Development and Preliminary Testing of a Patient Decision Aid to Assist Pharmaceutical Care in the Prevention of Cardiovascular Disease

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Study Objective. To develop and test a decision aid for patients with hypertension and/or dyslipidemia because a decision aid may assist in pharmaceutical care by providing relevant evidence-based information.

Design. Before and after use of a decision aid.

Setting. Hypertension clinic of a university hospital and a specialized coronary heart disease—prevention clinic.

Patients. A convenience sample of 16 patients receiving pharmacologic treatment for hypertension and/or dyslipidemia.

Intervention. A face-to-face interview was conducted before using the decision aid. This was followed by a telephone interview after the patient used the decision aid to assess the acceptability of the decision aid to the patient, as well as the patient’s knowledge, risk perception, and decisional conflict.

Measurements and Main Results. The decision aid consists of a booklet containing general, evidence-based information and a personal worksheet. The worksheet provides information on patient risk factors, personal estimates of cardiovascular disease (CVD) risk, the benefits of treatment options, and values clarification exercise. It invites patients to specify an action plan and follow their own progress over time. Most patients (86–93%) rated the presentation of the information as excellent or very good, 80% judged the information about lifestyle changes and drug therapy to be balanced, 93% rated the amount of information “just right,” and 100% found the decision aid useful. After using the decision aid, patients had higher knowledge scores for general risk factors (before, 91%; after, 100%, p=0.014), personal risk factors (73%, 92%, p=0.016), and treatment options (68%, 99%, p<0.001). More patients were able to estimate correctly their CVD risk category (50%, 93%, p=0.03) and their absolute 10-year CVD risk (0%, 93%, p<0.001), whereas the overall decisional conflict score decreased (p=0.007).

Conclusion. The decision aid was acceptable to patients and improved their knowledge, risk perception, and decisional conflict. Therefore, the feasibility and impact of using the decision aid in community pharmacies and medical clinics should be assessed.

Key Words: decision aid, cardiovascular disease prevention, hypertension, dyslipidemia, pharmaceutical care.

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Cardiovascular disease (CVD) remains the leading cause of death in North America. Treatment for hypertension and dyslipidemia reduces CVD morbidity and mortality, and clinical guidelines consequently underlie the need to detect and treat people adequately with these conditions. Nonetheless, management of these disorders is still far from optimal. In North America, only about half the patients with hypertension receive treatment, and only half of those receiving it are adequately controlled. Moreover, long-term adherence to treatment is very low, with approximately half of all patients discontinuing treatment within the first year.

A number of studies suggest that pharmaceutical care offered to patients with hypertension or dyslipidemia in community pharmacies may improve control of CVD risk factors, adherence to pharmacotherapy, and patient satisfaction. However, the interventions, which involved patient education, evaluation of patient CVD risk, development of a treatment plan, and patient follow-up, are complex and time consuming and therefore not easily implemented in this setting. The development of tools for facilitating such care is thus a matter of great importance.

Decision aids for patients are designed to help them make informed and individualized decisions about medical treatment. According to one group of investigators, decision aids should be used as adjuncts to practitioner counseling when there is no single "best" choice among equally effective options or when the best choice depends on how patients value benefits versus harm. By definition, a decision aid provides, at the very least, information about treatment options and their respective advantages and disadvantages. It also may include other types of information such as a description of the health problem, an estimate of the probable treatment effect based on a patient's risk factors, an exercise to help patients clarify their preferences regarding outcomes, a proposed strategy for making an informed decision, and examples of patients arriving at different treatment decisions. The decision aid may take the form of a booklet, a booklet with an audio- or videotape, a group presentation, or interactive computer programs; most developers are also producing Web-based applications.

A recent Cochrane Review identified more than 200 decision aids. A number have been validated, including one for women considering hormone replacement therapy at menopause, for postmenopausal women with osteoporosis, and for patients with ischemic heart disease. To our knowledge, however, no decision aid is as yet available for patients at high risk of CVD who have to decide about beginning antihypertensive or lipid-lowering pharmacotherapy.

We summarize the development and preliminary testing of a decision aid for patients with hypertension and/or dyslipidemia who wish to improve their cardiovascular health. Although designed to assist pharmaceutical care, the decision aid may be used by other health care professionals.

