are not familiar or intuitive and may be potentially confusing to patients. In developing such a scale for quality monitoring purposes awareness should be given to the likelihood that patient-centered care is not as familiar a concept to patients. Any numeric scale would need to be carefully constructed and studied to assure that it can be easily implemented and adequately reflects important patient-centered and decision quality endpoints.

Current measures of quality based on disease based outcome measures derived from evidence based guidelines promote reduction in clinical variation and increased standardization. However, performance measures should not be solely dependent on an outcome measures that do not reflect the processes patient centered decision making. Performance measures need to acknowledge and account for the individualization of care that results from the application of shared decision making. Ideally comprehensive quality programs designed to account for patient centered care will include measures of the processes involved in patient-centered communication. High quality decisions will be recognized as those that are informed by the evidence **and** successfully incorporate patient values into the decisions.

One proposed approach would be the application of an ‘incorporation standard.’ This incorporation standard has been used in research to evaluate the evidenced based decision making of psychiatry residents and their ability to contextualize general guidelines to individual patients.⁶⁹ Previous definitions of successful decisions which were defined as those which adhered to clinical practice guidelines, presupposing the existence of a predetermined best answer for all patients. In contrast, by evaluating the ‘contextual application of knowledge,’ the incorporation standard allows for the discernment of whether a guideline’s recommendations were simply ignored or rejected versus a conscious decision that a different choice was better for the individual patient. In this study the authors limited their discussion to evidenced based

decision making, focusing on contextualizing the evidence for the characteristics of the individual. They did not overtly address patient activation or the integration of patients' values and perspectives into the decision. Extending the concept of an incorporation standard to encompass patient-centered decision making could be a useful way to distinguish deliberation from determination. The processes of patient centered communication could be accounted for and a theoretical foundation for assessing quality in shared decision making may be found. Yet once again translating this concept into practical application for clinical quality monitoring programs may pose challenges.

Clearly further research and study is required to establish useful clinical measures for assessing the quality of patient-centered communication and quality of decision making.

Incentivizing Patient Centered Care

So while one concern about current quality monitoring programs is that success is defined by outcomes and not patient centered processes, another concern with the current structure of performance measures is their linkage to financial incentives and rewards through pay for performance programs. The disease based outcomes performance measures assess population level quality at the expense of individualized care, dis-incentivizing patient-centered care⁷⁰ and creating a potential ethical conflict.⁷¹ Proponents of patient-centered care highlight these concerns calling for acknowledgment of the perverse incentive created by current the manifestation of pay for performance and appeal for the creation of incentives that foster, instead of inhibiting patient-centered care.^{2, 25, 67, 70} Pay for performance could be restructured to encourage and reward patient-centered care through incentives linked to patient-centered constructs. In its position paper: **Pay-for-Performance Principles That Promote Patient-**

Centered Care: An Ethics Manifesto for the American College of Physicians, the ACP calls for pay for performance to measure and reward what matters to patients.⁷¹ However, the same difficulties exist in aligning pay for performance with patient-centered endpoints as exists for developing patient-centered performance measures. One solution is to look beyond performance measures and uses patient centered guidelines. Clinical practice guidelines can be made more patient-centered by highlighting places of clinical equipoise where shared decision making should be employed for preference sensitive decision points. Patient centered decisions could be linked to pay for performance through an assessment of the application of a decision aid or some other measure that indicates shared decision making occurred. As measures of patient-centered communication are clarified and operationalized, incentives can be linked to decision quality and pay for performance can be re-envisioned as a tool for supporting and encouraging patient-centered care.⁶⁷

Beyond the structure of pay for performance there may be other formats to create incentives for practitioners to provide patient-centered care. One example is by creating enhanced reimbursement for providers who demonstrate competencies in shared decision making and other patient-centered skills. This could be accomplished through a recognition program with some similarities to NCQA's patient centered medical home recognition process or through a registry of providers 'certified' in patient-centered communication.

Creating a medical care system that both expects and supports patient-centeredness will require systemic changes that realign payment structures with the values and activities of patient-centered care. Current fee-for-service reimbursement undermines the essential components of patient-centeredness, including longitudinal patient provider relationships and patient-centered

communication.^{25, 70} Policy makers will need to address these larger systems issues in order for the ideal of patient-centered care to be realized.

Guidelines as Tools for Patient-Centered Care

Besides creating patient-centered quality measures, and aligning incentive for patient centered care, another important approach to bridging the divide between evidenced based medicine and patient-centered care is incorporating patient-centeredness directly into the tools of evidence based medicine, specifically clinical practice guidelines. Currently guidelines are used in shared decision making by providing a synthesis of the current evidence and assisting with the translation of knowledge during the decision making process. However guidelines themselves are generally not patient-centered. Drawn from population level research, they do not adequately reflect the need for medical care to account for patient preferences nor do they account for patient's individual contexts.^{72,73}

To become more patient-centered guidelines could incorporate patients' perspectives explicitly in their development to lend a patient viewpoint to the process. Independent of whether or not this step is taken, in order for guidelines to become more patient-centered they will to incorporate the constructs of patient-centeredness into their recommendations. One approach would be for guidelines to include available evidence about patient preferences. However, critics caution that population based patient preference data encompasses its own set of drawbacks including lack of validity and adding a significant degree of unnecessary complexity and cumbersomeness to guidelines.⁷⁴

A more practical approach is for guidelines to explicitly state when recommendations are preference sensitive and highlight situations of clinical equipoise. By making clear preference

sensitive decision points and including evidence for the risks and benefits, guidelines can aid the deliberation process of shared decision making. The guidelines themselves could even then be used as a decision support intervention⁴⁵ or for more overt decision support, guidelines could be linked to validated decision aids or other tools designed for decision support.⁷² Special attention should be paid to presenting how risk is presented and calls for guidelines to avoid presenting risk as relative risk reduction (which creates potential bias) should be headed.⁴⁹ Ongoing research is exploring how to incorporate patient preferences and values and investigating methods to make guidelines more patient-centered.⁷² The inclusion of patient-centered constructs in guidelines will help close the gap between evidence based medicine and patient-centered care and can aid the shared decision making process.

Conclusion

Shared decision making bridges evidence based medicine with patient-centered care by fusing evidence with patient-centered communication to facilitate decisions that are based on sound medical knowledge combined with an individual patient's values and perspectives. This type of decision making will truly exemplify high quality care once appropriate measures of quality and systems are in place to account for the complex nature of high quality patient-centered decisions.

*The philosophies of one age have become the absurdities of the next,
and the foolishness of yesterday has become the wisdom of tomorrow.*

~ Sir William Osler

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