

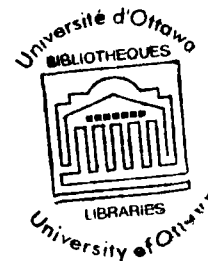
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**Evaluation of a Decision Aid for Transfusion Alternatives for  
Patients before Open Heart Surgery:  
Assessment of the Perceptions of Small Risks**

By

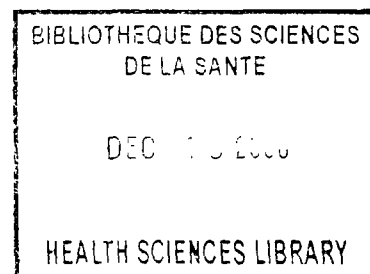
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**Thesis submitted to  
The School of Graduate Studies and Research  
in partial fulfillment of the requirements for the  
MSc degree in Epidemiology**

**University of Ottawa**



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Title: Evaluation of a Decision Aid for Transfusion Alternatives for Patients before Open Heart Surgery: Assessment of Perceptions of Small Risks

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July, 1999

Background: A decision aid (audiotape and booklet) describing autologous and allogeneic transfusion risks and benefits was developed and tested.

Objectives: Evaluation of the effect on knowledge, values, decisional conflict, and risk perception. Evaluation of acceptability and importance of others' opinions.

Design: Before and after trial.

Setting: Ottawa Heart Institute

Participants: 70 patients before heart surgery.

Results: Improved knowledge. No change in overall decisional conflict. Most preferred autologous predonation. Improved risk perception. Very acceptable to patients. Improved risk perception. Autologous predonation is an individual choice.

Conclusions: The decision aid was effective in improving knowledge and risk perception, and was acceptable to patients.

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I wish to dedicate the thesis to my family. My wife Martha, and daughters Kathy, Maureen and Meg, have been constant sources of encouragement and support.

## **Abstract**

### **Background**

Patients facing open-heart surgery have the choice of donating their own blood prior to surgery for their later use (pre-operative autologous donation), or accepting volunteer-donated (allogeneic) blood. A decision aid, consisting of an audiotape and a booklet, was developed to assist patients to make this decision. It defined “blood transfusion”, and clarified its role in heart surgery. Non-transfusion alternatives were listed. It described the two transfusion options, their risks and benefits and gave probabilities of complications. A summary chart allowed the patients to compare the pros and cons of each method.

### **Objectives**

1. To evaluate the decision aid’s effect on specific outcomes.
2. To evaluate the decision aid’s acceptability to heart surgery patients.
3. To assess the importance of others’ opinions in making the decision to pre-donate blood before heart surgery.

### **Design**

Before-after trial.

### **Setting**

Outpatient surgery clinics, Ottawa Heart Institute, University of Ottawa.

### **Participants**

A consecutive series of 70 patients who were to have open-heart surgery in the future. Patients were English-speaking and were potential candidates for autologous blood donation.

## Measurements

Knowledge, values (importance ratings), preference for transfusion method, decisional conflict and risk perception were measured before and after the decision aid was used. Decision aid acceptability and importance of opinions of others were measured after the decision aid.

## Results

There was a significant improvement in knowledge after the decision aid was used. Prior to the decision aid, the score was 67%, and after it was 85% ( $p < .001$ ). The mean overall decisional conflict score was unchanged at 1.7. (A score less than two indicates a tendency to make decisions.) There was a small but significant increase in the mean "uncertainty" subscale score from 1.5 to 1.8 ( $p = .02$ ). The importance ratings for AIDS, hepatitis and unknown infections due to allogeneic blood transfusion were predominantly "very important" and showed little change. The proportion of patients who rated the "number of transfusions" as "very important" increased from 42% to 54%. The proportion rating the "inconvenience of blood donation" as "unimportant" decreased from 57% to 47%. The changes in importance ratings were not statistically significant. Patients strongly preferred autologous donation before (70%) and after (76%) the decision aid. The proportion of patients with no clear preference for a transfusion method decreased after the decision aid from 24% to 10%. The change in the pattern of preferences was statistically significant, ( $p < .05$ ). Nine of fourteen previously uncertain patients favoured autologous donation after the decision aid.

Patients' estimates of the chance of having a transfusion improved significantly. Their estimates of the chance of AIDS, hepatitis, and acute reactions all improved significantly, but only the estimate of AIDS with autologous blood choice exceeded 50% correct responses. The vast majority of patients felt their chances of transfusion and of acquiring AIDS or hepatitis from a transfusion were the same as others.

The decision aid was felt to be the right length by 91%, clear by 88%, fair by 74% and helpful by 80% of patients. 95% would recommend it to others. When asked for their preferences for the way of presenting small risks, most patients preferred words (29%) or numbers (22%). Fewer preferred verbal risk comparisons (13%), a risk comparison chart (16%) or a combination of methods (15%). A small number (5%) had no preference.

The majority (93%) agreed or strongly agreed that the decision to donate one's blood is an individual choice. Information about others' choices, and the surgeon's recommendation was considered helpful, but not essential by 59%.

### Conclusions

The decision aid improved knowledge and reduced the number of patients who were uncertain of which option to choose. Values showed little change. The decisional conflict overall mean score was unchanged, but the mean uncertainty subscale score increased. Patients' perceptions of small risks improved. Most patients felt the decision aid was the right length, clear, fair and helpful. They would recommend it to others. Patients agreed that the decision to pre-donate their blood is an individual one.

### Implications for Future Research

The decision aid will be tested in a randomized controlled trial with a “usual care” control group. Some potential questions to be answered include: Does the decision aid affect values, decisional conflict and choices in patients who have no definite preference for a transfusion method? Is there an effect on satisfaction with the decision process, and with the decision actually made? Is the decision aid helpful in shared decision-making? Do patients who make the decision to pre-donate their blood act on their decision?

## **Chapter One**

### **Introduction**

#### **The History of Autologous Blood Transfusion in Canada**

Patients facing elective open-heart surgery including coronary artery bypass or valve replacement have a choice of transfusion methods. They may accept blood donated by healthy volunteers (allogeneic or "volunteer donated" blood), or they may donate blood prior to surgery for their own later use (pre-operative autologous donation (PAD) or "self-donated blood"). Transfusions of red blood cells may be required during or after surgery if there is significant bleeding (1). The patients must weigh the risks and benefits of each transfusion method, and make a decision at least several weeks prior to surgery. Autologous donation reduces the risk of transfusion-transmitted viral infections, but it involves some discomfort and inconvenience for the patient. The process of autologous donation begins with an assessment of the patients' fitness to donate their blood. Some patients, including those with severe cardiac disease requiring urgent surgery, and those with anemia or other medical problems, cannot participate. Patients each donate a unit of blood (300 ml.) weekly, two or three times in the few weeks prior to surgery. The blood can be stored up to 35 days. Blood that is not used by the patients is discarded.

The subject of blood transfusion has been very controversial in Canada due to the "tainted blood scandal". It is important to know the background of blood transfusion in Canada to understand the context or "framing" of patients' decisions whether or not to donate their blood prior to surgery (2,3). Blood

transfusion has been portrayed in a very negative light in Canada since the initial discovery of transfusion-transmitted AIDS in the early 1980's through to the current ongoing controversy over compensation of transfusion-transmitted hepatitis C victims. This history will be summarized and inter- and intra-institutional variation in transfusion practice will be reviewed.

The last decade has been marked by controversy and conflict over transfusion-transmitted infections in Canada. Acquired Immune Deficiency Syndrome (AIDS) first appeared in the United States in male homosexuals in the summer of 1981, and soon after was found in injection drug users. The first Canadian cases were diagnosed in 1982. In September 1983, the Canadian Red Cross Society (CRCS) learned of a Canadian infant with transfusion-transmitted AIDS. In September 1984, the first Canadian adult with transfusion-related AIDS was reported to the Laboratory Centre for Disease Control. A screening test for volunteer-donated blood was developed in the United States and it was implemented in the U.S.A. in early March 1985, along with donor screening for AIDS risk factors. Tragically for many Canadian blood recipients, blood testing was delayed until November 1985, and an estimated 133 preventable cases of transfusion-related AIDS occurred (4). 'Confidential unit exclusion', which gives donors an opportunity to designate confidentially that their blood should not be used for transfusions, was not generally used in Canada until the autumn of 1988.

The existence of "non-A, non-B" hepatitis had been known for many years, but there was no specific blood test for it until 1990. A 1988 Toronto study by

Feinman showed that the incidence of post-transfusion hepatitis was 9% in 1983-1985 (5). Over a third of patients went on to develop chronic hepatitis. There were two surrogate tests for hepatitis C in donor blood: the alanine aminotransferase (ALT) blood test and the test for an antibody to hepatitis B core antigen (anti-HBc). Surrogate testing was inefficient since it resulted in false positive tests, resulting in the rejection of some units that did not have hepatitis C virus, thereby adding extra costs to the system. Two U.S. retrospective studies, the Transfusion-Transmitted Viruses Study (TTV) (6) and the National Institutes of Health Study (7) showed that surrogate testing could reduce the incidence of post-transfusion non-A non-B hepatitis by 30 to 50%. Surrogate testing was introduced in the U.S.A. in 1986. Despite having the results of the Toronto study which showed that the incidence of post-transfusion hepatitis was similar to that in the U.S.A., the CRCS did not implement surrogate testing. Instead, it waited until a first-generation anti-hepatitis C antibody test was available, and began testing in May 1990. A prospective cohort study in cardiac surgery patients demonstrated a 60% relative risk reduction in hepatitis C seroconversion after implementation of surrogate marker tests (8). A 1995 study by Blajchman, Bull and Feinman later showed that the introduction of surrogate testing could have reduced the overall incidence of post-transfusion hepatitis by 40%, and the hepatitis C rate by 70% (9). The results of this failure by the CRCS to institute surrogate testing are tragic, and are well known to all Canadians because of the extensive coverage in the media. Dr. Paul Gully, who was then the Chief of Blood-borne Pathogens Division at the Laboratory Centre for Disease Control,

estimated that 28,600 patients contracted hepatitis C through blood transfusion from mid-1986 to mid-1990 (quoted in 4). The Expert Panel on Hepatitis C Epidemiology concluded in June 1998 that a “plausible range” of the number of individuals infected by post-transfusion hepatitis C in Canada between 1960 and 1992 was 90,000 to 160,000 (10).

In October 1993 the “Commission of Inquiry on the Blood System in Canada” under The Honourable Mr. Justice Horace Krever (popularly called the “Krever Commission”) was established. It delivered an Interim Report in 1995, and a Final Report in 1997 (4). Among its many recommendations was the establishment of a new national blood service. In September 1998, just prior to initial patient recruitment in this study, the operation of Canada’s blood system was taken over by the new Canadian Blood Service.

The use of autologous transfusion was first studied in Canada by a committee of medical directors in 1985 and pilot programs were begun in 1987. After the success of the pilot programs, the CRCS applied for authorization from its funding body, the Canadian Blood Committee (CBC), for the creation of a national autologous blood program. The CBC initially refused to authorize expansion of the program, and directed the CRCS to phase out the pilot projects. After receipt of advice from its advisory subcommittee, the CBC allowed the implementation of an autologous program, but gave no additional funding, and the CRC was forbidden from promoting the program. Despite this difficult beginning, autologous transfusion services are now available to most Canadians where major surgery is performed. The numbers of donors and units collected

rose to 11,349 and 21,124 respectively by 1997-1998 (11). There is a large regional variation in the percent of donations comprising autologous units. The lowest level for a city with cardiac surgery facilities is .6% in Edmonton and the highest is nearly 9% in Ottawa, a fifteen-fold difference. A survey of hospitals in eight countries has shown great differences in the availability of autologous transfusion for cardiac surgery, from over 90% of Canadian hospitals to less than 10% in the Netherlands (12).

## Patterns of Transfusion Practice

The need for transfusion varies with patient factors, such as the complexity of surgery, with institutional transfusion practice patterns and with the knowledge and attitudes of physicians (13). Goodnough and colleagues studied cardiac surgery transfusion practice patterns in 18 U.S. institutions and reported their results in 1991 (14) (15) (related editorial). Each institution selected 30 elective, first-time cardiac surgery patients. The number of patients transfused and the amount of blood and blood components used were recorded. Overall, 68% of patients were transfused, but the frequency varied widely from 17% to 100% between institutions. Only 8% of patients participated in an autologous blood program. A five-hospital U.S. study reported by Surgenor and colleagues in 1998 showed marked differences between hospitals in transfusion practices for cardiac surgery (16). The frequency of transfusion varied from 33% to 90% and the number of units of blood transfused per 100 patients ranged from 109 to 457 between hospitals. In hospitals with high transfusion frequencies, the numbers of units of blood, platelets and fresh-frozen plasma transfused per patient were also higher. The variability in transfusion frequency was confirmed in a 24 institution study reported in 1998, which showed a 27% to 92% between-institution range in the number of patients receiving red cell transfusions (17).

Not only does the likelihood of transfusion vary with the institution, but also with the transfusion method. A meta-analysis has shown that preoperative autologous transfusion increases the chance of being transfused with any blood

(18). This was confirmed in a retrospective study of patients in the Ottawa Heart Institute (19). There appear to be two reasons for this: blood donation results in a lower average hemoglobin level and some surgeons may be more liberal in their transfusion criteria in prescribing autologous blood (19,20). Guidelines for appropriate use of transfusions have been published (21-28). The Canadian Expert Working Group recommended that autologous blood be given for the same indications as allogeneic blood (21). Goodnough reviewed the development of guidelines for transfusion in the context of bypass surgery (29).

### Current Risks of Transfusion

Volunteer-donated blood is tested for Human Immunodeficiency Virus Type 1 (HIV-1) using a very sensitive p24 test that greatly reduces the risk of transfusion-transmitted AIDS from 1/493,000 to about 1/1,000,000 donations. (The 95% CI for 1/493,000 is 1/202,000 to 1/2,778,000). Blood is also tested for HIV-2, hepatitis B (risk 1/63,000 donations, 95% CI 1/31,000 to 1/147,000) hepatitis C (risk 1/103,000 donations, 95%CI 1/28,000 to 1/288,000), syphilis, and human T-cell lymphotropic virus (HTLV-1) (1/641,000 donations, 95% CI 1/256,000 to 1/2,000,000). The risks are low, but the 95% confidence intervals are wide. Hepatitis B and C viruses make up 88% of the aggregate risk of 1/34,000. (8,30-32).

Autologous blood does not carry a risk of virus transmission, but it does not remove the risk of clerical and administrative errors resulting in the transfusion of mismatched blood. This occurs in about 1 in 19,000 transfusions and is fatal in 1 in 800,000 transfusions (33). The rate of ABO incompatible

transfusions was estimated to be 1/33,000. A survey of British hospitals had a similar estimate (34). There may be substantial under-reporting of transfusion errors, since 64% of errors by chance result in the transfusion of ABO compatible blood. Surveys which depend upon morbidity as an indicator may under-report errors (35). Goldman reported that administrative errors for autologous blood donation occurred in one in 149 units of blood in a Canadian centre (36) (37) .