Methods

Development of the Decision Aid

The decision aid was designed for patients considering lifestyle changes and drug therapy to improve their cardiovascular health and is based on the clinical guidelines for dyslipidemia and hypertension. It was developed by a panel of five researchers and clinicians and reviewed by an endocrinologist specializing in CVD prevention, as well as by two clinical pharmacists. It was reviewed by a linguistic specialist to adapt the language used to a grade-6 level.

Description of the Decision Aid

The French and English versions of the decision aid (entitled "Making Choices: Life Changes to Lower Your Risk of Heart Disease and Stroke") are available through the Web site of the
Ottawa Health Research Institute.\textsuperscript{27} It is made up of a booklet and a personal worksheet. The booklet provides general information on CVD, CVD risk factors, drug options (antihypertensives and lipid-lowering drugs), and lifestyle changes such as healthy diet, physical activity, smoking cessation, healthy weight, and stress control. Evidence-based information on changes in high-density lipoprotein cholesterol (HDL), low-density lipoprotein cholesterol (LDL), and blood pressure is provided for each treatment option (lifestyle change and drug therapy). The drugs are grouped by class (e.g., resins, niacin, fibrates, and statins). For each class, the most frequent side effects and the average change in LDL, HDL, and diastolic and systolic blood pressure are reported. The lifestyle changes and drugs are further summarized in two separate tables at the end of the booklet, so patients can make direct comparisons of the effect of each approach on LDL, HDL, and blood pressure. Finally, a four-step decision-making strategy is suggested that enables patients who want to improve their cardiovascular health to integrate relevant personal information, clarify their preferences, and determine their stage of change with regard to the various treatment options. They are then in a position to specify a treatment plan in collaboration with a health care professional and follow their own progress over time. Examples are provided of two patients who follow the steps and come to different decisions about the nonpharmacologic and pharmacologic treatment options.

As Figure 1 shows, the personal worksheet is designed to help a patient apply the decision-making process. Sections 1 and 2 need to be completed by a research assistant or a trained health care professional. Sections 3 and 4 are designed to be completed by the patient and his or her health care professional.

In the first step, the patient's cardiovascular health is evaluated: modifiable risk factors are identified, and his or her 10-year CVD risk is estimated by using the previously validated Cardiovascular Health Life Expectancy Markov Model.\textsuperscript{32} Based on United States data, this model estimates the risk of coronary heart disease as well as stroke. For given levels of CVD risk factors, the model describes the yearly probability of transition to three causes of death: coronary disease, stroke, and other. The yearly probabilities associated with these transitions are estimated by using multivariate logistic regression coefficients derived from the Lipid Research Clinics program prevalence and follow-up studies.\textsuperscript{33} The proportion of subjects developing nonfatal CVD is estimated by the ratio of nonfatal:fatal events predicted by the results of the Lipid Research Clinics Coronary Primary Prevention Trial,\textsuperscript{34} Framingham Heart Study,\textsuperscript{35} or the Scandinavian Simvastatin Survival Study.\textsuperscript{36} To make it easier for patients to understand, risk is illustrated by a 100-face figure; a 20% risk, for example, is expressed by shading 20 of the 100 faces. For patients without CVD symptoms, an estimate is also made of CVD age, that is, the average age of Canadians of the same sex who have a similar CVD risk. For example, a 50-year-old man may have a CVD age of 55 years, meaning that his life expectancy may be reduced by 5 years if he does not change his CVD risk factors. The estimate of the CVD age is based on the following formula: patient's age + (life expectancy of Canadians of the same age and sex) \textsuperscript{37} – life expectancy predicted by the Cardiovascular Health Life Expectancy Markov Model. The estimate of the CVD risk and CVD age are derived from the results of U.S. studies and Canadian life-expectancy statistics and can be reasonably generalizable to North Americans.

In the second step, the worksheet provides an estimate of the potential changes in CVD risk that may come about with various lifestyle changes and drug therapy. Thus, we report the estimated CVD risk associated with reduced LDL, increased HDL, and lower blood pressure that may be achieved by adopting the lifestyle changes and taking the drugs. Also, we report the change in CVD risk associated with smoking cessation and with the modification of all modifiable risk factors. It was assumed for this purpose that lifestyle changes could reduce LDL by 5%, increase HDL by 5%,\textsuperscript{39–42} and lower systolic and diastolic blood pressure by 10 and 5 mm Hg,\textsuperscript{43–46} respectively. It also was assumed that appropriate drug therapy could reduce LDL by 35%, increase HDL by 10%,\textsuperscript{36, 48} and lower systolic and diastolic blood pressure by 15 and 10 mm Hg,\textsuperscript{40, 50} respectively. Finally, again using a 100-face figure to illustrate estimated risk, we report the estimated net reduction in CVD risk if all modifiable risk factors are modified. For patients with no CVD symptoms, we also provide an estimate of cardiovascular age once all risk factors are modified. Patients are then asked to indicate their preferences with regard to each of the treatment options by drawing stars beside them; five stars signify that they judge the option to be very important for
**Step One: Your Personal Risk of Heart Disease and Stroke**

