Co-designing and piloting educational materials with patients and healthcare providers for syncope in the emergency department

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ABSTRACT

Objective: The purpose of this study was to identify barriers and design interventions to promote adherence to 2017 Guideline for Syncope Evaluation and Management.
Methods: Focus groups and interviews were conducted to understand preferences, needs and barriers from patients and providers. Educational materials for patients were developed following a co-design, iterative process with patients, providers and hospital staff. The academic medical center's (AMC) Patient Education Department and Patient & Family Advisory Council reviewed materials to ensure health literacy. We piloted usability and feasibility of delivering the materials to a small cohort of patients.
Results: From Feb to March 2020, 24 patients were asked to watch the video. Twenty-two watched the intake video; of those 8 watched the discharge video. 95% of participants found the intake video informational and 86% would recommend it to others; 100% found the discharge video informational and would recommend it to others. Patients who watched both videos reported the videos improved their overall stay.
Conclusion: Our study described a patient-clinician-researcher codesign process and demonstrated feasibility of tools developed to communicate risk and uncertainty with patients and facilitate shared decision making in syncope evaluation.
Innovation: Engaging end users in developing interventions is critical for sustained practice change.

1. Introduction

Syncope, or fainting, is a common reason that patients seek medical care in the United States. One-half of all Americans are estimated to have a syncopal experience at some point during their lives, with recurrence rates as high as 9.3% [1,2]. An estimated 1% to 3% of all emergency department (ED) visits—and up to 6% of all hospital admissions—are due to syncope [2-6]. Despite advancements in our understanding syncope, accurately diagnosing patients remains a challenge. Upon arrival to the ED, almost half of all syncope patients are not diagnosed as syncopal due to patients being asymptomatic at the time of presentation [7]. The difficulty in diagnosis leads to unnecessary testing and inappropriate admissions [7,8]. As a result, syncope costs have increased significantly in the United States presenting a substantial financial and safety burden to patients [9].

Aiming to provide guidance on optimizing the diagnosis and management of syncope, a collaboration of the American College of Emergency Physicians, Society for Academic Emergency Medicine, American College of Cardiology (ACC), American Heart Association (AHA) and Heart Rhythm Society (HRS) issued a Guideline for the Evaluation and Management of Patients With Syncope in 2017 [8]. The 2017 Syncope Guideline represents an effort to standardize clinical practice and reduce unnecessary services. The standard ED diagnostic evaluation involves a history, physical examination, electrocardiogram, and laboratory testing, when indicated [4,10]. Diagnostic tests for syncope should not be routinely ordered, and the decision to order any tests should be guided by information obtained from the patient's history or physical examination. However, overtesting is common due to concern of potential serious underlying cause of a syncopal event. For example, computerized tomography (CT) scans of the brain are frequently ordered, but published research has confirmed that abnormalities that could cause a syncopal event are rarely found [11-15]. Overtesting can result in tremendous, unnecessary medical expenses and can cause harm to the patient. Injudicious use of head CT to investigate syncope is not only costly

but also exposes patients to high levels of radiation (Head CT: 2.0 mSv (200 mrem); 8-month background dose accumulation) [16]. Even if there is no risk of physical harm from the test itself, patients may experience the psychological harm as they deal with the uncertainty of ambiguous tests and the fear factor involved in false-positive results [17].

The awareness and implementation of the 2017 Syncope Guideline remained low [18,19]. Many factors drive provider decisions to order lab testing and advanced imaging that may be of limited utility for low-risk patients, including physician risk aversion; patient expectations (real or perceived); and lack of applicable clinical decision instruments. This study aimed to (1) understand factors driving overtesting from patient and clinician perspective, (2) codesign and develop patient-centered tools to facilitate clinician–patient discussions and engage patients in syncope care in the ED setting, and 3) test the feasibility and usability of developed tools.

