Clinical Research Awareness Initiative

EXPLORING THE IMPACT OF SHARED DECISION MAKING IN CLINICAL TRIAL CONSIDERATION

TransCelerate BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

SHARED DECISION MAKING & CLINICAL TRIALS

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Abstract

Background/aims:

The number of registered studies on ClinicalTrials.gov has increased five fold in the past decade, yet participation in trials continues to be limited, in part because of the difficulty in weighing options in light of patient preferences. To enable patients to better understand clinical trials as an option, this paper explores shared decision making in patient-provider conversations.

Methods:

To address the objectives, the team followed an iterative process involving literature reviews, interviews with subject matter experts and assessments of existing decision aids and shared decision making training resources followed by feedback sessions with research sites, decision aid developers and training vendors.

Results:

We identified gaps between providing patients with support in articulating their preferences on available options to their healthcare providers and determining the information needed to make satisfying decisions along clinical, social and financial domains. Literature reviews on shared decision making during the patient journey in

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the clinical trial setting suggested an unmet need, specifically the lack of a decision support tool to assist patients and healthcare providers in eliciting patient preferences and values. We propose a set of considerations for shared decision making tool development that incorporates a patient's preferences and priorities along with those from clinical, industry and social stakeholders. We propose a study design that measures the impact of shared decision making and decision support tools on patient experience metrics/patient satisfaction.

Conclusions:

Shared decision making is increasingly recommended in health care and reduces the unbalanced communication between healthcare providers and patients. Extending the benefits of shared decision making to clinical trial consideration could improve patient decision satisfaction and have a positive impact on medicine development. We believe there is a need for creating and testing a multifaceted shared decision making training and decision support package that addresses both the interpersonal and informational gaps in decision making regarding clinical trial participation.

Keywords

shared decision making
patient experience
patient satisfaction
patient preferences
decision support
clinical trial
values clarification
TransCelerate

Introduction

Shared decision making (SDM) in patient-provider conversations is still emerging in application, but may increase in frequency as both research and clinical practice move in the direction of participatory medicine and increased focus on a patient's experience and satisfaction alongside clinical outcomes over time.[1] SDM is collaborative health care communication, which may use specific tools and techniques to engage patients in care decisions by providing balanced, evidence-based information on all options and eliciting patients' values, preferences and goals. While some research has indicated that SDM has the potential to improve patients' consideration of clinical trials, no research has yet investigated using an SDM tool to enable comparisons of all relevant options including research participation.

Patients often make decisions about whether to participate in clinical trials when the emotional and physical stakes are high. Mills et al. reviewed 33 cancer clinical studies with 6000 patients and identified several key barriers to participation in clinical trials: concerns with the trial setting; dislike of randomization; general discomfort with the research process; complexity and stringency of the protocol; presence of a placebo or no-treatment group; potential side effects; lack of awareness of trial opportunities; preconceived notion that clinical trials are not appropriate for serious diseases; fear that trial involvement would have a negative effect on the relationship with their physicians; and their physicians' attitudes towards the trial.[2] This list demonstrates that patients need better information, more effective communication and a framework to weigh the risks, benefits and personal values when considering clinical trial participation. An international survey conducted by CISCRP in 2017 found that over half of the 12,000 participants indicated they would begin their search for a clinical trial by asking their doctors.[3] Physician recommendation to participate in clinical trials is a key deciding factor for patients to overcome the general fear of unknowns associated with the disease, treatment and consideration for clinical trials.[4] This reinforces the notion that doctors are patients' trusted resources and that successful communication between the two parties is essential to address the unique needs during each individual patient's decision-making process.

> ***"Participation in a clinical trial is a very individual choice. . . You really have to examine why you are doing it,"***
>
> — Linnea Olson, lung cancer survivor[5]

In addition to individual patient variation in deliberating options, healthcare providers (HCPs) also vary in their approach to introducing possible participation in clinical trials. First, clinical trials are not available at all clinical sites.[6] Second, HCPs may lack adequate time to gather, evaluate and discuss clinical trial information for trials that may be appropriate for individual patients.[7] Third, HCPs may be selective about which patients to introduce to the idea of clinical trial participation.[8] Fourth, some HCPs perceive discussion of clinical trials as intrusive to the patient-provider relationship.[9] Current practice in real-world decision making for patients often falls short, as patients may not be presented with all relevant options in a way that accounts for patient values and preferences.[10]