The most frequent errors were the late receipt of blood for surgery and receipt by the wrong hospital. A retrospective study of autologous blood at a large U.S. institution found that adverse reactions occurred with one in 625 units donated preoperatively and that 60% of the reactions were clinically important (38). The reactions included febrile nonhemolytic and allergic reactions. One acute hemolytic reaction occurred due to clerical error. Linden and Kruskall concluded that autologous blood programs require the same attention to process control and quality assurance as allogeneic blood programs do (37). The exact frequency human errors in the administration of autologous blood is unknown, but there is no evidence that it is lower than that of allogeneic blood errors.

Bacterial infection occurs in about 1 in 1,000,000 transfusions of either allogeneic or autologous blood (39-41). Immune suppression due to allogeneic blood transfusion is a potential complication that was not included in the decision aid due to its controversial nature. There is some evidence that allogeneic blood transfusions may increase the likelihood of postoperative bacterial infections (reviewed in 42).

Lee and colleagues studied the perceptions of autologous blood donors. Donors were willing to pay large amounts of money (over US \$1000) to donate their own blood (43,44). The amount correlated with the perceived chance of being transfused and the risk of complications. The provision of risk probabilities tended to reduce the willingness to pay. The subjects in these studies had already decided to donate their blood and are not representative of the population of pre-surgical patients. The participation rate was low (44%) in one study, and was unknown in the other.

### Alternatives to Transfusion

Erythropoietin, a hormone produced by the kidneys, stimulates the bone marrow and raises the hemoglobin level. Synthetic recombinant erythropoietin has been used pre-operatively to stimulate the marrow to raise the hemoglobin level, resulting in a reduced need for transfusions during or after surgery (45). Its disadvantages include high cost, lack of clinical studies, and adverse effects such as hypertension. Because it is not covered by the Ontario Ministry of Health, there is a substantial cost to patients. Several measures can be taken by the surgeon and anaesthetist to reduce the need for allogeneic transfusion. These include the use of drugs inhibiting the breakdown of fibrin (aprotinin and aminocaproic acid) and mechanical techniques such as acute normovolemic hemodilution (ANH) and intra-operative cell salvage. Goodnough, Rottman and colleagues have written narrative reviews of ANH and have concluded that it may be used as an alternative to autologous transfusion (46,47). However, in a meta-

analysis of methodologically sound trials in which perioperative transfusion was guided by a protocol, Bryson found no evidence of efficacy of ANH (48).

## **Chapter Two**

### **Critical Review of Pertinent Theory and Studies**

#### **Results of Decision Aid Trials**

Since there have been several comprehensive reviews of decision aid trials (49-51) and an annotated bibliography (52), the results will be summarized briefly here. O'Connor and her colleagues have reviewed the evidence of efficacy and the policy implications of decision aids (50) and a Cochrane review is in preparation. The Cochrane definition of decision aids is as follows: "interventions designed to help people make specific and deliberate choices among options by providing (at minimum) information on the options and outcomes relevant to the person's health status. Additional strategies may include providing: information on the disease/condition, the probabilities of outcomes tailored to a person's health risk factors, an explicit values clarification exercise, information on others' opinions and guidance or coaching in the steps of decision making and communicating with others." O'Connor and colleagues summarized the results of 31 decision aid trials, of which 21 were related to medical conditions. The media used included videodiscs, audio-booklets, decision boards, written materials, posters, computer programs and videotapes. Five concerned heart diseases, but none addressed transfusion therapy. Five were before/after studies that showed that the decision aids had the most effect on those who were undecided at baseline. There was much less effect on those who had a treatment preference at baseline. The randomized trials showed that decision aids resulted in conservative decision making. The before/after trials demonstrated that patients'

choices are more likely to be based on better knowledge, more realistic expectations, and personal values. The randomized trials confirmed these findings and showed a reduction in decisional conflict, restricted to the "feeling more informed" subcategory. The decision aids were also better than usual care at reducing exaggerated perceptions of disease risks and treatment benefits. They were ineffective in improving patients' "satisfaction with the decision" in comparisons with usual care. Decision aids were acceptable to patients and were feasible to use.

Quantitative presentation of probabilities and positive framing of outcomes encouraged expectations that were more realistic (3). Methods of presentation appeared similar in improving knowledge. The medium of the decision aid did not appear to be important. Simple brochures seemed to have effects similar to costly media.

Hersey and his colleagues have prepared a comprehensive report on informatics tools and decision aids used to support patient decision making about medical screening and treatment (49). The conclusions were similar to those of O'Connor and colleagues. Both O'Connor and Hersey highlighted the deficiencies of decision aid research, and established recommendations for future research. First, the impact of decision aids on a broad range of decisions should be studied, and a full range of outcomes should be evaluated. The outcomes include knowledge, attitudes, satisfaction, communication between patient and provider, patients' perceptions of practitioner's opinions, treatment selection, health behavior, health status, and costs. Satisfaction with both the

'decision process', and the 'decision actually made' should be measured.

Second, the design of studies should be sound. Randomized controlled studies comparing patients using the decision aid and those receiving usual care are preferred to minimize bias. The subjects should be patients who are at the point of decision making. Baseline measurements of outcome variables, including treatment preference, should be made. The decision aid intervention should be clearly described, since the format and content may both have an effect on outcomes. The "usual care" employed should also be clearly described. Sample sizes should be large enough to have adequate power to detect minimal clinically important differences. Factors that encourage use of the decision aid should be identified, since some decision aids have been used by a very low percentage of eligible patients. Decision aid research is still in its infancy, and adherence to these recommendations will enhance the quality of future studies.

## Decision Theory and Risk Perception Assessment

Decision aids are developed based on decisional theories that are derived from a variety of disciplines including economics, mathematics, psychology, and sociology. The common components of the theories include the alternatives (options), the possible outcomes, and the probabilities of each outcome. The Ottawa Decision Support Framework has provided the basis for the decision aid in this study (53,54). There are three stages in the framework, including: 1) assessment of patient and practitioner determinants of decisions, 2) provision of decision support and 3) evaluation of outcomes, including the quality of the decision and decision-making process, and patient outcomes. The determinants of decisions include the demographic, social and clinical characteristics of the patient. They include the perceptions of the decision, perceptions of others involved in making the decision and the resources to make and implement the decision. The perceptions of the decision, which are addressed by decision aids, include knowledge about the options and outcomes, expectations (probabilities), values, and decisional conflict. The second stage, provision of decision support, includes provision of information, clarification of values and expectations and guidance in personal deliberation about the options. The third phase is the evaluation of outcomes, including the quality of the decision, the decision-making process, and patient outcomes. According to the Ottawa Decision Framework, a “high quality decision” is one that meets the following four criteria: 1. It is based on adequate knowledge. 2. It is consistent with the patient’s values. 3. It is acted-

upon. 4. The patient and important others are satisfied with both the decision-making process and the decision made (54). Janis and Mann argued that it is very difficult to evaluate the success of a decision that has more than one objective (55). There is no way to quantitate accurately the values of the good and bad consequences of a decision. Such attempts would lead to subjective ratings, and therefore would be of doubtful validity. They proposed, instead of using outcomes as criteria, to use the quality of the decision-making *procedures*. The quality of the procedures is readily measurable, and one can determine whether the decision leads to satisfaction or regret. They proposed seven criteria, and the four criteria above were derived from them. (The other three steps were re-evaluations.) The criteria were based on an extensive literature review, and were stated to be "plausible", but unproven. A decision-maker who follows the steps was said to use "vigilant information processing". The authors emphasized that one evaluates the quality of the decision-making *process*, not the quality of the outcome. Good decisions may lead to bad outcomes because of unforeseen complications. O'Connor defined "decisional conflict" as the "uncertainty about which course of action to take when the choice involves risk, loss, regret, or challenge to personal life values". When there is no alternative that satisfies all the objectives and all alternatives have risks of undesirable outcomes the situation is known as a "conflicted decision" or "choice dilemma" (56).

### What are "risk" and "perceived risk"?

Psychologists have examined "perceived risk" as a variable to explain peoples' preferences. The definition of "risk" is a difficult concept since the word means different things to different people (57). Professionals use "risk" to mean "probability", a "consequence or impact", or a "hazard". Keeney defined risk as "the chance of death from a cause" (58). The lay person may think of "risk" as conveying a sense of "danger" or even as an "opportunity" when applied to investments. "Probability" may be used in the classical sense as a proportion of times an event will occur given many trials, as a frequency such as "one in a million" or as a subjective impression that a future event will occur (59). There seems to be agreement among researchers that risk has two components: uncertainty and undesirability of outcomes (60). They differ in their emphasis on each aspect. "Perceived risk" may be thought of as a person's subjective impression of a risk (61).

The Ottawa Decision Support Framework includes the assessment of "expectations", which are the perceived likelihoods of benefits and risks, as part of the assessment of patient and practitioners' perception of the decision. Perceived susceptibility and perceived seriousness of a disease are important determinants of preventive health behavior in the traditional Health Belief Model and in the reformulated model to predict compliance (62). In the Health Belief Model personal risk perception or "perceived threat" is derived from an evaluation of perceived seriousness of an illness and perceived personal susceptibility. The likelihood of a person taking a preventive health action depends on the perceived

threat, motivation, and perceived barriers. Perceived risk has been incorporated into a model used to explain the development of symptoms after chemical exposure (63).

Why is risk perception important? Vertinsky and Wehrung outlined the importance of risk perception from the government perspective (64): Public fears have a strong influence on public policy. Public concern about the safety of the blood supply has played an important role in the formation and maintenance of the autologous blood program. Public perceptions may have economic effects, by influencing what people buy. The impact of public risk communication programs will depend on an understanding of how people think about risks. Risk perceptions affect information seeking and interpretation of information. Last, understanding risk perception is important in designing risk communications that promote trust and confidence in the regulatory and risk management processes.

### Utility Theory

The foundation of decision theory is the set of axioms of utility theory, originally set out by von Neumann and Morgenstern more than a half-century ago (65). There are three main axioms: transitivity, independence and continuity of preferences. These axioms define how a rational person should act when faced with uncertainty, and are therefore constitute a normative model. The preferences may be expressed as values (preferences under certainty) or utilities (preferences under uncertainty)<sup>1</sup>. It is important that the axioms are not predictive

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<sup>1</sup> "Values" in a technical sense refers to preferences elicited under questions framed under certain outcomes, either by scaling or choice response methods (110). "Values" may also refer to

of how an individual will act under uncertainty, but instead act as norms or standards of rational decision making. According to 'expected utility models' of decision making, one assesses the options of a decision, and all the possible consequences of each option. Each consequence is assigned a measure of worth such as a utility. The probability<sup>2</sup> of each consequence is assessed (subjectively or objectively) and the 'expected worth or value' of each consequence is calculated as the product of probability and worth (66). The expected value of an option is the sum of the expected values of its consequences. The best option is the one with the greatest expected value. Behavior decision theory is concerned with the study of this model. The most general model is the 'subjective expected utility model', in which probabilities are subjective<sup>3</sup> and worth is expressed in 'utilities'. Although this normative or prescriptive model is appealing in its simplicity, there is a growing awareness that it is a poor descriptor of how people actually make decisions.

### Prospect Theory

Psychologists have studied the process of decision making and have found that preferences violate the axioms of expected utility theory in certain classes of choice problems. Kahneman and Tversky have developed an alternative to expected utility theory called "Prospect Theory" (67,68). The conclusions are based on the results of experiments involving choices between

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the importance a patient attaches to an outcome in a decision-making context. "Utilities" refers to cardinal utilities under uncertainty.

<sup>2</sup> The probability of an event is defined as the "relative frequency of the event over an indefinitely large (or infinite) number of trials".

<sup>3</sup> Expectations are "subjective judgements about the probability or likelihood that specific outcomes or consequences will result from a course of action" (56).

various risky prospects comprising monetary gambles. The subjects were university students and faculty. They showed that people overweight outcomes that are certain compared to those that are probable, a finding they have labeled the "certainty effect". People are risk-averse when faced with a choice of gains, but are risk seeking when faced with a choice of losses, called the "reflection effect". When given a choice between two prospects which share components, people tend to disregard the shared components and concentrate on the different factors, a finding they call the "isolation effect".

The authors postulate that there are two phases in the decision process: an early "editing phase" and a subsequent "phase of evaluation". The editing phase consists of operations that organize and simplify the choices: During this phase, people code outcomes as gains or losses relative to a reference point. They combine probabilities that have the same outcomes, and segregate risky from riskless components. Components that are shared tend to be cancelled out. Outcomes with low probability are discarded. Dominated alternatives are thrown out without further consideration. Following editing, the person evaluates the edited prospects, and chooses the one with the highest value. The overall value of a prospect is determined by a weighted probability scale, and a subjectively weighted outcome scale.

Subjective probabilities are formed using simplifying rules of thumb called "heuristics" (2,68). The "representativeness heuristic" implies that the probability of an outcome is assessed by the degree to which the outcome resembles a known outcome. This leads to logical errors such as ignoring the baseline

probability and the sample size. The "availability heuristic" refers to the assessment of probabilities by the ease with which an outcome is recalled. "Anchoring and adjusting" implies that the decision-maker starts with an estimate of the probability and moves it up or down. The initial estimate may be in error, or the adjustment may be wrong.

The studies of "Prospect Theory" have important methodological flaws. The subjects were all university students and faculty, so the findings cannot necessarily be generalized. The experiments were done using monetary gambles in a laboratory environment, and did not measure "real life" risks. It is doubtful that the results of monetary gamble experiments can be applied in other risky situations. They formed conclusions from mean values and statistical significance, ignoring the fact that many of the subjects did not exhibit the stated biases.

### The Psychometric Approach

The original work on risk perception was published by Starr three decades ago (69). He defined risk as "fatalities per hour of exposure" and benefits as "the average annual benefit per person involved in dollars". Using archival data on risks of death from various activities, and economic benefits, he established relationships between risks and benefits. He found that people are willing to accept "voluntary risks" that are 1000 times greater than "involuntary risks". Activities with higher risks tended to have greater benefits. His method showed "revealed" rather than directly measured preferences. Starr's contribution was original but his economic and risk data were incomplete and he used many

assumptions. His findings were later contradicted by the findings of psychometric studies.

Psychologists have concentrated on the processes of risk perception. The psychometric approach, as championed by Fischhoff, Slovic and colleagues, uses psychological scaling and multivariate analysis techniques to study risk perceptions (70-72). In contrast to Starr's finding, they found that perceived benefit was inversely related to perceived risk. They reasoned that risk perceptions are described by qualitative characteristics including voluntariness, immediacy of effect, catastrophic potential, equity, novelty, controllability, familiarity and dread. They have used factor analysis to produce the familiar "cognitive maps" of environmental and health hazards (71,72). There was a high correlation between the characteristics. The qualitative factors are grouped into a "dread risk" and "unknown risk" on a planar diagram. They have shown that peoples' risk perceptions and attitudes towards hazards are related to the position of the hazard in the "factor space". Hazards such as nuclear reactor accidents rate highly in "dread" and "unknown" factors, while familiar hazards such as downhill skiing are of much less concern, in spite of their much greater personal risk. Slovic has pointed out the differences between the experts' unidimensional probabilistic concept of risk, and the lay persons' richer multidimensional concept. Later, the dimension of "trust" was added to the psychometric approach (73). Sjoberg added "attitude" in a study of the risk perception of nuclear power, and found an increase in the variance explained (74). In an early study done in the Netherlands, two factors were found after

factor analysis: “technological risk” and severity of consequences” (75). This study also found a poor correlation between risk and benefit.

