PROTOCOL COVER PAGE

Protocol Title	Creating a Patient Centered Report Card for Solid Organ Transplant Candidates
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Scientific Assessment	Nationally-based, federal funding organizations
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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
Version 2	05/03/22	Add 97 subjects to the protocol that were already recruited for interview, focus groups and usability testing. This along with the 50 subjects that can be enrolled in the trial at HCMC, brings the total maximum enrollment to 147.	No

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ABBREVIATIONS/DEFINITIONS **ABBREVIATIONS/DEFINITIONS**

- EMR Electronic Medical Record
- HHS Hennepin Healthcare System
- HHRI Hennepin Healthcare Research Institute
- HIPAA Health Insurance Portability and Accountability Act of 1996
- IRB Institutional review board
- ITS2 Internal Transcribed Spacer 2
- PI Principal Investigator
- PHI Protected Health Information
- SRTR Scientific Registry of Transplant Recipients
- UMN University of Minnesota
- FDA Food and Drug Administration
- RCT Randomized Controlled Trials
- OPTN Organ Procurement and Transplantation Network
- AHRQ Agency for Healthcare Research and Quality
- USRDS United State Renal Data System
- BMT Bone Marrow Transplant
- ICS Informatics Consulting Services
- ISRS International Standard on Related Services
- CTSI Clinical and Translation Science Institute
- FWA Federal wide Assurance
- HSCT Hematopoietic Stem Cell Transplant
- ITT Intention-to-treat
- IE Information Exchange
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1.0 **Objectives**

1.1 Purpose:

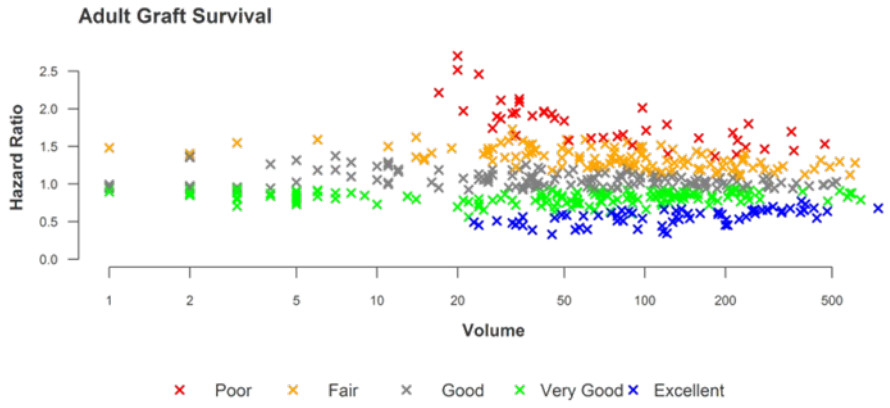
Evaluate the effectiveness of the patient-centered SRTR report card among kidney transplant candidates. A randomized controlled trial (RCT) of all transplant candidates evaluated at the Hennepin Healthcare System (HHS) transplant centers will be conducted. One group with be shown the existing SRTR report cards and then the new patient-centered report cards (funded by AHRQ) on the web. The new patient-centered report cards were developed with feedback from the general public, local transplant candidates, their family members and national transplant recipients. The feedback was collected using data from emails and phone calls received by SRTR, Amazon Mechanical Turk randomized surveys, interviews and focus groups and subsequent usability testing of functioning prototypes with local candidates. (n=97 for subjects in interviews and focus groups and usability testing).

2.0 **Background**

2.1 Significance of Research Question/Purpose:

On average, every 10 minutes someone is added to the organ transplant waiting list (1). Previous studies have shown that kidney transplant is a more effective treatment than dialysis (2). For patients with end-stage liver, heart, or lung disease, life is often not sustainable without a transplant. However, on average, every day 79 patients undergo transplant but 18 others die waiting (1). *Mortality on the waiting list remains high*. Thus, transplant is cost effective (3-8). Chronic comorbid conditions are increasingly common (9). *Most transplant candidates have end-stage organ failure due to a variety of chronic diseases, and thus represent a priority AHRQ population.*

Figure 1: Adjusted adult graft survival hazard ratios for kidney, heart, liver, and lung transplant centers, from publicly available SRTR report cards.



