

Editor's key points

- ▶ Type 2 diabetes mellitus (T2DM) is a common condition that is well-suited to shared decision making, but the complexities involved have historically made this impractical. To navigate this challenge, the authors have developed a comprehensive outcome-focused decision aid to assist clinicians in collaborating with their patients to make value-based, evidence-informed decisions.
- ▶ The encounter-based, interactive online tool, available in English and French, expands upon prior decision aids for T2DM by providing patients with a personalized 10-year risk of T2DM events along with an up-to-date overview of the quantified benefits and harms of available medication options. The decision aid is structured as 4 steps: 1) calculating risk; 2) asking what matters most to the patient; 3) selecting medication options; and 4) summarizing the discussion.
- ▶ The tool is intended to be filled out by clinicians or clinical staff and used during clinical encounters for discussions between patients and clinicians. By engaging in 2-way dialogue, clinicians and patients can come to a collaborative decision about the best individualized treatment course.

Shared decision-making approach to type 2 diabetes management

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Abstract

Objective To provide an online interactive decision aid to facilitate shared decision making in the context of medication choices for patients with type 2 diabetes mellitus (T2DM).

Sources of information The best available clinical prediction model for patients with T2DM was selected based on a review of guidelines, DynaMed, and UpToDate and a search of PubMed. A list of pharmacotherapeutic options for T2DM was compiled based on a review of guidelines, narrative reviews, and expert opinion. To determine the benefits and harms of each treatment, federated search engines were searched for meta-analyses of randomized controlled trials, supplemented by individual randomized controlled trials for outcomes not reported in meta-analyses.

Main message Approximately 2.1 million Canadians have T2DM, with a resulting increased risk of death, cardiovascular disease, and microvascular outcomes. While more than a dozen medication options are available, decisions regarding these medications are challenging, as patients vary in their preferences. Shared decision making has the potential to individualize these difficult decisions, but the number of diabetes-related outcomes and available treatment options have made this historically impractical. It is within this context that the PEER Diabetes Medication Decision Aid was developed. This decision aid provides patients with personalized 10-year risk estimates for 6 clinically important diabetes-related outcomes. The tool also allows patients to focus on the outcome that matters most to them and to compare the benefits and harms of up to 12 different treatment options. This information is displayed in personalized absolute numbers, along with practical considerations such as cost.

Conclusion The PEER Diabetes Medication Decision Aid provides a practical tool that can enable patients with T2DM to come to autonomous and well-informed medication decisions.

Approximately 2.1 million Canadians have type 2 diabetes mellitus (T2DM),^{1,2} increasing their risks of death, cardiovascular events, heart failure, and microvascular outcomes. While there are more than a dozen medications available to manage such risks,^{3,4} research has shown that patients with T2DM vary in their medication preferences.^{5,6} In particular, one discrete-choice experiment found that patients with T2DM were split in their medication preferences between empagliflozin (41%), sitagliptin (31%), oral semaglutide (11%), or none of these options (17%); each option was presented with a unique risk-benefit profile across 8 different benefits and harms.⁵ Preference sensitivity was also demonstrated in the TriMaster crossover randomized controlled trial (RCT), where 38% of patients preferred canagliflozin (mostly owing to its perceived efficacy), 35% preferred sitagliptin (for a mix of perceived efficacy and safety), and 25% preferred pioglitazone (mostly owing to its perceived safety) after experiencing each treatment.⁶

Shared decision making (SDM) has the potential to help individualize these medication decisions to align care with patient preferences and values. In the classic sense, SDM involves conveying that a choice exists, presenting alternatives, and becoming better acquainted with the patient (including their values and preferences).⁷ By engaging in 2-way dialogue through these steps, a clinician and patient can come to a collaborative decision about the best individualized treatment course.

While T2DM medication choices are theoretically well-suited to SDM, patients and clinicians may feel overwhelmed at the prospect of considering so many different options and outcomes. In this context, this article presents the PEER Diabetes Medication Decision Aid, which aims to facilitate SDM for medication decisions for patients with T2DM. This tool expands upon prior decision aids for patients with T2DM (eg, Mayo Clinic's Diabetes Medication Choice tool⁸) by providing each patient with a personalized 10-year risk of adverse effects along with an up-to-date overview of the quantified benefits and harms of available medication options. The encounter-based, interactive online tool is intended to be filled out by clinicians or clinical staff and used during clinical encounters for discussions between patients and clinicians. It is freely available from <https://peerevidence.ca/toolbox/diabetes> in both English and French.