2. Methods

2.1. Phase 1: use-centered principles in understanding barriers (see Fig. 1)

We applied use-centered principle [20-22] to gain understanding on patients' and clinicians' needs and concerns. From October 2018 to June 2019, we conducted patient and provider focus groups and interviews at four academic medical center campuses to identify common issues experienced by syncope patients when presenting to the ED. The focus groups and interviews were audio recorded. Recordings were transcribed verbatim and quality checked by an independent researcher. Transcriptions were entered into NVivo 12 (QSR International, London) for analysis. Transcriptions were coded using a rigorous team-coding approach. Disagreements in coding were discussed until consensus among coders was reached. The entire research team met to discuss the codebook and its relevance to the data, and codebook revisions were made as needed. The two original coders then co-coded each transcript. The data collection and analysis methodology of patient and provider interviews are described in detail in previous publications [18,23].

2.2. Phase 2: co-design and refine educational materials

Based on the findings and input from stakeholders which revealed the need to address patient and caregivers expectations and concerns [18,19,23], we worked with clinicians and patients to codesign prototypes of educational tools to be used based on the information gathered in Phase 1.

Information from patient interviews also showed that the discharge education on syncope was not consistent. Upon reviewing the current patient discharge documents, we found a multipage format that was not easy to follow and inclusion of extraneous information. As example, stroke information was provided to patients with vasovagal syncope, which may potentially generate unnecessary patient questions/concerns and may not help patients understand their condition. The development of educational materials and tools (i.e., education sheet and videos) was an iterative process with multiple cycles of review, feedback, and revision. Multiple team meetings including both researchers and clinicians were spent on review and revision before sending the materials for final evaluation. After the team agreed on material edits, all educational materials (including the video described below) were reviewed by the Hospital Patient Education Department from a health literacy perspective to be sure they were at the appropriate reading level (i.e., following NIH recommendation, be written at a grade 6–7 reading level). After the first set of revisions based on suggestions and feedback from Patient Education, we met with the Cardiovascular Patient and Family Advisory Council (PFAC) for formal demonstration of the materials and solicitation of feedback. The PFAC consists of current and former patients who have received cardiovascular treatment and care at our hospital. The PFAC endorsed the organizational flow of the handouts and videos, also thought the language was clear. The PFAC members made suggestions for improvement including adding a short explanation of EKG, increasing font size, alternating two voices through the video instead of first half vs. second half. Based on the PFAC comments, the documents were further refined.

2.3. Phase 3- piloting tools in the ER

Testing the usability of interventions prior to implementation can help to detect obstacles in acceptability, ease of use and inform the implementation approach [24]. Therefore, we conducted a usability test of the materials in the hospital ED from February–March 2020. Prior to the pilot study, we met with a nurse champions and ED directors to develop buy in from and codesign pilot process with the ED staff and doctors [25]. We toured the ED to understand the workflow, and ED nurses provided suggestions on options of integrating patient education into workflow for the closed-loop communication between patients and providers. To garner
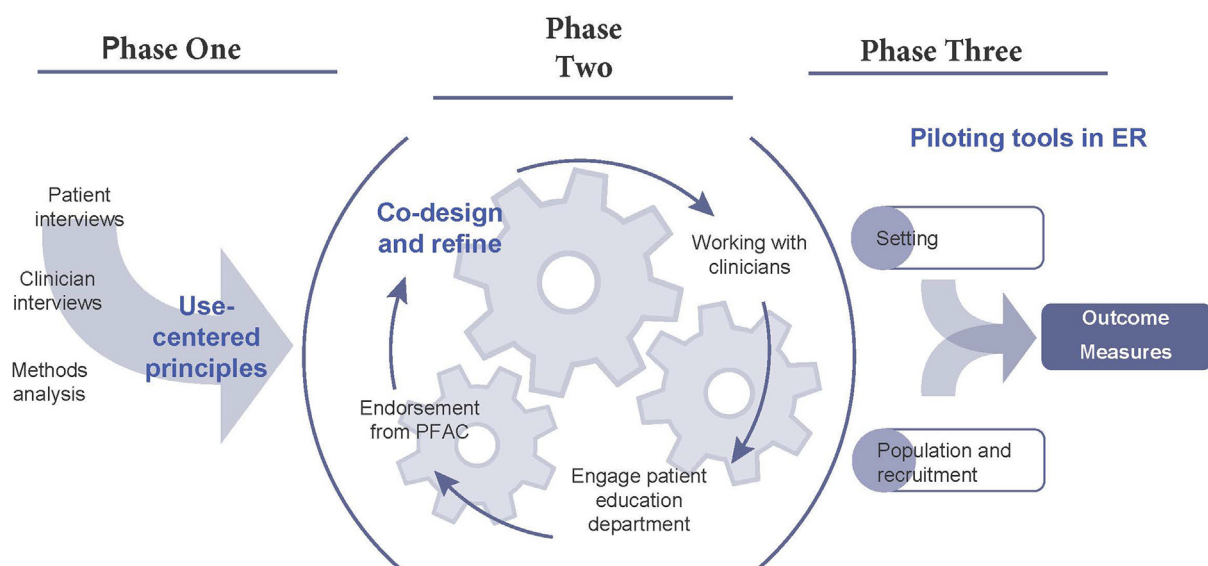

