Preventive Medicine Reports 30 (2022) 101994

Contents lists available at ScienceDirect

Preventive Medicine Reports

journal homepage: www.elsevier.com/locate/pmedr

Short communication

The design and development of an encounter tool to support shared decision making about preventing cardiovascular events

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ARTICLE INFO

Keywords:
Shared decision making
Encounter tools
Decision aids
Cardiovascular disease prevention

ABSTRACT

Patients at high risk for cardiovascular disease (CVD) tend to receive less intensive preventive care. Clinical practice guidelines recommend shared decision making (SDM) to improve the quality of primary CVD prevention. There are tools for use during the clinical encounter that promote SDM, but, to our knowledge, there are no SDM encounter tools that support conversations about available lifestyle and pharmacological options that can lead to preventive care that is congruent with patient goals and CVD risk.

Using the best available evidence and human-centered design (iterative design in the context of ultimate use with users), our team developed a SDM encounter tool, CV Prevention Choice. Each subsequent version during the iterative development process was evaluated in terms of content, usefulness, and usability by testing it in real preventive encounters. The final version of the tool includes a calculator that estimates the patient's risk of a major atherosclerotic CVD event in the next 10 years. Lifestyle and medication options are presented, alongside their pros, cons, costs, and other burdens. The risk reduction achieved by the selected prevention program is then displayed to support collaborative deliberation and decision making.

A U.S. multicenter trial is estimating the effectiveness of CV Prevention Choice in achieving risk-concordant CV prevention while identifying the best strategies for increasing the adoption of the SDM encounter tool and its routine use in practice.

1. Introduction

A persistent mismatch in primary cardiovascular disease (CVD) prevention exists between individual patient risk and the intensity of intervention, with patients at lower CVD risk receiving more intensive prevention (Ko et al., 2004). This risk-treatment paradox exists even as patients have an increasing array of lifestyle and pharmacological options for prevention. This suggests an opportunity to improve the quality of CV prevention by supporting the formulation of preventive plans commensurate with a patient's risk and consistent with patient goals in the context of patient-clinician conversations.

Shared decision making (SDM) is a method of care by which patients and clinicians work together in conversation to co-create a plan of care (Kunneman et al., 2016). The American College of Cardiology/American Heart Association (ACC/AHA) guidelines for primary CVD prevention recommend the use of SDM (Arnett et al., 2019) to formulate preventive care plans. Encounter tools have been shown to promote SDM conversations. Our team developed a SDM encounter tool that calculates individual CVD risk and can be used to guide SDM conversations. The tool, CV Prevention Choice, was based on Statin Choice, a widely used, point-of-care encounter tool known to facilitate discussions about statins for primary CV prevention (Leppin et al., 2019); the effectiveness of which

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https://doi.org/10.1016/j.pmedr.2022.101994
Received 20 April 2022; Received in revised form 8 August 2022; Accepted 17 September 2022
Available online 19 September 2022
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has been evaluated in randomized trials. CV Prevention Choice extends that work to include lifestyle interventions like diet, exercise, and smoking cessation, and a broader range of medications (including diabetes medications). It is specifically designed to be used during the encounter, and it includes information on cost, side effects, routine, and other benefits (de Meester Christophe et al., 2019; Sheridan et al., 2011). Unlike other SDM tools that focus primarily on providing information about treatment options to patients, this tool was developed specifically for SDM conversations in the clinical encounter (Wieringa et al., 2019).

This article describes the development of CV Prevention Choice, which is currently being evaluated in a hybrid implementation-effectiveness pragmatic trial in three diverse U.S. health care systems funded by the National Institutes of Health, National Heart, Lung, and Blood Institute [R01HL151662] (Ridgeway et al., 2021). This work was approved by the Mayo Clinic Institutional Review Board (IRB#20–003945).

1.1. Methods and results

1.1.1. Developing the tool's content to fit its purpose

The purpose of SDM conversations is for patients and clinicians to collaborate in developing a plan of care that most appropriately responds—medically, emotionally, and practically–to the patient's problem (Hargraves et al., 2019). In order to move from a problem to an appropriate response, SDM conversations require 4 functional components—recognition and characterization of a problem, identifying potential ways of responding, deliberating between options, and concluding in a sensible plan. CV Prevention Choice is designed to support these conversational functions, as shown in Fig. 1.

To assist in characterizing the patient's threat of atherosclerotic cardiovascular disease (ASCVD) and to invite reflection on its perceived significance, the tool includes a calculator that estimates the patient's risk of a major ASCVD event in the next 10 years and presents that risk using a 100-person pictograph depicting how many of 100 people (based on the patient's calculated risk) will and will not experience such an event. This presentation invites patient and clinician to explore if and how to address this threat.