You have the following risk factors:

- Abnormal cholesterol [ ] [ ]
- High blood pressure [ ] [ ]
- Smoking [ ] [ ]
- Lack of exercise [ ] [ ]
- Overweight or obese [ ] [ ]
- Diabetes [ ] [ ]
- Heart attack or stroke [ ] [ ]

If we follow 100 people like you over the next 10 years, on average ___

would have a heart attack or stroke

___ would not

For the average North American of your age and sex, the risk of having a heart attack or stroke is between ___% and ___%

You would have the same risk for heart disease and stroke as the average North American ___ years of age.

---

**Step Two: Possible Benefits of Life Changes**

<table>
<thead>
<tr>
<th>Life change</th>
<th>Number of people out of 100 who will have a heart attack or stroke over the next 10 years</th>
<th>How important is the benefit (1-5 stars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>HLD with lifestyle changes</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>HLD with medication</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>T HEL with lifestyle changes</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>T HEL with medication</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>1 blood pressure with lifestyle changes</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>2 blood pressure with medication</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Quit smoking</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Changing all risk factors</td>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>

If 100 people like you changed all their risk factors over the next 10 years on average,

___ would have a heart attack or stroke

___ would not

You would have the same risk for heart disease and stroke as the average North American ___ years of age.

---

**Step Three: Your Plan of Action**

☐ Check the options you are interested in considering over the next 3 months. Be specific about changes.

### LIFESTYLE OPTIONS

<table>
<thead>
<tr>
<th>Alternative</th>
<th>Already doing this</th>
<th>Will try doing this</th>
<th>Thinking about doing this</th>
<th>Specific Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy diet</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>i.e. buy more fruits and vegetables on shopping day</td>
</tr>
<tr>
<td>Lose weight</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>i.e. join a weight loss group</td>
</tr>
<tr>
<td>Increase exercise</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>i.e. walk 30 minutes/day from parking lot to office</td>
</tr>
<tr>
<td>Quit smoking</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>i.e. will stop smoking and use nicotine patches</td>
</tr>
<tr>
<td>Reduce stress</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>i.e. listen to relaxation cassette each day</td>
</tr>
<tr>
<td>Limit Alcohol</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>i.e. limit alcohol to one drink less per day</td>
</tr>
</tbody>
</table>

**MEDICATION OPTIONS (if appropriate)**

<table>
<thead>
<tr>
<th>Alternative</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Other</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

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**Step Four: Your Progress**

☐ You may complete this section with your practitioner to follow your progress over the next three months.

<table>
<thead>
<tr>
<th>Goal</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifestyle Changes</td>
<td>☐ possible options</td>
<td>☐ the options you are following</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alternative</th>
<th>Goal:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy diet</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Lose weight</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Increase Exercise</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Quit smoking</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Reduce stress</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Limit Alcohol</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>MEDICATIONS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Set blood pressure</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Your Results</td>
<td>Ideal values</td>
<td>Record your results</td>
</tr>
</tbody>
</table>

**Lab results**

- **LDL Cholesterol**
- **Total/HDL Cholesterol**
- **Blood Pressure**
- **Carotid Artery Plaque**

<table>
<thead>
<tr>
<th>Alternative</th>
<th>Goal:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>Carotid Artery Plaque</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

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**Figure 1. Decision aid personal worksheet.**
them, whereas one star means they do not consider it important.

In the third step, the objective is to define an action plan for the next 3 months. In collaboration with their health care professional, patients are asked to identify the options they would be interested in considering for the period. The process is based on Prochaska and DiClemente's stage-of-change model and is intended to help health care professionals provide relevant counseling. For each treatment option—healthy diet, weight loss, increased physical activity, smoking cessation, stress reduction, limited alcohol intake, and/or lipid-lowering or antihypertensive drug therapy—patients indicate if they are already doing it (action or maintenance stage), will try doing it (preparation stage), or are thinking about doing it (contemplation stage). The health care professionals are then to review patients' preferences and stage of change regarding each option so that they can offer guidance in developing a 3-month plan.