Fig. 1. Phases of codesign. Phase 1: Application of use-centered principle to gain understanding on patients' and clinicians' needs and concerns. Phase 2: Initial development of materials with clinicians and patients to codesign prototypes of educational tools to be used based on the information gathered in Phase 1. Phase 3: Usability test of the developed materials in the hospital ED.

buy-in, we also conducted educational (academic detailing) sessions with the Emergency Medicine physicians, hospitalists, cardiologists, and other staff who were involved in syncope evaluation and management to explain the conduct of the planned pilot study and teach syncope protocols. Via four one-hour meetings, we were able to present our study and the importance it would have in patient education and syncope care delivery. Based on nurses and ED educator feedback, we codesigned a feasible process for the pilot that would minimize workflow disruption.

To identify syncopal patients, we received a daily list of eligible patients (code R55) using hospital daily ED and admission rosters and the electronic health record (EHR) data source. In addition, we added printed flyers at the registration desk so that staff and doctors in the ED knew why we were there and what we were doing. These flyers also allowed for direct contact from the ED to the research assistant (RA) if a syncopal patient had arrived.

Educational videos were developed by our team using our patient interview findings and the Choosing Wisely Campaign [23,26,27]. To better inform the patient of what to expect when they are in the ED after a syncopal episode, we approached syncope patients to watch our intake video (Fig. 3). The video, "What to Expect in the ED after You've Fainted" was presented to the patient and family caregiver, if any, after being triaged. The video content explains what syncope is as well as what kinds of tests and treatments the patient can expect to receive during their ED visit. Before the patient was discharged, they were approached to watch the second video, "What to Expect When Leaving the Hospital" which explains how to help them understand their discharge paperwork as well as how and when to follow-up with the primary care provider and a specialist, if appropriate. The videos can be played on a patient's phone by scanning a QR code or an iPad carried by the research assistant. Additionally, headphones were offered to the patient to ensure the audio volume was loud enough to be easily understood. After each video the patient and caregiver (if any) were asked to rate on a Likert scale how they would rate the information shown (5 = very helpful to 1 = not helpful) and if they recommend showing the video to other patients.

3. Results

3.1. Patient and clinician interviews

Our focus group interviews conducted with diverse clinicians and stakeholders revealed multiple provider-perceived patient-level barriers, such as the need to satisfy patients' preferences for aggressive testing and communication challenges [18]. The results of the provider focus groups and interview regarding care of the syncopal patient indicated: (1) uncertainty surrounding syncope as a diagnosis and the Syncope Guidelines, (2) rise of consumerism in health care and the pressure to satisfy patients, (3) communication challenges with patients, (4) provider differences in standardized care and change, and (5) organizational implementation process and change fatigue [18].

Soliciting perspectives directly from patients and their family caregivers provided an important complement to those findings. Importantly, our findings aligned with the barriers reported by clinicians and healthcare stakeholders. Three major themes resulted from these focus groups: clarity regarding their diagnosis, context surrounding their care plan and diagnostic approach, and the need to feel seen, heard and cared about by their health care team [23].

Specifically, patients and caregivers preferred an aggressive approach to testing. Patients desired clarity regarding the underlying cause of their syncopal episode, which led to requests of extensive diagnostic testing. Participants in our study noted an absence of sufficient communication and engagement, despite their desires for it [23]. Tests were ordered and administered without explanation, diagnoses were rendered and recorded in the medical record without being communicated to patients, and some patients did not feel they had the opportunity to share important contextual information surrounding their syncopal episode. Participants in our study who discussed positive patient experiences often did so in the context of detailed and respectful communication.