The tool uses the pooled cohort ASCVD calculator (used for primary prevention and for people between 40 and 79 years) drawing as much information as available from the electronic health record (EHR) (Goff David et al., 2014), supplemented by coronary calcium scores, family history of premature cardiovascular disease, and risk factors particular to women. For these latter risk indicators, the tool requires some data entry and states that the patient's risk will be higher than displayed. For example, depending on the result, the tool adds a note stating that, "Your coronary calcium score > 100 means that your risk may be higher than shown. Consider further discussion with a preventive cardiologist." Similar alerts appear when the patient reports a family history of premature (males < 55 years, females < 65 years) coronary artery disease in a first degree relative or when they report sex-specific risk factors, often overlooked in clinical conversations about CVD risk (Agarwala et al., 2020), such as early menarche, history of preeclampsia, gestational hypertension, gestational diabetes, pregnancy loss, preterm delivery (<37 weeks), and menopause.

In support of the next conversational function, the tool helps identify two strategies—pharmacological and lifestyle activities—that can be

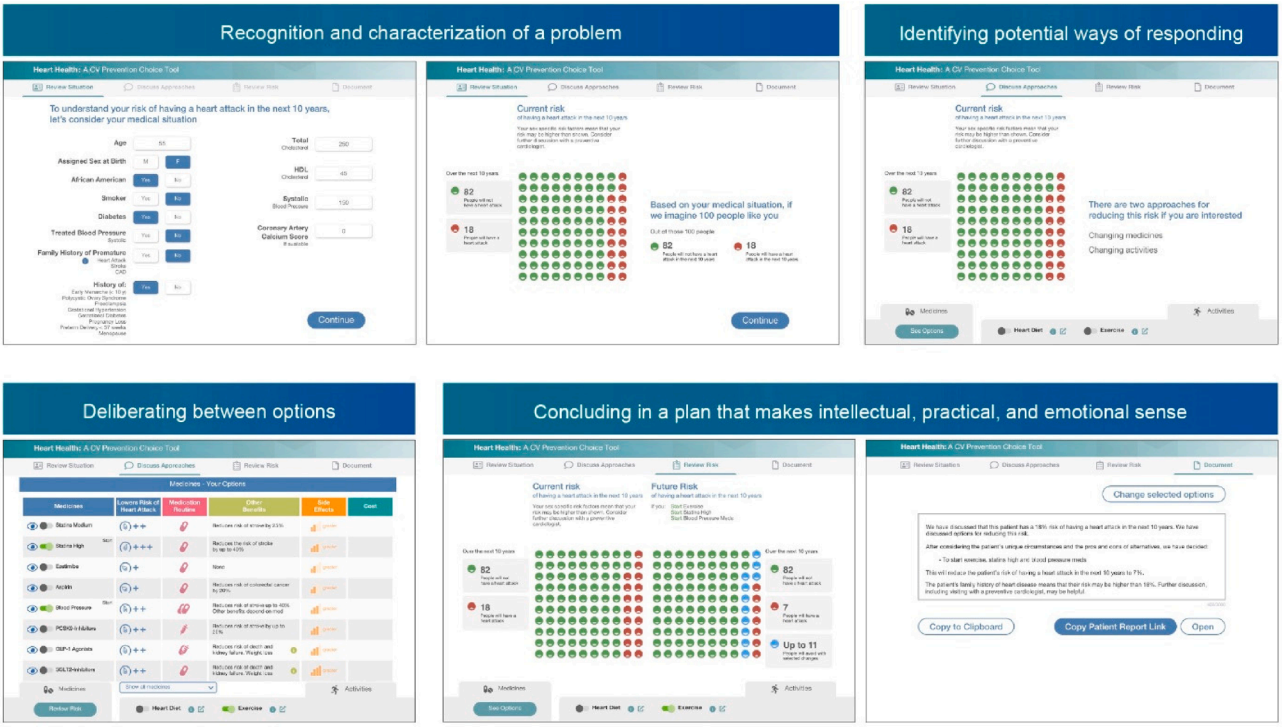

Fig. 1. Screens of the CV Prevention Choice tool and their purpose in the conversation. This figure shows six screens of the CV Prevention Choice tool and the functional component of SDM conversations that it aims to support: 1) Recognition and characterization of a problem (screen showing the patient's situation at baseline and 10-year ASCVD risk at baseline), 2) Identifying potential ways of responding (screen showing the 10-year ASCVD risk at baseline and two approaches for risk reduction), 3) Deliberating between options (screen showing lifestyle and medication options), 4) Concluding in a plan that makes intellectual, practical, and emotional sense (screen showing revised 10-year ASCVD risk after selecting components of the prevention plan and documentation of the conversation and decisions made).

used to reduce ASCVD risk. Interventions were selected based on systematic literature reviews showing these can reduce ASCVD risk. Lifestyle strategies include the Mediterranean diet, physical activity, and smoking cessation; pharmacological options include statins, aspirin (recommended by US Preventive Services Task Force for adults 40–59 years with 10 % or greater 10- year CVD risk), and other lipid, blood pressure, and glucose lowering drugs that may be used individually or in combination to reduce cardiovascular risk.

