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Development and testing of shared decision-making interventions for use in emergency care: A research agenda

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Abstract

Decision aids are evidenced-based tools designed to increase patient understanding of medical options and possible outcomes, facilitate conversation between patients and clinicians, and improve patient engagement. Decision aids have been used for shared decision-making (SDM) interventions outside of the ED setting for more than a decade. Their use in the ED has only recently begun to be studied. This article provides background on this topic and the conclusions of the 2016 Academic Emergency Medicine consensus conference SDM in practice work group regarding “Shared Decision Making in the Emergency Department: Development of a Policy-Relevant, Patient-Centered Research Agenda.” The goal was to determine a prioritized research agenda for the development and testing of shared decision-making interventions for use in emergency care that was most important to patients, clinicians, caregivers, and other key stakeholders. Using the nominal group technique, the consensus working group proposed

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prioritized research questions in six key domains: (1) content (i.e., clinical scenario or decision area), (2) level of evidence available, (3) tool design strategies, (4) risk communication, (5) stakeholders, and (6) outcomes.

Introduction

The formal study of shared decision-making (SDM) in the emergency department (ED) has only recently begun.[1] Given the many therapies, diagnostic tests, and clinical pathways available for use in the ED, there are often clinical scenarios in which more than one course of action is medically reasonable. In scenarios such as these, clinicians can engage patients in SDM by: (1) sharing information regarding potential options and their associated risks, benefits, and outcomes, (2) deliberating with patients (and/or their surrogate), and (3) deciding together on the best option for the patient given their values, preferences, and circumstances.[2] This process can occur informally, via conversation, or in a more standardized fashion using patient decision aids (also known as decision support interventions).[1]

Decision aids are evidenced-based tools designed to increase patient understanding of medical options and possible outcomes, facilitate conversation between patients and clinicians, and improve patient engagement.[3] Decision aids have been used for SDM outside of the ED setting for more than a decade.[3] The first randomized clinical trial conducted in the ED, however, was conducted relatively recently.[4] In a study comparing use of a decision aid to usual care demonstrated that SDM for patients with low-risk chest pain led to greater patient knowledge and satisfaction, fewer admissions for cardiac stress testing, and no difference in the rate of adverse cardiac events.[4,5] Further studies investigating the development and testing of decision aids to facilitate SDM in the ED for the management of pediatric and adult blunt head trauma as well as low-risk chest pain are ongoing.[4,6–8] Further research is needed to identify which clinical situations are best suited for SDM and what methods are best regarding the SDM process, as well as to develop and test SDM interventions in the ED.

The objective of our task force was to develop a prioritized research agenda outlining important study questions to guide future investigations pertaining to the development and testing of SDM interventions in the ED.

Methods

Starting in the summer of 2015 we convened a multidisciplinary task force of emergency clinicians, health service researchers, patient representatives, and decision aid designers with experience in SDM to create a research agenda for the development and testing of SDM tools in the ED. The research agenda was developed for the 2016 Academic Emergency Medicine consensus conference “Shared Decision Making in the Emergency Department: Development of a Policy-Relevant, Patient-Centered Research Agenda” held in New Orleans, Louisiana on May 10, 2016. The task force discussed the framework for the research agenda and developed research questions via monthly conference calls, regular email communications, and in person meetings at the consensus conference. The task force

proposed an initial list of 43 key research questions and divided into six broad domains: (1) content, (2) level of evidence available, (3) tool design strategies, (4) risk communication, (5) stakeholders, and (6) outcomes. Individual members of the task force were then assigned to categories based on their interests and areas of expertise.

At the consensus conference, 35 attendees representing patients, funding agencies, emergency medicine, pediatrics, research, and public health with roles ranging from medical student to attending physician to program managers participated in our break out session on developing and testing SDM in the ED. Attendees broke up into sub-groups based on interest and expertise, had multiple rounds of discussion, and used a nominal group technique (consensus-building methodology involving structured, iterative rounds of input to identify, review, prioritize, discuss, and reprioritize research domains and questions) to develop a prioritized research agenda proposed in this consensus document and listed in the sections below.[9,10]

Results/Discussion

I. Content

Broad Question: *Which clinical scenarios are most appropriate for the use of SDM in the ED?—*SDM is likely appropriate in clinical scenarios which meet at least one of the following criteria: (1) equipoise of risk and benefit, (2) a high-risk intervention with uncertain or variable efficacy,[11] (3) invasive, low-yield interventions, or (4) lack of definitive evidence regarding the optimal choice. A recent study identified a number of areas where emergency clinicians feel that SDM is appropriate.[12] However, little empirical data exist regarding the current use of SDM. Table 1 highlights clinical scenarios in which SDM may be appropriate.

