IRB Minimal Risk Protocol Template

General Study Information

Principal Investigator: Victor Montori, MD and Colleagues

Study Title: QBSAfe: A novel approach to diabetes management focused on Quality of life, Burden of treatment, Social integration and Avoidance of Future Events

Protocol version number and date: Version 4; September 8th, 2020

Research Question and Aims

Hypotheses:
The QBSAfe toolkit will be co-developed with patients, family caregivers, and clinicians and will focus on palliating symptoms, alleviating burden of treatment, facilitating social connections, and optimizing treatment safety. It will include recommendations for how to elicit these components during clinical encounters and will include specific strategies/drugs to use, criteria for when to intensify/de-intensify therapy, co-adjuvant medical and nonmedical interventions, and tools to help clinicians coordinate care among team members and assess response to treatment.

Aims, purpose, or objectives:
To develop the QBSAfe toolkit for patients with diabetes mellitus.

Background (*Include relevant experience, gaps in current knowledge, preliminary data, etc*.):

Diabetes care has traditionally focused on targeting and maintaining specific levels of glycemic control (average glucose, or HbA1c) to reduce the risk of diabetic complications. However, this approach is problematic. Therapies to achieve target HbA1c levels (even modified targets) may impose significant burdens on patients (taking medications, injecting insulin, monitoring blood sugars, adjusting diet and exercise), may create or add to financial problems (increase premiums or out-of-pocket costs), may lead to hypoglycemia or other adverse events, and – overall – may not necessarily improve the quality of life, even in the long term. Older patients with multiple chronic conditions are especially vulnerable to the added burdens of diabetes care as they often already have multiple other comorbidities and/or functional impairments.

About 30 million Americans have diabetes and the vast majority takes medications to control their blood sugars. In addition to diabetes, about half of the older patients have multiple other comorbidities and functional impairments, and one or more geriatric conditions. As a result, glycemic management in this population is challenging. Multiple chronic conditions and impairments make it challenging to self-manage complex tasks (such as insulin administration and dosing), may leave patients overwhelmed and overburdened by the work required to manage their conditions, and increase the risk of adverse events (such as hypoglycemia). Social isolation and limited social support, poor financial, physical, and mental health, and personal and social complexities limit the capacity of patients and caregivers to shoulder the mushrooming treatment workload. We

showed that patients with diabetes experience high treatment burden and routinely discuss this with their clinicians, but these discussions rarely lead to any efforts to address this burden. We also found that hospitalizations for hypoglycemia pose a significant health threat for older adults and are now more common than admissions for hyperglycemia.[1] These results suggest that a paradigm shift is needed – from the narrow focus on reaching hemoglobin A1c targets – even modified ones – to a more holistic approach that responds to patient needs, fits within the patient's context and capacity, and prevents iatrogenic harms.

To shift the paradigm of care for people with diabetes – from the narrow focus on reaching HbA1c targets to prioritizing patient-centered goals – we are developing and testing the QBSAfe toolkit. QBSAfe is a way of caring for patients with diabetes that helps clinicians focus on what is important to patients. The domains of QBSAfe include **Q**uality of life, **B**urden of treatment (medication administration, costs, and monitoring), **S**ocial connectivity, and **A**voidance of **F**uture **E**vents (including hypoglycemia and other adverse events, as well as diabetic complications). We propose to create a semi-structured "interview guide" (such as is used in qualitative research) and to train clinicians to begin the visit with questions that probe at the main domains of QBSAfe. This approach will allow clinicians to hear the story from the patient's point of view, to identify problems/issues that need to be addressed, and together decide/prioritize what issues demand action.

Study Design and Methods

Methods: *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol.*

This will be a three-site study conducted at Mayo Clinic Rochester, Yale University, and Trinity Health of New England. Mayo Clinic will serve as the IRB of Record for Yale University; Trinity Health of New England will receive oversight from their own IRB following the approval of the Mayo Clinic IRBe application.

Observations of clinical encounters

To complete data collection, encounters of patients and clinicians will be observed (by a study team member and/or using an audio-/video-recording device) at Mayo Clinic Rochester, Yale University, and Trinity Health of New England. We will identify patterns of patient-clinician conversations regarding the treatment of diabetes mellitus. The information will be summarized by our research team and integrated with knowledge from previous decision support work. Study team members involved with the recruitment process may also follow-up with patients and clinicians following their visit to get feedback regarding their conversation. For patients, this will happen by phone in the form of an interview. For clinicians, this will happen in the form of a focus group. In addition, patients and clinicians may receive a short questionnaire to assess their experiences with the conversation and their perceived fit of the care plan.

We will explicitly indicate during an appointment if we plan to use a recording device in the room and ask for written consent from the patient and clinician prior to the appointment. These recordings will be used to further review and debrief with the team members on the protocol that cannot all be present at one time for the encounter.

Field testing and iterative development

We propose to create a semi-structured "interview guide" (such as is used in qualitative research) and to train clinicians to begin visits with questions that probe at the main domains of QBSAfe. Clinicians will be trained to start with open ended questions, and then to probe with follow-up questions. This approach will allow clinicians to hear the story from the patient's point of view, to identify problems/issues that need to be addressed, and together decide/prioritize what issues demand action. Since clinicians may not yet know how to address some of the issues that come up, we plan to develop guides for commonly encountered issues within the domains (for example, fatigue or chronic pain within the Q domain; difficulty performing multiple finger sticks each day within the B domain; loneliness within the S domain). The commonly encountered issues will be linked to possible solutions; solutions will be derived from review of the existing evidence and content experts. The prototype may be presented to the Knowledge and Evaluation Research (KER) Unit Patient Advisory Group (PAG) for input and refinement.