2.2 Preliminary Data: Our preliminary data and other data suggest room for improvement in quality and efficiency of care. Using SRTR's publically available PSRs, we described the variation in risk-adjusted hazard ratios for allograft failure at 1-year post transplant for all solid organ transplant centers (Figure 1). Allograft failure was defined as return to dialysis, transplant, or death. We also surveyed all kidney transplant centers in the US and showed considerable variation in the structure and process of care (10). The PI and collaborators have shown that the structure and process of care plays a role in patient adherence to immunosuppressive medications (11). Others have shown variation in aggressiveness of liver transplant centers (12, 13).

2.3 Relevance to proposed work: Variation in post-transplant outcomes and in risk tolerance at transplant centers is not known to all patients. Informing patients of their choices through our innovative study can improve their chances of undergoing transplant and improve post-transplant outcomes.

***Dissemination of a new website and a printout of SRTR report cards that will be functional even after the proposed project is completed*:** The proposed project will deliver a new website and printouts of the SRTR report cards, which SRTR will use to provide information to the public about each transplant center in the country. Since this project is being carried out by Dr. Israni, SRTR Medical Director (PI on this proposal), the final website will likely be adopted for use by SRTR. SRTR and OPTN lack the qualitative and design collaborators and easy access to transplant candidates needed to carry out the project. Therefore, the project team will develop and evaluate patient-centered SRTR report cards that will effectively communicate comparative information to transplant candidates on their alternatives when choosing transplant centers.

In the future, SRTR staff can also inform patients and their family members about the new patient-friendly website. The SRTR website will prominently display a link for patients and their family members. This website currently receives more than 100,000 hits annually and the most common hits are to the section that displays the report cards.

Potential for the proposed project to improve outcomes: We will *change the paradigm* for how patients choose a transplant center by using report cards tailored to an individual's clinical profile, thereby improving a broad set of patient-centered outcomes, effectively navigating the system of transplant centers with varying candidate acceptance criteria, creating greater satisfaction with the center selection process, and resulting in potentially better post-transplant outcomes. Transplant candidates could use the website to refer themselves directly to centers with better outcomes, thereby becoming *empowered*. Candidates who are turned down at one center could use the report card to find other centers more likely to transplant patients like them. Such public information is also likely to change transplant center behavior (14-16). Centers currently unwilling to transplant high-risk candidates could see patients choosing a nearby center that does transplant such candidates. This

could motivate a risk-averse center to review its practices and potentially accept more high-risk candidates. *Thus, the patient-centered report cards can provide incentives to improve access to transplantation.*

3.0 **Study Endpoints/Events/Outcomes**

3.1 Primary Endpoint/Event/Outcome: The primary outcomes are two separate assessments of the comprehension of the report card. To assess comprehension, the correct response to the following type of question will be assessed, "Which of the following transplant centers have the most experience with transplanting candidates over age 70?" There will be one correct answer; respondents will be told to assume they are in a specific zip code or state and are over age 70 and then asked to choose one of the several transplant center report cards shown or respond "Don't know." Another example of the question used to assess comprehension will be used, "Which of the following transplant centers have the most experience with transplanting candidates with body mass index (BMI) over 40?" There will be one correct answer; respondents will be told to assume they are in a specific zip code or state and have a BMI over 40 and then asked to choose one of the several transplant center report cards shown or respond "Don't know." Similar measures used previously by Dr. Hibbard, to determine the best way to present report cards to the general public (17). We will also determine comprehension of key concepts in the reports, to identify participants' ability to determine whether a center performs transplants on "patients like me."

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s): Perceived value of information will be determined via patient responses to the following question, "How useful is the information in the report card in helping you choose a transplant center for you or your family?" Response choices to the questions will be based on a 5-point Likert-type scale (Example: 1 = not at all useful to 5 = very useful). We will also measure satisfaction with decision-making and decisional conflict using the effective decision subscale of the Ottawa Decisional Conflict Scale, which has been validated in multiple studies (18-21).

These questions will be written on cards if the intervention is conducted face-to-face. If conducted via HIPPA compliant zoom call, the questions will be placed in the chat box for the subject to refer to them during the intervention.