Case descriptions

The following are 2 hypothetical cases, based on the cumulative experiences of clinicians using this tool in their practices, that illustrate the use of the decision aid.

Case 1. D.K. is a 55-year-old White female patient presenting to follow up on her hemoglobin A_{1c} (HbA_{1c}) results since making substantial improvements to her nutrition and physical activity, resulting in her having lost 20 lbs. Her HbA_{1c} level 6 months ago was 8.5%, which has now decreased to 7.5% without medications. She has no prior medical history and is taking no medications, supplements, or naturopathic products. Her in-office systolic blood pressure is 130 mm Hg, and pertinent laboratory parameters include the following: serum creatinine level of 70 µmol/L (estimated glomerular filtration rate [eGFR] 85 mL/min/1.73 m²), urine albumin-creatinine ratio of 2 mg/mmol, total cholesterol level of 4.0 mmol/L, and high-density lipoprotein cholesterol level of 1.0 mmol/L. She does not have polydipsia or polyuria. A link to the PEER Diabetes Medication Decision Aid with D.K.'s specific information entered is available from <https://shorturl.at/cfmuH>.

Case 2. M.M. is a 65-year-old Hispanic male presenting for follow-up of long-standing T2DM. His main concern is about his decline in kidney function and

fear of kidney failure based on his sister's experience requiring thrice-weekly hemodialysis. His history is also relevant for hypertension, chronic obstructive pulmonary disease, ongoing smoking (20-pack-year history), and bilateral knee osteoarthritis. His current medications include 10 mg of ramipril daily, 20 mg of atorvastatin daily, and 1 g of metformin twice daily. His in-office systolic blood pressure is 128 mm Hg, and pertinent laboratory parameters include the following: serum creatinine level of 145 µmol/L (eGFR 45 mL/min/1.73 m²), urine albumin-creatinine ratio of 80 mg/mmol, total cholesterol level of 3.7 mmol/L, high-density lipoprotein cholesterol level of 1.2 mmol/L, and HbA_{1c} level of 9.0%. He does not have polydipsia or polyuria. A link to the PEER Diabetes Medication Decision Aid with M.M.'s data entered is available from <https://shorturl.at/qtz17>.

Sources of information

To select the best available clinical prediction model (also known as a risk calculator), we reviewed guidelines, DynaMed, and UpToDate, and we searched PubMed for systematic reviews and validation studies of clinical prediction models for 1 or more major complications of diabetes in patients with T2DM. We ultimately selected RECODE,⁹⁻¹¹ which incorporated variables readily available in clinical practice, predicted most major complications of diabetes with reasonable performance (ie, discrimination and calibration), and had been externally validated in a cohort generalizable to a Canadian population.

We compiled a list of pharmacotherapeutic options for T2DM based on guidelines, narrative reviews, and expert opinion.^{4,12} To select the best available evidence for benefits and harms of included interventions, we searched federated search engines (ACCESSSS and Trip Database) for meta-analyses of RCTs, supplemented by individual RCTs for outcomes not reported in meta-analyses.

A complete list of sources of evidence used in the PEER Diabetes Medication Decision Aid is available in the decision aid frequently asked questions section: <https://decisionaid.ca/diabetes/faq.html>.

Development. The PEER Diabetes Medication Decision Aid was developed in accordance with the Ottawa Decision Support Framework and the International Patient Decision Aid Standards checklist.^{13,14} This was done in collaboration with a group of primary care physicians and pharmacists. These clinicians provided feedback throughout the development process and used the decision aid with patients as part of pilot testing.

Main message

Overview of the decision aid. The decision aid is structured as 4 steps: 1) calculating risk; 2) asking what matters most to the patient; 3) selecting medication options;

and 4) summarizing the discussion. These steps are intended to emulate the process of SDM and are to be used during discussions between patients and clinicians.

Step 1. Calculating risk: Using the RECODE clinical prediction model, the decision aid estimates individualized patient risks based on multiple clinical characteristics (current medications, medical history, and laboratory test results). Specifically, the decision aid calculates the risk of death, myocardial infarction or stroke, heart failure, kidney failure (defined as need for dialysis or serum creatinine concentration >290 µmol/L), severe vision loss (<20/200 visual acuity according to the Snellen chart), and neuropathy (defined as pressure sensation loss) over the next 10 years. The decision aid will default to population averages for laboratory values, allowing for approximation of risk when patient-specific values are unavailable. The decision aid limits the range of acceptable age values (eg, ages 30 to 74 years) based on the population included in the development of the RECODE risk calculator used in the decision aid. A further discussion of the validity of the RECODE model and its comparison to other models is available in the decision aid frequently asked questions section (<https://decisionaid.ca/diabetes/faq.html>).

