MAYO CLINIC

IMPLEMENTATION TEAM MANUAL

The Statin Choice Decision Aid
Implementation Toolkit

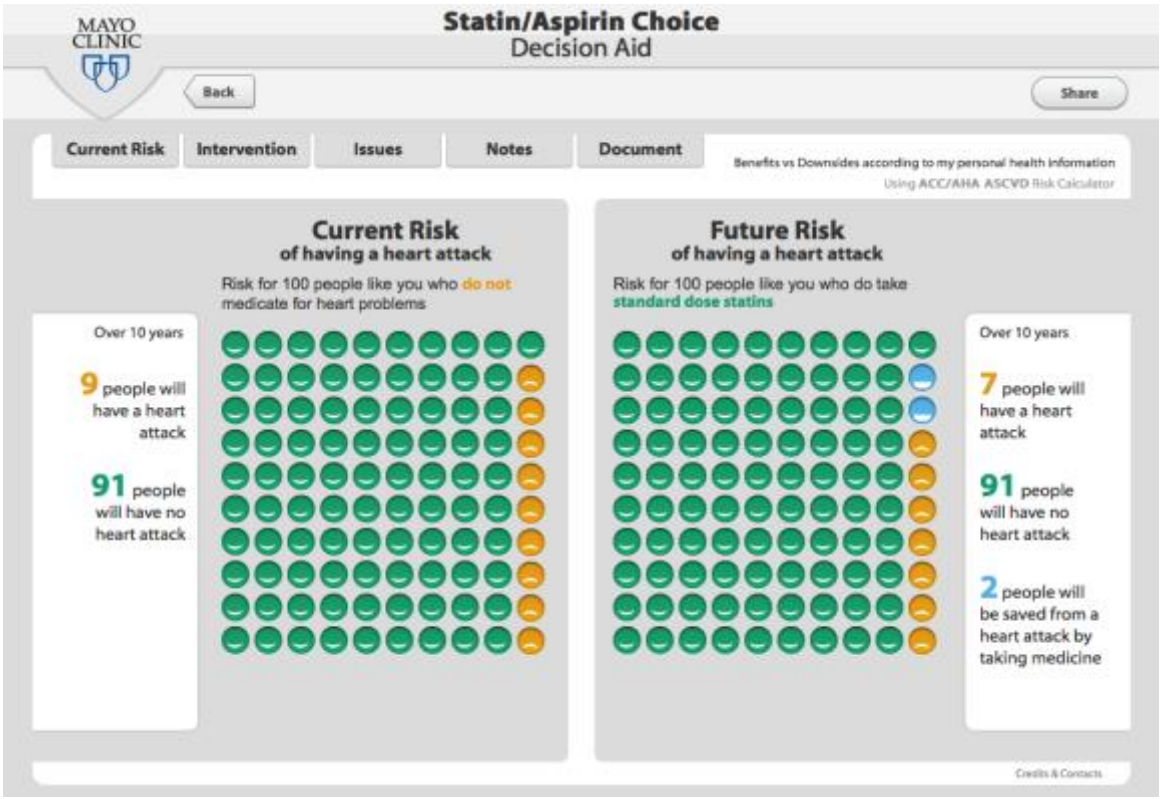
KERUNIT
KNOWLEDGE AND EVALUATION RESEARCH

Hello,

This manual is intended to serve as a guide for organizations aiming to implement shared decision making (SDM) for point-of-care dicussions about reducing cardiovascular risk. It assumes you want to use the Statin Choice Decision Aid (SCDA) as a key tool for achieving this. That's right: the Decision Aid is not, in and of itself, SDM. Rather, it's a tool for making SDM fit more naturally and efficiently into the clinical encounter. As a member of the implementation team, you, more than anyone else in your organization, should know this! What? You're confused? You don't even HAVE an implementation team?!

No worries.

That's what this toolkit is for: to help you in understanding the things you need to do to succeed with implementation. We've broken it down into 3 "easy" steps ☺.