4.0 **Study Intervention(s)/Interaction(s)**

4.1 Description:

Before the intervention, the study design with use of hypothetical scenarios will be explained to the participant. The concept of randomization will be also be explained. The participants will be asked a few questions to assess their understanding of the study design, specifically the hypothetical nature of the scenarios. We will also assess whether they understand the concept of being randomized to see one

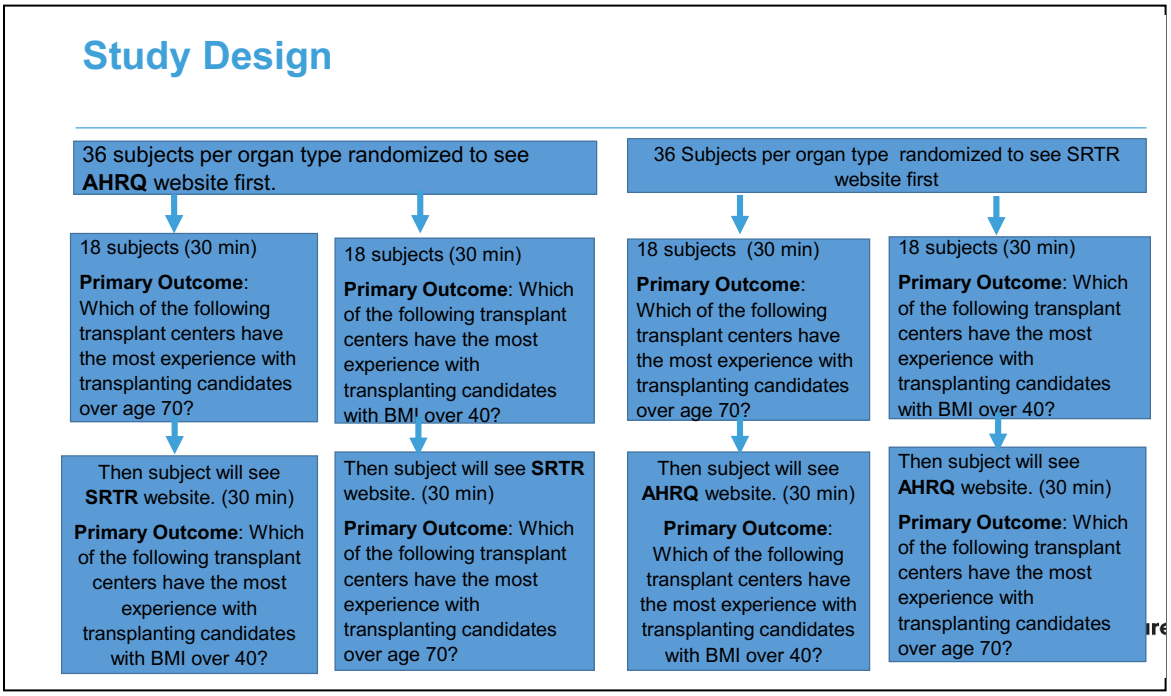
website first and then the other. Only those participants that understand the study design will be invited to participate in the intervention and will be randomized. For subjects that are randomized, a survey will be administered verbally to collect demographic information and information about their kidney disease and comorbidities. The functional health literacy and numeracy assessment and health status questionnaire will be completed. Subjects will be stratified by the transplant center site and then block randomized. One group will be shown the existing SRTR website with its existing SRTR report cards and then the website with the new patient-centered AHRQ report cards for kidney transplants. The other group will be shown the two websites in opposite order. Each participant will have at most 30 minutes to view each of the websites. After viewing each website, responses to the intervention will be collected. Sessions where participants are reviewing the websites will be recorded using Zoom. Figure 2 shows the study design whereby subjects will be block randomized once to one of the four groups consisting of 18 subjects each. At the end of the study, the patients will have access to both the websites.

The study interventions can be administered in person on a laptop. During the COVID-19 pandemic, the intervention can be administered remotely via email and zoom. The link to the websites will be sent via encrypted email and the intervention will be recorded via zoom. The recordings for subjects at Hennepin Healthcare will be stored on computers at that site.

If participant does not have your own electronic device or internet, the study will send the participant a study iPad with internet that participant can use for the intervention and then to send back to the study team. We will provide detailed instructions on how to use the iPad and Zoom application. The study will also pay for a FedEx pick up from the participants' home to return the iPad to the study team after the completion of the intervention.

Figure 2: Study Design of the Randomized Trial.

5.0



Procedures Involved

5.1 Study Design: This aim will entail an RCT of kidney transplant candidates at HHS transplant centers to evaluate the new report card.

5.2 Study Procedures: The study entails assessing knowledge and perceived value of information along with measure of satisfaction with decision-making and decisional conflict. Open-ended questions that provide feedback on the sites will also be collected at the end of the study procedures. This study involves one study visit, approximately 90 minutes in length, to review the two report card websites. This study visit will be done in person or online using Zoom.

The first 5 participants at each site will be enrolled in a vanguard study to optimize the study design. If no change in study design is required, these subjects will be analyzed in the main study.

