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NARRATIVE REVIEW

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Patient autonomy and shared decision-making in the context of clinical trial participation

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Abstract

Aims: This study aimed to explore how incorporating shared decision-making (SDM) can address recruitment challenges in clinical trials. Specifically, it examines how SDM can align the trial process with patient preferences, enhance patient autonomy and increase active patient participation. Additionally, it identifies potential conflicts between SDM and certain clinical trial aspects, such as randomization or blinding, and proposes solutions to mitigate these issues.

Materials and Methods: We conducted a comprehensive review of existing literature on patient recruitment challenges in clinical trials and the role of SDM in addressing these challenges. We analysed case studies and trial reports to identify common obstacles and assess the effectiveness of SDM in improving patient accrual. Additionally, we evaluated three proposed solutions: adequate trial design, communication skill training and patient decision aids.

Results: Our review indicates that incorporating SDM can significantly enhance patient recruitment by promoting patient autonomy and engagement. SDM encourages physicians to adopt a more open and informative approach, which aligns the trial process with patient preferences and reduces psychological barriers such as fear and mental stress. However, implementing SDM can conflict with elements such as randomization and blinding, potentially complicating trial design and execution.

Discussion: The desire for patient autonomy and active engagement through SDM may clash with traditional clinical trial methodologies. To address these conflicts, we propose three solutions: redesigning trials to better accommodate SDM principles, providing communication skill training for physicians and developing patient decision aids. By focussing on patient wishes and emotions, these solutions can integrate SDM into clinical trials effectively.

Conclusion: Shared decision-making provides a framework that can promote patient recruitment and trial participation by enhancing patient autonomy and engagement. With proper implementation of trial design modifications,

communication skill training and patient decision aids, SDM can support rather than hinder clinical trial execution, ultimately contributing to the advancement of evidence-based medicine.

KEYWORDS

communication skills training, patient autonomy, patient decision aids, shared decision-making, trial design, trial participation

1 | INTRODUCTION

Patients and clinicians constantly await new and better treatment options improving outcomes and reducing side-effects. Evidence-based medicine (EBM) is the desirable foundation for clinical decision-making and requires high quality medical knowledge.[1] To achieve high level of evidence, clinical trials are essential to compare treatment options and validate new approaches. An adequate number of participants is crucial to perform good quality clinical trials. However, the willingness of trial participation may be limited with patient recruitment often being critical and numerous trials being closed early due to low accrual.[2] Reasons for low trial participation include inadequate information about the process of trial attendance, a higher (financial or logistical) burden compared to standard of care or patients' fear of the unknown.[3]

Patients have individual wishes, beliefs and expectations and have an active role in the clinical decision-making of their disease, which may stand in contrast to rigid protocols, randomization or blinding procedures that go along with clinical trials.[4] To address the individual patient's preferences and assign an active role to the patient, the communication between healthcare providers and patients ideally occurs within shared decision-making (SDM). In SDM the physician openly and transparently addresses the different options and includes patients' preferences and needs. Worrisome patients can be encouraged to participate without an increased risk of decisional regret. Patient autonomy in SDM plays an important role to remove barriers and increase awareness of personal preferences.

This review addresses challenges that arise from the competing interest of supporting patient autonomy and SDM on the one hand and promoting trial recruitment on the other hand. We want to create awareness for this problem, as awareness may promote trial inclusion of well-informed patients, while decreasing dropout rates and decisional regret. Furthermore, we want to discuss trial design, communication skills training and patient decision aids (PtDAs) as possible solutions to overcome these challenges.

2 | CLINICAL TRIALS AS THE FOUNDATION FOR EBM

Ideally, clinical decision-making is based on EBM, as introduced in 1992 by Guyatt et al.[5] Rationalism investigated a pathophysiological cause to diseases, deducting treatment rationales upon it. This principle led to an objective rating of clinical research, in terms of levels of evidence[5] allowing a more differentiated and transparent appreciation of evidence (Table 1).[6] Grading of recommendations based on the underlying level of evidence became crucial when developing clinical guidelines.[7]

Knowledge for EBM is based on the results of clinical trials. To ensure valuable and reliable results, high quality studies with sufficient participants are required and patient accrual is crucial.