> ***"There is a lot of debate about 'is this patient healthy enough for my clinical trial?' and I actually was kind of skeptical because I thought, 'she's coming from hospice, she's got a lot of other illnesses,' but her family, and the patient, wanted something better for her, and so I took a little bit of a risk and put her on a clinical trial..."***
>
> — Dr. Brian Druker, Director of the OHSU Knight Cancer Institute[11]

One mission of TransCelerate BioPharma Inc is to find ways to engage patients and HCPs in clinical trial participation. The consortium explored overcoming existing barriers through a combined approach of awareness and action-based initiatives. In 2018, TransCelerate introduced the One Person Closer campaign by publishing video vignettes of patients, HCPs and researchers sharing their personal stories of participation in clinical trials. TransCelerate also embarked on an effort to engage HCPs' reasoning and decision making to improve trial awareness and referral. The three components of this HCP awareness and engagement campaign are the following:

Emotional

Inspire HCPs to believe in research, both from a patient value and a personal value perspective, leading to greater motivation to become involved.

Cognitive

Help HCPs understand why research is a sensible choice for consideration, using rational arguments and educating them on clinical research and its intrinsic value.

Skill/Resource

Equip HCPs to become skilled advisors to their patients with regard to options and decisions in a simple and effective manner.

To aid in achieving the third goal, a TransCelerate team researched the role of SDM in the clinical trial setting. HCP trainings in SDM for clinical care exist and have been shown to be efficacious in improving the structure of patient-provider conversations. Since 1999, seven Cochrane systematic reviews of SDM techniques and tools have consistently found that their use in clinical care improves knowledge, results in more realistic expectations, lowers decisional conflict, increases patient involvement in decision making and increases agreement between values and choice.[12] When examining the literature, the team found neither HCP training nor tools designed specifically to facilitate conversations related to clinical trial participation.[13, 14] This paper describes an opportunity for creating and testing an SDM intervention that addresses both the interpersonal and informational gaps in ongoing decision making about all options including clinical trial participation.

Methods

To address the objectives, the team followed an iterative process involving literature reviews, interviews with subject matter experts and assessments of existing decision aids and SDM training resources followed by feedback sessions with research sites, decision aid developers and training vendors. The team examined three areas in the literature: SDM in healthcare, patient perceptions of clinical trials and eliciting patient preferences and values clarification in health care settings.

The team interviewed staff at academic research sites and cancer centers to learn the tools, processes and considerations used to identify relevant treatments and clinical trials, as well as to facilitate the decision-making conversation with individual patients when assessing appropriate options. The team also met with decision aid vendors to learn about the time and technical issues involved in developing decision aids and related training, distributing them for use among patients and physicians and assessing their impact on patient outcomes.

Results

Reviewing the literature for potential ways to pair SDM with the patient journey in the clinical trial setting revealed how little has been done, the unique set of information and support needs described by patients and gaps that could become opportunities to improve existing approaches.

The team observed that there are two components to patient decision making. The first is having an array of options to consider for which the patient may be eligible and the second is having an evaluation framework that helps patients consider the options according to their values, preferences and goals of care.[15, 16] The team noted that there are several approaches underway related to the first component through physician workflow products such as Roche's NAVIFY Tumor Board, which integrates active clinical trials among the array of options physicians present to patients, and Cota's Cota Nodal Address (CNA) system, which stratifies patients for treatment recommendations based on "prognostic attributes."[17, 18]