Step 1

Assemble the Implementation Team

There's no way around it. The most effective and efficient way to achieve success is to bring together people from your organization with different connections and experiences and with different types of influence and expertise. If you have a pre-established quality improvement team or other multidisciplinary team that is used to implementing organizational initiatives those folks would probably represent a great start. If that team has pre-existing procedures and common strategies that have worked in the past, that's even better! If not, no worries. Here's who you need:

1. **The clinician champion:** Usually this person is a physician that is respected by his or her colleagues for having sound clinical judgement and for providing patient-centered care. The ideal clinician champion also is a good communicator. Most importantly, the individual has to be EXCITED about SDM and Statin Choice. He or she must use the tool in practice and make an intentional effort to encourage colleagues to use it as well during implementation.

2. **The project director:** This can be anyone with authority to provide overall project orientation and make decisions related to resource commitment and allocation. Because multiple departments and service lines are in play (e.g. clinical care, information technology, communications), it usually means someone from the C-suite level.

3. **Information technology liaisons:** In order to integrate the tool into the electronic environment you will need someone from information technology leadership that can allocate resources and assign the project to the appropriate individual(s). It is helpful to invite the individuals that are assigned to the project (the "worker bees") to join the team as early in the process as possible.

4. **The quality expert:** We've found it is helpful to engage a person at your organization who manages quality metrics and improvement initiatives. This individual will likely know how to best synergize the project with ongoing priorities. He or she will also be able to help the team to think through the implications of the project on quality measures and how these can be optimized.

5. **The project manager:** This person needs to keep everyone on task. He or she will have organizational skills and will be responsible for arranging meetings and tracking

progress. This could be a nurse or an administrative assistant if a dedicated project manager is not available. Whoever it is, the person needs to have the confidence and authority to "bug" people. (P.S. Everyone else on the team also needs to commit to not being bugged when bugged ☺)

6. **The clinical workflow informants:** This person/these people are usually nurse managers or administrators for clinical sites or service lines. They know how the clinics operate from check-in to check-out and can be the "go-to" contacts to support implementation and to tell you what is and isn't working.

7. **The integrator:** This is not any particular person, but is the person everyone knows should be involved in the project. He/she gets stuff done and is respected around the organization, perhaps because of his or her track record. This person may be the "EMR guru" who also happens to be a clinician, for example.

In recruiting the team, it is best to reach out to leadership first (assuming you are not leadership). For example, you could send something like the following SBAR along with a link to the video demo of the tool (link):

S: Shared decision making is advocated by the America College of Cardiology/American Heart Association for cardiovascular risk reduction and the initiation of Statin therapy, yet we do not do this routinely in practice at (our organization).

B: Current guidelines say we should have risk-tailored, shared decision making conversations with patients when deciding whether to start them on statin therapy. Currently, we click on a calculator within the EMR to find the patient's 10 year risk, but there is no systematic support for shared decision making. The American College of Cardiology/American Heart Association and many others recommend the Mayo Clinic Statin Choice Decision Aid, which calculates risk but also helps to frame a shared decision making conversation. The tool has been proven in multiple trials and is well accepted by clinicians. It is also free to use and can be automated into the EMR workflow.

A: I have used the Statin Choice tool in my practice and patients really like it. It is visually very nice. I find it also helps me in my efforts to provide efficient, patient-centered care. Mayo has a toolkit that guides organizations in implementing the tool into practice and integrating it into the EMR (link). There is even a clinical program for Epic. Testimonials from other organizations seem to imply this can be done relatively easily (link).

R: We assemble a team to explore feasibility of implementing the Statin Choice Decision Aid system-wide.

Step 2

Prepare the Implementation Team

Once your team is assembled, you will need to become experts in both SDM and and the Statin Choice tool. Reserve a conference room and block a half day on the calendar for the team's kickoff workshop. It is important that everyone is there. It also helps if everyone brings a laptop or tablet to practice with the tool. You will also need to print out enough copies of the organizational assessment (link) for everyone to have one. Finally, you will need to record the group's thoughts and plans, so a whiteboard or flipchart is handy.

Here is the agenda for the kickoff workshop:

1. **Introductions (5-30 mins):** Team dynamics are important; everyone should feel comfortable. If there are people that don't know each other it is a good idea to have an ice-breaker. It does not matter who facilitates the meeting, so long as that person is comfortable doing so and he/she can create an open dialogue. It is important everyone feels open to give input.

2. **Overview of Purpose (2 mins):** The project director or clinician champion should clearly and succinctly state the purpose of the project and the rationale for the workshop. He or she should state that the goal is to leave with an actionable plan for implementation.