Next, the tool supports discussion of options informed by issues that are frequently brought up in conversation, and which are especially relevant to successfully adopting preventive interventions including expected benefits, potential harms, and practical considerations, e.g., medicine routine and costs. We gathered information on the average cost of medications per month without insurance in the U.S., recognizing that these estimates will vary greatly depending on the patient's insurance policy. Even if the exact cost is unknown, previous work has shown that adding this information to the encounter tool encourages patients and clinicians to discuss cost in 3 out of 4 visits (Politi et al., 2020). Most often, encounter tools such as this one will encourage conversations regarding drugs, insurance, and health care costs (Espinoza Suarez et al., 2020). The full list of references used to inform the tool's content can be found in **Appendix 1**. This procedure follows our successful implementation of issue cards in prior work (Breslin et al., 2008; Zeballos-Palacios et al., 2019). After a set of interventions are selected, the users can see how their use will reduce ASCVD risk using the same 100-person pictograph.

1.1.2. Prototyping and refining the tool to improve its function and foster SDM

For tools to support SDM conversations, patients and clinicians must be able to integrate them into clinical encounters and use them to formalize a plan. Thus, a key to developing useful tools is observing how they are used in clinical encounters.

Methods for designing and observing CV Prevention Choice were similar to methods this study team has used for more than a decade (Leppin et al., 2019; Breslin et al., 2008; Zeballos-Palacios et al., 2019). Designers began by videorecording and reviewing five primary preventive cardiology encounters of patients and clinicians who consented to participate (Mayo Clinic, Rochester, MN). Reviewers focused on carefully observing the interaction between patient and clinician without using an encounter tool to understand how usual conversations unfolded, including the steps followed, the topics discussed, and the questions asked. Observations were fundamental to designing the CV Prevention Choice tool and informed iterative prototype development.

Next, the study team invited 2 clinicians working in preventive cardiology, 1 in internal medicine, and 1 in primary care to test a prototype version of CV Prevention Choice with their patients. The first version was tested with a total of 6 patients and the second version with a total of 5 patients. All clinicians tested it with at least 2 patients. All encounters were video recorded and reviewed by two trained members of the study team. The purpose of these observations was to understand how problems are expressed, which options are presented and how, whether patients and clinicians have an adequate method to distinguish between options, and to determine if the conversation reveals coherent, individualized reasons for doing what is decided. Observations were also used to identify difficulties in the way we had chosen to present the tool's content, including risk information. Information from user feedback and observations in real-world encounters were evaluated by our study team (which includes designers, experts in shared decision making, and clinicians from multiple disciplines), who decided on improvements. Details of proposed changes were documented on a collaborative online wiki, including who proposed the change, the reason for and a description of the proposed change, and whether it was completed (see **Box 1** examples). The study team evaluated 3 versions of the tool before arriving at a version ready for implementation in the trial.

Box 1. Examples of prototyping refinements

1. An example of refinements in content

Misuse: The first version of the tool did not contemplate any factors that could potentially modify (increase or decrease) the 10-year ASCVD risk displayed after entering the patient's medical situation.

How was the problem identified? During the prototyping phase in the clinic the cardiologist had a patient with relevant history of premature CVD in first degree relatives. The tool displayed a risk that was inaccurate for that patient and it did not provide any guidance for the patient's specific situation.

How did we respond? In case that the patient had one or more of the 3 situations included in the tool that could modify the patient's 10-year ASCVD risk, we alerted that the risk may be different than displayed. We also added a recommendation of further discussion or referral to a preventive cardiologist. Although it is impossible to adapt this tool to all possible scenarios, it was improved thanks to the feedback and discussion with experts and users during the prototyping process.

2. An example of refinements in usability

Misuse: The first version of the tool created a PDF report with the information added, the risk calculation, the medications and activities discussed, and the final decision made. The purpose of the report was to be printed and given to the patient as a personalized take-home handout.

How was the problem identified? During implementation at one site, users identified that printing the report was not possible in daily routine and requested that a copy of the report be appended to the patient's chart.

How did we respond? We added a button 'Copy Patient Report Link' that creates a URL string that could be copied into the patient's chart. This report could also be displayed for point-of-care printing, if preferred.

Data availability

The data that has been used is confidential.

1.2. Discussion

Guidelines recommend SDM for individualized CV prevention plans. Encounter tools can support this recommendation, enabling the co-creation of prevention plans that reflect patient goals and priorities and are congruent with each person's estimated ASCVD risk. This risk plays a central role in the CV Prevention Choice tool, but it does so only to assist in decision making, offering a useful approximation, accurate and precise enough to support reasonable decisions.