For consented patients who will be participating in the study remotely, the study team will contact patients via email to confirm the patient's email address. If participants do have their own electronic device with good internet connection, the study team will send a Zoom link for the Zoom testing session to check patient technology and ability to share their screen.

If a participant is willing to participate but has any issues with internet connection or/and missing or inadequate electronic device, the study team will send the participant a study iPad with internet that participant can use for the intervention

and then to send back to the study team. We will provide detailed instructions on how to use the iPad and Zoom application. The study will also pay for a FedEx pick up from the participants' home to return the iPad to the study team after the completion of the intervention.

When the clinical coordinator confirms good technology connection (through patient personal electronic device or study iPad). The study coordinator will schedule a 90 minute Zoom study visit. A sample script for the day of this study visit is attached.

If a participant prefers a face to-face study visit and this is allowed based on local site guidelines, the study intervention can be administered in the clinic. A study coordinator will help patients to work on study's iPad and record the Zoom session of the visit.

We estimate that the total time for the study visit will be around 90 min. After viewing each website, responses to the intervention will be collected.

5.3 Follow-Up: Data that will be collected includes demographic information, information regarding participants' kidney disease and other comorbidities, and the recordings of the study sessions during which participants evaluate the two report card websites. Following the study intervention, there is no follow up for this study.

5.4 Individually Identifiable Health Information: This study will involve use of individually identifiable health information. All subjects will sign a HIPAA authorization form separate from the consent form.

6.0 **Data Banking**

6.1 Storage and Access: The identifiers for all Hennepin Healthcare subjects will be stored at Hennepin Healthcare. The recordings will be banked for future use for 5 years after the study is completed and stored at the respective sites. The PI and the study team will have access to the de-identified data and the recordings.

6.2 Data: The identifiers collected with the initial survey will be destroyed at the end of the study.

6.3 Release/Sharing:

Data will only be accessed by researchers involved in this study and designated lab personnel. The Principal Investigators, will be responsible for the confidentiality of banked data.

7.0 **Sharing of Results with Participants**

N/A – No assessments are performed that may be shared with participants.

8.0 **Study Duration**

8.1 Each participant will be enrolled in the study and the duration anticipated to enroll all study participants is two years. The duration anticipated to complete all study procedures and data analysis is seven years.

9.0 **Study Population**

9.1 Inclusion Criteria: All adults seeking a kidney transplant are eligible for the RCT. We will focus on recruiting kidney waitlist candidates.

9.2 Exclusion criteria are inability to speak or understand English, visual impairment, and inability to give consent. All vulnerable populations except for those listed in the table titled vulnerable populations, will be excluded.

9.3 Screening: Screening will be done by viewing potential participants' information in their electronic medical record (Epic). The research coordinator at Hennepin Healthcare will have access to Epic at HHS and File MakerPro. Within Epic, researchers will first look at a potential subjects 'Patient Type' to determine if the he or she has opted in or opted out of research.

If the patient has opted in to research, preliminary screening will take place before initial approach.

If the patient has opted out of research, the researcher will not contact the patient via mail for recruitment. If the opt-out patient has an appointment at HHS, they may be approached in-clinic, by the treatment team, per clinic guidelines.

Patients will be approached either in-person, by mail (followed up via a phone call) or by encrypted email if the study is first presented by the care team and the patient wishes to learn more about the study (see section 12.1). Allowing for these approaches for recruitment enables us to reach more than just the newly waitlisted patients (those who are in for appointments more frequently) and ensures a wider net of patient availability.

Before the intervention, the study design with use of hypothetical scenarios will be explained. The concept of randomization will be also be explained. The participants will be asked a few questions to assess their understanding of the study design, specifically the hypothetical nature of the scenarios. One such sample question is: In one of the scenarios being tested, a 71 year old candidate is looking to find a transplant center that transplants patients like him or her. So how old is the person that is looking for information about transplant centers? "

We will also assess whether they understand the concept of being randomized to see one website first and then the other. The participants will be asked a question to assess their understanding of the randomization process. One such sample question is: Can you tell me how it will be decided which patients in this study get to see the SRTR website first and which will get to see the AHRQ website first?

Only those participants that understand the study design as denoted by giving the correct answers to the screening questions will be invited to participate in the intervention and will be randomized.