The interview data from both providers and patients highlighted the necessity to develop implementation strategies for setting patients' expectations and alignment between patient needs and guideline application.

3.2. Tools developed

We developed the following educational tools and materials to help explain the recommended tests and treatment for syncope, prepare patients to talk to their providers, and provide suggestions on how to avoid future syncopal episodes.

3.2.1. Discharge documents and patient education sheet

Clinicians have expressed challenges in communicating with patients and hoped to be equipped with effective tools and resources to help facilitate their conversations with patients and their family caregivers. The documents we developed allow for active listening on the clinician's part and can allow for open-ended questions. This approach builds trust with the patient, allowing the clinician to present facts along with an interpretation of their clinical significance to correct misconceptions and assist patients to make logical, informed decisions. In addition, while a patient's time in the ED is not precious (e.g., there is often a long wait to be seen by a provider), the providers' time with the patient is often minimal. Our educational materials (documents and videos) are intended to make better use of the time that patients are waiting to be seen by providing them with contextual information that can help them understand their diagnosis and prepare for questions they may have of the provider when he/she arrives. Our discharge documents were added into the health care systems' electronic database to be given to those patients that had any syncopal diagnosis code (R55). The discharge documents included information about the potential cause(s), prevention/treatment strategies, and warnings based on their syncope diagnosis (See Supplementary Material).

The Know Your Syncope handout is a one-page document that can be given to patients to help them learn more about their syncope diagnosis (Fig. 2). The Syncope handout was designed to be given to the patient in the ED or upon discharge so that they can learn more about their syncope diagnosis and should be accompanied by verbal discussion of the material by a clinician. The corresponding syncope type can be checked in the box on top so that the patient knows which syncope applies to them. Compiling all four potential syncope causes will ensure the providers to explain the types to the patient as well as inviting the patient to ask questions. This handout provides answers to such questions as:

- What is the cause of the problem? Each column of the patient education material focuses on a specific syncope.
- What can the patient do to prevent the problem? This row briefly explains to the patient what they can do to prevent a syncopal episode from happening.
- How can the syncope be treated? This row brings up talking points that can be followed up via the patients' primary care physician or other provider.
- What to do if the syncopal episode happens again? This row lets the patient know if this is a serious event and they should seek immediate medical attention.
- What is the medical name of the patients' condition? This term will allow the patient to do their own research on their syncope based on the correct medical terms.

3.2.2. Patient videos

To help set patient expectations of what they are likely to experience when they are in the ED after a syncopal episode, two short videos were developed. The first video "What to Expect in the ED After You've Fainted" is intended to be presented to the patient and family caregiver (if present) after initial triage in the ED. The video explains what syncope is as well as what kinds of tests and treatments the patient can expect to receive during their ED visit. The videos can also serve as another tool to improve patient-clinician communication. The video text instructs patients to "Tell

Fainting due to…	Reflex or Reaction ☐	Low Blood Pressure ☐	Head or Brain Problem ☐	Heart or Blood Vessel Issue ☐
Possible Causes	• Standing for a long time • Body gets too hot • Exercising for a long time • Strong feeling of emotion or pain	Quick drop in blood pressure due to: • A quick change in posture (such as standing too quickly) • Water loss (Dehydration) • Medicines that lower blood pressure	• Brain bleeding or swelling • Previous head injury or concussion • Stroke like symptoms	Less blood goes to the brain due to: • Unusual heart rate (heart beats too fast or slow) • A heart valve problem • A heart muscle problem
How to Prevent	Try to avoid the causes listed above. It may also help to: • Drink plenty of fluids • Do moderate exercise • Eat saltier foods	• Be careful when you stand. Let your blood pressure get stable before moving • Talk with your doctor about any medicine you take that lowers your blood pressure	• Protect your head from injury. Wear protective gear such as a helmet.	• Follow the diet and exercise plan your doctor recommends
How to Treat	• A medicine may help you • Talk with your doctor	• Your doctor may ask you to drink more fluids and add salt to your diet	• Talk to your doctor • If you have brain bleeding or swelling you may need surgery	• Talk to your doctor • Treatment depends on what caused the fainting • You may need surgery or an implant
When to Seek Medical Help	• If you faint again for no known reason • If you faint and your fall causes serious injury	• If you faint again for no known reason • If you faint and your fall causes significant injury • If you cannot keep your blood pressure under control • If you have questions about your blood pressure medicine	• If you faint after having a head injury • If you have the "worst headache" of your life • If you have nerve pain or muscle weakness	• If you feel your heart is racing • If you feel chest pain • If your symptoms do not go away
Medical Term	• Vasovagal Syncope • Neurocardiogenic Syncope	• Orthostatic Hypotension • Postural Hypotension	• Cerebrovascular Syncope • Neurogenic Syncope	• Cardiac Syncope • Cardiogenic Syncope • Cardiovascular Syncope