The prototyping process described above has been implemented and tested for other encounter tools designed by our group (Breslin et al., 2008; Zeballos-Palacios et al., 2019; Montori et al., 2007). The strength of the process is that the structure of the tool imitates the structure of the conversation commonly followed during consultations, and as such, helps clinicians do what they need to do in collaboration with their patients and avoids forcing users into undesired workflows. We prepared a video demonstration of the suggested use of the tool to share with potential users. However, it is expected that the tool will be used differently according to the needs of each patient. It may also be flexibly employed in different types of clinical encounters (e.g., primary care, preventive cardiology, endocrinology), where clinicians may have

different approaches to discussions about medications or lifestyle changes.

Our approach of treating SDM as the everyday work of patients and clinicians figuring out what to do results in tools that clinicians want to use, as evidenced by the more than 13,000 monthly uses of the Statin Choice encounter tool worldwide. Our team was able to leverage the successful design work that underpinned that tool's development, necessitating fewer observations than we generally employ (Montori et al., 2007) and thus eluding the restrictions to clinical observations borne out of the response to the COVID 19 pandemic.

There are limitations to our process and ways in which it varied from what is recommended by existing standards (Witteman et al., 2021). Mainly, we lacked the participation of potential users in the pre-prototyping phase. Furthermore, 81 % of patients in observations were white and 60 % were male, and all observations were made at one healthcare system. We sought to overcome these limitations by socializing the tool early. This led to additional insights from users, including those submitting feedback through social media, which we integrated into the tool, most notably the addition of sex-specific risk factors into the risk estimation (Elder et al., 2020).

User-centered design supports development of tools that are usable, useful, and desirable. However, implementing these interventions in practice is often complicated, and both risk calculation tools and SDM encounter tools have poor uptake in clinical practice (Alsulamy et al., 2020). Embedding encounter tools in the EHR is one approach to more seamlessly populating risk calculation in the tool and integrating it into the clinical workflow, but targeted efforts may still be needed to increase adoption and use.

CV Prevention Choice is being evaluated in a hybrid design implementation-effectiveness study (Ridgeway et al., 2021). Hybrid effectiveness-implementation trials aim to speed translational research to meet the needs of users and decision makers (Curran et al., 2012). In this hybrid trial, CV Prevention Choice has been embedded in the EHR of three geographically diverse U.S. health systems, and the study team is using implementation facilitation strategies to engage care teams, identify issues with adoption and use, and respond with refinements to the tool or workflow adaptations. Modifications to the tool and detailed accounts of the implementation strategies are being systematically documented for evaluation, which will also include fidelity assessments. This approach is aimed at developing a rich understanding of implementation in diverse settings and patient populations. The trial will also evaluate the effectiveness of SDM as a strategy to improve risk-concordant preventive care planning.

1.2.1. Conclusions

A key determinant of adoption is if interventions are useful, desirable, feasible, and sustainable in practice. The development process described herein was focused on achieving these goals. Going forward, by working closely with users and other stakeholders within diverse healthcare systems, we seek to understand and overcome barriers to the uptake and use of CV Prevention Choice and to the practice of SDM to reduce the burden of cardiovascular disease.

CRediT authorship contribution statement

Sandra A. Hartasanchez: Conceptualization, Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing. **Ian G. Hargraves:** Conceptualization, Methodology, Software, Validation, Resources, Writing – review & editing, Visualization. **Jennifer E. Clark:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Derek Gravholt:** Writing – review & editing. **Juan P. Brito:** Conceptualization, Writing – review & editing. **Megan E. Branda:** Writing – review & editing. **Yvonne L. Gomez:** Writing – review & editing. **Vivek Nautiyal:** Writing – review & editing. **Charanjit S. Khurana:** Writing – review & editing. **Randal J. Thomas:** Investigation, Writing – review & editing. **Victor M. Montori:** Conceptualization, Methodology, Validation, Writing – review & editing. **Jennifer L. Ridgeway:** Conceptualization, Methodology, Resources, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

The data that has been used is confidential.

Acknowledgements

We would like to thank the clinicians and patients who were involved in prototype development and observations, including Dr. Randal Thomas, Dr. Thomas Gerber, Dr. Andrew Majka, and Dr. John Matulis III. We would like to thank Dr. Darrell Newman for his participation in additional video demonstrations of mock clinical encounters. We would like to thank Carolyn Thomas for her feedback on the importance of including sex-specific risk factors.

Funding

This work was supported by the National Institutes of Health, National Heart, Lung, and Blood Institute (R01HL151662), and the Mayo Clinic Care Network. The sponsor had no role in the study design; collection, management, analysis, or interpretation of data; writing of the manuscript; or the decision to submit the manuscript for publication.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2022.101994.

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