10.0 **Vulnerable Populations**

10.1 Vulnerable Populations:

Vulnerable Population	
Population / Group	Identify whether any of the following populations will be targeted, included (not necessarily targeted) or excluded from participation in the study.
Children	Excluded from Participation
Pregnant women/fetuses/neonates	Excluded from Participation
Prisoners	Excluded from Participation
Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders	Excluded from Participation
Non-English speakers	Excluded from Participation
Those unable to read (illiterate)	Excluded from Participation
Employees of the researcher	Excluded from Participation
Students of the researcher	Excluded from Participation
Undervalued or disenfranchised social group	Included/Allowed to Participate
Active members of the military (service members), DoD personnel (including civilian employees)	Included/Allowed to Participate

Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc.	Excluded from Participation
Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare.	Excluded from Participation
Individual or group with a serious health condition for which there are no satisfactory standard treatments.	Excluded from Participation
Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior).	Excluded from Participation
Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research.	Excluded from Participation

10.2 Additional Safeguards:

This is a study that is open to all kidney transplant candidates who fit study inclusion/exclusion criteria. All vulnerable populations except for those listed in the table above will be excluded.

11.0 **Number of Participants**

11.1 Number of Participants to be Consented

The table shows the required sample size for ranges of detectable differences and within-person correlation.

	Correlation						
	0.0	0.1	0.2	0.3	0.4	0.5	0.6
0.20	107	98	89	79	67	56	45

Detectable	0.22	90	82	76	66	56	47	38
Difference	0.24	76	71	64	55	48	40	33
	0.25	70	66	59	51	44	37	*
	0.26	66	61	55	48	41	34	*
	0.28	57	53	46	41	35	30	*
	0.30	51	45	41	36	32	27	*

On the conservative side, we will power the study to detect a proportional difference as small as 25% and therefore plan to enroll at 72 subjects for each organ trial. Recruitment will continue until this desired sample size is achieved. Given the low-risk nature of this project, there will be no stoppage rules based on interim analysis for recruitment.

This 72 is in addition to the 130 subjects enrolled in the interviews and focus groups and usability testing. Thus the total enrollment will be 130 + 72= 202. The 97 subjects already enrolled along with the 50 subjects that can be enrolled in the trial at HCMC, brings the total maximum enrollment to 147 at HCMC.

12.0 **Recruitment Methods**

12.1 Recruitment Process:

The research coordinators will screen kidney transplant candidates at HHS until an appropriate number have agreed to participate. Patients may be recruited a number of ways:

- Patient direct contact at the Hennepin Healthcare transplant clinic or hospital - the study coordinator will ascertain an appropriate time to introduce the study to the patient during a standard of care visit and ask if they are interested and willing to participate in the study. If they agree to learn more, the investigator or study team member will close the door and in the presence of family (if requested), begin the consent process.
- By mail – alternately, eligible patients will be sent an invitation letter along with consent materials by mail. The invitation letter will state that they are being invited to the study because they are a transplant candidate at the Hennepin Healthcare. A study coordinator will then contact the patient by phone to introduce the study and ask if they are interested and willing to participate after allowing time for the invitation letter to arrive. Patients will be instructed to sign and return the consent materials by mail if they wish to participate in the study.
- Electronically if waiver of consent not provided by IRB- Patients may be consented electronically using an e-consent platform (REDcap HHRI) with an accompanying phone call or video feed to conduct the consent conversation. The subject will review the e-consent in detail and have the chance to ask questions. Study personnel will then ask the subject questions to ensure that

they understand the information presented in the consent discussion using a teach back method.

- By care team - If allowed by local sites, care team members may ask potential participants if they are interested in learning more about this study by email. If so, the study team may send potential participants the study invitation letter by encrypted email.

The research coordinator will keep a log of all participants who do not meet eligibility criteria and why. The coordinator will assess whether the participant has a smartphone, tablet or computer through which the participant can access the websites being studied.

Patients who agree to participate in the study will be consented and randomized. All participants will read, sign, and date a consent form before undergoing any study procedures. A copy of the signed consent form will be given to the participant. Patients who are consented by mail will not be considered as enrolled in the study until the study team has received their signed consent form. The consent process will be ongoing until recruitment goals are met.

12.2 Source of Participants:

The sites for the RCT include HHS. Participants will be recruited from the adult kidney transplant candidate.

12.3 Identification of Potential Participants:

Potential participants will be recruited based on information from their medical record—they must be kidney transplant candidates with either evaluations or waitlisted at the HHS. All potential patients under the care of the Hennepin Healthcare use an EMR that will be accessed to screen for adult patients. During the chart review, patients meeting exclusion criteria will be excluded. All potential transplant candidate participants are patients of the Hennepin Healthcare.