Research regarding the effectiveness of SDM can take two general directions: scenario-specific interventions and general interventions. The former is most recognizable in the medical literature (e.g., the development and implementation of a decision aid for admission versus discharge for patients with low risk chest pain), but the latter (such as policy and educational interventions) may also play an important role in the general uptake and use of SDM by emergency clinicians.

Priority Research Questions:

- For which medical decisions do ED patients want to engage in shared decision-making?
- For which medical decisions do other stakeholders believe the use of SDM has value?
- What is the best strategy to minimize contamination of the intervention in ED SDM research?
- What information do stakeholders believe is important to include in a decision aid?

II. Level of evidence available

Broad Question: *What is the role for SDM in high uncertainty or low-evidence settings?—*SDM may be appropriate in both high- and low-evidence scenarios. High-evidence scenarios are those in which high-quality evidence exists, but clinical equipoise remains, or the trade-offs between risks and benefits warrant patient input. Examples include disposition for low risk chest pain patients, computed tomography (CT) for minor head trauma, lumber puncture for SAH after negative head CT, and intravenous fibrinolytics for acute ischemic stroke. High-evidence scenarios (with complicated risk/benefit tradeoffs) present a challenge to clinicians because of the need to interpret and explain complicated risks and benefits to patients. Because of this, research involving the development and testing of decision aids is particularly relevant to these types of scenarios.

Low-evidence scenarios may be more common in daily practice, as individual patients often do not conform perfectly to inclusion criteria of published research studies, or specific clinical scenarios may not have been studied. Discussions regarding the aggressiveness of care at the end of life can be considered low-evidence in many instances, as emergency clinicians may not have enough evidence at the time of treatment to prognosticate accurately. [ADD GROUP 5, MANUSCRIPT PALLIATIVE CARE AND GERIATRICS REFERENCE HERE] Treatment decisions, such as how to optimally manage acute pain (non-steroidal medications, opiates, ketamine, nerve blocks), could also potentially be considered in this category. Decision aids may be appropriate for some low-evidence scenarios and could facilitate patient education and communication, despite uncertainty and lack of high quality data.

While further research may close information gaps for some low-evidence scenarios, researchers should consider developing and testing interventions that promote SDM outside of traditional high-evidence scenarios. An undue emphasis on the need for high-quality information may detrimentally affect use of SDM by devaluing it as a process of mutualistic decision-making and discouraging the use of SDM in scenarios that are not clearly delineated by clinical evidence.[13] While little experimental evidence exists regarding the risks and benefits of the sharing of uncertainty in the ED context, there is general agreement that clinicians should acknowledge uncertainty and transparently discuss it with their patients. The ideas that emerge from this dialogue have been referred to as “shared-mind” – a collaboration and understanding between clinicians and patients and families that improves decision-making.[14]

Priority Research Questions:

- What is the best method for the communication of certainty and uncertainty between clinicians and patients in the ED?
- What are optimal tools and approaches to facilitate patient engagement and SDM in low-evidence scenarios?

III. Tool design strategies

Broad Question: *How can SDM tools best be developed for use in the ED?—* Although decision aids are prevalent and well-studied in the outpatient clinical setting,[3] those designed specifically for use in the ED are relatively uncommon, and few have undergone formal evaluation.[1,5,8,15] In the outpatient setting, best practices for decision aid development include iterative refinement and adaptation to the local setting, with the goal of using the decision aid to create a conversation between the clinician and the patient.[2] Specific developmental steps include (1) review and synthesis of the evidence, (2) analysis of usual practice, (3) development of an initial prototype, (4) field testing by patients and clinicians, and (5) successive iterations and refinement based on end user feedback and the quality of the conversation the tool promotes.[16] This design strategy has been used for ED-based decision aid development as well.[5,6,8] Internationally, there are accepted standards for systematic and transparent development of decision aids that include (1) understanding how patients best prepare for discussing specific decisions, (2) discovering how clinicians best prepare to discuss specific decisions with patients, (3) expert review by patients not involved in producing the decision aid, (4) expert review by health professionals not involved in producing the decision aid, (5) field testing with patients who are facing the decision, and (6) field testing with practitioners who counsel patients who face the decision.[17] There are only a few studies reporting the testing of ED-specific decision aids, and fewer still that meet the above criteria, particularly regarding the involvement of clinicians and patients/surrogates in the development process.[1]

