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Clinician's use of the Statin Choice decision aid in patients with diabetes: a videographic study nested in a randomized trial

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Abstract

Objective To describe how clinicians use decision aids.

Background A 98-patient factorial-design randomized trial of the *Statin Choice* decision vs. standard educational pamphlet; each participant had a 1:4 chance of receiving the decision aid during the encounter with the clinician resulting in 22 eligible encounters.

Design Two researchers working independently and in duplicate reviewed and coded the 22 encounter videos.

Setting and participants Twenty-two patients with diabetes (57% of them on statins) and six endocrinologists working in a referral diabetes clinic randomly assigned to use the decision aid during the consultation.

Main outcome measures Proportion and nature of unintended use of the *Statin Choice* decision aid.

Results We found eight encounters involving six clinicians who did not use the decision aid as intended either by not using it at all (n = 5; one clinician did use the decision aid in three encounters), offering inaccurate quantitative and probabilistic information about the risks and benefits of statins (n = 2), or using the decision aid to advance the agenda that all patients with diabetes should take statin (n = 1). Clinicians used the decision aid as intended in all other encounters.

Conclusions Unintended decision aid use in the context of videotaped encounters in a practical randomized trial was common. These instances offer insights to researchers seeking to design and implement effective decision aids for use during the clinical visit, particularly when clinicians may prefer to proceed in ways that the decision aid apparently contradicts.

Keywords: decision aid, diabetes, randomized trial, shared decision making, video analyses

Decision aids are tools that can help clinicians share evidence-based information about treatment options with patients in order to increase the likelihood that patients will be informed about research evidence and help them participate in the decision-making process [1]. We design decision aids for use during the clinical visit, making it a design criterion that the decision aid should start a conversation about the issue between patients and clinicians (i.e. physicians, nurse practitioners) [2]. An exchange of information and views can set the stage for chronic disease decisions that respect both the best available research evidence and the values and preferences of the informed patient, thereby facilitating shared treatment decision making [3].

How clinicians use decision aids in practice during the clinical visit has received little research attention. In part because of limited adoption of decision aids in practice, the available literature focuses on clinicians' perceptions rather than direct observations of actual use during the clinical encounter [4–6]. For example, based on systematic reviews of 31 publications covering 28 studies – mostly qualitative – from the UK, USA, Canada and Netherlands among others, Gravel and colleagues studied health professionals' perceptions of barriers and facilitators to using decision aids [4]. The barriers most often reported were time constraints (18/28), lack of applicability because of patient characteristics (12/28), and lack of applicability because of the clinical situation (12/28). The most cited facilitators were: provider motivation (15/28), positive impact on the clinical process (11/28) and positive impact on patient outcomes (10/28).

Despite the contributions of such studies to the understanding of clinicians' attitudes towards using decision aids, they do not account for the ways in which clinicians actually use and misuse decision aids in the clinical encounter.Amore naturalistic study of clinicians' use of decision aids during the office visit should help answer this important question in translating the science of decision support into practice.

Methods

The Statin Choice trial

The present study of clinicians' use of the *Statin Choice* decision aid during the visit is part of a larger cross-sectional observational qualitative design nested within a 98-patient randomized trial of this decision aid vs. a standard educational pamphlet [7].

Another publication describes in detail the development of the decision aid [2]. In brief, the decision aid *Statin Choice* is a single-page document informing patients of the risks and benefits of statins (cholesterol-lowering medications that reduce cardiovascular risk). This decision aid, designed for use during the visit, relies on a graphical representation of risk (100 ordered faces indicating both the likelihood of having and not having an adverse event) to indicate a tailored estimate of the 10-year coronary heart disease risk for patients like the

participant who take or do not take statins (the latest version of this decision aid can be downloaded from our website, http://kerunit.e-bm.org). Of importance, clinicians who participated in the trial provided input into the design and content of the decision aid.