All members of the research team have access to Epic. The research team will run a report for potential participants who meet inclusion/exclusion criteria for the study. An eligibility report may be generated by FileMaker and EPIC that have similar information for kidney transplant candidates.

The study coordinators will create a patient list to evaluate possible participants against inclusion and exclusion criteria. Coordinators will exclude patients who have declined to participate in research, unless this study is presented by the care team and the patient wishes to learn more about the study.

While preparing invitation letters, the study team may review the list to determine if some potential participants are coming into clinic for routine care. If a potential participant is coming into clinic for routine care, the study team may approach the potential participant in clinic.

12.4 Recruitment Materials:
An IRB-approved recruitment letter will be sent to potential participants recruited via mail. An IRB-approved phone script will also be used to contact potential participants after the recruitment letter is sent. No recruitment materials (other than the IRB-approved consent form) will be used for potential participants recruited in person.

12.5 Payment: Participants will receive a $40 Target e-gift card or check for their participation. Parking costs will be covered for patients participating in the in-person study visits.

13.0 **Withdrawal of Participants**

13.1 Withdrawal Circumstances:

If a subject is unable or unwilling to complete the study tasks (interventional testing), they may be withdrawn from the study without their consent.

13.2 Withdrawal Procedures:
If a subject withdraws their consent, study staff will no longer use or disclose their health information. However, information already collected cannot be retrieved or destroyed and may be used as part of the study.

13.3 Termination Procedures:

The study may terminate early and at any time for administrative reasons. In the event that this occurs, the IRB will be notified of this decision.

14.0 **Risks to Participants**

14.1 Foreseeable Risks: Foreseeable risks to participants include loss of confidentiality of their responses, as collected during the RCT. The likelihood of the loss of confidentiality will be low because of the research processes detailed below.

Participants will be sent a link via encrypted email to the websites being studied (the intervention occurs via Zoom). The websites are available to the public. When the intervention is done remotely the participant will share their screen with the research coordinator using a password protected video conference service such as Zoom. Participants will be instructed to shut down all other programs and pages so as not to accidently share other information on their computer with the research coordinator. The coordinator will take notes on which pages of the website are viewed and how long participants took to respond to the questions posed. The responses to survey questions and knowledge questions will be recorded by the coordinator on paper that only has the unique study code and no personal identifiers. Thus, no names will be attached to the surveys,—they will be labeled only with the unique study code. The identifiers for the respective subjects will be kept separately. The Zoom conference call will be recorded (audio and video), and stored on a HHRI computer or server.

The randomized clinical trial participants will be instructed not to use their full names since the intervention will be recorded. The recordings will be used to determine whether the study procedure was followed correctly. For example, the recordings will be reviewed to ensure that there were no prompts given inadvertently to the participant to help the participant get the correct answer. The recordings will also be reviewed to determine locations in the websites that were difficult for the participant to navigate.

14.2 Reproduction Risks: N/A

14.3 Risks to Others: N/A

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception: N/A

16.0 Potential Benefits to Participants

16.1 Potential Benefits:

Despite the availability of best medical care, patients with end-stage disease have difficulty finding transplant centers that transplant patients like them. The cost of caring for these end-stage disease patients is high and transplantation is cost-effective and life-saving. Participation in the study confers no direct benefit to the study subjects.

Understanding the needs of transplant candidates and creating a patient friendly website that allows them to find transplant centers that transplant patients like them, will be useful for all future transplant candidates. This study could improve access to transplantation and potentially improve outcomes post transplantation. Given the lack of direct benefit to study participants, it is important to recognize that the risks are also minimal, the major risk being loss of confidentiality. The safeguards planned will minimize this risk.

17.0 Statistical Considerations

17.1 Data Analysis Plan:

Before initiating outcome analyses, we will perform exploratory analysis to examine frequency distributions for all baseline variables, with particular attention to variable ranges and skewness. We will examine group comparability at baseline between the two RCT arms to assess whether randomization succeeded in creating equivalent groups. These analyses will help determine potential need to incorporate additional covariates in later analyses using propensity-based methods (22-25). Relevant baseline measures include socio-demographic factors, health literacy and numeracy assessment, and baseline survey information.

17.2 Power Analysis: The table shows the required sample size for ranges of detectable differences and within-person correlation.

		Correlation						
		0.0	0.1	0.2	0.3	0.4	0.5	0.6
Detectable Difference	0.20	107	98	89	79	67	56	45
	0.22	90	82	76	66	56	47	38
	0.24	76	71	64	55	48	40	33
	0.25	70	66	59	51	44	37	*
	0.26	66	61	55	48	41	34	*
	0.28	57	53	46	41	35	30	*
	0.30	51	45	41	36	32	27	*

On the conservative side, we will power the study to detect a proportional difference as small as 25% and therefore plan to enroll at 72 subjects. Recruitment will continue until this desired sample size is achieved.