The fourth step allows patients, in collaboration with a health care professional, to define their treatment goals in terms of ideal HDL, LDL, blood pressure, CVD risk, and cardiovascular age and to follow their own progress over time.

Conceptual Framework

The decision aid booklet and the personal worksheet are based on two conceptual frameworks: the Ottawa Decision Support framework and the Leventhal and Cameron Self-regulatory Model. The Ottawa Decision Support framework is a useful theoretic model to identify factors that may influence decision making, whereas the Self-regulatory Model is useful to identify factors that may influence adherence to or continuance of a chosen option.

The first objective of the decision aid is to improve the quality of decision making, in which, patients understand options and probable outcomes, clarify the personal importance of probable outcomes, and participate in decision making. According to the Ottawa Decision Support framework, patients facing options for dyslipidemia or hypertension may have unresolved decisional conflict (uncertainty) about which options to pursue because of inadequate information, unrealistic expectations (risk perceptions), unclear values, and inadequate support and skills in making and implementing a choice. Those in the early stages of decision making have higher decisional conflict than those in later stages; high decisional conflict is associated with decision delay, discontinuance, dissatisfaction, and decisional regret.

In accordance with the Ottawa Decision Support framework, the decision aid was designed to address decisional needs as follows. Knowledge deficits are resolved with evidence-based information. Unrealistic expectations (e.g., risk perceptions) are realigned with probabilities of outcomes with and without treatment that is tailored to the patients' health profile. Unclear values are resolved with detailed information on outcomes and a values clarification exercise, in which the patient values the most important strategies for cardiovascular risk reduction. Patients are supported through a structured process of decision making, including balanced examples of how others go through the steps. Therefore, one can hypothesize that exposure to decision aids in those who have high decisional conflict will reduce decisional conflict and associated problems of inadequate knowledge, unrealistic expectations (risk perceptions), unclear values, and inadequate support.

The second objective is to improve adherence to the treatment options that are chosen. Developed to explain and predict adherence to treatment, the Self-regulatory Model is particularly relevant to developing a decision aid because it considers the patient to be an "active problem solver, whose health-related behavior is an attempt to close the perceived gap between current health status and future goal state." According to the Self-regulatory Model, patients' responses to illness follow three broad processing stages, which are at once both cognitive and emotional: first, representation of the health problem; second, development and implementation of an action plan; and third, appraisal of the action plan. Table 1 shows how the decision aid and pharmaceutical care may assist patients at each Self-regulatory Model stage and indicates the potential impact on outcomes.

Decision aid-assisted pharmaceutical care may influence patients' representation of their cardiovascular health by giving them general, evidence-based information about the health problem and patient-specific information on CVD risk factors, estimated CVD risk, and the estimated benefits of the various treatment options. At this stage, pharmaceutical care may involve documenting a patient's CVD risk factors and reviewing the CVD information in steps 1 and 2 of the personal worksheet. A pharmacist may explore patients' beliefs and answer their
<table>
<thead>
<tr>
<th>Stage of Self-Regulatory Model</th>
<th>Description of Decision Aid</th>
<th>Description of Pharmaceutical Care</th>
<th>Impact on Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representation of the health problem</td>
<td>Presents general evidence-based information on CVD, risk factors, and treatment options</td>
<td>Reviews medical history</td>
<td>Improves patient’s knowledge</td>
</tr>
<tr>
<td></td>
<td>Gives personalized information on risk factors</td>
<td>Documents CVD risk factors</td>
<td>Results in more realistic perception of CVD risk and potential benefits and risks of treatment</td>
</tr>
<tr>
<td></td>
<td>Estimates CVD risk and benefits of various treatment options</td>
<td>Discusses the information in the decision aid</td>
<td></td>
</tr>
<tr>
<td>Development of an action plan</td>
<td>Estimates benefits of various treatment options</td>
<td>Explores patients’ beliefs about drug and adverse effects</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Invites patients to clarify their preferences and stage of change regarding various treatment options</td>
<td>Answers patients’ questions</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provides examples of patients who have defined their own plan of action</td>
<td>Reviews treatment plan</td>
<td>Decreases decisional conflict</td>
</tr>
<tr>
<td></td>
<td>Asks patients to summarize their plan of action on paper and to be specific about behavioral changes (e.g., eat less cheese, walk 20 min every day)</td>
<td>Refers patients to other resources when appropriate</td>
<td>Increases patient’s sense of empowerment</td>
</tr>
<tr>
<td>Evaluation of the action plan</td>
<td>Defines treatment objectives for each risk factor (e.g., blood pressure, lipid levels, weight loss, smoking)</td>
<td>Provides required counseling on lifestyle changes (e.g., smoking cessation)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Invites patients to monitor their progress over time</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CVD = cardiovascular disease.