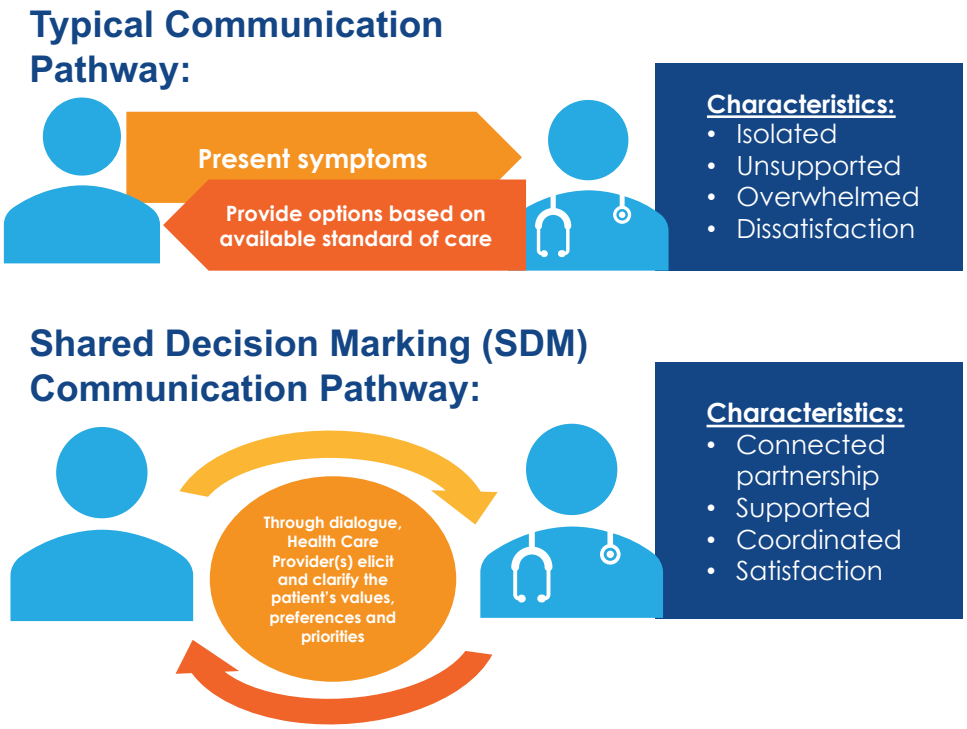
The team identified the following gaps related primarily to the latter decision-making component concerning values clarification:

1. There is no decision aid or related SDM training that allows physicians to present patients the full array of clinical treatment and trial participation options.
2. There is no decision support tool that enables patients to articulate and document their preferences about available options in their medical record and to determine the information they need to make informed decisions throughout their care along clinical, financial and social domains.

3. There is no prior research pairing either a decision aid or a values clarification tool in a healthcare setting where clinical trials are among the options.
4. Research sponsors are not consistently tracking patient and HCP satisfaction with the clinical trial participation decision using validated outcome measures.

The team has focused on bringing attention to these gaps by illustrating a SDM communication pathway as the desired future state (Figure 1), capturing the dynamic and iterative nature of the process. The team further explored the patient's "decision journey" when considering options. The SDM communication pathway would foster a sense of partnership between the patients and the HCPs. Through discussions with research sites, patient advisors, HCPs, decision support tool vendors and pharmaceutical development sponsors, the team illustrated the role of values clarification and elicitation where patient preferences are the evaluation mechanism for patients and HCPs to assess appropriate options including available clinical trials at a given institution (Figure 2). The team noted a call to action for research to examine the impact of an SDM intervention.[19] This paper explores how employing a formal SDM process and providing decision support for patients at the site level may produce measurable improvements in patient and HCP satisfaction with clinical trial considerations compared to a traditional communication pathway. A secondary question is whether operational metrics for enrollment and retention can be attributed to changes in patient and HCP satisfaction.

Figure 1. A shared decision making (SDM) communication pathway



Limitations and considerations

1. This work has not considered interventions such as medical devices, surgeries, etc.
2. While the team believes SDM has applications for clinical trial participation decision making across therapeutic areas, much of the literature available for review referred to oncology treatment or research settings.
3. The team determined that specific decision and support tools should be developed by an independent organization to avoid the perception of a research sponsor's conflict of interests in characterizing options for patients.

Discussion

Integrating clinical trial participation into the SDM conversation is a complex process, with two key aspects. First, the array of options for which the patient may be eligible may include established standards of care as well as available clinical trials, which vary in terms of what is being studied and where. Second, there is the process of the patient articulating his/her values, preferences and goals to his/her care team; documenting these preferences in the patient's record; and then using that lens to evaluate each option as it becomes relevant over time.

Practicing SDM offers patients and HCPs the opportunity to seek and consider appropriate research participation options throughout the entire continuum of a patient's care.[20] Additional stakeholders, including the research sponsor, third-party developers of clinical decision support tools, HCPs and research site staff, can align to provide decision support. This discussion explores the role that each of these stakeholders can play to facilitate meaningful patient-provider dialogue and to measure the impact of SDM interventions on the patient's satisfaction with decisions involving clinical trial participation.