Rather than telling patients they have “high blood sugars” or “diabetes,” this calculator can be used to convey the absolute impact of risk factors on a patient’s risk of clinically important outcomes (Figure 1). Conveying this information helps facilitate a decision that is well informed and respectful of patient autonomy. However, it is important to note that simply changing a risk factor in the calculator is not indicative of what would happen to risk if the risk factor were changed by a treatment. That information can come only from RCT evidence on specific treatments. For example, D.K.’s predicted risk of death would be

lower if her HbA_{1c} were 6.5%, but this does not mean that lowering her HbA_{1c} to this value with treatment will reduce her risk of dying (and in fact, according to the ACCORD trial, this would *increase* her risk of dying).¹⁵ This is further illustrated by certain so-called glucose-lowering medications, such as sodium-glucose cotransporter-2 (SGLT2) inhibitors and glucagonlike peptide-1 (GLP1) receptor agonists, providing cardiovascular benefits that are largely independent of their HbA_{1c}-lowering effects.¹⁶⁻¹⁸

Step 2. Asking what matters most to the patient: This step is an opportunity to engage in a 2-way dialogue with the patient about how they value these 6 outcomes. This step addresses preference elicitation, a core part of SDM, and presents an opportunity to focus the discussion on a particular outcome according to patient preferences, reducing decisional complexity. This choice will also change how step 3 is displayed in the decision aid (as described further below). While the options provided in step 2 relate solely to “efficacy” outcomes (eg, death, retinopathy), information is also provided in step 3 to facilitate discussion of other important considerations tied to potential patient goals (eg, minimizing medication burden).

Step 3. Selecting medication options: This step can show the impact of up to 12 medication options. To guide the discussion, only medications that have proven efficacy for the chosen outcome in step 2 are selectable (medications with no known effect—either no evidence or evidence of no effect—are grayed out). Medications that have no proven benefit for any of the 6 outcomes are grayed out regardless of which outcome (even “everything”) is selected in step 2. Finerenone is a special case, as it has been studied only in patients with T2DM who have either reduced eGFR or albuminuria,¹⁹ so it is only selectable for patients meeting these criteria (Table 1).

Figure 1. Diabetes-related outcome 10-y risk estimates for patient D.K.