*Associated with specific stages; however, each of the outcomes may be influenced at each stage of the model.

questions about drug therapy. Pharmaceutical care assisted by the decision aid, consequently, may enhance patients’ knowledge and the accuracy of their perception of the risks and estimated benefits of treatment.

The decision aid also is designed to assist patients and health care professionals negotiate a plan of action. In the worksheet, the benefits of the various treatment options are estimated, and patients are invited to clarify what their preferences and stage of change are with respect to the various treatment options. They are given examples of two patients who have used this information to define their own plan of action with their health care professionals. This process thus prepares them to negotiate their treatment plan with a health care professional. When a decision aid is used in community pharmacies where patients are filling a prescription for an antihypertensive or lipid-lowering drug, the pharmacist may review and discuss the patients’ action plans and, when appropriate, refer them to other health care professionals or counsel them on specific lifestyle changes such as smoking cessation. This decision-making process may decrease patients’ decisional conflict and heighten their sense of empowerment.

Finally, by defining specific treatment objectives and inviting patients to monitor their own progress over time, a decision aid supports pharmaceutical care in the evaluation of the efficacy of treatment. Pharmacists may follow patients’ progress, provide them with specific counseling, and make recommendations to treating physicians when appropriate. Consequently, persistence with and adherence to pharmacotherapy may be enhanced, progression through the stages of change for lifestyle modifications stimulated, treatment efficacy increased, and cardiovascular health improved.

Preliminary Testing of the Decision Aid

A before-and-after study design was used with
a convenience sample of patients with hypertension and/or dyslipidemia who were recruited from the hypertension clinic of a university hospital and at a specialized coronary heart disease-prevention clinic; approval was obtained from the McGill University Health Centre institutional review board. The objectives of the study were to document patients' opinions about the decision aid and evaluate the extent to which they understood the information and experienced lower decisional conflict. We included in the sample English-speaking patients aged 18–74 years with a diagnosis of hypertension or dyslipidemia confirmed in their medical chart, who agreed to participate and signed the informed consent form.

To estimate their CVD risk and the potential benefits of different lifestyle changes, we documented their CVD risk factors: age, sex, systolic and diastolic blood pressure, lipid profile (HDL, LDL, and total cholesterol), smoking status (yes or no), height and weight, current diagnosis of CVD, and diagnosis of diabetes mellitus (yes or no). Participants completed a questionnaire administered first in a face-to-face interview before using the decision aid and again in a telephone interview within 2 weeks after using it. The same interviewer administered the first and second questionnaires to all participants. The acceptability of the decision aid to the patients was assessed at the second interview. Patient knowledge, risk perception, and decisional conflict were evaluated at both interviews.

Knowledge

Patient knowledge was assessed on the basis of 16 statements regarding general CVD risk factors (5 items), personal CVD risk factors (4 items), and available treatment options, including both lifestyle changes and drugs (7 items). Patients were asked to indicate if each statement was true or false, or if they were not sure. The statements about personal CVD risk factors were “I have an abnormal blood cholesterol,” “My blood pressure is too high,” “I am physically inactive,” and “I am overweight.” The accurate response to each statement came from information collected from hospital or clinic charts before the decision aid was used. Blood cholesterol level was considered abnormal if for patients without CVD, total cholesterol was above 201 mg/dl and HDL was below 46 mg/dl for men or 54 mg/dl for women. Hypertension was defined as a diastolic blood pressure of 90 mm Hg or greater and/or systolic blood pressure of 140 mm Hg or greater. Overweight was defined as a body mass index greater than 25 kg/m². Patients were considered sedentary if they reported doing less than 30 minutes of exercise 3 times/week.