There are several criticisms, which have been put forward regarding the psychometric studies of risk perception, as summarized by Cutter (76) and Sjoberg (74). The studies used highly selected groups such as university students as subjects, compromising external validity. The studies need to be reproduced using subjects of both genders, stratified by age, socioeconomic status, race, culture, education and other relevant variables. Second, the studies aggregated results and used them to represent the group as a whole. It would be preferable to show that there is a range of opinion within each group. Sjoberg has shown that it is easier to obtain high correlations by comparing group means than it is by comparing the raw data of individuals (74). If the correlations are done at the individual level, the psychometric approach explains much less of the variance in risk perception. Third, the studies considered a broad comparison of hazards, and it would be more productive to focus on specific hazards rather than ranking them. Fourth, risk was narrowly defined as the probability of death, while other risks such as injury and illness were not considered. Fifth, the willingness to act on the perceptions was not assessed. Finally, there is no underlying theory to support the psychometric approach. The risk dimensions were selected from suggestions in the literature, not from a theoretical framework. The cognitive psychology studies are cross-sectional, and do not take into account the variation of risk perception with time. Rogers studied people in two Texas cities, one of which (Odessa) had a chemical fire, and the other

(LaPorte) had a long-term controversy over an incinerator (77). He concluded that social processes are at least as important as physical and psychological dimensions of risk. Renn, in a review of risk perception and risk communication, also concluded that risk perceptions are processed by the media, social groups, institutions and individuals, and these processes are important in generating the societal impact (78).

The problem of sample selection bias is common to most of the studies of risk perception. In the initial study by Decision Research in Eugene, Oregon, Fischhoff, Slovic and Lichtenstein studied 76 members of the League of Women Voters and their spouses (70). Slovic studied perceived risk in four groups, comprising 30 college students, 40 members of the League of Women Voters, 25 business and professional members of the "Active Club", and 15 experts (72). The results of this study cannot necessarily be extended to all members of each category given the selection process and small sample sizes, and they certainly cannot be extended to the general population.

### Conjoint Expected Risk

Weber and Bottom have proposed an axiomatic theory called "Conjoint Expected Risk (CER)" (60,79). This theory differs from others in considering the net effects of both risks and benefits in risk perception. The perceived risk is a linear function of probabilities of breaking even, positive outcomes and negative outcomes, and the expected values of positive and negative outcomes. The model has been tested using financial gambles. Holgrave and Weber compared

the psychometric and simplified CER models for financial and health risks in a non-randomly selected group of postgraduate students (80). They found that the CER model explained more variance than the psychometric model. They proposed forming a hybrid model to incorporate the psychometric "dread" factor with the simplified CER model. So far, there is little experimental evidence to support this model, but it is a promising combination of algebraic and psychometric models. Further validation of this theory in a clinical setting is required.

### Cultural Theory

Cultural theorists proposed that individuals choose what to fear, and how much to fear it, to support their way of life (81). These risk selections correspond to 'cultural biases' (worldviews or ideologies). The cultural biases support different patterns of 'social relations', which are patterns of interpersonal relationships. They proposed three types of social relations: hierarchical, egalitarian and individualist. Hierarchists value social order and approve of regulated technology. Egalitarians perceive technology to have high risks and low benefits. Individualists support self-regulation and allowing market forces to prevail. They favour technology and feel that institutions can regulate themselves and compensate for any damage they cause. Wildavsky and Dake used risk ratings of 25 technologies as dependent variables, and looked at self-rated knowledge, personality, political orientation, and cultural biases as explanatory variables. They found little relationship between self-rated knowledge and risk

perception. They identified a “technologically pro-risk” personality, corresponding to the hierarchist, and a risk-averse personality corresponding to an egalitarian. Overall, egalitarians were technologically risk-averse, and both individualists and hierarchists were technologically risk-taking. They concluded that worldviews best account for risk perceptions. Sjoberg, however, calculated that cultural theory explains only 5% of the variance of risk perception (74).

### Health Risk Perception in Canada

Krewski and colleagues carried out a large survey of health risk perceptions in Canada in 1992 (82,83). The 1500 subjects were asked to rate the risk of 33 hazards in four categories including “almost no health risk, slight health risk, moderate health risk, and high health risk”. The hazards were rated with respect to the “Canadian public as a whole” and ten hazards were rated with respect to “the health risk to you and your family”. There was a hierarchy of risks with cigarette smoking rated as the highest risk by the largest percentage of subjects. Transfusions were not included in the list of hazards. The importance of media coverage was evident in the high perceived risk of breast implants, since there had been a large amount of publicity on the subject just before the survey. Women rated hazards as “high risk” more often than men did. Those who were over 55 years of age, Quebec residents or less educated also rated hazards as being “high risk” more often. People were well aware of personal health and environmental hazards. There was a high degree of concern about chemical pollution. Subjects were unwilling to accept a higher health risk even if a hazard conferred economic benefit. Many felt that a risk-free environment was possible

in Canada. Physicians and government agencies had the greatest confidence as information sources, and they were deemed also to have the greatest responsibility in protecting the public. Two generalized attitudes or "worldviews", fatalism and egalitarianism, were correlated with high perceptions of risk. A group of ten hazards was compared with respect to The risk to the individual and the risk to the public. A consistently higher percentage of respondents rated the risk to the public higher than the risk to the individual for each hazard.

This study showed there are many factors that influence risk perceptions, including gender, age, geographic area, education, and certain attitudes toward life in general. This study's large sample size and stratified random sampling procedure increased external validity. One potential bias was that interpretations of the terms employed in the questions, such as "high health risk" might have varied from person to person. Negative publicity had a very powerful influence on risk perception, as shown by the comparison in which about 60% of both college and high school educated people rated breast implants as "high risk". Only 11 to 12 of the hazards were rated as "high risk" by over 50% of the respondents in any of the comparisons, indicating that there was still substantial between-subjects disagreement on the importance of many hazards. The study looked at the attitudes of subjects, or "worldviews", but did not look at the factors intrinsic to the hazards, such as "dread" or the degree to which the hazard is "unknown". The response rate in the survey was low at 55%, and this reduced confidence in applying the findings to the population in general.

In a related study, Slovic and colleagues compared perceptions of chemical hazards in toxicologists and the lay public. (84). The toxicologists had much lower perceptions of risk for all hazards and more favourable attitudes toward chemicals than did the lay public.

## **Chapter Three**

### **Study Objectives**

The objectives of the study were:

- 1) To evaluate a decision aid for cardiac patients facing open heart surgery, designed to assist patients making the decision about whether to donate their own blood prior to surgery, or not to donate. The evaluation included the following outcomes: knowledge, values, preferences, decisional conflict and the acceptability of the decision aid.
- 2) To assess the perceptions of cardiac patients of the probabilities of transfusion, and of the risks associated with each transfusion method.
- 3) To assess the importance of the opinions of other patients and of physicians in making the choice of transfusion methods.
- 4) To prepare for a randomized controlled trial of the decision aid by developing efficient methods of patient recruitment and follow-up, assessing the clarity and content of the decision aid, and pilot-testing the outcome measures.

### **Reasons for the choice of the subject**

Cardiac patients face a choice of self-donation of blood, which lowers the chance of allogeneic transfusion, or accepting volunteer-donated blood (if needed) for cardiac surgery. Each option has risks and benefits. Self-donation carries the risks of symptoms at the time of donation, and it does not obviate the risks of bacterial contamination or human errors in blood administration. Some

patients who donate their own blood may still need allogeneic blood if their own donated blood is used up. Autologous transfusion is more expensive than allogeneic transfusion, (85) and it is not cost-effective (86,87). The main reason for the higher cost is that about one half of the autologous blood units collected are discarded, while very few allogeneic units are discarded. Autologous blood donation is inconvenient for the patient, and requires extra visits to the hospital or blood centre. The risks of viral diseases due to allogeneic transfusion have declined to extremely low levels with improved donor screening and sensitive blood tests. Despite this, there continues to be public concern about the safety of the blood supply. There is a need for a decision aid to provide cardiac patients with facts about the options, potential consequences of each option, and the probabilities of each consequence.

There have been very few studies of patients' perceptions of very small risks. The choice of a transfusion method involves the tradeoff of the inconvenience and higher cumulative risk of human error of autologous transfusion, versus the small risk of viral disease with allogeneic transfusion. This study was an excellent opportunity to study the perception of small risks in a decision-making context.

### Potential Contributions to the Field

The first contribution was the initial evaluation of the decision aid prior to the randomized controlled trial. The study highlighted areas in the decision aid that were unclear or needed improvement by studying changes in knowledge,

values, decisional conflict and preferences. Patients' impressions were recorded in a post-test questionnaire. The study of decision aids in cardiac surgery has received little attention in the past. The patient population comprised a group with severe heart disease not amenable to medical therapy or angioplasty. They had made the important decision to proceed with open-heart surgery in the very recent past (often within a few minutes of the study interview!), and were faced with the decision about whether to donate blood for surgery. The decision-making context for transfusion alternatives was characterized by severe chronic heart disease with a propensity to acute deterioration, a recent history of a stressful decision, and the future prospect of a relatively high-risk procedure (2% mortality). The decision aid could potentially have a role in improving knowledge and expectations, reducing decisional conflict, and changing patient preferences for transfusion methods.

The second contribution of the study was the evaluation of patients' perceptions of small risks related to treatments. It examined the accuracy of patients' estimates of the chance of receiving a transfusion, and the risks of complications including transfusion-transmitted viral disease (HIV and hepatitis), and acute reactions due to human error, bacterial contamination and allergies. A new approach to assess probability perception was evaluated. This approach compared probabilities to familiar population sizes, giving patients a reference for very small probabilities. It was hoped that this might allow patients with little mathematical knowledge to understand very small risks.

The third contribution of the study was the evaluation of the importance of the opinions of others in the decision to donate one's own blood, and the helpfulness of information about others' decisions.

## **Chapter Four**

### **Methods**

#### **Study Design**

The study was a before-after trial of a decision aid for patients making the decision whether or not to donate their own blood prior to open-heart surgery.

#### **Subjects**

The patients were a series of male and female patients attending the Ottawa Heart Institute outpatient clinics. All patients were to be scheduled for open-heart surgery, either coronary bypass surgery, valve surgery, or both. They were faced with the choice of donating or not donating blood for their own later use.

#### **Inclusion/Exclusion Criteria**

The subjects were over the age of 18 years and were able to speak and read English. Those with cognitive, speech or hearing impairment serious enough to interfere with comprehension of the consent form, decision aid, or questionnaires were excluded. Subjects were excluded if they were not candidates for autologous blood donation because of one of the following reasons: urgent surgery, severe valvular heart disease, severe non-cardiac disease precluding autologous donation, or inability to come to the hospital to donate blood because of long distances or lack of transportation. Patients who had had a transfusion in the past were eligible for the study.

#### **Intervention**

The decision aid consisted of an audiotape and a booklet (88) (booklet and script are appended). The decision aid was developed by an expert panel,

which included specialists in internal medicine, cardiac surgery and cardiac anesthesia. The decision aid was based on the Ottawa Decision Framework. It described three aspects of the decision alternatives: a description of surgical blood loss and transfusion, the pros and cons of allogeneic and autologous transfusion (including the probabilities of transfusion and adverse outcomes), and the steps in the decision process.

The decision aid initially contained three options: allogeneic transfusion, autologous transfusion, and erythropoietin. After consultation with surgical and anaesthetic colleagues, erythropoietin was removed because it was expensive, the Ontario Ministry of Health Drug Benefit Plan did not cover it, and it had not been well evaluated in a cardiac surgery setting. The author's role in the decision aid development was re-writing the decision aid and audiotape script after erythropoietin was excluded, verifying the expected values, and arranging the acceptability testing in five former cardiac surgery patients. Minor modifications were made in the wording of the audiotape script after it was evaluated by the former surgical patients.

### Setting

The Ottawa Heart Institute provides comprehensive care for heart patients from Eastern Ontario and Western Quebec. During the year November 1, 1997 to October 30, 1998, 1488 patients (27% female) had heart surgery at the Institute. The commonest operation was coronary bypass surgery (70%), while valve (11%) and combined valve/bypass operations (13%) were less frequent.

The remainder comprised a variety of other procedures. There were six cardiac surgeons at the time of the study, while usually there are eight.

### Patient Recruitment and Timing of Study Events

Patients were initially interviewed in the Ottawa Heart Institute clinics, except for one, who was interviewed at his home. All patients had been referred for cardiac surgery by their cardiologists, and most were being seen for the first time by the surgeon. Spouses usually accompanied the patients, and were allowed to attend the study interview. Eligible study patients were identified by the surgeon or his assistant, and approached by them to participate. Most patients were seen after the surgeon, but 11 of 59 (19%) were interviewed before the surgeon arrived. Five of the six surgeons were not aware of the study questionnaire contents. Surgeons were asked not to alter what they usually told patients about autologous donation for the purpose of this study. The amount of information on autologous transfusion given to the patients varied greatly between surgeons, and for this reason, efforts were made to include patients from all six surgeons.

The baseline questionnaire was administered in the clinic. The purpose of the decision aid, and the questionnaires were explained and informed consent was obtained. Additional explanation about the questions was given if this was required. We were careful not to influence the patients' answers. The risk perception questions were carefully explained to all subjects. The patients were given the decision aid and post decision aid questionnaire to take home, completed the questionnaire on their own, and mailed it to the investigator. Most

patients completed the second questionnaire promptly within one to two weeks. At the time of the study, the waiting periods for surgery for elective patients varied from three to twelve months depending on the surgeon. It was not possible to determine how many patients who initially favoured self-donation eventually donated blood because of the long waiting times. The autologous program protocol required a consultation with a hematologist, who excluded patients who were medically unfit to donate blood. In addition, patients who developed increased symptoms and required urgent surgery were unable to donate blood. Recruitment began Oct.5, 1998, and finished Jan. 5, 1999.

### Questionnaires

The patients completed questionnaires before and after using the decision aid. Demographic details, heart surgery history, transfusion history, and sources of transfusion information were recorded at the first interview. The baseline questionnaires included a knowledge test, a rating of values, an opinion scale for transfusion preferences, a decisional conflict scale, and risk perception questions. The follow-up questionnaire included the same questions as the baseline questionnaire, and also included questions on the acceptability of the decision aid and the importance of the opinions of others in making a decision to self-donate blood.

### **Measures**

#### Knowledge:

A 15-question test was based on information provided in the decision aid. Potential answers were "true", "false", or "unsure". The questions were brief, and definitions of "self-donated blood" (autologous blood) and "volunteer-donated

blood” (allogeneic or homologous blood) were given. Potentially confusing medical terms such as “autologous” and “allogeneic” were not used. Patients were allowed to clarify the meaning of questions at the baseline interview. Answers were scored as one point for each correct answer, and zero for each incorrect or “unsure” response. Scores were expressed as the percentage of correct responses for the total number of questions. The questions are included in the appendix. The true/false/unsure response format has been used successfully in previous decision aid trials (51) (53,54) (89). Content validity is assured because the test is based on evidence-based information verified by the panel of experts. The populations included in the trials were patients with cancer or atrial fibrillation, and women considering hormone replacement therapy.

### Values

Patients rated the personal importance of three potential complications (AIDS, hepatitis B and C, and unknown infections), the number of transfusions (including self-donated blood) and the inconvenience of making extra trips to donate blood. Ratings were expressed on an 11-point scale from zero (not at all important) to 10 (extremely important). This measure has been found to discriminate between those making different decisions (54).