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Fig. 2. Know Your Syncope Handout. Document developed in Phase 2 that can be given to patients to help them learn more about their syncope diagnosis. It should also be discussed with the patient by a clinician. The corresponding syncope type can be checked in the box on top so that the patient knows which syncope applies to them.

your doctor if you hit your head or injured yourself when you fainted, if you have been bleeding, and what medications you are taking. You should also tell your doctor if you or any of your family members have fainted in the past, or have died suddenly. This information can help doctors make the best decisions about your care." The videos encourage patients to ask questions. Prior to discharge, a second video can be shown to the patient to help them understand their discharge paperwork as well as how and when to follow-up with a primary care provider and a specialist, if appropriate. The second video, "What to Expect When Leaving the Hospital," can be administered using the same methods as the first educational video (Fig. 3, Video workflow).

3.3. Pilot study to validate educational materials

The pilot stopped after four weeks, rather than the originally designed 8-week period due to COVID-19, but demonstrated feasibility and acceptability. Twenty-four patients were asked to participate; two declined to participate. Twenty-two patients watched the first intake video; eight of those patients watched the second discharge video. While the majority of patients responded positively to the educational videos, we also learned that the majority of patients were not aware of the term "Syncope". Seventy-seven percent of patients viewed the intake and discharge videos on a provided iPad; 23% used their own mobile device. Ninety-five percent found the intake video informational and 86% would recommend it to others; 100% found the discharge video informational and would recommend it to others. Overall, 91.7% (22/24) of approached patients watching education videos with

voiced approval. All patients who watched both videos reported that the videos improved their overall stay. Though we did not collect Protected Health Information (PHI), we did obtain verbal consent (permission) from patients to review materials and provide feedback. Per 45 CFR §46.117 (c), IRB allowed a waiver the requirement to obtain a signed consent as this was an expedited protocol.