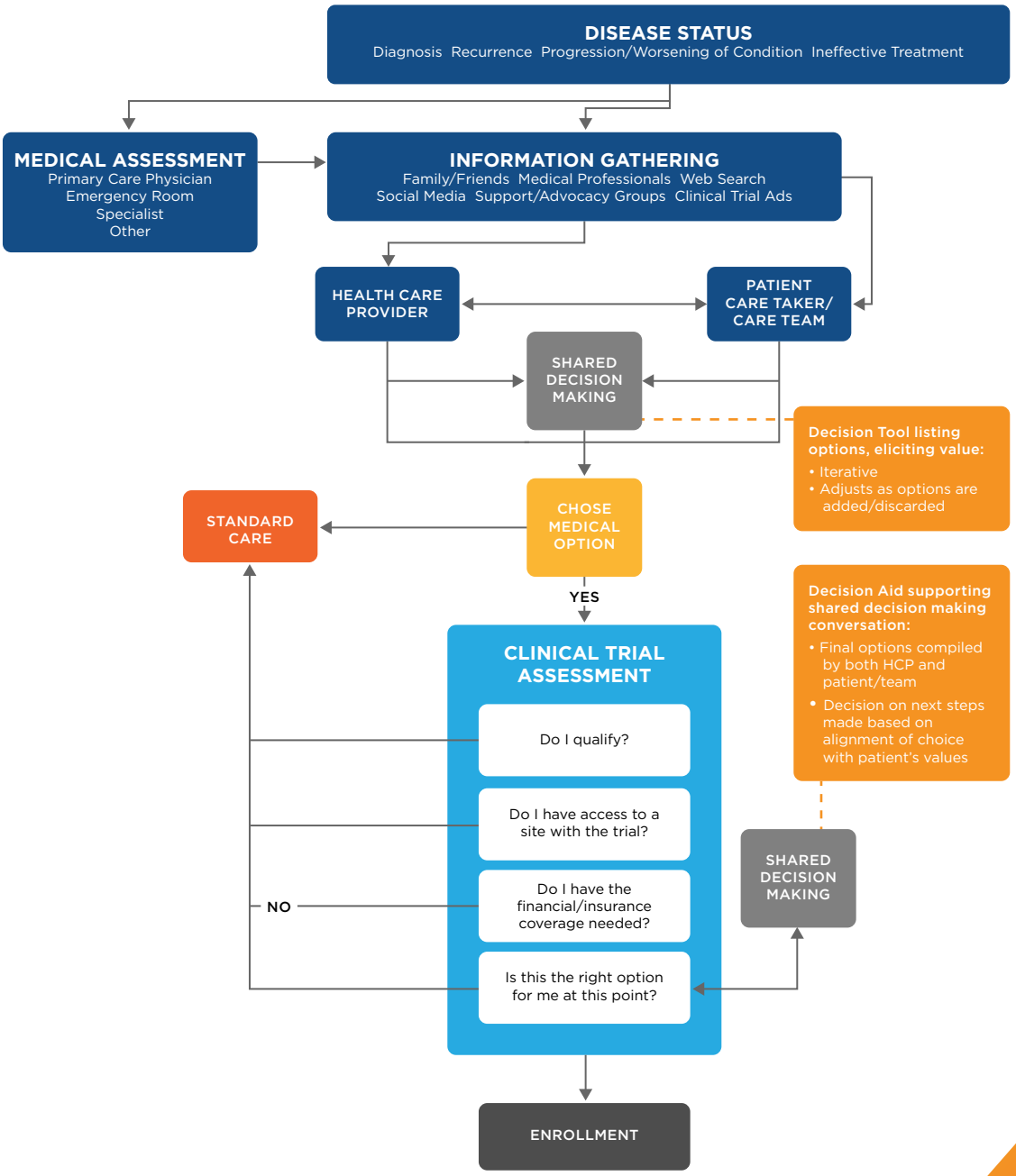
Patient considerations

The Patient Journey Decision Tree (Figure 2) illustrates the dynamic nature of the patient's decision-making process with patients considering what is best for them among the array of available options under changing conditions in their health status. While the literature describes many barriers, it indicates that patients seek to answer the following questions along clinical, financial, convenience and social domains to arrive at a decision about research participation[21]:

1. Do I qualify clinically?
2. Can I afford it financially?
3. Is it convenient?
4. Is this the right option for me right now? (decision point including social influences)

Patients seek to answer these questions as fully as possible relative to available standards of care, not only to determine which option is best suited for them at a given point in time, but also to remain engaged in their care planning as both disease status and available options evolve.[20, 22] These priorities are consistent with those reported in more general research about health care consumer decision making.[23]