Regardless of the design strategy employed, SDM tools should focus on encouraging communication between patients and clinicians. Conversation – the thoughtful back and forth exchange of information, questions, and points of view – is the collaborative process needed in SDM in order to share preferences and thoughtfully consider evidence.[2,18] This focus on conversation adds some activities to the development process, such as understanding a particular decision-making context and identifying the social, emotional, environmental, and cultural barriers that may need to be addressed in order for conversations to occur. Once identified, these unique characteristics can inform the design of the tool and ensure that the decision aid serves to facilitate the conversation for the patient; a way for them to share about their life or an expression of what is important to them. Of course, the tool itself is not sufficient to ensure that SDM occurs. Successful use of a decision aid and engagement with the patient may be a product of clinician motivation and local ED culture and deserves further study [ADD GROUP 3, MANUSCRIPT DISSEMINATION AND IMPLEMENTATION REFERENCE HERE]. In addition, limited research has been conducted exploring how decision aids can be integrated into the EMR in such a way that they both facilitate clinician workflow and promote the clinician-patient conversation.[8]

Priority Research Questions:

- How can decision aids be best integrated into the EHR?
- What are the essential components of a SDM conversation in the ED?
- How can methodologies for decision aid development from other clinical settings be used to develop ED decision aids?

IV. Communication of Risk

Broad Question: *What are the best approaches to the communication of risk between emergency clinicians and patients?*[19]—In the past two decades there has been an increase in research examining the best way to communicate risk to patients.[20–27] Current literature suggests that including numbers, ideally in the form of natural frequencies, can help patients understand risks.[22,24,25] Absolute risks are preferred over the number needed to treat or relative risks,[24,28]and, when not overwhelming, charts or tables can facilitate understanding.[20,21,25,29] Pictographs, which are charts in which icons are used to represent patients, and different colors are used to visually signify different clinical outcomes (previously called “icon charts”, “crowd charts” or part-to-whole” charts), have gained favor, particularly for low numeracy populations.[20,23,27,29–32] These charts help decrease “denominator neglect” by graphically including those with and without an outcome of interest.[31,33] Animated icons, however, should be avoided as they may detrimentally affect recall.[19] Several guidelines exist regarding how to best communicate risk to patients.[29,38] We have summarized ED-appropriate recommendations based on current evidence in Table 2. Despite an expanding literature base, few studies have addressed this issue in the ED environment.

Priority Research Questions:

- How do different clinical scenarios within the ED require different approaches to the communication of risk?
- In the context of a high acuity ED presentation, what is the best approach to communicate risk?

V. Stakeholders/People

Broad Question: *What are the needs of the various stakeholders?*—Insufficient engagement and communication among key stakeholders is a common problem in developing tools for SDM. A disconnect between stakeholders and tool designers may result in ineffective tools, or tools that do not address end users’ concerns and needs. Because these materials play an important role in the decisions made by patients, it is essential to engage those who will use the tools at the earliest stages of their development. While stakeholders such as the patient and the clinician should be involved in early development of SDM tools, other stakeholders may play key roles in a given clinical scenario, such as caregivers/surrogates, parents, nurses, administrators, payers, and policy-makers.

Patients and Caregivers: While knowledge regarding their condition has been cited by patients and their surrogates as the most important potential outcome of a SDM conversation in the setting of chest pain and pediatric minor head trauma,[6] what is important to patients and their caregivers may differ based on each clinical scenario. For example, if discharge is an option, coordination of outpatient care or access to outpatient resources may rise in importance. It is likely that the needs and concerns of ED patients differ from those of patients cared for in other settings and therefore the needs and concerns of stakeholders should be investigated anew for ED-based SDM interventions.

For situations involving caregivers it may be important to recognize that the caregivers present in the ED may not represent all the stakeholders involved with a particular patient. There may be key individuals in a patient's support network who may be overlooked as stakeholders in the patients' healthcare.