### Opinion about treatment choices

The patients were asked to express their current transfusion preference by checking a box on an 11-point scale. They were asked: “If your doctor asked you right now to make a choice about transfusion methods, please show where you would be on the scale below by placing a check mark in one of the boxes. Show

how strongly you feel about your choice by where you place your check mark." The scale was labeled with "volunteer-donated blood" at the left end, "self-donated blood" at the right end, and "uncertain" in the middle. Choice predisposition scales have been found to have high test-retest reliability. They correlate with values and expectations, and are sensitive to change (54).

### Decisional Conflict Scale

The O'Connor Decisional Conflict Scale was modified to include the choices of 'self-donated' and 'volunteer-donated' blood. There were five subscales: uncertain (3 questions), uninformed (5 questions), unclear values (3 questions), unsupported (4 questions) and ineffective decision (4 questions). Since the last subscale concerned those who had made a choice, undecided patients were not required to answer these questions. Mean scores for each subscale were calculated. An overall mean decisional conflict score was calculated as the mean of the scores of the first fifteen items. The decisional conflict scale has been shown to have a high test-retest coefficient and alpha coefficient (90). It discriminates between those making and delaying decisions (90,91). It is sensitive to change following decision aids (51,54), and discriminates between different interventions (53,89,92).

### Risk perception questions

1) Number having a transfusion: Patients estimated the number of people out of 100 who need a transfusion, both for those who accept volunteer-donated blood and those who choose to self-donate blood. Probability scales have been used in

previous decision aid trials (53,54). They have high test-retest and alpha coefficients. They are sensitive to change following a decision aid (54).

2) Relative chance of being transfused: Patients rated their chances of being transfused relative to other patients' chances. Previous studies have shown that subjects tend to under-rate personal risks compared to others. Conversely, patients might also have felt that certain factors, such as complexity of surgery, might increase the chance of bleeding.

3) Risks of transfusion: Patients estimated their probabilities of having complications (AIDS, hepatitis and immediate reactions) for both choices, either to accept volunteer-donated blood or to self-donate blood. They also rated their risks compared to other patients' risks. Because it was very difficult to imagine very small risks, patients were carefully instructed about the meaning of the probabilities during the interview. Risks were stated in words, and were compared to familiar populations. For example, "one in ten million" was explained as follows: "Imagine that everyone in the province of Ontario had a transfusion and only one person had a complication. That would be an extremely small risk." This was repeated for each risk level until the patient verbally confirmed that he or she understood the concepts. A list of risk probabilities comparing risks to regional population sizes was incorporated in the questionnaire for later reference in the post-decision aid test. The decision aid gave the expected values of the number of people out of a million expected to have a complication, for both choices. We felt it would be unreasonable to expect patients to estimate the "number of people out of a million getting a complication" before the decision

aid, and therefore asked them to estimate their own chances closest to familiar round numbers, such as "one in a million". They were also given the options of stating an exact chance if they knew it, or replying "I have no idea of the chance." In scoring, the exact estimates were given priority if the patient gave answers in both formats for a question. Exact answers were recorded in the correct "closest to" category to have a uniform scoring system for all patients. For example, the chance of an immediate reaction with the volunteer-donated blood choice is 43 people out of 1,000,000 , or one in about 23,000. The correct answer is the one that is closest to this, which is "one in twenty-five thousand".

#### Acceptability of the Decision Aid

Patients rated the decision aid on its length, clarity, fairness, and helpfulness. They were asked whether they would recommend it to others. Their preferences in the way small risks were presented were assessed. Written comments were recorded. The acceptability questions have been used in previous decision aid trials and have content validity as determined by experts in the field (51,53,54).

#### Others Opinions

Patients were questioned about the opinions of others, including other patients, their own surgeon, and other surgeons. They were asked to indicate agreement or disagreement with six statements. Ratings were measured on a five-point scale, from "strongly agree" to "strongly disagree". The patients estimated the number out of 100 other patients who would choose to self-donate blood after they reviewed the audiotape and booklet. A series of three questions

asked how important information about other patients choices, their personal surgeon's recommendation, and other surgeons' recommendations were in making their own decisions. The patients ranked the helpfulness of others' opinions on a four point scale as "essential", "helpful", "a little helpful", or "not at all helpful" in making their own decisions. The patients were questioned about what their surgeons thought they should do: self-donate, choose volunteer-donated blood, neutral, or "I don't know".

### Sample Size

The method of Cohen (93) was used to estimate sample size of 60 patients. The sample size was calculated using a two-sided repeated measures test (Cohen's case 4), a test-retest correlation coefficient as low as 0.4, an effect size of 0.5, a probability of a type one error of .05 and a probability of a type 2 error of .20. The effect size and the test-retest correlation coefficient were derived from the data on validation of the decisional conflict scale (90) and from the evaluation of a decision aid for hormone replacement therapy (54).

Total recruitment was increased during the study to 70 patients to allow for attrition due to admission for acute deterioration (7 patients), return of very incomplete questionnaires (2 patients), failure to return a questionnaire (one patient), and inappropriate inclusion of one unstable patient. Overall, 59 of 62 clinically stable patients returned completed questionnaires (95%).

### Analyses

Descriptive statistics were used for the demographic data. Knowledge scores were compared using paired t tests and descriptive statistics. Each

knowledge item was given a score of one for a correct response and zero for an incorrect or unsure response. The score for each patient was the number of correct responses. The paired t test is based on differences between pre-decision aid and post-decision aid scores for each individual. Decisional conflict scores were compared using both paired t tests and Wilcoxon signed rank tests. Since the p values obtained were very similar, only the paired t tests are reported here. Decisional Conflict Scale scores are reported as a mean (total/number of questions) for each of the five subscales. The individual's overall mean score was based on the first 15 questions (total for each individual divided by 15), since not all patients completed the last 4 questions. The mean overall decisional conflict score at a time period was calculated as the sum of the individual mean scores divided by the number of subjects.

The choice of statistical test for subgroup analysis was based on the size of the subgroups, data type (nominal, ordinal or interval), and distributional assumptions of the tests. Subgroup analyses were done to evaluate the changes in knowledge and in the DCS uncertainty subscale from pre-decision aid to post-decision aid using the Wilcoxon signed rank test for paired variables. Comparisons of subgroups at a point in time, either pre-decision aid or post-decision aid were done using the Mann-Whitney and Kruskal-Wallis tests for independent variables.

Values were amalgamated into "unimportant" (0-2), "intermediate" (3-7) and "very important" (8-10). Changes in values were assessed using the Stuart-Maxwell test, a nonparametric test for paired variables, used when there are

three categories or levels (94). (There are two formulas, one with a single degree of freedom for ordered variables such as values, and another formula with two degrees of freedom for nominal variables.)

The choices scale results were amalgamated into “strongly favouring volunteer-donated blood” (1-3), “uncertain” (4-8), and “strongly favouring self-donated blood” (9-11). Pre-decision aid and post decision aid choices were compared using the Stuart-Maxwell test. The choice scale results were further amalgamated into those who had made a choice pre-decision aid and an “uncertain” group for subgroup analysis of the uncertainty subscale.

Descriptive statistics were reported for the opinion scale, sources of experience and information, decision aid acceptability questions, and for the “importance of others’ opinions” questions. Correlation tables and alpha statistics were provided for the two series of questions on the importance of others’ opinions. The risk perception responses were described using descriptive statistics, and the proportions of correct responses for each question were compared using McNemar’s test for correlated proportions. The chances of transfusion and complications relative to others pre-decision aid and post-decision aid were compared using the Stuart-Maxwell test. Post-decision aid risk perception subgroup analysis by educational level was done using  $\chi^2$  tests. Analyses were done using SPSS Version 8.0, except for the Stuart-Maxwell tests, which were done using a hand calculator.

## Ethics Approval

The proposal was submitted to the Ottawa Heart Institute Human Research Ethics Committee and received approval on July 13, 1998. The Consent Form is in the Appendix.

## Chapter Five

### Results

#### Patient Characteristics

The demographic details of the study population are shown in Table 1a. Eleven of the 59 patients were female (19%, 95% C.I. 9 to 29). This proportion was lower than the Ottawa Heart Institute proportion for women having heart surgery. Women tended to be older than men (mean age 67 years compared to 59 years) and to have valve or combined bypass and valve surgery more frequently than men: 5/11 (45%) of women compared to 6/48 (13%) of men. Women had a lower frequency of post-high school education than men did: 1/11 (9%) versus 21/48 (44%). The typical respondent was male, English-speaking, with at least high school education, and undergoing his first heart surgery which was a coronary bypass. The investigators strove to recruit patients from all six surgeons in order to provide a representative sample of the patient population. The numbers of study patients per surgeon were: seven from two surgeons, ten from two surgeons, eleven from one surgeon and fourteen from one surgeon.

Table 1b summarizes the characteristics of patients who had surgical consultations during the study period, but were not entered. Several characteristics such as marital status, language spoken at home and education were missing or incomplete on the charts, and are not included. A retrospective chart review was done on all available charts of patients having consultations during the study period, to allow comparison of the characteristics of study

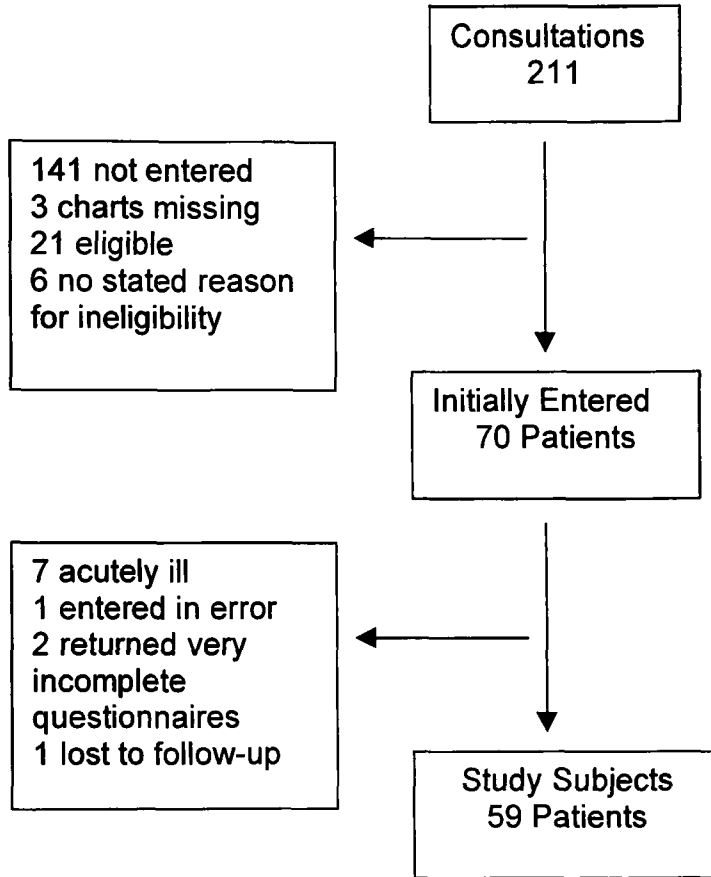
subjects with those who were not entered (Figure 1). Twenty-seven patients met eligibility criteria but had not been entered in the study. Twenty-one (78%) had either had planned to donate their blood or had done so. Six (22%) had no stated reason for ineligibility to donate their blood. There were five women (19%) and 22 men (82%). Eighteen (68%) were to have bypass surgery, seven (26%) valve surgery, and two (7%) “other” surgery. The characteristics of these potentially eligible patients therefore were similar to those of patients who participated in the study.

### Knowledge Test

The responses for each question are included in Table 2 and are expressed as percentages of responses that were correct or unsure. Prior to the decision aid the average score was (mean  $\pm$  SD) 67%  $\pm$  12 (range 40% to 93%) and after the decision aid the average score rose to 85%  $\pm$  16 (range 33% to 100%). Differences between post-decision aid and pre-decision aid scores were normally distributed. A paired t-test was done, and showed the following results: mean absolute increase 18%  $\pm$  17, 95% CI of the difference 14% to 22 %, two-tailed  $t = 8.1$ ,  $df = 58$ ,  $p < .001$ . Subgroup analyses for education, gender and language spoken at home were done using Mann-Whitney tests to evaluate the scores by groups at each period (pre-decision aid and post-decision aid) and Wilcoxon signed rank tests to evaluate within-subgroup changes between periods. The nonparametric Mann-Whitney and Wilcoxon signed rank tests were used because of the small size of some subgroups, and the negatively skewed distributions of the post-decision aid scores. The patients were divided into two

educational groups: those with “high school or less” (n=37) and “more than high school” (n=22) education. Each educational group showed a highly significant increase in knowledge scores. The median score for the “high school or less” group rose from 67% to 80% and the median score for the “more than high school” group rose from 67% to 100% ( $p < .001$  for each comparison). A Mann-Whitney test showed that the post-decision aid median scores by educational group were not significantly different ( $p = .06$ ).

**Figure 1. Retrospective Chart Review of Consultations Done During the Study Period**



<b>Table 1a. Patient Characteristics</b>		
<b>Age and Gender</b>		
	<b>Number (%)</b>	<b>Mean Age (Age Range)</b>
Female	11 (19)	67 (47-64)
Male	48 (81)	59 (36-79)
Total	59 (100)	61 (36-79)
<b>Marital Status</b>		
	<b>Number</b>	<b>Percent</b>
married or common law	47	80
single	3	5
widowed/widower	4	7
divorced/separated	5	9
total	59	100
<b>Language spoken at home</b>		
English	45	76
Bilingual French/English	13	22
Other	1	2
<b>Education</b>		
less than grade 9	9	15
high school or greater	32	54
trade certificate/college diploma or higher	18	31
university degree	10	17
The above groups are not mutually exclusive		
<b>Type of Surgery</b>		
coronary bypass	48	81
valve replacement	7	12
valve repair	1	2
bypass and valve surgery	3	5
<b>Previous Heart Surgery</b>		
first heart surgery	53	90
past heart surgery	6	10
previous PAD	0	0

**Table 1b. Patient Characteristics: Patients having consultations during study period but who were not entered**

<b>Gender</b>	<b>Number (%)</b>	<b>Percent</b>	<b>Mean Age (Age Range)</b>
Female	41	30	68 (40-89)
Male	98	71	63 (26-87)
Total	139 (missing 2)	100	65 (26-89)
<b>Residence</b>			
Ottawa/Hull	58	42	
Outside City	80 (missing 3)	58	
<b>Type of Surgery</b>			
Coronary Bypass	86	61	
Valve Surgery	41	29	
Valve + Bypass	10	7	
Other	4	2	
Total	141	100	
<b>Study Criteria for Inclusion/Exclusion</b>			
Non-English Speaking	4	3	
Severe Aortic Stenosis	18	13	
Urgent	46	33	
Other (potential exclusion criteria e.g. distance)	46	33	
Eligible	21	15	
Unknown	6	4	
Total	141	100	