17.3 Statistical Analysis:

The primary analysis will be based on the conservative "intention-to-treat" (ITT) approach. We will use a chi-square test and logistic regressions for analyzing primary and secondary measures. A sensitivity analysis will be conducted excluding subjects that did not enter the correct hypothetical information into the website. The research coordinator will record the amount of time subjects spend with each website and the webpages viewed by each subjects and that information will be analyzed for descriptive analysis. Other subset analysis will be conducted but presented as ad hoc analysis.

17.4 Data Integrity:

The PI is responsible for the integrity of the data for this study. The study recordings will be used to determine whether the study procedure was followed correctly. For example, the recordings will be reviewed to ensure that there were no prompts given inadvertently to the participant to help the participant get the correct answer

The recordings will be stored. If the recordings are presented in publications and presentations, the presented recordings will focus on the website that subjects are navigating but without the subject's voice and face being shown. These recordings can highlight strengths and weaknesses of the websites in order to motivate future improvements to the web site.

18.0 Health Information and Privacy Compliance

Individually Identifiable Health Information:

Under the HIPAA Privacy Rule, research studies are permitted to use and disclose protected health information with the authorization of the research participants, or without individual authorization in limited circumstances. Outside of that none of this information will be released outside of the covered entity.

18.1 Select which of the following is applicable to your research:

☐ My research does not require access to individual health information and therefore assert HIPAA does not apply.

☒ I am requesting that all research participants' sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization), only if IRB does not grant waiver of consent.

☐ I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

☐ An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

18.2 Identify the source of Private Health Information you will be using for your research (Check all that apply)

☐ I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me

☒ I will collect information directly from research participants.

☐ I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

☒ I will pull records directly from EPIC.

☐ I will retrieve record directly from axiUm / MiPACS

☐ I will receive data from the Center for Medicare/Medicaid Services

☐ I will receive a limited data set from another institution

18.3 Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

Please see pertinent recruitment and screening sections above. Within EPIC, research team members will first look at a potential participant's "Patient Type" to determine if he or she has opted in or opted out of research. If the potential participant has not opted out of research, preliminary screening will take place prior to the research team approaching the potential participant. If a potential participant has opted out of research, the research team will not look into the chart and will not be able to do preliminary screening. Instead, the researcher will approach the potential participant in person to ascertain interest in the study. If the potential participant expresses interest in the study, the researcher will inform the potential participant that his or her medical record will be reviewed to determine eligibility and ask for the potential participant's permission to view his or her medical record for this purpose.

18.4 Approximate number of records required for review:

There are approximately 300 kidney transplant candidates on the waiting list at at HHS. The records of these candidates will be screened to enroll 50 of the 72 subjects in the RCT.

18.5 Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes

☐ This research involves record review only. There will be no communication with research participants.

☐ Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

☒ Communication with patients will take place in-person, via phone, video conference calls, through mail, and encrypted email. Email communication will be used to share initial details about the study (if the patient is approached by a care team member and would like to hear from the study team via email), the Zoom session information, and to provide patient compensation following their study session if they prefer to be compensated by email.

18.6 Access to participants:

Investigators have permissible access to patient records via EPIC and their treating relationship with the patients. Research team members have EPIC access via NERS and will only access records and PHI as outlined in the protocol above.

18.7 Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply).

☐ In the data shelter of the Information Exchange (IE)

☐ Store ☐ Analyze ☐ Share

☐ In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

☐ Store ☐ Analyze ☐ Share

☒ In REDCap (recap.ahc.umn.edu)

☒ Store ☒ Analyze ☒ Share

☐ In Qualtrics (qualtrics.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In OnCore (oncore.umn.edu)

☐ Store ☐ Analyze ☐ Share

☐ In the University's Box Secure Storage (box.umn.edu) for M-Health patients

☐ Store ☒ Analyze ☒ Share

☒ Store ☒ Analyze ☒ Share

☐ In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

☐ Store ☐ Analyze ☐ Share

☒ Other:

Data will be maintained in paper, digital, and audio formats. De-identified data collected on paper will be transferred to a database stored on a secure server at Hennepin Healthcare Research Institute (HHRI). Paper data will be stored in filing cabinets in the researchers' locked offices. All computers require users to log-in with usernames and passwords.