We will then iteratively field test the prototype toolkit within patient-clinician encounters and further develop the prototype based on its performance. For field testing and iterative development, encounters of patients scheduled to discuss management of diabetes mellitus with their clinician will be observed (by a study team member and/or using a video recording device) at Mayo Clinic Rochester, Yale University, and Trinity Health of New England. Prior to the scheduled patient-clinician encounter, patients who have agreed to participate and provided consent will be asked to complete a pre-encounter questionnaire. Study team members involved with the recruitment process may also follow-up with patients and clinicians following their visit to get feedback regarding the QBSAfe toolkit. For patients, this will happen by phone in the form of an interview. For clinicians, this will happen in the form of a focus group. In addition, patients and clinicians may receive a short questionnaire to assess their experiences with the conversation and their perceived fit of the care plan.

We will explicitly indicate during an appointment if we plan to use a recording device in the room and ask for written consent from the patient and clinician prior to the appointment. These recordings will be used to further review and debrief with the team members on the protocol that cannot all be present at one time for the encounter. Based on communication patterns identified, refinements to the toolkit will be made.

Iterations of the prototype will be developed with input from study team members and based on experiences to-date. The process of field testing will continue until the study team, stakeholders, and PAG members reach a consensus that the prototype is successful in involving patients in the decision-making process. Based on our experience, up to 20 versions may be necessary to achieve this goal.

All patients who participate in the study will be asked for their permission to use the data collected through their participation in the study (such as audio or video recordings) for ongoing registry purposes for IRB-approved research, training and educational purposes. In situations such as video recordings, files will only be retained for future use as long as both the clinician and the patient in the video agree to this.

Patients at Yale University may be identified and recruited ahead of their scheduled clinical appointment via telephone. Due to limited space and resources at the Yale University campus, patients who express interest will be asked to come in early for their scheduled appointment to go through the consent process. To compensate patients for the extra time required, the cost of parking will be covered by the research team.

In situations where the ability to recruit, consent, or observe clinical encounters (for observation of clinical encounters and field testing and iterative development) in person is not feasible, telephone and e-mail will be

utilized. For patients, recruitment will take place over the phone prior to their scheduled clinical appointment. Study team members will introduce the study and go through the consent process for patients who are interested in participating. Similarly, recruitment for eligible clinicians will take place over the phone or by e-mail. Both patients and clinicians will be given an opportunity to have all of their questions and concerns addressed, as well as sufficient time to make an informed choice regarding participation. A variety of different methods (deemed acceptable by IRB) will be used to obtain consent from participants based on participant preference: 1) paper consent sent via fax or mail and returned in the same method, 2) scanned consent sent to participants via e-mail and returned to the study team via e-mail, and/or 3) Electronic Informed Consent. If Electronic Informed Consent is preferred, participants will receive the appropriate consent document to their e-mail via DocuSign in PTrax (more language on this process is included in the IRBe application under "Written Consent"). For patients and clinicians who have a tele-medicine or virtual appointment scheduled with their clinician, observation/recording will take place through Zoom or other Mayo Clinic-approved platforms. If recording within the used platform is unavailable, recording will take place similarly to in-person encounters with a recording device (i.e. GoPro).

Some data analysis will be conducted at Yale University and Trinity Health of New England by using SharePoint/SimpleShare. All data will be stored securely on password-protected servers and SharePoint/SimpleShare. Password-protected USB drives may also be used to store electronic files in situations where connection to SharePoint/SimpleShare is limited or unavailable. These USB drives are encrypted and will be used in accordance with Mayo Clinic's Portable Computing and Telecommunication Devices Policy. These USB drives may be shared externally to Yale University and Trinity Health of New England.

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 100

Subject population (children, adults, groups): Adult patients with diabetes mellitus

Inclusion Criteria: Diagnosis of diabetes mellitus; existing appointment with participating clinician

Exclusion Criteria: Do not speak English; severe vision/hearing impairments or unable to give informed consent for any reason

All patient encounters will involve patients seen at Mayo Clinic Rochester, Yale University, and Trinity Health of New England.

Activity	Participant	Inclusion Criteria	Exclusion Criteria	Consent / Authorization
Observations of Clinical Encounters	Patients	- Adults ≥ 18 years	- Major barriers to providing informed	Written consent

And Field Testing and Iterative Development		- Appointment for management of diabetes mellitus - English speaking	consent (i.e. dementia, severe hearing or visual impairment)	
	Clinicians	- Clinicians who meet with patients for management of diabetes mellitus	None	Written consent
	PAG Members	- Adults ≥ 18 years - Member of the KER Unit PAG	None	Oral permission / HIPAA does not apply

Biospecimens

Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

Prospective collection of biological specimens other than blood: _____

Review of medical records, images, specimens

Check all that apply (data includes medical records, images, specimens).

☐ Only data that exists before the IRB submission date will be collected.

Date Range for Specimens and/or Review of Medical Records:
Examples: *01/01/1999 through 12/31/2015*, or all records through *mm/dd/yyyy*.

Note: The Date Range must include the period for collection of baseline data, as well as follow-up data, if applicable.

☒ The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol.*

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

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Data Analysis

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement: N/A

Data Analysis Plan: This study is for the development (not testing) of a communication toolkit.

Endpoints
Primary:
Secondary:

Citations:

1. Lipska KJ, Ross JS, Wang Y, et al. National Trends in US Hospital Admissions for Hyperglycemia and Hypoglycemia Among Medicare Beneficiaries, 1999 to 2011. JAMA Intern Med. 2014;174(7):1116–1124. doi:10.1001/jamainternmed.2014.1824