2.1 | Problems and challenges of clinical trials as foundations of EBM

Studies and systematic reviews found that clinician behavior is one of the most relevant factors defining patient accrual in clinical trials[8,9] Other factors include patient preference for another treatment, concerns about increased time requirements and suboptimal

TABLE 1 Levels of evidence, adapted from Sackett et al.[6] RCT—randomized controlled clinical trial.

Level of evidence	Type of study
1a	Systematic reviews and meta-analyses of randomized controlled clinical trials (RCT)
1b	Individual RCT
2a	Systematic reviews of cohort studies
2b	Individual cohort studies and low-quality RCTs
3a	Systematic reviews of case–controlled studies
3b	Individual case–controlled studies
4	Case series and poor-quality cohort and case–control studies
5	Expert opinion based on clinical experience

communication. The reasons include inadequate communication with lack of time and missing transparency, leading to refusal or decisional regret and high dropout rates.[10] Besides a missed opportunity to implement new findings, funding can be lost and the collected data may never be sufficiently analyzed.

Findings generated by randomized controlled clinical trials (RCTs) are frequently criticized for their limited external validity. Outside the context of the study, physicians need to transfer research findings to clinical cases, where deviating clinical scenarios need to be addressed. The population in a RCT often does not mirror the target clinical patient population but tends to be younger and show less comorbidities.[11] Furthermore, high level evidence-based guidelines usually provide general recommendations, while the treating clinician needs to incorporate more individual, case-specific patient-related information, for example, needs to evaluate fitness, comorbidity, and personal preference, to find the most suitable treatment. This can lead to differences in treatments between similar clinical scenarios.[12] Decision-making in these highly individual and specific situations gets complicated by the fact that different institutions may use decision criteria not integrated into the decision-making by others—so called insular criteria.[13] This phenomenon may explain why two experts may propose two different treatment plans to a patient, based on the same clinical information and evidence-based knowledge. Individual factors affecting the choice of treatment options include factors such as the availability of specific devices, treatment reimbursement or simply geographical location.[14,15]

RCTs are irreplaceable to obtain Level 1 and Level 2 evidence (Table 1) and therefore proper design in conduction and data collection of studies is crucial. However, suboptimal study design may be reason for trials to be prematurely closed[16] or adverse events may be reported poorly.[17] This may arise concerns and influence SDM.

3 | SDM

Several attempts at defining 'SDM' have been made.[18] Among the first and most cited is the definition of Charles et al. from 1997.[19] Their model of SDM originates from an oncological setting with different equally viable treatment options available. It defines the exchange of information between patient and physician to find an agreement for the preferred treatment as a key feature of SDM. Initially, an equal partnership between physician and patient was pursued.[20] Nowadays the patient is primarily the responsible decision maker consulted by health professionals.

From an ethical point of view, the involvement of patients via SDM is favorable, since the patient is the one who must bear the consequences of the decisions. This is especially of concern when patients are treated within clinical trials with unknown benefits or even potential disadvantages of different treatment options. Patients want to actively collaborate with the health care provider in the decision-making process.[21] There is some evidence, showing that SDM might have a positive effect, mainly on affective-cognitive, but also on behavioral and health outcomes.[22] A systematic review from 2008 analyzed the effect of SDM-intervention in a group of 11 heterogeneous RCTs.[23] In six of these trials a positive effect of SDM was recognized. The better outcomes of the SDM groups regarded patient satisfaction, psychological and physical well-being, and treatment adherence. The authors assume a beneficial role of SDM especially in medical situations where long-term decisions need to be made and where long-standing relationships between physician and patient are present.

For SDM to be effective, the patient and the physician need to active. Both share information to collaborate in a partnership to find the best treatment option. To do so, the health care provider needs good communication skills and a profound knowledge of the individual situation. Additionally, the patient's wishes and values need to be taken into consideration.

Despite its positive effects, SDM is accompanied by challenges and has some limitations (Figure 1).