4. Discussion and conclusion

4.1. Discussion

4.1.1. Understanding patients' needs and preferences

Patients' needs and preferences play a critical role in care delivery. Patients presenting to emergency department with syncope desire care from a clinician that will listen to their story along with a potential diagnosis. If available, patients' would also like an explanation of why the syncopal event occurred and prognostic information [28,29]. Insight into the medical evaluation and management process help set patients expectations through a better understanding of guideline-recommended care and to reduce anxiety and fear related to symptoms. The set of tools/materials our study developed helps to educate patients on guideline recommended tests and treatment for syncope and suggestions to avoid future syncopal episodes. [23,30] The patient educational material aims to align patient expectations regarding testing with guideline recommendations, as well as to better explain specific syncope diagnoses and why testing may or may not be indicated for a particular type of syncope. The care delivered in an
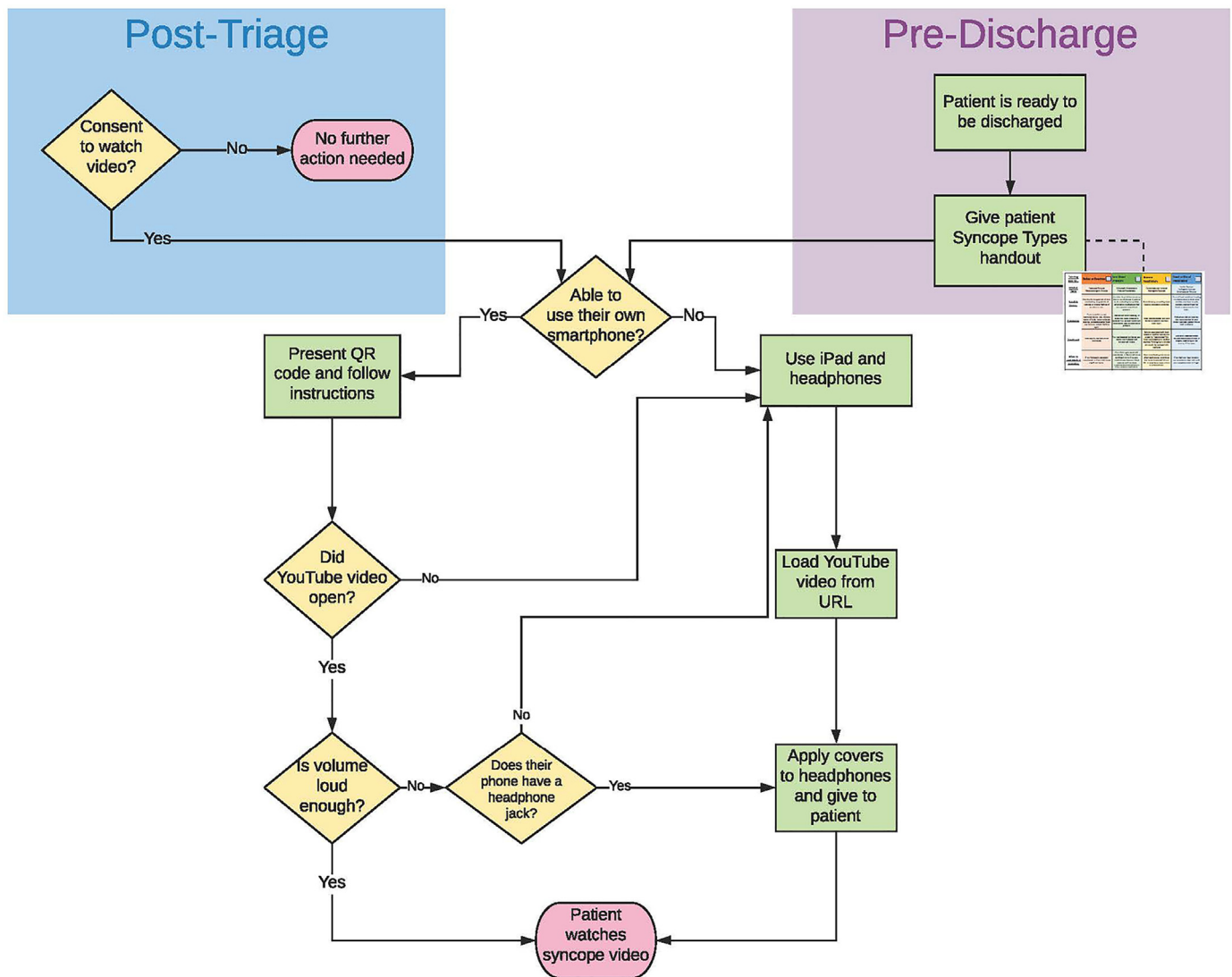
Fig. 3. Post-triage and Post-discharge Video workflow. Process used to approach patient and show them syncope videos. These were used to inform the patient of what to expect when they are in the ED after a syncopal episode.

effective, understandable and shared decision-making approach has been demonstrated by other evidence-based protocols [26,27,31].

4.1.2. Health systems approach

Many patients lack understanding of their medical condition. Indeed, the majority of patients seen for a syncopal diagnosis in our focus group had no recollection of the term "syncope" indicating poor uptake of existing verbal or written information. In addition to why the patients had a syncopal event, they want to understand the history (if any), prognosis, and treatment of their syncope [32]. Patient education promotes patient-centered care and increases adherence to medication and treatments. An increase in adherence leads to a more efficient and cost-effective healthcare delivery [33]. Educating patients about syncope ensures continuity of care and can reduce future complications associated with syncope, such as reoccurrence and low quality of life [34]. The most efficient method for a health care system to distribute educational videos or materials would be through system-wide patient education platform in a patient's room and/or in the patient's EHR, along with a review of the educational materials from the provider. By codesigning our tools and material with the frontline providers and the health system Patient Education Department, we sought endorsement from the frontline and the system, enhancing the acceptability and usability from the providers as well as system operationalization (i.e., integrated into

EHR). Patient education by health care providers has been shown to increase the patients' understanding of their condition along with adherence to treatment plans [35]. This leads to behavioral change and improvements in patient health [36].