The *Statin Choice* trial execution and main results have appeared elsewhere [7]. Briefly, this trial, approved by the Mayo Institutional Review Board, used a 2 ¥ 2 factorial randomized trial design resulting in one of four visits (i.e. 22 visits) in which clinicians and patients used the *Statin Choice* decision aid during the consultation. Participating patients had type 2 diabetes and were able (had no major cognitive, sensorial or language barriers) and willing to provide written informed consent; 57% were already on statins (we enrolled patients already taking statins so that clinicians could use the decision aid to review the decision to use statins and to evaluate whether the intervention could enhance drug adherence in those who opted to continue; participating providers and patients were blind to this hypothesis). Participating clinicians, who also gave written informed consent to participate in the trial, were endocrinologists (faculty and trainees) delivering care in their usual setting: a referral clinic in a tertiary care centre for patients with diabetes and other metabolic concerns.

In this context, clinicians introduced the decision aid to patients as part of a study to help patients with diabetes and their clinicians make choices about cholesterol medication. During most visits the clinician's focus seemed not on ameliorating cardiovascular risk (the focus of the *Statin Choice* decision aid), but on improving glycemic control. These medical encounters were structured along history taking, review of laboratory tests, a physical examination and discussions of lifestyle issues, including diet and exercise, blood sugar control and self-management education. The discussion about use of statins occupied no more than 5 of the 40–50 minute consultation visit usually at the beginning or at the end of the visit.

Participating clinicians randomly allocated to using the *Statin Choice* during the consultation received 2–5 minutes of training that consisted in one of the investigators using the decision aid with the clinician as if the clinician was the patient. After the clinician's first use of the decision aid, the investigators, who had watched this visit on a remote video monitor, would offer suggestions to the clinician whenever they observed important deviations from the intended use of the

decision aid. The encounters reported here include these and every subsequent visit.

The trial results supported the notion that the decision aid furthered the conversation, reduced uncertainty around the decision and improved short-term adherence to statins [7].

Video recording

Video recording of the visits took place through an unobtrusive camera mounted on the ceiling of each of the consultation offices. This angle provided direct view of the patient, the clinician and the space between them, often a desk surface with a computer monitor. The decision aid was printed in a large A3-sized paper that occupied that space. Patients and clinicians could turn off the video or the audio or both from a wall panel that also indicated the camera status, although this feature was never used. The audio in each of the videos was isolated and transcribed directly.

Video analyses

To analyse the 22 video recordings and the direct transcripts of their audio (of the 23 eligible encounters, one was not video recorded because of equipment malfunction), we employed a qualitative technique, conversational analysis, to assess patient– clinician communication during the medical encounter [8,9]. One of us (R.A), devised the analytic approach by (1) reviewing the literature on shared decision making in chronic disease [3] and about the development of the *Statin Choice* decision aid [2]; (2) generating criteria for the proper use of decision aids; and (3) checking these criteria with the authors of the decision aid (A.J.W., V.M.M). Based on these criteria, R.A. and A.J.W. coded transcripts to determine how clinicians used the *Statin Choice* decision aid during the trial.

Coding scheme

The intended or expected use of the decision aid required the clinician to use the decision aid to disclose to patients the risks and benefits of taking or not taking statins in quantitative terms. While the

wording in the decision aid invited the patient to take part in the decision-making process, the decision aid did not require a particular extent of patient participation in deliberation or decision making, allowing for patients and clinicians to arrive at a model of decision making in usual ways. The intended use of the decision aid allowed for stylistic deviations (e.g. trivial changes in wording) as long as this idiosyncratic use did not contradict the information in or purpose of the decision aid.

We judged that clinicians had not used the decision aid as intended when (1) it was not used at all; (2) when clinicians used the decision aid merely to convey that there was no choice for the patient but to be on statins based on current recommendations [10,11]; or (3) when clinicians communicated grossly inaccurate data or omitted critical information about risks or benefits (coding guide available upon request).

Working independently, two researchers separately coded each videos and audio transcripts (the video provided non-verbal context to the utterances in the transcript and clarified silences). These researchers were an anthropologist who generated the coding scheme, had not participated in the design or conduct of the trial, and was not familiar with the care of people with diabetes (R.A.), and a nurse practitioner caring routinely for patients with diabetes who participated in the design and use of the decision aid and who participated in the design and conduct of the trial (A.J.W.). We compare the chance-independent inter-rater reliability of these researchers using the *Phi* statistic [12]. In case of disagreements, the two coders compared notes and discussed the best code for the encounter until they reached agreement, using the rules used to reach that agreement in future codes. All eligible recorded interactions were of sufficient quality to allow transcription and codification.