3.1 | Aspects of SDM

Prerequisites for the application of SDM include good communication within a functional physician-patient-relationship, skilled physicians and sufficient time.[24,25]

Overall, time restrictions are the most often reported barrier.[26] Furthermore, there may be medical conditions such as dementia or cognitive impairment, where the application of SDM is complicated.[27] In many situations there is also a lot of uncertainty regarding benefit, side-effects, and risks of different treatment options. Confronting patients with these uncertainties can induce confusion an anxiety and may overall lead to less decision satisfaction.[28] There is also a certain percentage of patients, who do not want to play an active role in the decision-making process.[29] Therefore, individual assessment of the patient's wish to participate in decision-making is crucial.

3.2 | The conflict between patient autonomy and trial participation

Clinical trial participation adds further complexity to the decision-making process. Several factors need to be

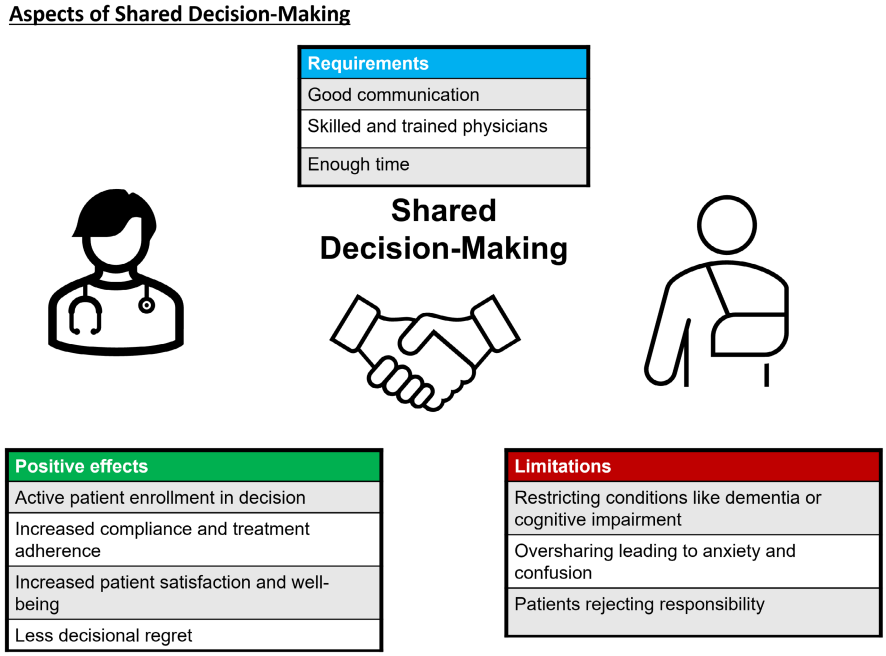

FIGURE 1 Requirements, positive effects and limitations of shared decision-making.

considered which are related, both to the treating physician and to the patient. In general, the majority of physicians expects an improved quality of care for enrolled patients,[30] as well as a potential benefit for the patient by early access to novel therapies. However, there are also several aspects which make physicians reluctant to enrol patients in a clinical trial: trial enrolment is associated with an increased administrative workload[30,31] often without appropriate incentives or compensations.[32] Additionally, in some situations physicians may favor a specific treatment arm in a randomized trial[32,33] and want to avoid randomization to the less preferred arm. Furthermore, trial availability at the patient's cancer center and strict inclusion criteria in many trials are cited as some of the most common structural barriers for the treatment within a clinical trial.[32]

Conflicts between patient autonomy and trial participation often occur when the patient already has a specific preference. Clinical trials, especially RCTs, often have uncertain outcomes. Participants might be assigned to the experimental group or the control group (which might receive a placebo). This uncertainty clashes with the preference of a patient who wants a particular treatment option. Furthermore, misconceptions are not uncommon. Some patients might believe that participating in a clinical trial will guarantee them the best possible treatment, not understanding that the trial's main purpose is often to gather data on the safety and efficacy of an intervention. In any case, clinical trials come with a lot of information including protocols, potential side effects, the structure of the study, follow-up requirements, etc. potentially leading to information overload.