Only the investigators have permissible access to the study records. Consents will be kept in a locked drawer in a secure room that requires keypad access.

No names will attach to the surveys, audits or tapes; they will be labeled only with the unique code. At the end of the study, we will delete the zoom recordings.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a smartphone (iPhone or Android devices) that you have not already identified in the preceding questions

☐I will use a server not previously listed to collect/download research data

☒I will use a desktop or laptop not previously listed HHS location for HHS patients

☐I will use an external hard drive or USB drive ("flash" or "thumb" drives) not previously listed

☐I will use a mobile device such as an tablet or smartphone not previously listed

18.8 Consultants. Vendors. Third Parties. Not applicable

18.9 Links to identifiable data:
None .

18.10 Sharing of Data with Research Team Members: Data will be shared within the University of Minnesota's Box.

18.11 Storage and Disposal of Paper Documents: Any paper documents generated at the HHS sites will be stored on-site in the research offices HHS. The office space is secured by key-card or door-code access only. All study documents will be stored through the required length of storage outlined by the study protocol and grant materials. Likewise, M-Health documents will be stored on M-Health site.

19.0 Confidentiality

19.1 Data Security:

Data will be maintained in paper, digital, and audio formats. Electronic data from the de-identified paper forms will be stored on a secure server at HHRI. All servers have encryption and require users to log-in with usernames and passwords. Paper data will be stored in filing cabinets in the researchers' locked offices. Electronic locations for data storage, analysis and sharing: HHRI secure server.

20.0 Provisions to Monitor the Data to Ensure the Safety of Participants

20.1 Data Integrity Monitoring.

This is a minimal risk project, collecting quantitative and qualitative data from interviews. The principal investigator will be responsible for overseeing the data integrity throughout the project.

20.2 Data Safety Monitoring. N/A – this research involves no more than minimal risk

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury: N/A - minimal risk.

21.2 Contract Language: N/A

22.0 Consent Process

22.1 Consent Process (when consent will be obtained):

Potential participants will be approached either in clinic, via mailing followed by a phone call from study personnel, or encrypted email (see section 12.1). At the time of approach, participants will be given a consent form for review. Patients will be consented either in person, by phone, or electronically using REDCap HHRI.

Participants consented by phone will mail their signed consent form back to the study team. Participants will be given a copy of the consent form for their records.

All potential participants will be given time to think about the study information presented to them. They will be encouraged to ask questions and discuss the study with individuals other than the study personnel. Subjects will have adequate time to review the consent form and ask questions before signing the consent form. Subjects will be informed of the voluntary nature of the study. The individual presenting the study will stress the fact that the subject's care and/or relationships with the HHS will not be affected by the subject's decision to participate or not to participate.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception): N/A

22.3 Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): NA

22.4 Non-English Speaking Participants: N/A

22.5 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age): N/A

22.6 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent: N/A

22.7 Adults Unable to Consent: N/A

23.0 **Setting**

23.1 Research Sites:

The research will take place locally at the HHS. Subjects will be recruited from the Hennepin Healthcare Clinic.

23.2 International Research: N/A

23.3 Community Based Participatory Research: N/A

24.0 **Multi-Site Research**

24.1 Study-Wide Number of Participants:

This study is performed at HHS. This site will enroll kidney transplant candidates as subjects for the RCT.

24.2 Study-Wide Recruitment Methods: N/A

24.3 Study-Wide Recruitment Materials: N/A

24.4 Communication Among Sites: N/A

24.5 Communication to Sites: N/A

25.0 Coordinating Center Research

HHS is Coordinating Center for this research study.

25.1 Role: The data coordinating center will be involved in receiving de-identified data from each of the sites and doing the final analysis.

25.2 Responsibilities: The data coordinating center will hold regular calls with the coordinators at each site to ensure that proper procedures are used. During these calls, the coordinating center will ensure that the most current version of the protocol is being followed and that amendments to the protocol are communicated to all centers.

25.3 Oversight: Provide each participating center FWA number with OHRP (if the research is federally funded). The protocol events at HHS will be reported to the IRB at HHS.

25.4 Collection and Management of Data: The data will be collected in a central data collection tool such as RedCap with no identifiers. The identifiers will be maintained at the individual study site only. The de-identified data will be used for analysis.

26.0 Resources Available

26.1 Resources Available:

To assist with this study, the study will utilize services from Hennepin Healthcare Research Institute.

HHS will provide regulatory and clinical coordinator support for the study for subjects enrolled at HHS.

27.0 References

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