Results

Use of the decision aid as intended

The between-reviewer simple agreement for classifying the use of the decision aid as intended or not intended was 82%; chance-independent agreement was acceptable (*Phi* = 0.73). In the 22

encounters that included the decision aid, the six participating clinicians used the decision aid as intended in all but eight instances. For the majority of patients who had already decided to take statins prior to their consultation, the information the clinician conveyed with the assistance of the decision aid confirmed their choice as all decided to continue to use statins. The perceived benefits – however marginal for those at low risk (<10%) for coronary events at 10 years – and manageable or absent side effects appeared to contribute to shape these decisions.

Box 1 offers an example of an interaction between a clinician and a middle-aged man recently diagnosed with diabetes. This example illustrates the intended yet not ideal use of the decision aid and its effect on patient's decision making. While the reviewers classified this encounter as one in which the clinician used the decision as intended, the clinician introduced some comments that indicated his own preference for the patient to use statins (e.g. by pointing to the patient's elevated LDL-cholesterol levels) and left the patient to deliberate on this information. This illustrates the intended role of the decision aid: to create an informed patient enabled to participate to the extent desired in making the decision.

Unintended uses

Five of the six clinicians did not use the decision aid as intended at least once: one clinician did not use the decision aid in any of his three encounters (which focused almost entirely on glycemic control); two other clinicians did not use the decision aid in one encounter each. One clinician used the decision aid to advance his agenda that all patients with diabetes should take statins. Two clinicians offered misleading presentations of the probabilistic information about risks and benefits of statins. Except for the clinician who never used the decision aid, all unintended uses occurred after the first use of the decision aid.

In the cases where the decision aid was not used at all, either cardiovascular risk reduction through cholesterol control was not addressed, the clinician disclosed risk/benefit information to the patient without the decision aid, or the patient was already on statins.

When the decision aid was used to advance a specific therapeutic agenda, the clinician presented the decision aid to illustrate his

Box 1 Intended use of the decision aid

Dr: [Your cholesterol] should be half of what it is now. Let's go over this together

[The clinician then introduces the decision aid; the patient puts his glasses on].

Dr: What is your risk of having a heat attack in the next 10 years? This table shows that you have an estimated 15–30% chance of having a heart attack in the next 10years.

[Pointing to the first chart that describes patient's risk of not taking statins for this risk group]

Dr: Out of 100 people like you, about 20 will have a heart attack in the next 10 years, and about 80 will not.

[Pointing to the second chart that describes the patient's risk if he decides to take statins]

Dr: From 80 to 85 [patients that avoided a heat attack], from 20 to 15 [patients that had a heart attack], that's a significant risk reduction in relative terms, not absolute.

Dr: '*Statins do not cure cholesterol; it is like your diabetes problem. You need to take them every day.*'

[Patient asks the clinician for his opinion. The clinician then mentions that outside this study he recommends statins because it reduces cardiovascular risk but notes that it does not eliminate risk. Referring to the chart he notes]; Dr: They are not all greens *[referring to the colour of the 'happy faces' used to denote the number of patients who would not have a heart attack in 10 years]*.

Dr: Based on the information, what do you want to do? Even with the best diet and exercise we expect 15% reduction in cholesterol levels, but your level is 160; it is too high. It needs to go well below that. This is entirely up to you; you are the person that is going to take the medication. I am not here to tell you what to do. My job is to give you the best evidence that we have. The decision is all yours, alone. And this is true for all conditions. This is how I, [Institution] envision my role. I don't want to put words into your mouth. What do you want to do?

Patient: The side effects are minimal *[The patient decides that he wants to talk further with his primary physician before making a decision about starting statin use*.

belief that all diabetic patients should take statins. The script in Box 2 is particularly telling of the conflict between the clinicians' agenda of aggressive treatment and the role of choice implicit in using a decision aid: the clinician refers to the investigators as 'they' and suggests 'they' made a mistake in making him use the decision aid in this patient, who already knows more about the issues. In this

Box 2 Unintended use – agenda-driven misuse

Dr: It looks like your cholesterol and stuff is controlled rather well. One of the things **they** have us down here for, **they** want me to do this portion of it which is this business of why are you taking a statin. Did you have the information? Patient: I don't have any information.