Clinicians: As SDM requires more than one willing participant,[34] the buy-in of the practicing emergency clinician is essential for a successful SDM interaction. Feedback from clinicians as stakeholders should be sought and incorporated during the tool-design process. Physician-described barriers to the use of SDM are well-documented and include time, acuity, and patient characteristics as well as a myriad of other factors.[35] For example, it may be prudent for researchers to examine the amount of time an interaction takes and how the SDM encounter affects patient flow and length of stay in the ED, if these factors are important to clinicians.

Parents and children: Both the American Academy of Pediatrics and the United Nations promote the involvement of parents/guardians and children in medical decisions,[36] but this involvement comes with unique challenges, particularly in the setting of emergency care. The ability of a child to be involved varies by age and maturity, and although parents are presumed to have their child's best interests in mind, parental preferences may differ from those of the child, or the preferences may differ between legal guardians/parents. Parental preferences may be complicated by inter-parental disagreement and by factors unrelated to the child's health and wellbeing, such as the cost of decisions, missed days of work, the care of siblings, and other logistical issues of an ED visit. Regardless of challenges, pediatric emergency care may warrant frequent SDM with children and their guardians as decisions that are considered fairly benign in the adult ED, such as venipuncture, have a different risk-benefit ratio in the pediatric ED. Although a recent meta-analysis found that SDM interventions in pediatrics generally increased knowledge while decreasing decisional conflict,[36] further research is warranted to address the unique challenges of involving children and their parents in SDM in the ED.

Other stakeholders: For the advancement of SDM, particularly in light of the challenges of research translation, researchers must be aware of other stakeholders such as administrators, payers, and policy makers. While physicians may be reticent to implement an intervention that will cost them time, administrators may be interested in the intervention's effect on cost, patient satisfaction, resource utilization, and patient safety.

Priority Research Questions:

- How and when does the presence of a caregiver affect decision-making and understanding in complex and high-acuity situations?
- What is the role of policymakers/payers in the development and testing of SDM interventions in the ED?
- How can stakeholder input be incorporated in the development of decision aids?

- What are the best approaches to assessing capacity and willingness to participate in SDM of the patient and all caregivers involved?

VI. Outcomes

Broad Question: *What outcomes should be the focus of SDM research in the ED?—*The past decade has seen a large increase in randomized controlled trials examining SDM interventions, though the vast majority have not taken place in the ED.[3] These studies often have multiple endpoints, including patient-centered outcomes such as knowledge, decisional conflict, engagement, trust in physician, the receipt of value-congruent care, and patient satisfaction, as well as more traditional outcomes such as cost or percentage of patients choosing surgery, admission, or further testing. As the appropriate outcomes for any particular study are best determined by the relevant stakeholders and may vary by clinical scenario, only some of the myriad of important outcomes are discussed here.

Patient knowledge, satisfaction, trust, and engagement: Numerous studies suggest patients prioritize knowledge, satisfaction and engagement as important outcomes. Additionally, while measuring these outcomes can be challenging, validated measures exist.[37–40] Thus, the design of any SDM investigation should consider these as primary or key secondary outcomes.

Morbidity, mortality, and safety: Many of the scenarios appropriate for SDM offer a less resource-intensive choice which theoretically could be more or less safe. For example, in the decision regarding admission versus discharge for chest pain patients at low risk for ACS, stakeholders are likely to believe “missed myocardial infarctions” in discharged patients is an important outcome. Conversely, the more resource-intensive choice (such as lumbar puncture after negative head CT in a low-risk headache patient) may also pose risks of iatrogenic injuries and adverse effects. As many of these risks are low, many studies will be underpowered to detect significant differences.

Timing of SDM Intervention and Prior Diagnosis: One of the unique challenges in the ED is the timing of the SDM intervention. Throughout the continuum of the ED evaluation there is a variable amount of information (results of diagnostic testing) and opinions (ED clinician, nurse, subspecialist consult, etc) that have been shared with the patient and caregiver. When patients receive conflicting information they may become confused about their diagnosis and disposition, which may impede their ability to engage in SDM. Thus SDM tool deployment should consider timing of the intervention relative to the continuum of ED care.

Costs and resource utilization: Cost may be an important outcome for patients and caregivers, clinicians, administrators and payers. However, costs may be viewed differently by different stakeholders (such as costs to the system versus out-of-pocket costs to patients). Resource utilization, such as admissions, CT scans, and ED length of stay, may be important to administrators and payers, and of varying importance to individual clinicians and patients.