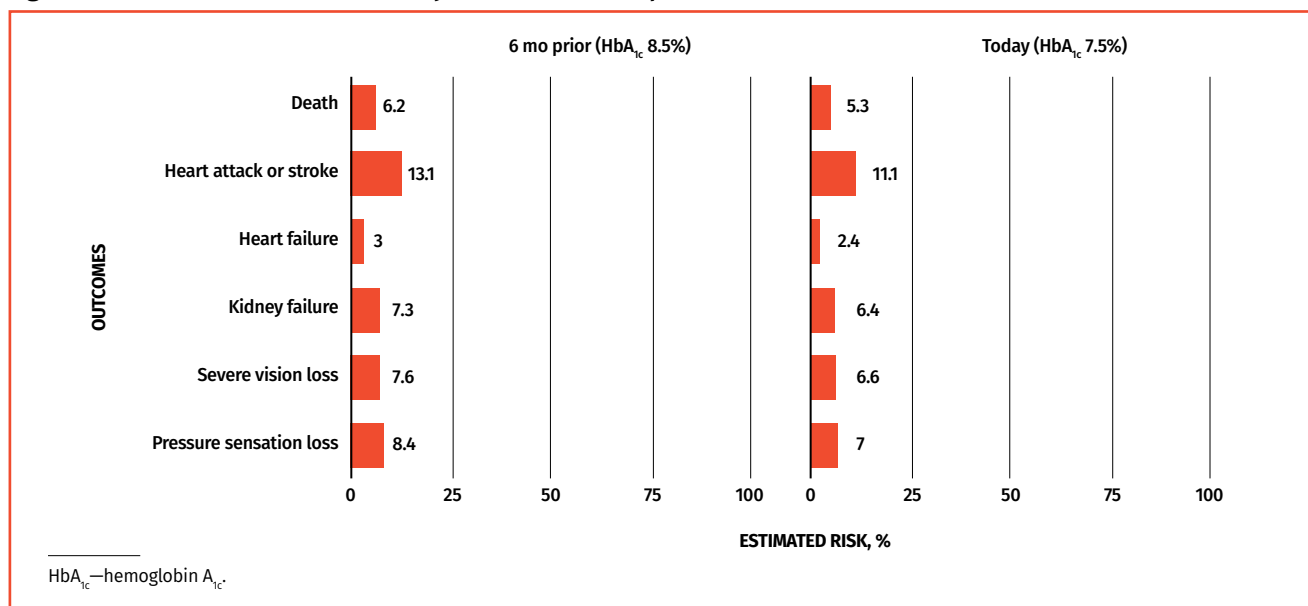


Table 1. Excerpt from the decision aid's FAQ section* outlining the evidence for medication options that reduce the risk of adverse kidney outcomes in patients with T2DM

TREATMENT	RR FOR OUTCOMES IN PATIENTS WITH T2DM					
	DEATH	ASCVD	HEART FAILURE	KIDNEY FAILURE	SEVERE VISION LOSS	NEUROPATHY
ACE inhibitors or ARBs	0.75	0.75	0.80	No albuminuric CKD: NA Albuminuric CKD: 0.60	NA	NA
Finerenone	0.90 (RR=1.00 if eGFR ≥60 mL/min/1.73 m ² and ACR ≤30 mg/mmol)	1.00	0.80 (RR=1.00 if eGFR ≥60 mL/min/1.73 m ² and ACR ≤30 mg/mmol)	0.85 (RR=1.00 if eGFR ≥60 mL/min/1.73 m ² and ACR ≤30 mg/mmol)	NA	NA
GLP1 receptor agonists	0.90	0.90	1.00	0.85	NA	1.00
SGLT2 inhibitors	0.90	0.90	0.65	No albuminuric CKD: 0.70 Albuminuric CKD: 0.65	NA	1.00

ACE—angiotensin-converting enzyme, ACR—albumin-creatinine ratio, ARB—angiotensin receptor blocker, ASCVD—atherosclerotic cardiovascular disease, CKD—chronic kidney disease, eGFR—estimated glomerular filtration rate, FAQ—frequently asked questions, GLP1—glucagonlike peptide-1, NA—not applicable (owing to absence of evidence), RR—relative risk, SGLT2—sodium-glucose cotransporter-2, T2DM—type 2 diabetes mellitus.
*See the FAQ section for an up-to-date list of references: <https://decisionaid.ca/diabetes/faq.html>.

Medications that were already inputted in step 1 will show as “already taking” and will also not be selectable.

If “everything” is selected in step 2, the right column will display every outcome in a bar graph illustrating the absolute risks with and without selected medications. When a single outcome is selected in step 2 (eg, kidney function), 2 comparative smiley face graphs are displayed illustrating the current risk and the risk with medications selected in step 3, with cumulative relative risk displayed underneath.

Multiple options can be selected at the same time (eg, metformin, an SGLT2 inhibitor, and a statin), which will display their additive effects as calculated by multiplication of risk ratios (eg, combining 2 medications both with 25% relative risk reductions will produce a 44% cumulative reduction [$100 \times (1 - [0.75 \times 0.75])$], rather than 50%). This can be used to show that a more intensive approach does not necessarily produce the benefits patients may expect owing to diminishing returns with each additional medication, and that no regimen can entirely eliminate risk. The calculation importantly assumes that these benefits are consistent across all medication combinations and populations—an assumption supported by the findings of individual trials (eg, empagliflozin's benefits being independent of baseline characteristics and background therapy²⁰).

A drop-down arrow within each medication button can be clicked to display each medication's side-effects, cost in Canadian dollars, and other practical considerations (eg, pill-taking routine, link to a sick-day management action plan). This allows for a balanced discussion of each medication's pros and cons, supported by numerical information when available. Although the estimated cost is provided by the decision aid, clinicians will need to supplement this information with a discussion of public versus private drug coverage.

Notably, intensive glycemic control or glycemic targets are not available options within the tool. This simplifies the decision-making process, as considerations such as side effects and cost cannot be estimated from an HbA_{1c} target. Additionally, since the publication of RCTs comparing different HbA_{1c} targets,²¹ several new medications have been introduced that improve diabetes-related outcomes independent of their effects on blood glucose levels.³ Consequently, there is uncertainty regarding the generalizability of these older HbA_{1c}-targeting trials to contemporary practice.

Step 4. Summarizing the discussion: This step provides a summary of all medications selected in step 2 and their overall impact on all 6 outcomes, and it allows for a final choice to be made (use, do not use, or take more time to consider) for each medication selected in step 3.