<b>Table 2. Knowledge Scores</b>				
<b>Question</b>	<b>Answer</b>	<b>Pre Decision Aid (%)</b>	<b>Post Decision Aid (%)</b>	<b>Difference Post-Pre DA (%)</b>
All heart surgery patients are transfused	<b>correct</b>	<b>29</b>	<b>76</b>	<b>47</b>
	unsure	27	12	-15
Transfusions replace lost blood	<b>correct</b>	<b>93</b>	<b>97</b>	<b>4</b>
	unsure	7	0	-7
Transfused for small blood loss.	<b>correct</b>	<b>70</b>	<b>85</b>	<b>15</b>
	unsure	22	7	-15
VDB is convenient for the patient.	<b>correct</b>	<b>83</b>	<b>86</b>	<b>3</b>
	unsure	10	2	-8
VDB* may be given quickly if needed	<b>correct</b>	<b>97</b>	<b>95</b>	<b>-2</b>
	unsure	2	0	-2
Serious complications are rare with VDB.	<b>correct</b>	<b>49</b>	<b>78</b>	<b>29</b>
	unsure	46	5	-41
Infections may be transmitted by VDB	<b>correct</b>	<b>97</b>	<b>95</b>	<b>-2</b>
	unsure	3	2	-1
The wrong blood may be given in error with VDB.	<b>correct</b>	<b>90</b>	<b>88</b>	<b>-2</b>
	unsure	3	3	0
AIDS is frequent with VDB	<b>correct</b>	<b>36</b>	<b>80</b>	<b>44</b>
	unsure	20	9	-11
SDB* reduces viral risk.	<b>correct</b>	<b>97</b>	<b>93</b>	<b>-4</b>
	unsure	2	2	0
SDB-reduces the chance of transfusion.	<b>correct</b>	<b>27</b>	<b>61</b>	<b>34</b>
	unsure	27	3	-24
There is no chance of wrong blood with SDB.	<b>correct</b>	<b>42</b>	<b>73</b>	<b>31</b>
	unsure	10	5	-5
Donating may cause symptoms.	<b>correct</b>	<b>29</b>	<b>80</b>	<b>51</b>
	unsure	39	5	-34
There is still chance of VDB after SDB.	<b>correct</b>	<b>78</b>	<b>93</b>	<b>15</b>
	unsure	10	2	-8
Extra tests and trips are required to donate	<b>correct</b>	<b>86</b>	<b>97</b>	<b>11</b>
	unsure	10	0	-10
<b>Averages</b>	<b>correct</b>	<b>67</b>	<b>85</b>	<b>18 (95% CI 14 to 22)</b>
	unsure	16	4	-12
* Abbreviations: VDB: Volunteer-Donated Blood (Allogeneic) SDB: Self-Donated Blood (Autologous)				

The effect of the patients' language spoken at home on knowledge scores was evaluated by dividing patients into two groups: those whose language was English (n=45) and those whose language was French or "other" (bilingual group) (n=14). There were significant increases in knowledge scores in each group: English ( $p < .001$ ) and bilingual ( $p = .03$ ). Baseline scores were equal in the English and bilingual groups (medians = 67%). Post-decision aid scores were significantly higher in the English (median = 93%) than the bilingual group (median = 73%) ( $p = .001$ ).

The scores of men (n=48) were compared with those of women (n=11). There were highly significant increases in knowledge in men ( $p < .001$ ) and in women ( $p = .005$ ). The pre-decision aid knowledge scores were equal (medians = 67%). Post decision aid scores were also not significantly different: men (median = 90%) and women (median = 80%) ( $p = .20$ ).

Several of the concepts were straightforward, and the responses were correct for the majority of patients. Patients had difficulty with the following concepts, and question-specific mean scores were under 50% on the pre-decision aid test:

1. Transfusions are used selectively, and not all patients are transfused (29% correct).
2. Serious complications of volunteer-donated blood are rare (defined in the questionnaire as "under 1 in 10,000") (49% correct)
3. Acquired Immune Deficiency Syndrome (AIDS) is rare with volunteer-donated blood (36% correct).

4. Choosing to self-donate blood increases the chance of being transfused with any blood (27% correct).
5. Self- donation does not eliminate the chance of receiving the wrong blood (47% correct).
6. Donating blood may cause symptoms such as fainting and chest pain (29% correct).

All but one of the question-specific scores increased to over 75% on the post- decision aid test. Only 61% of patients on the post-decision aid test recognized that there is an increased chance of transfusion with self-donation of blood, but there was an improvement from 27% correct to 61% correct (34% absolute increase)<sup>2</sup>.

There was a decrease in “unsure” responses on all questions (average 12% reduction). There was a small increase in incorrect responses on seven questions, no change on two, and a decrease on six questions (average 6% decrease in incorrect responses). The median and modal increase in the number of correct responses was three. Prior to the decision aid, 9 of 59 patients (15%) achieved 80% or more correct responses on the knowledge questions, and none had a 100% score. After the decision aid, 44 of 59 patients (75%) had a score of 80% correct or greater, and 21 had a score of 100% correct.

#### Values (Importance Ratings)

The importance ratings are shown in Table 3. AIDS was rated as “very important” by 52 of 58 (90%) prior to the decision aid, and by 53 of 58 (91%)

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<sup>2</sup> There was an error in the first few copies of the decision aid, with the omission of “58%” on page 10, the rate of transfusion after self-donation, but this was corrected for all other booklets.

afterward. Hepatitis was considered to be “very important” by 51 of 58 (88%) prior to the decision aid, and by 53 of 58 (91%) afterward. The findings were very similar for unknown infections: 51 of 58 “very important”: ratings before and after the decision aid.

The ratings for “reducing the number of transfusions I receive, (including self-donated blood)” showed more change, with a trend toward increased ratings. Pre-decision aid, 24 of 57 (42%) rated this in the “very important” range, and this increased to 31 of 57 (53%) post-decision aid. However, 18 patients increased their ratings, and 16 decreased them. The ratings for the inconvenience of making extra trips to donate blood were “unimportant” for 33 of 58 (57%) before the decision aid and 27 of 58 (47%) after the decision aid. None of the changes in values was statistically significant by the Stuart-Maxwell test: AIDS ( $\chi^2$  (1df) = .4,  $p>.5$ ), hepatitis ( $\chi^2$  (1df) = .8,  $p>.3$ ), unknown infections ( $\chi^2$  (1df) = .06,  $p>.75$ ), number of transfusions ( $\chi^2$  (1df)= .6,  $p>.4$ ), and inconvenience ( $\chi^2$  (1df)= 2,  $p>.10$ ).

<b>Table 3. Values Comparisons Pre and Post Decision Aid.</b>					
<b>1. AIDS</b>					
		Post-Decision Aid			
		unimportant	intermediate	very important	Total
	unimportant	0	0	1	1 (2%)
Pre Decision Aid	intermediate	0	2	3	5 (9%)
	very important	0	3	49	52 (90%)
	Total	0	5 (9%)	53 (91%)	58* (100%)
<b>2. Hepatitis</b>					
		Post-Decision Aid			
		unimportant	intermediate	very important	Total
	unimportant	0	0	1	1 (2%)
Pre Decision Aid	intermediate	0	2	4	6 (10%)
	very important	0	3	48	51 (88%)
	Total	0	5 (9%)	53 (91%)	58 (100%)
<b>3. Unknown infections</b>					
		Post-Decision Aid			
		unimportant	intermediate	very important	Total
	unimportant	0	1	1	2 (3%)
Pre Decision Aid	intermediate	0	2	3	5 (9%)
	very important	1	3	47	51 (88%)
	Total	1 (2%)	6 (10%)	51 (88%)	58 (100%)
<b>4. Number of Transfusions</b>					
		Post-Decision Aid			
		unimportant	intermediate	very important	Total
	unimportant	1	0	6	7 (12%)
Pre Decision Aid	intermediate	5	9	12	26 (46%)
	very important	2	9	13	24 (42%)
	Total	8 (14%)	18 (32%)	31 (53%)	57 (100%)
<b>5. Inconvenience of Blood Donation</b>					
		Post-Decision Aid			
		unimportant	intermediate	very important	Total
	unimportant	23	5	5	33 (57%)
Pre Decision Aid	intermediate	3	6	4	13 (22%)
	very important	1	5	6	12 (21%)
	Total	27 (47%)	16 (28%)	15 (26%)	58 (100%)

\*one patient's results were missing

<b>Table 4. Preferences for Methods of Transfusion.</b>					
<b>1. Overall</b>		<b>Post Decision Aid</b>			
		strongly VDB	uncertain	strongly SDB	Total Number (%)
	strongly VDB	4	0	0	4(7%)
Pre Decision Aid	uncertain	2	3	9	14(24%)
	strongly SDB	2	3	36	41(70%)
	Total Number (%)	8(14%)	6(10%)	45(76%)	59(100%)
<b>2a. Female</b>		<b>Post Decision Aid</b>			
		strongly VDB	uncertain	strongly SDB	Total Number (%)
	strongly VDB	2	0	0	2(18%)
Pre Decision Aid	uncertain	0	1	2	3(27%)
	strongly SDB	1	0	5	6(55%)
	Total Number (%)	3(27%)	1(9%)	7(64%)	11(100%)
<b>2b. Male</b>		<b>Post Decision Aid</b>			
		strongly VDB	uncertain	strongly SDB	Total Number (%)
	strongly VDB	2	0	0	2(4%)
Pre Decision Aid	uncertain	2	2	7	11(23%)
	strongly SDB	1	3	31	35(73%)
	Total Number (%)	5(10%)	5(10%)	38(79%)	48(100%)
<b>3a. English</b>		<b>Post Decision Aid</b>			
		strongly VDB	uncertain	strongly SDB	Total Number (%)
	strongly VDB	3	0	0	3(7%)
Pre Decision Aid	uncertain	1	3	6	10(22%)
	strongly SDB	1	3	28	32(71%)
	Total Number (%)	5(11%)	6(13%)	34(76%)	45(100%)
<b>3b. Bilingual</b>		<b>Post Decision Aid</b>			
		strongly VDB	uncertain	strongly SDB	Total Number (%)
	strongly VDB	1	0	0	1(7%)
Pre Decision Aid	uncertain	1	0	3	4(29%)
	strongly SDB	1	0	8	9(64%)
	Total Number (%)	3(21%)	0	11(79%)	14(100%)
<b>4a. High school or less</b>		<b>Post Decision Aid</b>			
		strongly VDB	uncertain	strongly SDB	Total Number (%)
	strongly VDB	3	0	0	3(8%)
Pre Decision Aid	uncertain	2	2	7	11(30%)
	strongly SDB	1	1	21	23(62%)
	Total Number (%)	6(16%)	3(8%)	28(76%)	37(100%)
<b>4b More than high school</b>		<b>Post Decision Aid</b>			
		strongly VDB	uncertain	strongly SDB	Total Number (%)
	strongly VDB	1	0	0	1(5%)
Pre Decision Aid	uncertain	0	1	2	3(14%)
	strongly SDB	1	2	15	18(82%)
	Total Number (%)	2(9%)	3(14%)	17(77%)	22(100%)

## Transfusion Preferences

The preferences of patients pre-decision aid and post-decision aid are shown in Table 4. Prior to the decision aid, 70% were strongly predisposed to self-donation and this increased to 76% post-decision aid. Nine of the 14 uncertain patients changed to strongly favouring self-donation. The changes in preferences were statistically significant by the Stuart-Maxwell test ( $\chi^2$  (2df) =6.8,  $p<.05$ ) Only two patients switched from self-donated to volunteer-donated blood, and none made the opposite change. Both women and men showed a small increase in the number strongly predisposed to self-donated blood. There was no significant change in preferences in a subgroup analysis when the patients were grouped by gender or language. There was a significant change in preferences in the group with high school or less education ( $\chi^2$  (2df)=7.2,  $p<.05$ ) by usual criteria. However, corrected for multiple comparisons, (new alpha =.05/3=.02), the result was not significant. In this group, 7 of 11 (64%) uncertain patients switched to self-donated blood, and two switched to volunteer-donated blood.

## Decisional Conflict

The results of the Decisional Conflict Scale measurements are shown in Table 5. All patients completed the first fifteen items. The last four items, which refer to decisions actually made, were completed only by those who had made a decision whether or not to self-donate blood. For this reason, only 43 patients completed the "ineffective choice" questions before the decision aid (16 missing) and 55 completed the section post-decision aid (4 missing). Forty completed both sections. The mean total scores were not statistically different by the paired t

<b>Table 5. Pre and Post Decision Aid Decisional Conflict Scores</b>					
	<b>Pre Decision Aid</b>	<b>Post Decision Aid</b>	<b>Difference</b>	<b>t-test</b>	<b>p value</b>
			<b>Pre-Post DA</b>		
			<b>and 95% CI</b>		
<b>Total DCS Score<sup>a</sup> (SD)</b>	1.69 (.59)	1.66 (.56)	.03 (-.14, .20)	0.4	0.69
<b>Subscore (SD)</b>					
<b>Uncertainty</b>	1.5 (.8)	1.8 (.9)	-.3(-.6,-.1)	-2.5	0.02
<b>Uninformed</b>	1.6 (.7)	1.5 (.5)	.1(-.02, .4)	1.8	0.08
<b>Unclear Values</b>	1.7 (.8)	1.5 (.6)	.2, (-.04,.4)	1.6	0.11
<b>Unsupported</b>	1.8 (.6)	1.9 (.8)	-.1 (-.3, .2)	-.3	0.79
<b>Ineffective choice (40 patients)</b>	1.2 (.4)	1.5 (.6)	-.3 (-.4, -.1)	-2.7	0.01
<b>Expressing no problems with each DCS item (score 2 or less)<sup>b</sup></b>					
easy choice	83%	81%	2%		
sure what to do	85%	85%	0%		
clear best choice	88%	83%	5%		
know alternatives	97%	97%	0%		
know VDB pros	76%	91%	-15%		
know SDB pros	91%	95%	-4%		
know VDB cons	90%	93%	-3%		
know SDB cons	81%	93%	-12%		
know importance of pros of SDB	91%	97%	-6%		
know importance of cons of SDB	78%	97%	-19%		
clear which is more important	85%	93%	-8%		
enough information on others	39%	45%	-6%		
feel no pressure from others	100%	97%	3%		
have enough support	81%	84%	-3%		
have enough advice	78%	81%	-3%		
informed choice	95%	89%	6%		
reflects values	100%	94%	6%		
will stick with	100%	93%	7%		
satisfied with	98%	95%	3%		
<sup>a</sup> Decisional Conflict Scores are calculated by summing the scores from individual items (ranging from 1 to 5) and dividing by the number of items In this study the first fifteen items were used to calculate the score, since patients were not required to complete the last four items if they had not made a choice. Scores range from 1 (low decisional conflict) to 5 (high decisional conflict). A score above 2.5 indicates a tendency to delay choices and a score of less than 2 indicates a tendency to make choices <sup>b</sup> A score of 1 indicates "strongly agree" and a score of 2 indicates "agree". Scores of 1 or 2 on an item by an individual were amalgamated into a "no problem" response. The percentages of patients with "no problem" responses for each item are shown					

test,  $p=.69$ . There were significant increases in uncertainty and ineffective choice subscales. Patients were divided into two groups: those who had a strong preference for either self-donated blood or volunteer-donated blood ( $n=45$ ), and those who were uncertain ( $n=14$ ) prior to the decision aid. The median score in the uncertain group decreased from 2.3 pre-decision aid to 2.0 post-decision aid but this change was not significant by a sign test ( $p=.6$ ). The median uncertainty score in the group with strong preferences increased from 1.0 to 1.2. This increase was highly significant by a sign test ( $p < .001$ ).