3. **Webinar Session 1 (30 mins):** First watch Session 1 of the implementation team webinar (link). This will provide an overview of SDM and the SCDA.

4. **SCDA Video Demo (10 mins):** Next watch the SCDA video demo provided in the toolkit (link) as a team. Pay careful attention to the language used to convey risk. Discuss as time allows.

5. **SCDA Practice (30 mins):** Now, pair up and practice using the tool (either on a laptop or tablet) through role play. You can access it at: https://statindecisionaid.mayoclinic.org/. Take turns playing the clinician and the patient. You can use your own information (what you know) to populate the variables. When playing the clinician, pay careful attention to your language; try to emulate the wording on the demo. When playing the patient, pay careful attention to your experience. Debrief amongst the group. Use the W^3 approach if helpful:

- **What:** What happened? What stood out? What was different from the norm?
- **So What:** Why is that important to you? To your organization?
- **Now What:** What actions make sense?

6. **Break (30 mins):** Catch up on emails, use the restroom, grab something to eat.

7. **Webinar Session 2 (30 mins):** Watch Session 2 of the implementation team webinar (link). This will provide an overview of lessons learned from other organizations that have implemented the SCDA. It will prepare you to conduct an organizational assessment and to lay out your plan for implementation.

8. **Organizational Context Assessment (30 mins):** After watching Session 2, complete the organizational assessment (link) provided in the toolkit as a group. This is a facilitated discussion. Designate someone to synthesize and record the group's thoughts on a whiteboard or flipchart.

    - **Step 1:** Hand each person a copy of the assessment (link) and give them 5-7 minutes to complete independently.
    - **Step 2:** Then take a few minutes to report out the ratings (1 to 10) of each person for each domain of acceptability, feasibility, and appropriateness.
    - **Step 3:** Spend the remaining 20 minutes discussing the reasons for the ratings. Come to an agreement on a final rating as a group for each domain/question (from 1 to 10).

9. **Strategy Selection (15 mins):** After conducting the organizational evaluation, consider what strategies you will use to optimize each of the 3 domains. Peruse the SCDA Implementation Toolkit (link) in making your selections. Also reflect on the experiences of the organizations described in Session 2 of the webinar.

    - **How will you improve appropriateness?**

        i. Use campaign to express importance (helps clinicians know this is encouraged by leadership)

        ii. Develop marketing materials (expresses to patients and public the patient-centered identity of the organization)

        iii. De-implement competing/overlapping tools

- **How will you improve feasibility?**

    i. Develop and email video of how to use in internal environment after placed in EMR (excellent if you know clinicians will watch, but what if they won't?)

    ii. Communicate initiative and demonstrate tool at clinician/nursing meetings (essential)

    iii. Have Grand Rounds/CME/education about the topic (good for maintaining interest and expressing the rationale)

- **How will you improve acceptability?**

    i. Putting link to tool in EMR (okay)

    ii. Integrating tool fully so that it auto-populates (much better)

10. **Action Plan (15 mins):** After selecting your strategies, organize them into a timeline and delegate responsibility. **Do not leave without a plan for a follow-up meeting!** Here is a **sample** action plan template and example:

Organizational Statin Choice Implementation Action Plan

SAMPLE

Date	What	Who
Every Tuesday	Send out action items and progress reports weekly	Project manager
Tomorrow	Schedule quarterly team meetings	Project manager
Next standing meeting	Discuss with service line managers	Project director/clinician champion
This week	Determine whether we could	Quality expert

	use for MOC	
This week	Reach out to Mayo about usage reports/tracking	Clinician champion
This week	Engage Cardiology	Clinician champion
TBD	Engage marketing/PR	Project
This week	Begin EMR Integration	IT Liaisons
In 1 month	Pilot testing with super users	Integrator
In 3 months	End EMR Integration	It Liaisons
Fall provider meeting	Go-Live!	Clinician champion
Fall provider meeting	Provider/Clinician Meeting demo	Clinician champion
Day after fall provider meeting	Electronic Video Demo Emailed	Integrator
At fall nurse meeting	Nurse Meeting	Integrator/Workflow informants
Ongoing	Clinical Team Presentations	Clinician champion
With quarterly clinic meetings	Follow-up clinic site visits/training	Project manager