To facilitate documentation of these complex discussions, the “generate note for EMR” button generates a note that can be copied and pasted into your electronic medical record and edited with any additional information. The “link to save/share” button generates a persistent link that will bring you back to the current page (retaining all personalized risk variables, preferences, and medication choices), which can be shared with the patient (eg, for further consideration of the decision) or other clinicians. This can also be used to populate information in step 1 prior to the patient encounter (eg, by the clinician or their medical office staff) to streamline workflow. No personal identifiers are contained in this link, mitigating concerns regarding confidentiality.

Case resolutions

Case 1. Using the calculator in step 1, D.K.'s estimated 10-year risks range from 2.4% (heart failure) to 11.1% (heart attack or stroke). D.K. believed all the outcomes were equally important and decided to focus on “everything.” As metformin is generally considered a

first-line agent for T2DM, this is discussed as an option for D.K., highlighting that it lowers the risk of myocardial infarction and stroke but does not have proven benefit for other outcomes. D.K. decides to pursue treatment with metformin as it offers the greatest benefit for heart attack and stroke prevention, which for her offsets the potential side effects at minimal cost. At her 3-month follow-up, D.K. is satisfied with her choice and feels reassured that her clinician can present additional therapy options in the future if necessary (eg, if her estimated risks meaningfully change).

Case 2. Using step 1 with a focus on M.M.'s concerns regarding dialysis, his estimated 10-year risk of kidney failure is 20.2% (which is also selected as the priority in step 2). Since M.M. is already taking an angiotensin-converting enzyme inhibitor, his remaining options to reduce the risk of kidney failure include an SGLT2 inhibitor, a GLP1 agonist, and finerenone. These can be considered 1 at a time or selected in various combinations to illustrate their impact on kidney failure and other outcomes. After considering each of the 3 medications, M.M. decides to start an SGLT2 inhibitor (owing to its renal benefits [Box 1] and minimal side effects); take more time to consider using a GLP1 agonist (as it could also provide a weight-loss benefit,

although he wishes to start 1 medication at a time); and not to use finerenone (as he is uncomfortable with the risk of hyperkalemia, having seen his sister previously struggle with electrolyte abnormalities). To support M.M.'s desire to further consider using a GLP1 agonist, his clinician copies the "link to save/share" link and emails it to M.M. At his 3-month follow-up visit, M.M. states that he has reviewed the decision using the link and has decided that the additional benefits from adding a GLP1 agonist are meaningful to him and is hoping to discuss that further.

Conclusion

Type 2 diabetes mellitus is a common condition that is well-suited to SDM, but the complexities involved have historically made this impractical. To navigate this challenge, we have developed a comprehensive outcome-focused decision aid to assist clinicians in collaborating with their patients to make value-based, evidence-informed decisions.

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Contributors

Dr Blair J. MacDonald wrote the original draft and reviewed and edited the manuscript. **Dr James P. McCormack** reviewed and edited the manuscript. **Dr Ricky D. Turgeon** conceived of the manuscript idea, reviewed and edited the manuscript, and provided supervision. All authors approved the final version for submission.

Competing interests

None declared

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Box 1. "Generate note for EMR" for patient M.M.

I have used the PEER Diabetes Medication Decision Aid available from <https://peerevidence.ca> to discuss medication options with the patient to reduce their risk of diabetes-related complications.

Based on the RECODE clinical prediction model and the changes below, we estimated the following risks over the next 10 years:

- Death: 26.4% (from 32.6%)
- Heart attack or stroke: 32.0% (from 39.5%)
- Heart failure: 13.7% (from 21.0%)
- Kidney failure (dialysis or serum creatinine >290 µmol/L): 11.1% (from 20.2%)
- Severe vision loss (<20/200 visual acuity by Snellen chart): 14.2% (from 14.2%)
- Sensation loss: 20.1% (from 20.1%)

After discussing the benefits and harms of available options and eliciting patient preferences, we have decided to ...

- **Use:** SGLT2 inhibitor, statin, ACE inhibitor, or ARB
- **Don't use:** Finerenone
- **Take more time to consider:** GLP1 receptor agonist

<https://decisionaid.ca/diabetes/?guid=33f95bf7759d46bea4597a649a9a3578>

ACE—angiotensin-converting enzyme, ARB—angiotensin receptor blocker, EMR—electronic medical record, GLP1—glucagonlike peptide-1, SGLT2—sodium-glucose cotransporter-2.

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