Disposition: SDM in the ED not only considers whether further testing needs to be done, but also how this decision impacts whether a patient is admitted to the hospital or discharged home. This decision is often unique to the ED setting and may have a significant impact on the willingness of both the clinician and the patient/caregiver to engage in SDM. From both the patient and clinician perspective, the time from ED discharge to outpatient follow-up can be problematic. Thus, the timeliness of outpatient follow-up and its temporal relationship to ED discharge should be considered when developing a SDM intervention where the decision includes hospital admission or ED discharge. Questions that patients and clinicians may be concerned with include: 1) specific directions and discharge instructions, including explanations of diagnoses made, significance of test results, importance of continuing treatment, and what to return for; 2) If the patient has been referred to a doctor or specialist from the ED, how do they go about following up with them? Is the doctor's office aware of the need for follow-up? Should the patient call them or will the doctor contact the patient to arrange follow-up? 3) How do ED test results get communicated back to the patient's doctor? 4) What if I don't have a primary care provider? Are there ED personnel I can contact after my visit, before follow-up, if I have questions?

Priority Research Questions:

- Which patient oriented outcomes (knowledge, satisfaction, quality of life) should be measured in ED SDM research?
- What are the best methods to measure patient-oriented outcomes in the ED?
- Are there outcomes that should always be included in ED studies of SDM, or does each scenario require an individualization of outcomes based on the needs of the stakeholders?
- When considering the entire ED evaluation, how does the timing of SDM engagement influence the outcomes that are chosen?
- Are there outcomes other than traditionally used outcomes that may be relevant to stakeholders?
- When ED discharge is one of the outcomes of a SDM tool, how does this impact the patient's decision and the amount of information required as part of the discharge process?

Conclusions

As researchers embark on the formal study of SDM in the ED, developing and testing new tools and conversational approaches to facilitate clinician and patient information exchange and deliberation regarding emergency-care decisions, it is critical to maintain a focus on keeping the clinician-patient communication at the forefront. The consensus research agenda put forth in this document proposes high-priority questions in six broad domains relevant to the development and testing of SDM interventions. This agenda is designed to guide future analysis of SDM interventions in the emergency-care context, and to provide a framework for defining the structure and characteristics of SDM in the ED setting. Furthermore, we

contend that combining the existing practice of patient engagement with formalized SDM interventions will strengthen the human connection necessary to achieving optimal outcomes.

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Table 1

Clinical scenarios in which SDM may be appropriate.

Specific Scenarios	Published & Ongoing Research
Low risk chest pain: disposition *	Studied in a single center and recently completed multicenter trial[4,5]
Low risk head trauma: imaging *	Currently under investigation[6,8]
Stroke: tPA *	Qualitative work,[13] Development of decision aid[14,15]
End of Life Care	ICU intervention under investigation[16]
Suspected renal colic: imaging *	
Acute Otitis Media: Treatment	In development
LP after negative head CT for SAH *	
Pain medication choice upon discharge	Observational study[17]
CTPA after low-positive D-dimer *	Hypothetical study[18]
Syncope: disposition *	Qualitative work[19]
Stable PE patient: disposition *	
Stable community acquired pneumonia: disposition *	
Management of well-appearing febrile infants <2 months of age	
Bronchiolitis: disposition	
CT for diverticulitis	
Analgesic selection/opiate prescribing	Qualitative work,[20] Prospective observational studies[17]
Antibiotics for URIs	Mixed methods study under investigation[21]

tPA: tissue plasminogen activator. LP: lumbar puncture. CT: computed tomography. SAH: sub-arachnoid hemorrhage. CTPA: computed tomography pulmonary angiography. PE: pulmonary embolism.

* Indicates endorsement as appropriate “all” or “most of the time” by a majority of EM physicians in a recent survey.[12]

Table 2

Evidence-based guide to the communication of risks and benefits in SDM scenarios.[33,42]

1. Use plain language.
2. Using numbers will help improve patient's understanding of risk.
   - **A.** Use absolute risks, not relative risks.
   - **B.** Use frequencies with a constant denominator (100 or 1000, avoid "1 in X").
   - **C.** Define a reference class (denominator) and keep this constant ("*Of 100 patients like you…*")
   - **D.** Use an incremental risk format to highlight changes from baseline.
3. Keep in mind the variation in literacy and numeracy within the target group, and use pictographs when applicable.
4. Consider presenting only the information most critical to the patients' decision-making, even at the expense of completeness.
5. Note the time interval over which a risk occurs.