Dr: You can look at that [the *Statin Choice* decision aid]. This explains why, **at least from their perspective** in doing this particular study to try and help patients be educated and why to treat with a statin which is Zocor . . . you also take Tricor, but that is mostly for triglycerides and Zocor is mostly for cholesterol. Your numbers read rather good. You are at 142, 79, triglycerides, which is absolutely excellent. Forty-six is the HDL cholesterol and the LDL is 80. Goals for diabetes, now, are about 70 or less. But **they** have circled your risk factors in regards to your risk of having heart disease. **But you already know** heart disease is something you may experience. This is the difference if you use the statin, how many people would have a heart attack and how many people would not. These are the people, because of the statin, who would be avoiding a heart attack. The higher the risk, the better the improvements. **I absolutely believe everyone with diabetes belongs on a statin.** I think your [primary care] doctor is doing the right thing. Is there a difference between 80 and 70? Nobody knows. I think where you are, I would be quite content with that. That is excellent. That is helping your arteries out. So does blood sugar control. The same thing with blood pressure, keeping that in control also protects your heart. Studies that have been done and studies we are currently doing show when you control all those three main factors aggressively, the risk, the number of people having a heart attack keep dropping. When you control all three, it cuts it at least 50% or more. So it is pretty impressive. That is, again, your eyes, and nerves and all of the other reasons with that control. . . . Questions? Patient: No, not any more.

Dr: **I think you don't need a whole bunch of this** to convince you of that, you already have some complications that convince you without too much doubt that you need to take care of the diabetes.

instance, the clinician paid little attention to the uncertainty inherent in population-based risk information. Instead, he combined a certain belief in the value of statin therapy with the quantitative risk information in the decision aid to impress upon the patient the need for aggressive control of all risk factors in all patients. Other videos also show clinicians making preference statements in favour of statin use, but without fundamentally affecting the decision aid

Box 3 Unintended use – inaccurate information

The clinician introduces the use of the decision aid and discusses the cardiovascular risk factors and medications the patient is taking to reduce his cardiovascular risk.]

Dr: What does this mean? If you take 100 people like you, probably about 10, roughly, would have a heart attack in the next 10 years and 90 would not. Another way to look at this is to take 100 diabetics in a room; the 90 in green are never going to have a heart attack in the next 10 years. You are in this group down here where 10 might [get a heart attack].

[The clinician informs a patient in the decision aid's lowest risk category (less than 15% risk of myocardial infarction in the next 10 years) that he is among the 10 people out of 100 like the patient who will have a heart attack in the next 10 years. This use directly contradicts the information on the decision aid that conveys risk/ benefit information in a probabilistic and impersonal way. For example, the decision aid text reiterates that the information refers to 'our guess of what will happen to 100 people like you'. Here is your risk if you decide not to take statins. About 10 will have a heart attack in the next 10 years, and about 90 will not.]

[The text on the aid itself notes that patients should 'keep in mind that we do not know what will happen to you'. The clinician however ignores it and continues with the description]:

Dr: So the question is, is it worth starting this medication in order to reduce your risk out of the 10 there. If we started on statins in your case, there would be two out of the 10 that would end up not having a heart attack. It would reduce that risk. For eight, it wouldn't change that outcome. So for the two that would be taking would be helpful, but for eight there wouldn't be any difference.

[Again, here the clinician departs significantly from the text of the Statin Choice decision aid by focusing on the 10 of 100 people expected to have a heart attack rather than on the 100 people one would need to treat with statins as indicated in the aid.]

[The clinician continues to use decision aid as intended, including asking the patient what he wants to do about statins. The patient decided to consult with his primary care physician before making a decision about starting statins].

presentation. In contrast, one clinician misused the decision aid by fundamentally changing the presentation in the decision aid and introducing conflicting and contradictory risk/benefit information about statin use to the patient (Box 3 describes that encounter).

Discussion

Principal findings

In this study, clinicians used the decision aid as intended, that is, to provide information about the risks and benefits of taking and not taking statins, in 64% of the interventions. After a short introduction to the decision aid, only in two cases did clinicians offer incorrect information about risks and benefits of statin use to patients. These findings demonstrate that, when designed properly, basic training is largely sufficient for the proper use of the decision aid during the clinical encounter.