4 | SOLUTIONS

While the reconciliation of trial accrual and promoting patient autonomy within SDM is certainly challenging, there are some possible solutions we want to discuss in the following (Figure 2).

4.1 | Solutions for promoting SDM and patient autonomy

4.1.1 | Trial design

Clinicians and researchers should be aware of the potentially competing interests between patient autonomy and trial participation. Ideally, this should already be addressed when the trial is designed.[34] Concepts like randomization and blinding within clinical trial may be necessary from a methodological point of view, but those may restrict patient autonomy and patients cannot be informed if they are treated with a drug or placebo causing insecurity. While different treatment arms within a randomized trial may appear medically equivalent (based on the available knowledge), they may involve quite different procedures.

Within a clinical trial there may exist evidence for different, medically equivalent therapies, though that does not mean that the various options are all equivalent for the patient. This makes the conduction of some trials very difficult. As for example, in early-stage nonsmall cell lung cancer, there are basically two different oncological treatments available: surgery and stereotactic body radiation

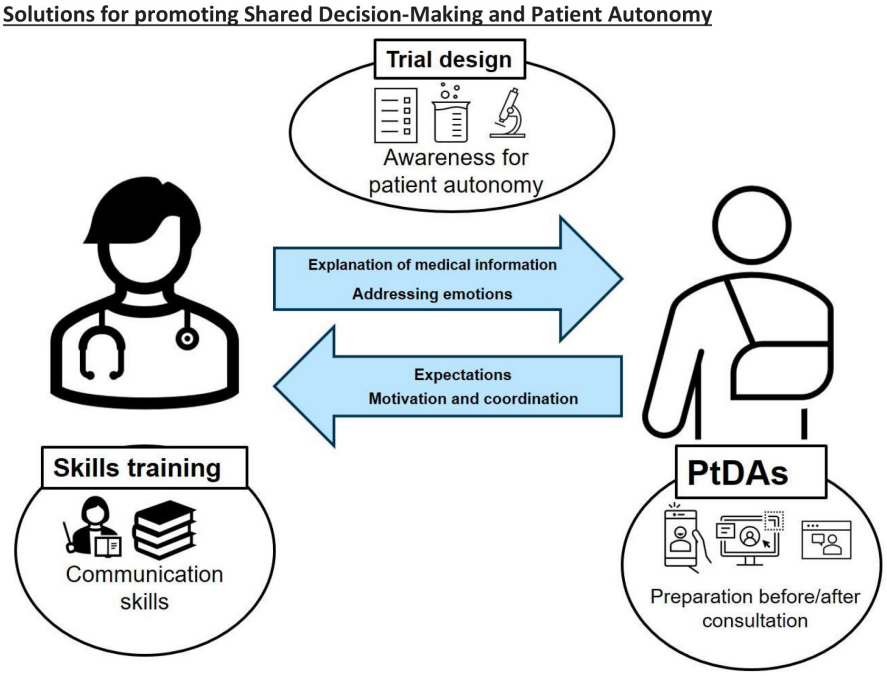

FIGURE 2 Trial design, communication skills training and patient decision aids as possible solutions.

therapy (SBRT). There has been great interest in obtaining high-level evidence on which treatment leads to a better oncological outcome and two RCTs[35] have been initiated. However, both trials closed early due to poor accrual of patients. While there has been a meta-analysis of the results of both trials the question on which therapy is better for treatment, remains unresolved. Keeping in mind the patients' demand for participation in the decision-making, it is understandable that patients do not want to be randomized to either surgery or SBRT. While from an oncological point of view, according to current knowledge both treatments are reasonable and potentially equivalent, the two treatments have very different implications regarding procedure and possible side effects for the patient.

While adequate trial design may not overcome such problems, researchers should be aware of them to plan what questions with which methodologies can be realistically answered.[34] Additional effort for the patient due to trial participation should be kept as low as possible to minimize the entrance bar for participation into clinical trials.[36]

4.1.2 | Communication skills training

SDM and explaining complex concepts of medical evidence and clinical trials requires physicians to have good communication skills. Good communication skills are not just passively acquired by physicians over time, but they are actively learned.