The post-decision aid questionnaires were examined for evidence of "acquiescence" or "yea-saying" bias (92). Overall, nine of 59 (15%) of patients answered "strongly agree" to every question, and three (5%) answered "agree" to every question. This tendency to give the same positive answer was present in seven of 45 (16%) of those who spoke English at home, and in five of 14 (36%) of the bilingual group. Since "yea-saying" was present in a minority of patients, it was not likely to have been an important bias in the decisional conflict scale results of the study.

The "ineffective choice" subscale means included only those subjects who had made a choice before and after the decision aid, and the results are not relevant to the subjects as a whole. This group had low decisional conflict scores initially, and had a significant increase post-decision aid.

### Risk Perception

The results of the risk perception questions are shown in Table 6 and in the bar charts (Figures 2 to 9). The patients estimated the number out of 100

who would need at least one transfusion during or after heart surgery, both for those making the choice to accept volunteer-donated blood and those choosing to self-donate. The Ottawa Heart Institute statistics were used as benchmarks. None of the patients estimated the frequencies correctly pre-decision aid, but 60% and 25% were correct for volunteer-donated and self-donated choices post-decision aid respectively. There was a carry-over effect, with 25% of patients mistaking the correct answer for volunteer-donated blood also as the correct answer for self- donated blood.

**Table 6. Risk perception**

	Pre-Decision Aid % Correct	Post Decision Aid % Correct	Difference Post-Pre DA	p value
Number transfused VDB Choice	0	60	60	<.001
Number transfused SDB Choice	0	25	25	<.001
Chance of AIDS VDB Choice	13	42	29	0.001
Chance of AIDS SDB Choice	14	52	38	<.001
Chance of hepatitis VDB Choice	4	32	28	<.001
Chance of hepatitis SDB Choice	0	18	18	0.002
Immediate reaction VDB Choice	0	28	28	<.001
Immediate reaction SDB Choice	4	27	23	<.001

The results were highly significant by the McNemar test for correlated proportions, with  $p \leq .002$  in each case.

The method of response to the questions on small risk perception was recorded. Six of 57 patients (11%) stated an exact frequency, 39 (68%) used the "closest-to" responses, and 12 (21%) used a combination of responses.

The chance of AIDS with the choice of VDB was correctly estimated by only 13% pre-decision aid, but post-decision aid, 42% were correct ( $p = .001$ ), and an additional 32% were within one category of the correct answer. The

percent with "no idea" decreased from 34% to 2 %. The frequency of AIDS (due to the possible requirement for additional allogeneic blood) with the choice of self-donation was correctly estimated by 14%, with 32% having "no idea" pre-decision aid. There were correct responses in 52% post-decision aid ( $p < .001$ ), 18% were within one category, and only 4% had "no idea".

Correct estimates for the chance of hepatitis B or C with the choice of VDB rose from 4% to 32% ( $p < .001$ ) and the "no idea" frequency fell from 38% to 4%. The majority (58%) underestimated the risk. The patients' estimates of hepatitis with the choice of SDB followed a similar pattern, but there was a much more pronounced under-estimation of risk, with 37% estimating "one in ten million" post-decision aid. The "no idea" frequency fell from 36% to 4%.

"Immediate reactions" include mismatched transfusions ("wrong blood reactions"), allergic reactions, and bacterial contamination of blood. With the choice of VDB, 38% of patients had "no idea" of the chance of an immediate reaction pre-decision aid, and none knew the correct answer. Post-decision aid, 28% knew the correct answer ( $p < .001$ ), and only 11% had "no idea". Forty-nine percent of patients under-estimated the risk. There was quite a marked tendency to under-estimate the risk of immediate reactions with SDB prior to the decision aid; 61% of patients erred by a factor of 100 to 1,000, and only 4% of patients gave the correct answer. Post-decision aid, the correct response rate rose to 27% ( $p < .001$ ), but the tendency to underestimate remained in 48% of patients.

The patients' perceptions of their own risks relative to others were tested for the chances of having a transfusion with each choice, and the chance of

contracting a viral illness, either AIDS or hepatitis from VDB. The results are shown in Table 7. There were four to five missing responses for each question. The results for the chance of having a transfusion were stable, with few changing their estimates of requiring a transfusion relative to others. There was an increase in the number of patients who felt that their risk for viral complications was greater than others, from five to nine patients. For the analysis, "much lower than others" and "lower than others" groups were collapsed. There was no significant difference in the pattern of relative chances for having a transfusion pre-decision aid and post-decision aid by the Stuart-Maxwell test.

Pre-decision aid, 58% felt the risk of an immediate reaction was greater for VDB, 40% felt it was the same, and only 2% felt that it was greater for SDB. Post-decision aid the correct responses increased from 2% to 34%. Forty-one percent felt the risk was higher for VDB and 25% felt it was equal. The differences were highly significant by the Stuart-Maxwell test, ( $\chi^2$  (2df) = 16,  $p < .001$ ).

The post-decision aid correct responses to the risk perception questions were evaluated by educational level using the Pearson  $\chi^2$  test. Since there were eight comparisons which were not previously planned, the significance level was set at  $.05/8 = .006$ . The group with higher education was significantly better in three of the eight comparisons: "Number transfused with VDB choice" ( $\chi^2$  (1df) = 10.0,  $p = .002$ ), "Number transfused with SDB choice" ( $\chi^2$  (1df) = 8.8,  $p = .003$ ) and "Chance of AIDS with SDB choice" ( $\chi^2$  (1df) = 8.2,  $p = .004$ ).

<b>Table 7. Patients' Perceptions of the Chances of Transfusion and Complications of Transfusion Relative to Other Patients</b>						
<b>1. Relative Chance of Transfusion With VDB</b>						
		<b>Post-Decision Aid</b>				
		much lower than others	lower than others	same as others	greater than others	Total
	lower than others	1	0	1	0	2 (4%)
<b>Pre-Decision Aid</b>	same as others	0	2	45	1	48 (89%)
	greater than others	1	1	1	1	4 (7%)
	<b>Total</b>	<b>2 (4%)</b>	<b>3 (6%)</b>	<b>47 (87%)</b>	<b>2 (4%)</b>	<b>54 (100%)</b>
<b>2. Relative Chance of Transfusion With SDB</b>						
		<b>Post-Decision Aid</b>				
		much lower than others	lower than others	same as others	greater than others	Total
	lower than others	0	0	2	1	3 (5%)
<b>Pre-Decision Aid</b>	same as others	2	0	46	3	51 (93%)
	greater than others	0	1	0	0	1 (2%)
	<b>Total</b>	<b>2 (4%)</b>	<b>1 (2%)</b>	<b>48 (87%)</b>	<b>4 (7%)</b>	<b>55 (100%)</b>
<b>3. Relative Chance of Hepatitis or AIDS With VDB</b>						
		<b>Post-Decision Aid</b>				
		much lower than others	lower than others	same as others	greater than others	Total
	lower than others	0	0	0	1	1 (2%)
<b>Pre-Decision Aid</b>	same as others	2	2	38	6	48 (89%)
	greater than others	0	1	1	1	3 (6%)
	much greater than others	0	0	1	1	2 (4%)
	<b>Total</b>	<b>2 (4%)</b>	<b>3 (6%)</b>	<b>40 (74%)</b>	<b>9 (17%)</b>	<b>54 (100%)</b>
<b>4. Relative Chance of An Immediate Reaction with VDB or SDB Choice</b>						
		<b>Post-Decision Aid</b>				
		higher for VDB	higher for SDB	equal chance	total	
	higher for VDB	12	12	7	31 (57%)	
<b>Pre-Decision Aid</b>	higher for SDB	1	0	0	1 (2%)	
	equal chance	8	7	7	22 (41%)	
	<b>Total</b>	<b>21 (39%)</b>	<b>19 (35%)</b>	<b>14 (26%)</b>	<b>54 (100%)</b>	

## Decision Aid Acceptability

The responses to the questionnaires are shown in Table 8.

<b>Length</b>		<b>Percent</b>	<b>Helpfulness</b>		<b>Percent</b>
much too long		2	very helpful		50
too long		6	somewhat helpful		30
about right		91	a little helpful		16
too short		2	not helpful		4
<b>Clarity</b>			<b>Recommend to Others</b>		
everything clear		52	definitely recommend		64
most things clear		36	probably recommend		31
some things unclear		11	probably not recommend		6
many things unclear		2			
<b>Fairness</b>			<b>Preferred way of presenting small risks</b>		
clearly slanted to VDB		6	by words (one in a million)		29
slightly slanted to VDB		11	by numbers (1 in 1,000,000)		22
balanced		74	by verbal comparisons		13
slightly slanted to SDB		7	comparison chart		16
clearly slanted to VDB		2	combination of methods		15
			none stated		6

The length of the decision aid was felt to be about right by over 90% of patients. Most felt that the decision aid was clear, balanced, and fair. Most also found it to be "very helpful" or "somewhat helpful". The vast majority (95%) would "definitely" or "probably" recommend it. The patients were asked about their preferences for methods of showing small risks. Preferences for "words" or "numbers" were the highest at 29% and 22%, and fewer favoured verbal risk comparisons or a risk comparison chart.

## Importance of Others' Opinions

The results are shown in Table 9. The first six questions evaluated the process of making a decision to donate blood before surgery. Three questions assessed the helpfulness of information of others' choices. There was agreement

that self-donation is an individual choice. Only a third felt that the decision depends on the doctor's opinion of the pros and cons. Less than one half felt that most patients would choose to self-donate, and that doctors would do so if they were patients. About half felt that information on other patients' choices, and the recommendations of their surgeon and other surgeons were at least helpful. About a third felt that this information was "not at all helpful". There was no agreement on the question of how many people out of 100 would choose to self-donate blood. More than a third did not know, and the majority was in the range of 50% to 100%. When asked "What do you think your surgeon thinks you should do?" 53% did not know. About one quarter felt he was neutral, and 17% felt that he would recommend self-donation. Only two felt that he would recommend the choice of volunteer-donated blood.

<b>Table 9. Importance of Others' Opinions in the Decision to Self-Donate Blood</b>				
<b>Patients' thoughts on how other patients decide about self-donating blood.</b>				
<b>Questions</b>	<b>Strongly Agree/ Agree (%)</b>	<b>Disagree/ Strongly Disagree (%)</b>		
1. Self-donation is an individual choice	93	0		
2. No right or wrong answer re self-donation	81	5		
3. Decision depends on patient's opinion of pros and cons	91	2		
4. Decision depends on doctor's opinion of pros and cons	35	44		
5. Most patients choose to self-donate	44	18		
6. Most doctors would choose to self-donate	48	7		
<b>Importance of information on others' choices and recommendations*</b>				
<b>Questions</b>	<b>Essential (%)</b>	<b>Helpful (%)</b>	<b>A little helpful (%)</b>	<b>Not at all helpful (%)</b>
8. Information about other patients' choices	6	38	21	36
10. Your surgeon's recommendation for you	9	53	11	28
11 Other surgeons' recommendations to their patients	4	51	14	31
* Totals may not add up to 100% because of rounding off				

## Patients' Comments

Fourteen patients wrote comments on the post-decision aid questionnaires. Four expressed concern about the greater chance of transfusion with self-donated blood. Patient 1 commented "Not aware that more people require transfusion from self-donated blood. Made me uncertain about my decision." Patient 12 was critical of the data on transfusion errors, since they were based on the experience in New York State prior to 1992. He felt that recent Canadian results should be better. Two other patients questioned why the risk of an immediate reaction from self-donated blood is higher than that of volunteer-donated blood. One patient commented that the negative aspects of self-donation were unclear, and wondered why the chance of transfusion is higher with self-donated blood. Several patients complained about the length and complexity of the questionnaires. One patient observed, "The question was never asked: What reason did you use to make your choice?" Several patients made positive comments about the decision aid, including, "Very informative", "Keep telling the truth", "Overall clear" and "It is well-presented work".

## **Chapter Six**

### **Discussion**

This is the first study of a decision aid designed to assist heart surgery patients to make the decision whether or not to donate their own blood prior to surgery. The decision aid was designed according to the Ottawa Decision Support Framework (54), with the goals of improving knowledge, providing more realistic expectations, and reducing decisional conflict. The study subjects were cardiac patients with coronary and/or valvular heart disease who were referred to cardiac surgeons for open-heart surgery. The study design was a before-after trial. Outcomes included knowledge, preferences, values, decisional conflict, risk perception and the importance of others' opinions.

#### **Study population**

The Ottawa Heart Institute serves a large area including Eastern Ontario and Western Quebec, and the patient population includes those with a variety of cultural and educational backgrounds. The previously mentioned gender imbalance is an Ontario-wide phenomenon (95). The rates of angiography, angioplasty and bypass surgery in Ontario are considerably higher for men than women at each age range. The rates for bypass surgery at ages 65 to 74 years are three times as high for men as for women (601 versus 197 per 100,000 population). Selection bias could have influenced the results by preferentially allowing patients with strong preferences for autologous donation to enter the study. The investigators took steps to limit this potential bias. Surgeons differed in their enthusiasm for autologous donation, in the amount of information about

pre-donation given to patients, in the proportion of their patients who were eligible for pre-donation and in the time spent with each patient. The author and/or the study nurse attended nearly all clinics during the three-month study period, and achieved good patient recruitment from each surgeon. A retrospective review of the charts of all patients having pre-operative surgical consultations during the study period found only 27 patients who appeared to be eligible, but who were not entered. Their characteristics were very similar to study subjects. The proportion who had pre-donated or made plans to do so was 21 of 27 (78%), similar to the 70% of study subjects who strongly preferred the self-donated blood option. The Ottawa region differs markedly from other Canadian centres in the proportion of blood collections which are autologous (9.0% of collections compared with the Canadian average of 2.4%) (11). This regional enthusiasm may explain in part the strong patient preferences for autologous donation in this study.

#### Potential Sources of Invalidity due to Study Design

The before and after (one group pretest-posttest) design used in this study has limitations in its ability to control potential sources of invalidity (96). The settings of the baseline and follow-up questionnaires were very different, introducing a potential maturation effect. The clinic setting was stressful, not only due to the discussion of heart surgery, but also due to the subject of the very long waiting periods for surgery, with the prospect of death or emergency admission before the proposed operation. After the initial interview, patients learned of the protocol for the autologous program, and were instructed on

actions to take in the event of an emergency. The instruction for the autologous program may have increased their values for the inconvenience of self-donation. Knowledge of this well-organized program may have influenced the preferences of uncertain patients. The before and after design cannot control for the possibility that the initial questionnaire may have influenced the results of the second questionnaire. The investigators were available to answer patients' questions in the clinic, but not at the time of the second questionnaire, and it is possible that this influenced some patients' answers. Since the patients were not selected on the basis of a test score, it is unlikely that regression to the mean occurred. It is unlikely that the patients who were withdrawn from the trial because of acute illness were different in any way from those who remained in the trial, given the unpredictable random nature of acute cardiac events in initially stable patients.

### Knowledge

The decision aid performed according to the predictions of the Decision Support Framework, with a significant improvement in knowledge overall, and in each subgroup according to educational level, gender and language spoken at home. How may the decision aid be improved? There were two important concepts were not well communicated: the chances of immediate reactions and the increased frequency of transfusion in autologous donors. The decision aid should be modified to address these shortcomings in communication. First, it should state clearly that the risk of immediate reactions due to human error and bacterial contamination is the same *per unit of blood*, regardless of whether it is

of autologous or allogeneic origin. Second, it should state the two reasons for the increased chance of transfusion in autologous donors: lower preoperative hemoglobin and more liberal transfusion criteria by surgeons (19,20). Since institutional transfusion practices vary widely in the USA, and may do so in Canada, the decision aid should state clearly that the probabilities of transfusion are based on local practices, and may be different in other institutions. If surgeons at other institutions wish to use the decision aid, the probabilities should reflect local transfusion practices.