Risk Perception

Patients' perceptions of their relative 10-year CVD risk were assessed by asking them to choose a phrase to complete the following statement: “Compared to the average North American of my age and sex, my risk of having a heart attack or a stroke in the next 10 years is: 1) lower than the risk of the average North American; 2) about equal to the risk of the average North American; or 3) higher than the risk of the average North American.” We determined the concordance between a patient's answer and an estimate computed with the Cardiovascular Health Life Expectancy Model; the model estimate is based on the distribution of the 10-year CVD risk for the Canadian population of the same age and sex. Patient risk in the lower, middle, or upper tertiles of the population distribution was considered, respectively, less than, approximately equal to, or greater than the risk of the average North American of the same age and sex. For example, if a patient's estimated risk was 21% and the lower and upper bounds of the middle tertile of risk for North Americans of the same age and sex were 4% and 11%, respectively, we concluded his or her risk was higher than that of the average North American of the same age and sex.

Patients' perceptions of their absolute risk was assessed by asking the following: “If we follow 100 people of your age and sex whose health is similar to yours, on average, how many will have a heart attack or a stroke over the next 10 years?” Twelve possibilities covering the entire range from “0 out of 100” to “100 out of 100” were proposed, with every “in-between” answer option covering a 10-point interval (e.g., “between 20 and 29 out of 100”). We assessed the concordance between the patient's answer and his or her estimated risk as computed by the Cardiovascular Health Life Expectancy Model. Thus, if the estimated CVD risk was 21% and the patient answered “between 20 and 29 people out of 100 will have a heart attack or a stroke over the next 10 years,” the answer was considered concordant.
Decisional Conflict

The perceived decisional conflict of the patients was assessed with the Decisional Conflict Scale.\textsuperscript{57}  
This self-administered 16-item scale measures a patient’s level of uncertainty when deciding about taking antihypertensive or lipid-lowering drugs (3 items). It also measures the main modifiable factors that contribute to such uncertainty: feeling uninformed (3 items), feeling unclear about what value he or she attaches to the benefits and adverse effects of the drugs (3 items), and feeling unsupported in making the decision (3 items). Finally, it measures the patient’s perception of the quality of the decision to take a drug (4 items). Decisions regarding pharmacotherapy are considered to be high quality if they are informed, are based on the value patients personally accord the various benefits and adverse effects, and are associated with a high expectation of adherence and strong patient satisfaction with the decision. Each item is scored from 1 (strongly agree) to 5 (strongly disagree). Subscale scores are summed and divided by the total number of items. Overall and subscale scores range from 1 (low decisional conflict) to 5 (high decisional conflict). On average, scores of 2 or less are associated with no difficulty in decision making, and scores higher than 2.5 are associated with decision delay.\textsuperscript{58}

Acceptability

Closed-ended questions were used to document patient opinion on the presentation of the information in the decision aid, the amount of information, the balance with which lifestyle options and drug therapy are treated, and the usefulness of the tool. Also, patients were asked to report what they liked and did not like about the decision aid and to offer suggestions for improving it.

Statistical Analysis

Descriptive statistics including median and proportions were used to describe the patient population and the acceptability of the decision aid to the patient. For each knowledge question, we reported the number and percentage of accurate answers. An overall score representing the number and percentage of accurate answers was computed for patients’ knowledge of general risk factors, personal risk factors, and treatment options. The distribution of Decisional Conflict Scale scores was described by the mean ± SD and the median (25th and 75th percentiles). To determine the statistical significance of the difference in the distribution of the knowledge and the decisional conflict scores obtained before and after using the decision aid, we used the Wilcoxon signed rank test, a nonparametric analog of the paired-sample t test. The statistical significance of the change in participants’ ability to correctly assess their CVD risk category and absolute risk after using the decision aid was determined with the McNemar χ² test for paired samples. A p value of 0.05 or less was considered to indicate a statistically significant difference.

Results

A total of 34 patients were approached, but 18
refused to participate. Sixteen were enrolled in the study, but one did not complete the post-decision aid questionnaire. As Table 2 shows, most participants were men (63%), and the median age was 57 years. Those with no CVD symptoms were younger (median age 53 yrs) than those with CVD (median age 57 yrs). All 16 participants were already taking antihypertensive and/or lipid-lowering drugs. The personalized evaluation of their cardiovascular health, described in the first step of the personal worksheet, revealed a high prevalence of patients who had a diagnosis of CVD (38%), high blood pressure (62%), dyslipidemia (50%), or diabetes mellitus (31%), and who were overweight or obese (75%), sedentary (50%), or smokers (19%). The estimated median risk was 25%. For patients without CVD symptoms, the median estimated CVD age was 59 years, whereas the actual median atrophic chronologic age was 53 years. As compared with the average Canadian of the same age and sex, more than half the patients (56%) were in the upper tertile of the risk distribution.