A recent multicenter RCT analyzed the effect of a skills training for oncologists on SDM in palliative treatment.[37] The training of the physicians (duration of 10 h) led to improved observer- and patient-reported SDM. A short communication course for physicians and research nurses also led to improved quality of informed consent and better understanding of patients for the main aim of a clinical study in a RCT of Hietanen et al.[38] There are a number of other examples for studies, in which it had been shown that a communication skills training for physicians can improve patient satisfaction and health literacy among a variety of different medical conditions.[39,40] A systematic review by Occa and Morgan[41] mentions several benefits of communication training programs, among others a potential higher rate of patient accrual to clinical trials.

4.1.3 | PtDAs

Medical decisions, including trial participation may be supported with materials and media assistance such as PtDAs. PtDAs are tools that can be used to inform in advance or reflect and confirm decisions. A patient-centered recruitment is ethical, medically valuable and guarantees a self-regulated patient with a reduced potential for decisional regret, also potentially preventing trial dropout.[42]

PtDAs are supposed to complement the physician consultation, either prior to the appointment or afterwards. PtDAs are divided in simple and detailed instruments whether they contain a straightforward information or a pool of information and facts leading to diverse choices. They can occur in many variations such as apps, web-based tools, videos or also in written form. PtDAs should contain facts and information, based on medical evidence, standard of care procedures,

Promoting trial inclusion while respecting patient autonomy

Prerequisites	Limitations	Possible Solutions
Motivation to participate in (randomized) trials	Inequality of treatment procedures Additional effort	Addressing patient's autonomy and wishes in trial design
Detailed information of patients	Time restrictions complexity of situations	Supporting information process with PtDAs
Good communication between physician and patient	Psychological influences	«Open communication» Communcation skills training
Empowered patients being able to make decisions	Lack of motivation and/or coordination	Recognizing patient's wishes and thoughts, education of patients

FIGURE 3 Prerequisites, limitations and possible solutions for promoting trial inclusion while respecting patient autonomy.

recommendation from guidelines as well as nondisease specific aspects such as personal preferences or psychological issues. Different frameworks were developed by the International Patient Decision Aid Standards and criteria for the PtDAs to ensure minimal requirements.[43] Ensuring quality means providing an objective tool for decisional help, not biased by the physicians' advice. PtDAs give patients the opportunity to prepare prior or post to an appointment by providing an open-access, easy understandable, transparent and straightforward information framework.

Patient groups using decision aids have been shown to have a higher match between their chosen option and what mattered most to them, due to improved knowledge.[44] In this study, the value-choice-agreement was improved in the PtDA group compared to the control group and less patients were indecisive.

While patients are often insufficiently informed prior to trial inclusion,[45] PtDAs can help to reduce this gap. In a study by Politi et al. it has been shown that patients that used PtDAs in the form of web-based tools were better informed about the trial participation and their preference-specific choice.[46] However, there was no difference in trial participation rates compared to the standard care group. On the other hand, a study concerning breast cancer prevention showed potentially increased knowledge and reduced decisional regret about clinical trial participation.[47]

While PtDAs alone may not necessarily increase trial participation, they can be a valuable addendum to promote patient autonomy and support in the (shared) decision-making.[42]

5 | CONCLUSION

This review is meant to establish awareness of the problem of trial recruitment and attract attention to the diverse issues. Since the patient's influence has grown in the last decades from paternalistic, physician-centered decisions over SDM with increased self-responsibility to patient autonomy, consultation and patient recruitment must be adjusted accordingly. We believe it is the best approach to communicate this conflict very openly with patients who are potential candidates for trial inclusion.

5.1 | Promoting trial inclusion while respecting patient autonomy

While the limitations will not be solved easily, awareness of the problem will improve trial design and implementing open communication and transparency with including patient preferences (Figure 3), hopefully lead to better patient autonomy, higher participation (without regret) and lower dropout rates, resulting in enhanced research. We believe implementing PtDAs may help in preparation and conduction throughout the trial.

AUTHOR CONTRIBUTIONS

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The authors declare no conflict of interest.

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Not applicable.

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