Step 3

Executing the plan

The third and final step is to execute the plan. Although it is essential to have a timeline when you develop your plan, we realize this may change. That's okay. The most important thing is that the project manager keeps people engaged through any delays. It is helpful for the implementation team to meet in person and brainstorm solutions to delays when they exist. **In our experience, many delays can be avoided or troubleshooted just by maintaining communication.**

At most organizations, the effort required to integrate the tool into the EMR should take no more than 1-2 weeks (this can vary based on the complexity of the integration and whether pre-existing strategies exist for your vendor—see EMR Integration Supports (link)). Efforts to communicate the presence of the tool and educate clinicians on how to use it will vary based on the size of your organization and how feasible it is to educate the clinicians. "At the elbow" support is important. We find it is helpful for someone to drop in on clinics from time to time and just remind the clinicians that the tool is there and demonstrate its use. Demonstration from within the internal workflow iis key. This will always spur questions and discussion.

If you want to track usage of the SCDA over time, you can work with your IT department to develop reports of when the tool is accessed from within the EMR (provided it is integrated into the EMR). For a more complete picture of total usage of the tool over time, our team may be able to provide Google Analytics reports for a small fee. If implementation is not going as well as you'd like, we also offer facilitation services (link?).

We're glad your organization wants to partner with patients in improving care. We look forward to hearing about your successes!

An Example of Encounter Decision Tools:

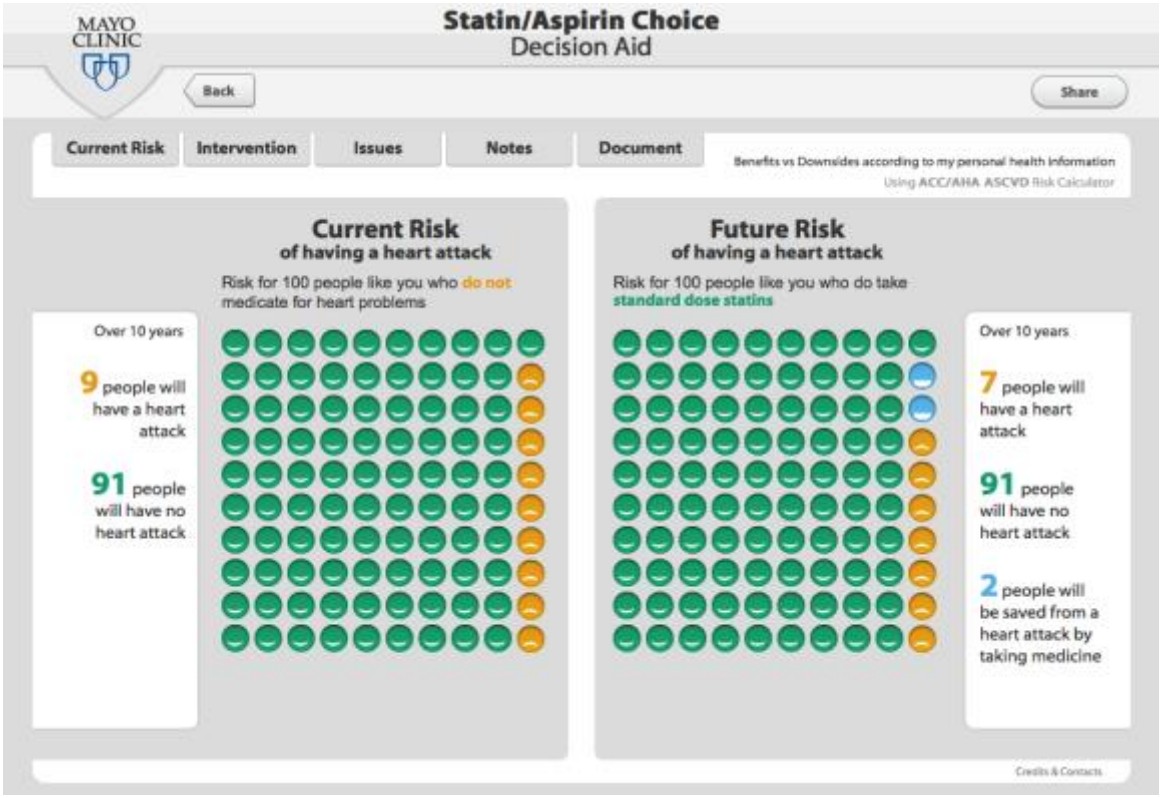


Figure 1. Statin Choice Decision Aid

Our tools are produced in a variety of formats including conversation cards, booklets and digital applications. An example of our work is the Statin Choice Decision Aid (Figure 1). For patients considering statins for primary prevention of heart disease the risks and benefits of statin therapy are in close balance and there are no strong clinical indications for or against therapy. Our digital online tool is designed to support an individualized conversation in which risk communication is essential. The tool draws out and clearly presents the patient's current risk of heart attack, along with how that risk changes with statin use. It also supports patients and clinicians in setting risk against other decisional issues such as cost and side effects. This tool improves the accuracy of risk communication 22-fold compare to usual care at the Mayo Clinic.

The Value of Encounter Decision Aids

In multiple randomized clinical trials in usual chronic care practice, in urban, suburban, and rural practices in the USA and elsewhere our encounter decision aids have been shown to create and support conversations between clinicians and patients. These tools are effective in the emergency department, primary care practices, specialty care and hospital. They are time

efficient adding less than 3 minutes to the consultation and are effective at reducing patient decisional conflict, enhancing patient knowledge about the options, and in promoting patient involvement in decision making. Our trials have also shown that clinicians can use these tools without training and still complete 60% of the steps necessary for their adequate use. Also, our trials show that these tools are particularly effective among patients with low socio-economic status and do not introduce further disparities in care.

2. Decision Aid Development

Principles of Developing Encounter Decision Tools

As leaders in Shared Decision Making and Decision Aid development, the KER UNIT identifies the following principles for successful decision aid development:

Conversation not Information

The decision support tools produced by the KER UNIT are designed to support and facilitate a respectful, illuminating and deliberative conversation between patients and their clinicians. In the course of an encounter, patient and clinician may each bring, draw out, and discover important matters and issues that bear on the decision. Some of these matters may be medical and technical; others may be personal issues and concerns that reflect who the patient is as a person and the life situation from which they come to the encounter. In this context, patient and clinician share the work of forming a decision together.

In our approach, the conversation is the focal point for development. The tools that we produce are secondary. Their role is to offer places for discussion and to appropriately present the best medical evidence as the conversation calls for it. Our tools are intended for shared use by patient and clinician, they are not designed to supply educational information to the patient divorced from conversation with a clinician.

Designed for Context

Each of our decision aids is designed to support a particular decisional problem. This problem represents a unique medical and life situation in which there is genuine uncertainty as to what the best course of action is. In development, we explore the best way to support patient-clinician deliberation for this problem. This means, for example, that the strategies explored for supporting osteoporosis treatment choice will be different than those supporting diabetes treatment choice.

This approach demands significant upfront exploration of the issues involved in decision making for the particular problem. It also requires extensive experimentation and testing in tailoring the decision aid to the demands of the situation. This experimentation is done, as much as is possible, in the real-life settings in which the decision aid will eventually be used. This requires access to, and the participation of patients and clinicians in initial observational work, and in trying out prototypes as we close in on the final decision aid design.

Development a Partnership

Successfully completing a new decision aid requires the coordinated effort of a large number of

people including clinicians, patients, content specialists, evidence-based medicine specialists, designers, administrators and study coordinators. Of particular importance are clinician champions to drive the project forward and provide access to other clinician partners, patients, visits and context. Also of particular importance is the voice of patients through a patient consultant and/or a patient advisory group.

Process Overview

The KER UNIT uses a practice-based, patient-centered approach for decision aid development grounded in user-centered design. We have developed and extensively validated this approach, and have executed it via a multidisciplinary research team comprised of designers, patients, clinicians, and decision making and evidence-based medicine scientists, and health literacy experts.

The development process for our decision aids spans the five modules shown in figure 2. How many of these modules the KER UNIT undertakes varies according to project. The first two modules represent the minimum work that the KER UNIT will complete when developing a new decision aid. The outcome of the first two modules is a field-tested low-fidelity prototype. The development process may be extended by the inclusion of the later modules.