Acceptability

In evaluating the decision aid (Table 3), most patients rated as excellent or very good the way the information was presented in the booklet (93%), in the summary table (87%), and in the worksheet (86%). Most found that the amount of information was “just right” (93%) and balanced (80%). Overall, 100% of patients rated the usefulness of the tool as excellent or very good.

Knowledge

Before using the decision aid, all patients were aware that high blood pressure, physical inactivity, smoking, and being overweight increase the risk of CVD (Table 4). Nine (56%) knew that high LDL levels increase the risk of CVD. After using the decision aid, all the participants answered every question correctly. The overall scores for knowledge of general risk factors were 91% before using the decision aid and 100% after (p=0.014).

With regard to patient risk factors, before using the decision aid, 6 (38%) of the 16 patients assessed their cholesterol status in a manner consistent with the definition; 73% (11 of 15) did so after. Before using the decision aid, 12 patients (75%) assessed their blood pressure status in accordance with our definition; after, 14 (93%) were able to do so. However, even before using the decision aid, most patients were able to report whether they were physically inactive and overweight or obese. Overall, the mean knowledge score for personal risk factors rose from 73% before using the decision aid to 92% after (p=0.016).

We also were able to observe improved knowledge of treatment options: the average knowledge score rose from 68% before to 99% after the decision aid was used (p=0.00). Most of the improvement was related to the questions on smoking cessation, the relative efficacy of diet and exercise, and the type of physical activity required to improve cholesterol levels and blood pressure.

Risk Perception

Before using the decision aid, only 50% of patients assessed their risk category adequately, but not one of them was able to assess his or her absolute CVD risk (Table 5). After using the
decision aid, 93% (14 of 15 patients) were able to report their risk category and their current 10-year risk adequately, indicating a significant improvement in their perception of their CVD risk.

### Decisional Conflict

The median (25th, 75th percentile) overall Decisional Conflict Scale scores were 2.0 (2.0, 2.5) before using the decision aid and 2.0 (1.9, 2.0) after (p=0.007, Table 6). These data suggest that Decisional Conflict Scale scores tended to decline slightly after the use of the decision aid. Before using the decision aid, 25% (4 of 16) of the participants had an overall score over 2.5, indicating relative discomfort with the decision to take drugs for their blood pressure or blood cholesterol; after, only 7% (1 of 15, p=0.38) did.

### Discussion

We developed a decision aid for patients at risk of CVD who wish to consider options for improving their cardiovascular health. The decision aid may assist pharmaceutical care by providing general and personal information to guide patients and pharmacists in assessing a patient's cardiovascular health and addressing decisional needs, defining a specific plan of action, and evaluating the efficacy of the treatment.

This preliminary validation with a small number of patients currently taking antihypertensive and/or lipid-lowering drugs suggests that the decision aid was acceptable to them.
Table 5. Perception of Risk

<table>
<thead>
<tr>
<th>Concordance</th>
<th>No. (%) of Patients</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before Using Decision Aid</td>
<td>After Using Decision Aid</td>
</tr>
<tr>
<td></td>
<td>(n=16)</td>
<td>(n=13)</td>
</tr>
<tr>
<td>Risk category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concordant estimation</td>
<td>8 (50)</td>
<td>14 (93)</td>
</tr>
<tr>
<td>Discordant estimation</td>
<td>8 (50)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Underestimation</td>
<td>3 (19)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Overestimation</td>
<td>5 (31)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Absolute 10-yr risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concordant estimation</td>
<td>0 (0)</td>
<td>14 (93)</td>
</tr>
<tr>
<td>Discordant estimation</td>
<td>16 (100)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Underestimation</td>
<td>7 (44)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Overestimation</td>
<td>9 (56)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