### Decisional Conflict

The decision aid had no effect on overall mean decisional conflict scores. Decisional conflict scale means were lower than in other studies (51,53,54), and about the same as measured in a study of antithrombotic agents in atrial fibrillation (89). Those who have no difficulty making and acting on decisions tend to have scores below 2.0, and those who delay decisions tend to have scores above 2.5 (90,97). The pre-decision aid and post-decision aid overall and subscore means were all below 2.0, indicating a tendency to make decisions. There was a small but significant increase in the 'uncertainty' subscale in those who had a strong preference initially. The increase in uncertainty is not necessarily detrimental, since it may indicate that some patients had become aware of important factors that made them doubt their initial preference. They then had an opportunity to improve their knowledge, clarify their values, and if necessary, change their preferences.

Since most patients had strong preferences and low decisional conflict before the decision aid, one might ask whether the decision aid was needed at all. Although most patients felt confident about their knowledge pre-decision aid, as shown by a low uninformed mean score, they were unaware of several gaps in their knowledge, as revealed in the knowledge test. The decisional conflict uncertainty subscale has a "ceiling effect", since patients may be confident of their knowledge by their own standards, and have important deficiencies by expert standards. The Ottawa Decision Framework definition of a "high quality decision" requires that it be "informed", implying that knowledge be adequate by expert criteria. By improving the patients' knowledge and expectations, the decision aid might improve long-term outcomes, including persistence with the decision, health-related quality of life, reduced distress from consequences, reduced regret, better use of resources, and satisfaction with care (54).

The timing of the patients' decisions to self-donate is unclear. The decisions appeared to have been made quickly, at the time of the consultation. If the decision aid were used before the consultation, the decision might be based on better knowledge and more accurate expectations.

#### Patients' values and preferences versus cost-effectiveness

Ninety percent of study subjects rated transfusion-transmitted viruses as "very important" before and after the decision aid. The high values were unaffected by knowledge of the very low probabilities of infection. Similarly, nine of 14 (64%) of uncertain patients preferred self-donation after the decision aid, in spite of this knowledge. The creation of realistic expectations without changing

the decision has occurred in previous decision aid trials (53,54). Autologous blood is more costly than allogeneic blood, because unused units are discarded and the personnel costs are higher (85). Previous cost-effectiveness analyses have found autologous donation not to be cost-effective by accepted standards (86,87). However, these analyses did not take into account the higher probability of transfusion in autologous donors (18), and the small probability of death in cardiac patients due to the donation procedure itself. Taking the higher probability of transfusion into account, patients who choose allogeneic or autologous blood have about the same risk of dying of an immediate reaction (two per million patients), and allogeneic blood has a slightly higher frequency of delayed death (two per million patients). Although the cost of autologous program is borne by the public in Canada, patients should be aware of the higher costs as well as the minimal benefits. The potential influence of economic data on patients' decisions is an important area for future research.

#### Values or importance ratings

The importance ratings or values for AIDS, hepatitis B and C, and unknown infections were predominantly "very important" and were unchanged after the decision aid (Table 3). It is not surprising that knowledge of the very low probability of viral infection did not reduce the importance ratings for viral infections for most patients. Dread and fear of the unknown influence patients' perceptions (70-72). The decision aid modified the perceptions of risks, but it did not change the feelings of "dread" or "fear". A "decision problem" is defined by the choices, possible outcomes, values and the probabilities of the outcomes.

The very adverse publicity about the disastrous consequences of "tainted blood" has resulted in strongly negative values for the outcomes. Fischhoff et al found that individuals are able to form an opinion about the value of an outcome when it is familiar, simple, and directly experienced (98). Nelkin has stressed that we should look at risk perceptions not in a narrow framework of health and safety, but as part of "complex systems of beliefs, values and ideals that constitute a culture" (99). She stated, "The media, in effect make risks visible and define a frame or context in which related events can be interpreted". Health professionals have not done enough to reassure the public about the very low risks of the blood supply. Because of the ongoing negative publicity, it may take years before full public confidence in the blood system is restored. Krever summarized the importance of communicating all aspects of risk to patients: "The risks inherent in blood components and blood products should be fully disclosed, even when the gravity or likelihood of a risk is still uncertain. Recipients of blood components and blood products must be able to make informed choices, in consultation with their physicians, about the relative risks of receiving blood or blood products (4 page 1051)."

### Risk Perception

Our risk perception questionnaires asked patients to estimate their personal risk of complications for each transfusion choice. The task of educating patients about very small risks is a difficult one. Redelmeier commented: "We have little intuitive understanding between the risk of one in 20,000 and a risk of one in 200,000."(100). In this study, we used local and regional population

comparisons to familiarize patients with the concept of probabilities, similar to the scale developed by Nesse and Klaas (101). Patients were very often successful in stating the exact probability, or in coming reasonably close (within one category of the correct answer) after using the decision aid. The patients' task was more difficult, because the decision aid used a "constant denominator" display of risks (e.g. "twenty in a million patients"), and the questionnaires used a "constant numerator" approach (e.g. "one in fifty thousand"). The "constant numerator" display of low probabilities is familiar to most people, and we felt it would be better understood in the pre-decision aid questionnaires. For the decision aid, the "constant denominator" approach was used to show the expected number out of a million having complications. Despite this imposition of mental arithmetic, most patients were quite good at estimating probabilities. It is not surprising that patients with "more than high school" education were significantly higher than those with "high school or less" on three of the eight questions. We felt that the Paling logarithmic scale would be too complex for most patients (102).

Slovic has pointed out that people are over-confident in their judgements based on heuristics (71). One form of this over-confidence is the belief that "It can't happen to me." He believed that the overly optimistic estimates of personal risks could be explained by the feeling of control over the risk, and the familiarity of the risk. The study by Krewski and colleagues confirms this impression (82). More respondents rated each of ten hazards as "high risk" for the "Canadian public as a whole" than for "to you and your family". We assessed patients'

estimates of their own risks compared to others' to see if this overconfidence was present. Most patients had not had a previous transfusion experience. Some patients may have recognized that they have risk factors for bleeding, such as having surgery that is more extensive than average, and therefore would have a higher chance of having a transfusion. There was no evidence of overconfidence in the study population. This may be because the patients lacked feelings of control over the risks, and familiarity with them.

Prior to the decision aid, the majority felt that the risk of an immediate reaction was higher for volunteer-donated blood and only one patient thought it was higher for self-donated blood. After the decision aid, a minority of patients (35%) recognized that the frequency is higher with self-donated blood. The findings concur with the patients' risk estimations shown in figures 8 and 9. Patients tend to under-estimate both the absolute risk of immediate reactions with self-donated blood, and the relative risk compared with volunteer-donated blood. This under-estimation is improved by the decision aid, but there is still much to be gained in accurately communicating this risk to patients.

### Acceptability

Patients rated the decision aid highly with regard to length, clarity, fairness and helpfulness. Most would recommend it to others. Although the majority preferred that risks be presented either by words or numbers, no single method of risk presentation appealed to everyone. Our findings agree with those of Mazur in this respect (103). It would be prudent to present risks in several formats, including words and numbers. In addition, it might be helpful to have a

chart to give a visual impression of the size of the risk. However, Weinstein found no benefit in using a visual “dot” chart in communicating small risks (104).

Robertson advocated the use of precise numbers instead of easily misinterpreted words (105). Another approach to risk presentation is the use of time intervals.

Weinstein found that the use of time intervals might reduce perceived threat (106). Our decision aid employed a combination of numbers, words, charts, and a risk comparison chart to communicate risks. Because of this multi-faceted approach it was more likely to appeal to patients with a variety of social and educational backgrounds.

## **Chapter Seven**

### **Conclusions**

This study has demonstrated that the decision aid “Making Choices: Blood Transfusion in Heart Surgery” improved patients’ knowledge and expectations, as predicted by the Decision Support Framework. It had a significant effect on choices, by a reduction in the number of uncertain patients. There was no significant change in values. Decisional conflict overall mean scores were unchanged, but uncertainty increased. Patients’ risk perceptions for the chances of transfusion, viral complications, and immediate reactions were improved. It was felt to be about right in length, clear, balanced and helpful by the majority of patients. Most would recommend it to others.

#### **Further research-implications for a randomized controlled trial**

This study will be followed by a randomized controlled trial of the decision aid compared with usual care in a larger population of patients. Some of the issues raised by the current study, which are applicable to the design of the randomized trial, are the following:

#### **Patient selection and timing of the intervention**

Most of the patients in this trial had already formed strong preferences for self-donation of blood by the time they were seen immediately after the surgical consultation. The timing of their decisions is unclear: Was the preference formed before the surgical consultation or at the time of the consultation? If the decision aid is to be most effective, it should be used at the time of decision-making. If it were provided before the consultation, patients would be more knowledgeable,

and more aware of their areas of uncertainty. They would have more time to consider their personal values. There would be an opportunity for shared decision-making. Moreover, we would have an opportunity to evaluate patient satisfaction with the decision-making process, and with the decision actually made (107-109). If the decision aid were prior to the consultation when more patients are uncertain, decisional conflict may be reduced in more patients. The use of the decision aid at the patients' homes prior to the consultation would allow baseline testing in a quiet relaxed environment, similar to that of the follow-up questionnaire, reducing the maturation effect.

#### Measurement of Outcomes.

The controlled trial will offer the opportunity to expand the range of outcomes measured. In the before-after trial, the patients' stated preferences were measured. How many of those who state a preference for self-donation actually go on to donate blood? In the before-after trial, ten percent of patients developed severe symptoms soon after the consultation, and required admission to hospital. Others might be declared unfit to donate blood after consultation with the transfusion specialist. Because of the anticipated high drop-out rate and the very long waiting times for elective surgery, a large number of patients would need to be followed for a long time to assess persistence with the decision.

A strikingly large proportion of patients felt that the decision to donate their blood is an individual one. Most either did not know the surgeon's preference, or felt that he was neutral. Since opinions were sampled after the consultation and decision aid, it is unclear what the patients' preferences might have been before

the consultation. Charles and her colleagues have clarified the concepts of shared decision-making and have outlined areas for future research (107). There are important questions to be answered, and many could be addressed in decision aid research. What is the patient's preferred role in decision-making? Can a decision aid, by providing the patient with relevant information and clarifying values, promote shared decision-making? Why do patients hold different preferences? Does the decision aid improve satisfaction with the decision-making process? A combination of questionnaires and semi-structured interviews would allow these questions to be addressed, taking into account the patients' determinants of decisions, as outlined in the Ottawa Decision Support Framework.

#### Role of Language and Culture

The multicultural Ottawa area is an ideal laboratory to assess the importance of language and culture in decision-making. We have shown that although bilingual patients can benefit from the decision aid, they tended not to benefit as much as those whose language spoken at home was English. It is important to have the decision aid translated into French, and to evaluate it in parallel with the English version.

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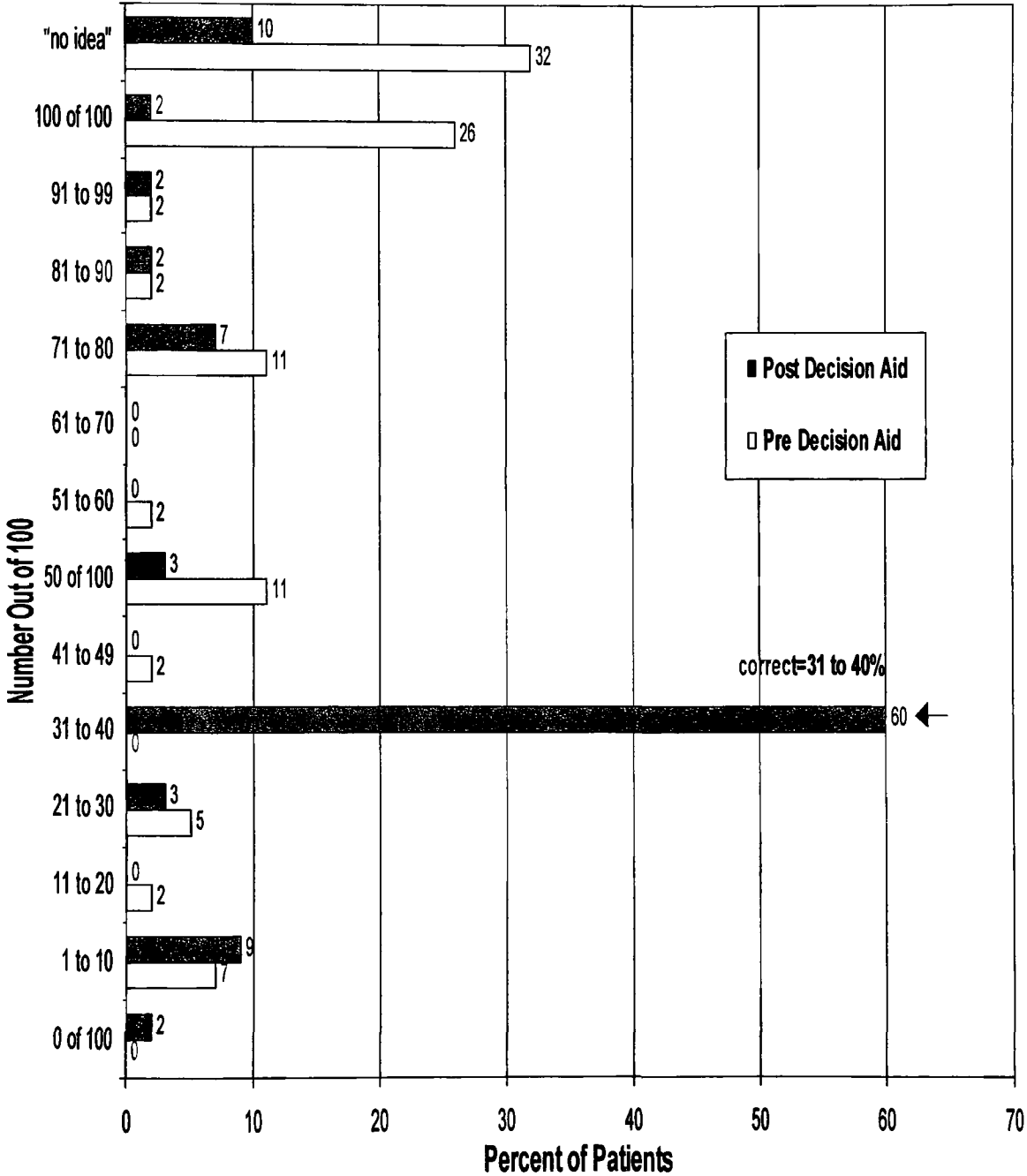
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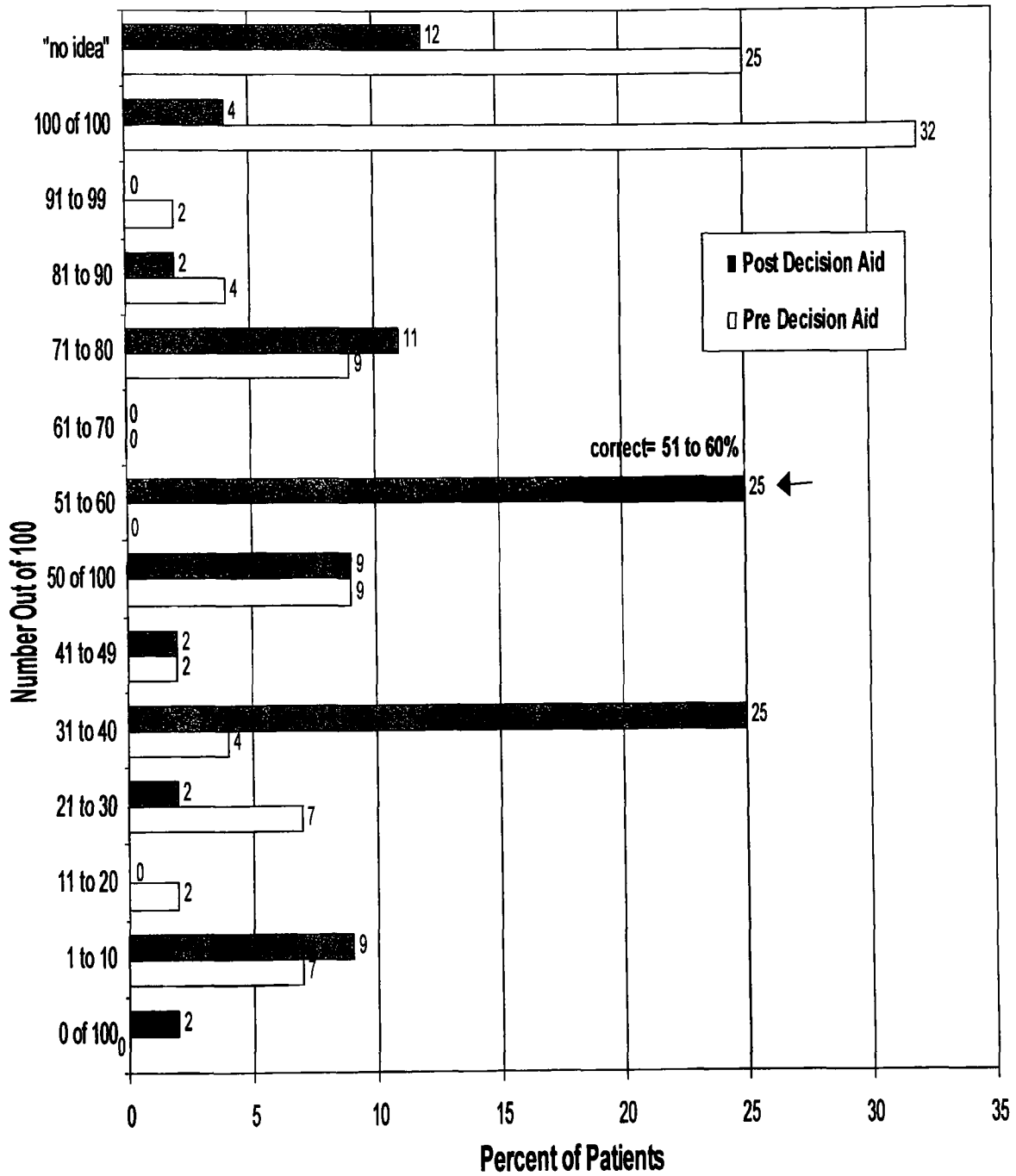
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**Figure 2. Patients' Estimates of the Total Number Transfused with Volunteer-Donated Blood Choice, Pre and Post Decision Aid**