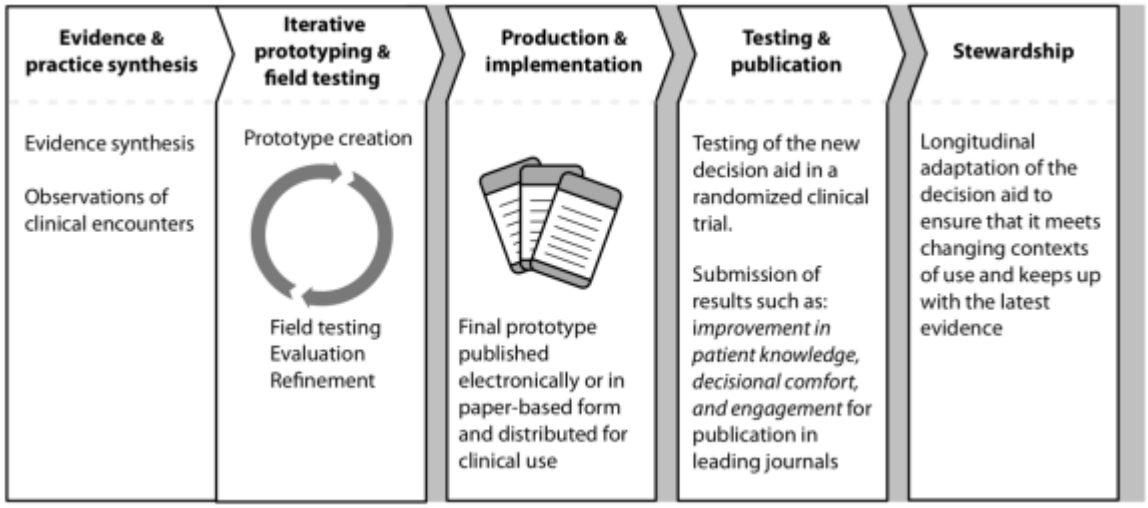


Figure 2. Modules in the Decision Aid Development Process

Details of each of the five modules and how they apply to this proposal follow.

Evidence and Practice Synthesis

Synthesis of Evidence

The development team will seek out systematic reviews and meta-analysis that bear on the

issues that could potentially contribute to the decision of interest. If these are not available or current, the KER UNIT knowledge synthesis, the world largest single-site producer of systematic reviews, is then involved to complete this step. The available syntheses are then produced in a grid format to quantitatively summarize where possible the impact of different interventions on the relevant outcomes and identify knowledge gaps.

We will then convene our key users and scientists (hepatologists, transplant surgeons, and other clinicians, patients, decision making and evidence-based medicine scientists) to a meeting in which they will review the synthesis and agree on its results and their associated credibility and applicability.

Observations of Clinical Encounters

Members of the research team led by our designer will observe real-life clinical encounters in which clinicians and patients discuss liver transplant treatment decision. In these observations we will look for patterns and issues of patient-clinician conversations as well as nonverbal behaviors and attitudes. In addition we will interview patients, family members, and clinicians to better understand their experience of the decision.

It is anticipated that Mayo Clinic Florida will be the primary site for observing decision encounters, supplemented where possible and useful by observations in Mayo Clinic Rochester. Our designer and a shared decision making researcher will spend two weeks in Florida conducting these observations. They will require access to patient-clinician conversations where liver transplantation is discussed. This access refers to the identification of relevant clinic visits, introduction of investigators to clinicians and clinic staff, and authorization to conduct the observations from relevant institutional instances. A local clinical champion and other staff should be identified to assist with facilitating this access. In the interests of limiting travel and costs, a study coordinator based in Florida or other personnel will be engaged to video record other encounters and send these recordings back to Rochester.

Early in the project a patient consultant and/or a patient advisory group should be identified and engaged to bring the voice and insight of patients into the design of the new decision aid.

IRB approval will be required to conduct, and later publish on the observations conducted in this phase of the project. The KER UNIT has expertise in preparing IRB submissions for this type of research. We will join with our collaborators in Florida to produce and submit IRB applications.

Deliverables for the Evidence and Practice Synthesis Module

We will produce two reports at the close of this module:

- a grid format summary of different interventions, relevant outcomes, and identified knowledge gaps

- a summary of the observational research and interactions with the patient consultant and/or the patient advisory group. The report will characterize patient and family involvement in current liver transplant decision making, patients' engagement with medical evidence, and patient-contextual issues that bear on liver transplant treatment choice.