Despite using the decision aid as intended in the majority of the clinical encounters, the decision aid was severely misused in eight encounters. Five out of six clinicians used the decision aid at least once in an unintended way and one avoided its use altogether with his patients despite investigators' reassurances that the goal of the decision aid was to facilitate the communication of risk/benefit information to patients, and that use would not interfere with clinician style, judgment or medical authority. The clinician we quoted as providing an example of the intended use of the decision aid (Box 1) is also responsible for one unintended use (he suggested that every patient should be on statins, using the decision aid to merely illustrate this point). Thus, individual clinicians varied in their use of the decision aid, even during a video-monitored randomized trial. This suggests that failures to use decision aids appropriately do not arise from fundamental opposition to decision aids, *per se*, but rather may arise from variability in the perceived relevance of decision aids to the care of different patients.

In addition to situations in which clinicians and patients engaged in shared deliberation, we identified situations in which clinicians, after using the decision aid, recommended a course of action without any patient input. In other cases, clinicians forced patients to deliberate on the information presented and make decisions alone. In still other instances, clinicians felt the need to add further meaning to the quantitative presentation in the decision aid and, in doing so, often framed the presentation in a way that could be construed as favouring statin use.

An alternative view is that these clinician *ad libs* represent subtle ways in which clinicians appropriated or resisted the use of the decision aid during the clinical encounter. In other words, clinicians may have perceived the decision aid as undermining their professional autonomy or challenging their clinician's role during the clinical encounter. Thus, further research could help determine the extent to which clinicians framing utterances are more likely to take place when clinicians perceive that the decision aid would lead the patient to adopt a course of action contrary to the clinicians' own preferences and recommendations.

Also, clinicians could have been responding to external pressures such as guidelines and quality-of-care standards when they misused the decision aid or uttered framing statements. Dominant clinical guidelines recommend and quality of care performance parameters require that most if not all patients with diabetes take statins aiming to achieve certain LDL-cholesterol goals [13]. These recommendations assume all patients with diabetes are at high coronary risk and that the lower the LDL cholesterol level the better the outcomes, and therefore they must take statins. While the available evidence only weakly supports these assumptions [14], these guidelines were often mentioned during the encounters we studied. Guideline and quality-of-care pressures, alongside marketing to clinicians and direct-to-consumer advertising provide a challenging environment in which to exercise informed choice and shared decision making [15].

Study limitations and strengths

This study has some limitations and strengths. We drew inferences from observing video recorded encounters, without access to the patient or clinicians' account of what happened during the visit. Furthermore, while the trial provided a unique point of entrée into clinician's use of the decision aid and shared decision making, it does not substitute for the observation of clinicians' use of such tools during their regular clinical encounters, when feasible. Whether our findings are applicable to other settings (e.g. continuity care, primary care) or decisions is unclear.

On the other hand, analysis of the video recordings and audio transcripts in this setting provides interesting hypotheses-generating

insights that do not come from stated barriers in practitioner surveys, but rather from directly observed behaviours. While this study does not investigate the ways clinicians would use the *Statin Choice* decision aid in their regular clinical encounters, it provides a quasi-natural experiment to explore the way clinicians actually used it. The unique opportunity to observe and analyse the actual use of decision aids in a clinical trial, employing two very different, highly qualified investigators (with different degrees of familiarity with clinical visits) using a common coding scheme with reasonable coding agreement, speaks to the strength of this study.

Furthermore, our findings appear consistent with the available literature on barriers (concerns about fit between the decision aid and the specific patient and clinical circumstances, for instance) to the use of decision aids [4–6]. In contrast to concerns about time constraints, our study demonstrated that providers could efficiently use a decision aid mostly as intended. It is not possible to identify particular motivators for use (beyond participation in the clinical trial); in many cases the decision aid was introduced to the patient as part of a research study, as opposed to being framed as part of routine or desirable clinical care.

Conclusion

In conclusion, while most participating clinicians were able to use the tool as intended with minimal training, unintended use of decision aids occurred commonly. This is particularly striking in the context of a randomized trial in which the clinicians agreed to participate and in which they knew they were video recorded. The gross unintended use and the subtler clinician utterances framing the information presented provide novel insights into the nature of clinical decision making in practice and represent areas of necessary future implementation research. Decision aids designed for use during the clinical visit need to take these insights into account for their successful implementation. When properly designed and implemented, these tools can help clinicians and their patients share information and enable patients to participate, to the extent they desire, in making treatment decisions.

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