Figure 2. Patient journey decision tree



Sponsor considerations

By focusing on the patient-provider conversation and decision support, sponsors may be able to include patient-centered outcome metrics related to patient experience alongside operational metrics such as enrollment. For example, "Recruitment" materials may become "Decision support materials," containing not only the clinical but also the financial and convenience-based information patients are seeking (Figure 2). Sponsors, including industry, academic researchers, large healthcare organizations or any researchers, can measure the impact of these materials on the patients' perception of the clinical trial consideration process with their HCPs, referral experience to the investigative site (if a clinical trial is selected) and subsequent decision satisfaction.

The team explored a study design to examine the impact of an SDM intervention on a patient's satisfaction when choosing among therapeutic and clinical trial options (manuscript in development). A key aspect of study design is determining what outcome measures to include with a goal of generating useful data that can be compared to data from other similar studies and develop a body of knowledge that informs clinical trial researchers and industry. The proposed study's outcome measures include validated instruments for decisional conflict prior to the patient's decision and for decision regret at a post-decision time point.[24, 25] Systematically measuring these outcomes across populations may help research sponsors and sites make decisions that are better aligned with individual patient preferences.

Decision support development considerations

The International Patient Decision Aids Standards (IPDAS) Collaboration recommends standards for decision aid developers to follow. In our discussions, decision aid developers observed that integrating clinical trial options into decision aids may be difficult because they vary from institution to institution and change frequently via protocol amendments and site availability. Therefore, adding clinical trial options to decision aids has the potential to decrease the shelf life of a given tool and its related training, making maintenance of the materials more resource-intensive than decision aids that include only more static, guideline-driven treatment options.

One priority for developers could be a values clarification tool that is compatible with the treating institution's electronic health records and clinical workflow systems. The vision would be a tool that allows HCPs and/or patients themselves to regularly document their preferences and assessments of their options via free text and narrative functions within the patient's electronic health record. This type of functionality would complement the institution's clinical decision support system,

ensuring that patients and HCPs are able to consider all options, including clinical trial participation, as they become available during the patient's care and evaluate them for how well they meet the patient's clinical circumstances and personal preferences.

Site and HCP considerations

Sites and HCPs may address the gap in using patient preferences to consider therapeutic and clinical trial options by including SDM interventions among their patient counseling, referral and care coordination services.[22] Research sites may work with sponsors to identify and use validated decision-related outcome measures to study the impact of SDM initiatives on overall patient experience and, specifically, the experience of people offered clinical trial participation among their options. Research site staff should consider SDM training to help patients explore and compare the potential benefits and risks associated with each available option including clinical trial participation.

Conclusions

Clinical trials have been and will continue to be fundamental in fostering the development of novel treatments in medicine and for understanding disease mechanisms. Given that participation in clinical trials continues to be a challenge to the drug development process, there is an unmet need for a platform to discuss clinical trials as a part of the continuum of options available to patients. This objective is in line with the current movement towards a patient-centric drug development process.

While patient experience data is not yet explicitly required by regulatory agencies, initiatives such as the FDA's Patient Focused Drug Development (PFDD) encourage collection of this data. PFDD aims to ensure that patients' experiences, perspectives, needs and priorities are captured systematically and incorporated meaningfully into drug development and evaluation with particular focus on approaches that facilitate patient enrollment in clinical trials while minimizing patient burden and providing information that is most important to patients related to treatment benefits, risks and burden in a way that supports their decision making.[26]

Our gap analysis showed an unmet need with respect to the use of a decision support tool that assists patients and providers to elicit patient preferences and values as they relate to participating in a clinical trial as a potential option. To be truly patient-centric, the SDM tool should be able to incorporate the patient's preferences and priorities along the clinical, financial and social domains. All these factors would be attributed weightings to help determine how each option impacts the patient's goals

over the entire term of his/her care. The development of SDM tools for the purposes of improving conversations should be co-created with patients, HCPs, SDM experts, technology providers and the health care industry.

SDM is one of many levers that can be utilized to increase conversations about clinical trials. For instance, initiatives promoting clinical trial awareness, access, and navigation (such as the TransCelerate One Person Closer campaign) will have synergistic effects. Integrating SDM along with the other initiatives should have a positive impact on the dual goals of executing and accelerating the development of medicines while also improving patient experiences.

Disclaimer

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