Iterative Prototyping and Field Testing

Syntheses of scientific evidence and clinical observations will inform the design of decision aid prototypes. In designing, we will go through an iterative process of:

- creating low-fidelity prototypes. Low-fidelity prototypes are paper-based simulations that are relatively quick to produce and can be used experimentally in patient-clinician conversations
- soliciting feedback on the content, format, ease of use, and patient-centeredness of prototypes from the research team
- testing low-fidelity prototypes in clinical encounters
- evaluating, refining or abandoning prototypes in order to come to a final prototype

The research team will include a designer, patients, hepatologists, transplant surgeons, clinicians, decision making and evidence-based medicine scientists, and a health literacy expert.

Prototyping is a core and distinguishing part of our development practice. Our most successful decision aids have been developed in close proximity to and experimentation within the clinical settings in which they will be used. The distance between Florida and Minnesota is a challenge for this project. We anticipate that prototyping will involve a combination of KER UNIT onsite prototype testing and refinement along with video capture of prototype encounters recorded in Florida and sent to Minnesota for review. We will also seek opportunities to prototype in Rochester where possible.

In testing prototypes we will examine and document conversations patterns, successes, problems, and challenges. When feasible, brief semi-structured interviews with patients and clinicians will be conducted after the encounters. The research team will then evaluate the quality of the conversations and the ability of the prototypes to facilitate shared decision making. This process will be repeated with subsequent prototypes until the research team and key users reach a consensus that the prototypes are successful in involving patients in decision making with their clinicians.

If the collaborators wish to publish on the development of the new decision aid, our preference, it will be necessary to obtain IRB approval for the field testing of low-fidelity prototypes in clinical encounters.

Deliverables for the Prototyping and Field Testing Module

This process will result in a final low-fidelity decision aid prototype, highly intuitive and requiring minimal training to use, and designed to meet the needs of patients and their clinicians working in fast-paced care settings.

Production and Implementation

In order to tailor the decision and evidence to the individual patient and the individual institution offering transplant it is likely that the final conversation support tool will best be delivered in an electronic, rather than a print format. This will also best allow the new decision aid to stay current and reduce costs of maintenance associated with the distribution and later retrieval for update of physical material. We have successfully partnered with Take The Wind, a Portuguese interactive healthcare media development company, on several projects. We recommend engaging them to produce the final working electronic decision aid. The KER UNIT designer will provide Take The Wind with the agreed upon low-fidelity prototype and work with them as they transition it into an electronic environment and refine its final visual presentation. It is anticipated that a period of electronic prototyping will be required to successfully translate the tool into the electronic environment. Protoypes developed by Take The Wind will be reviewed by the research team and piloted in clinical settings in a similar manner to the field testing of low-fidelity prototypes.

We anticipate that prototyping will involve a combination of KER UNIT onsite prototype testing and refinement along with video capture of prototype encounters recorded in Florida and sent to Minnesota for review.

The final decision aid will be license free. The Mayo Foundation for Research and Education will retain copyright of the materials produced and reserves the rights to conduct evaluation of efficacy and effectiveness of the decision aids or to repurpose the tool for other uses.

Deliverables for the Production and Implementation Module

This module will produce a finished electronic decision aid ready for hosting online for clinical use.

If the collaborators do not wish to publish a paper on the full development process for the decision aid we will produce a white paper that describes the research, prototyping, testing and thinking behind the new decision aid.

Testing the Decision Aid

If the collaborators wish to fully evaluate the effectiveness of the liver transplant decision aid in clinical practice, our preference, a cluster randomized pilot trial will need to be conducted.

We have a broad and successful experience evaluating decision aids in multiple sites within Mayo Clinic Health System and other medical centers. Typically, patients' outcomes —such as knowledge transfer, patient acceptability, treatment choice and adherence —are measured through surveys, medical record reviews and through collection of pharmacy records. Additionally, the extent to which clinicians involve patients in the decision making process and the fidelity with which they are able to use the decision aid as intended are measured through specific shared decision making scales. The results of these studies are published in leading journals.

In every randomized trial that we lead, the study team aims to keep the disruption of workflow and burden on clinical staff to a minimum. Specialist study coordinators are in charge of all aspects of patient recruitment and follow up. Experienced statisticians as well as researchers are responsible for the data analysis and the publication of final manuscripts and other dissemination tools.