4.1.3. Partnering with frontline team

Engaging end users in developing and testing interventions is critical for feasibility and sustained practice change. Codesign is an important and effective approach for strengthening interventions that target healthcare practices [25]. We did this as a multi-phase process; in the beginning of material development (content and delivery mode), during pilot planning and conducting, and in the phase of refining tools for subsequent effectiveness trial. In a busy ED, finding the time to talk through the options with patients and explain benefits vs. harm presents a serious challenge. The use of technologically facilitated educational materials, such as short videos, was particularly emphasized during provider interviews. Flexibility and adaptability were emphasized by frontline clinicians and staff. The project MISSION videos ensured multiple delivery options and flexibility for local editing, for example, videos can be edited by inserting a tailored intro and outro delivered by a recognizable, local clinician to enhance patient buy-in [34]. Patient-centered, frontline-endorsed educational strategies with tailoring capability will help sustain improved syncope care [37].

4.1.4. Impact of the educational toolkit promoting shared decision making

Shared decision-making in the ED is often inefficient and ineffective due, in part, to variable levels of patient health literacy and the lack of validated educational tools to facilitate clinician – patient discussions. Interviews conducted with clinicians for Project MISSION revealed pressure to satisfy patients' preferences for more aggressive testing, which may not align with guideline-based syncope evaluation and management [30]. The process of shared decision-making involves sharing information, soliciting patient values and preferences, and developing consensus for a treatment plan [26,38]. Patients often support shared decision-making to reduce low-yield test ordering—this has been demonstrated in the setting of pulmonary embolism, chest pain, and trauma [39-41]. Our study addresses research gaps on how best to communicate risk and uncertainty with patients, and what tools can facilitate shared decision making in syncope evaluation testing order at ED. Our educational materials were developed to explain the recommended tests and treatment for syncope to patients and prepare/advocate patients to talk to their providers. Patients longed for improved communication from their provider. These materials were designed to provide education and context to the patient prior to meeting with the provider so they can be better prepared with questions as well as expectations regarding their syncopal episode. By following the strategy of engaging patients in shared decision-making, clinicians can appropriately avoid unnecessary tests and treatments. Shared decision-making is likely to be an essential component of a multipronged approach to reducing unnecessary laboratory and imaging testing in the syncope evaluation and management at the ED [38,42]. This study demonstrates a cooperative approach to tailoring strategies in the development of patient education materials. Working with patients to create plans with them can lead to better adherence to the care plan.

4.1.5. Limitations

There are limitations to our study. Our pilot had to end early due to the COVID-19 pandemic, however the initial results demonstrated feasibility and usability. Patients and providers appeared to be generally satisfied with the educational information presented to them. The feasibility testing occurred only at one academic medical center ED, therefore the demonstrated feasibility may not apply in other health systems.

4.2. Innovation

This research frames innovation via the application of use-centered principle to gain understanding on patients' and clinicians' needs and concerns in care of the syncopal patient. It is important to consider both patients and frontline providers as end-users when developing patient educational materials. Promoting engagement from patients and providers enables health systems to bridge gaps between guideline recommendations and clinical practice. Engaging frontline and leveraging system infrastructure (e.g., EHR, patient education channel) in designing workflow is critical feasibility and practice change. Patient-centered, frontline-endorsed educational strategies with tailoring capability will help sustain improved syncope care.

5. Conclusion

Our study demonstrated feasibility and usability of tools designed to communicate risk and uncertainty with patients and facilitate shared decision making on syncope evaluation testing order at ED. Engaging end users in developing interventions is critical for feasibility and sustained practice change. Our study describes a codesign process for understanding perspectives and promoting engagement from patient and provider to bridge gaps between guideline recommendations and clinical practice.

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