Table 6. Decisional Conflict Scale Scores

<table>
<thead>
<tr>
<th>Item</th>
<th>Before Using the Decision Aid</th>
<th>After Using the Decision Aid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Median</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>2.3 ± 0.7</td>
<td>2.0</td>
</tr>
<tr>
<td>Feeling uninformed</td>
<td>2.3 ± 0.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Feeling unclear about values</td>
<td>2.3 ± 0.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Feeling unsupported in decision making</td>
<td>2.1 ± 0.4</td>
<td>2.0</td>
</tr>
<tr>
<td>Overall score</td>
<td>2.3 ± 0.5</td>
<td>2.0</td>
</tr>
</tbody>
</table>

Comparing the results obtained before and after using the decision aid suggests that it had a positive impact on their knowledge of their personal CVD risk factors and treatment options and the accuracy of their risk perception. In addition, there was a slight reduction in their perceived decisional conflict regarding pharmacotherapy. However, it is important to note that these participants were already receiving treatment for hypertension and/or dyslipidemia, were being followed by specialists in a university-hospital clinic, and were self-selected to participate in the study (16 of 34 patients were enrolled into the study). The impact of the decision aid must be tested among the general hypertensive and dyslipidemic population.

These findings are in line with the results of a systematic review of decision aids, which showed that, compared with controls, participants exposed to decision aids generally produce higher knowledge scores, more accurate risk perceptions, and lower decisional conflict scores and take a more active role in decision making. The use of a decision aid, however, was associated with no difference in anxiety level, satisfaction with the decisions made, or satisfaction with the decision-making process. Moreover, the effect of decision aids on decisions is variable; decision aids prevent overuse of treatments that informed patients do not value and increase the use of those they do value but were not adequately informed about. It is not yet certain whether decision aids affect continuance of treatment choice or preference-based quality of life. Finally, to our knowledge, there are no reports of pharmacists using decision aids; up to now, decision aids generally have been used by physicians or clinical nurses.

Prevention of CVD in North America is far from optimal. In Canada, only 16% of patients with hypertension are treated and adequately controlled, 23% are treated but not controlled, and 19% receive a diagnosis but are not treated; in 42%, hypertension is not even diagnosed. A comparable situation exists in the United States. Similar figures prevail too for dyslipidemia treatment. A major Canadian and U.S. retrospective cohort study based on administrative databases showed that only 50% of patients continued to
renew their lipid-lowering drug after 5 years.\textsuperscript{15} Moreover, patients failed to fill their prescriptions for lipid-lowering drugs about 40\% of the study year. In a study of elderly patients, the 2-year adherence rates were only 40\% for patients with recent acute coronary syndrome, 36\% for patients with chronic coronary artery disease, and 25\% for patients without CVD symptoms.\textsuperscript{14} Even among those who persist with treatment, then, adherence is very low. Therefore, a great deal of room exists for improving CVD prevention and for pharmacists to be involved.

Three recent community pharmacy studies suggest that pharmaceutical care may improve CVD prevention considerably by optimizing persistence with and adherence to pharmacotherapy. In the Project ImPACT (Improved Persistance and Compliance with Therapy) study, 397 patients were exposed to pharmaceutical care\textsuperscript{16} After an average of 2 years of follow-up, 94\% of participants were still taking a lipid-lowering drug, and average adherence to treatment was 90\%. Overall, 63\% of patients reached the National Cholesterol Education Program lipid goals. Unfortunately, with no control group, the study's results are difficult to interpret. The Study of Cardiovascular Risk Intervention by Pharmacists, a randomized controlled trial of the effect of a community pharmacist intervention on cholesterol risk management, demonstrated that, compared with the control group, a higher proportion of patients in the intervention group had a complete fasting cholesterol measurement or obtained a prescription for an increased dosage of a cholesterol-lowering drug or a new cholesterol-lowering drug.\textsuperscript{20} In another randomized, controlled study, more patients in the intervention group had a fasting lipid profile.\textsuperscript{39} Furthermore, larger reductions in total cholesterol and LDL were observed among patients in the intervention group than in the control group. Several studies have shown that pharmaceutical care in community pharmacies may improve the management of hypertension.\textsuperscript{22-26} However, such interventions are complex and time consuming in real life.

Conclusion

The use of a decision aid may be a valuable tool in assisting pharmaceutical care for patients at high risk of CVD. It may improve the effectiveness of the pharmaceutical care interventions and help patients achieve their
treatment goals for blood pressure and serum lipid concentrations. Two studies are under way to evaluate the feasibility of using the decision aid to assist pharmaceutical care in community pharmacies and family medicine clinics for patients beginning dyslipidemia or antihypertensive pharmacotherapy.

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