Stewardship

Changes in available treatments, evidence, and context of use mean that decision aids periodically require revision. Changes may range from small content changes, to the integration of new issues for discussion or other larger scale alterations to the decision aid.

The KER UNIT will support and facilitate small content changes in the decision aid for up to one year from the completion of the decision aid. While the KER UNIT will not charge for content changes during this period, Take The Wind may apply charges for the work of altering the electronic decision aid.

Costs and terms will be negotiated for the KER UNIT to make and manage any larger scale alterations to the decision aid. After the initial one-year post-development period, costs and terms will be negotiated for the KER UNIT to oversee any modifications to the decision aid as they arise.

3. Proposed One-Year Budget

This budget anticipates the costs involved in the first three modules in the development process—evidence and practice synthesis, iterative prototyping and field testing, production and implementation. The anticipated project duration is one year.

A. Personnel

Overall Project Leader (0.02 FTE): Dr. Victor Montori will provide overall project leadership for the KER UNIT team and have responsibility and accountability for the execution of this project..

Principal Investigator for Evidence Synthesis (0.02FTE): M. Hassan Murad, MD, MPH, will lead the synthesis of the evidence from the literature. He will review the evidence on liver transplantation and decide on updates as necessary.

Systematic review specialist (0.10 FTE): A review specialist is budgeted for any necessary updates to the knowledge synthesis component of this project across all relevant options and outcomes.

Principal Investigator for Practice Synthesis and Design (0.50 FTE): Ian Hargraves, PhD is the KER UNIT designer. He will lead the practice synthesis work through engaging key users; conducting, analyzing, and summarizing direct observations of typical consultations. He will also be responsible for the design and prototyping of the decision aid and oversee its final production.

Post Doctoral Fellow (0.50 FTE): A post-doctoral fellow in Shared Decision Making will assist Dr. Murad with knowledge synthesis and Dr. Hargraves in the practice synthesis and prototyping.

Study Coordinator (.75 FTE): A study coordinator with expertise in Shared Decision Making will assist with identification, arranging, and video recording of patient appointments in Florida. She will also provide coordination of the work in Minnesota and Florida to ensure that all milestones and deliverables are met within planned schedule and budget.

Administrative Support (0.10 FTE): A KER UNIT administrative assistant will coordinate and provide logistical support for all meetings amongst collaborators.

Information Technology Support (0.10 FTE): An IT specialist with expertise in the implementation of Shared Decision Making tools will provide support during the production and implementation phase of the project.

Key users: Clinicians and their patients from liver transplantation practices at Mayo Clinic, and our patient advisory group, will serve as our key users. They will not receive compensation except for our patient representative.

Scientists and experts: During the development phase, we will convene a meeting of the collaborators and research team to review prototypes and invite a decision making scientist (Dr Montori), an evidence-based medicine scientist (Dr Murad), and a health literacy expert (Dr Yost) to attend. Collaborators in Rochester and Jacksonville will participate in these meetings via video conferencing.

Total Personnel (including benefits): $192,060

B. Travel and Service Costs

Patient representative: Will be paid $1,500 for supporting the development of the tool.

Travel: We anticipate the KER UNIT designer and a researcher to require travel to Florida during each phase of the project. We anticipate the first trip (practice synthesis) to last 12 days, the second trip (field testing prototypes) to last 10 days, and the third trip (field testing final tool) to last 5 days. Costs include airfares, accommodation and meals during this time.

Digital Production: A contract to produce the digital version of the new decision aid will be negotiated with Take the Wind. Based on previous experience we estimate the cost of this work to be $70,000

Travel & service costs: $93,750

Estimate of direct costs: $285,810
Institutional indirect costs: $85,743

Project Total: $371,553

C. Testing for Efficacy

If the collaborators wish to test the effectiveness of the new decision aid in clinical practice through a randomized trial then the KER UNIT and the collaborators will design a protocol that establishes the full goals, scale, and conduct of the study. This protocol will also set the budget for testing. Based on our experience, testing the initial efficacy of a decision aid may incur direct costs in the order of $100,000-$300,000.

D. Stewardship

If the collaborators wish to engage the KER UNIT in maintaining the new decision aid so that it continues to keep current with the latest medical evidence and conditions of practice then the collaborators will negotiate the terms, scope and costs of this maintenance work.