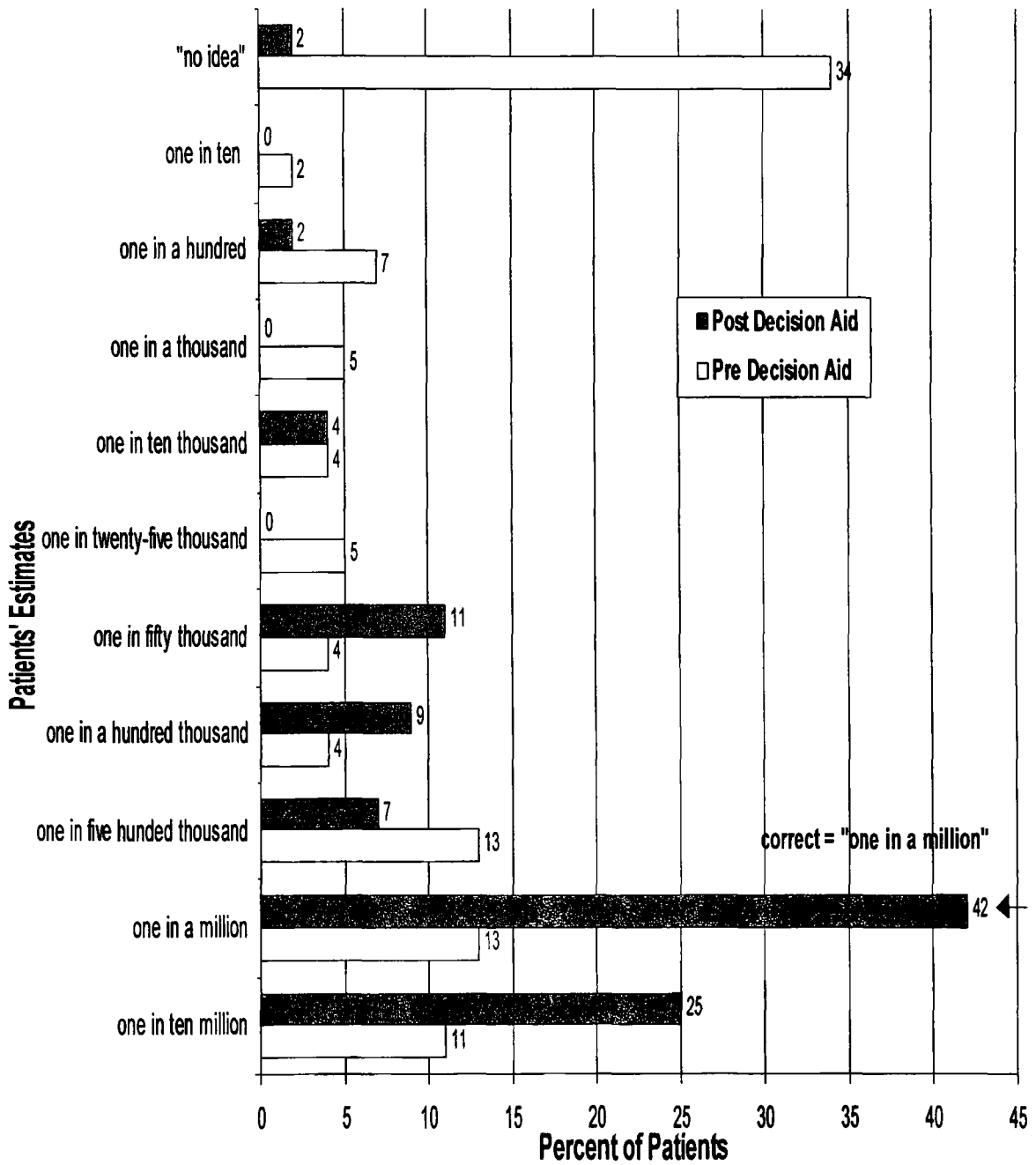


The correct answer is shown by an arrow on this and following charts. Page 99

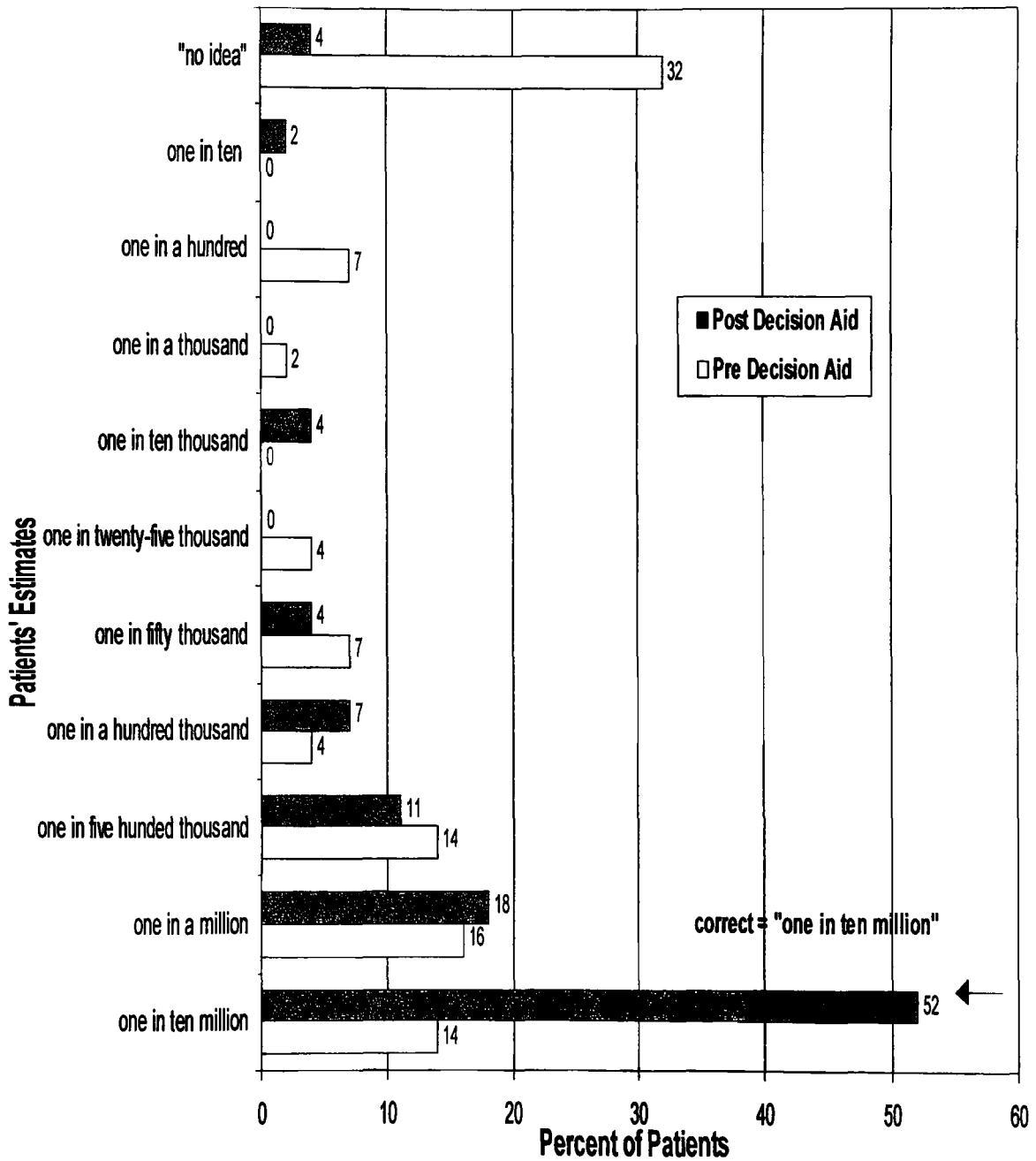
**Figure 3. Patients' Estimates of the Total Number Transfused with Self-Donated Blood Choice, Pre and Post Decision Aid**



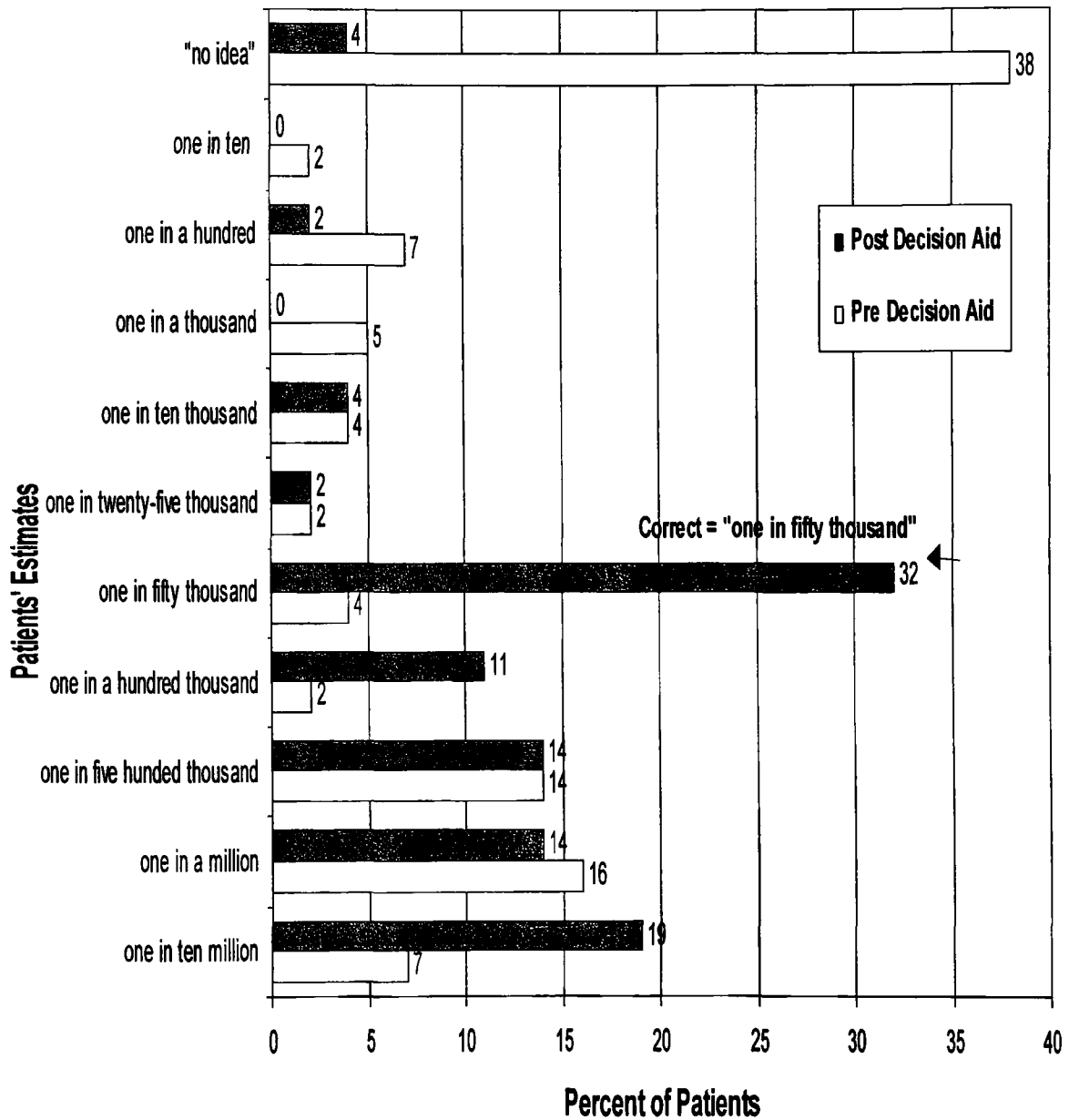
**Figure 4. Patients' Estimates of the Chance of AIDS with Volunteer-Donated Blood Choice, Pre and Post Decision Aid**



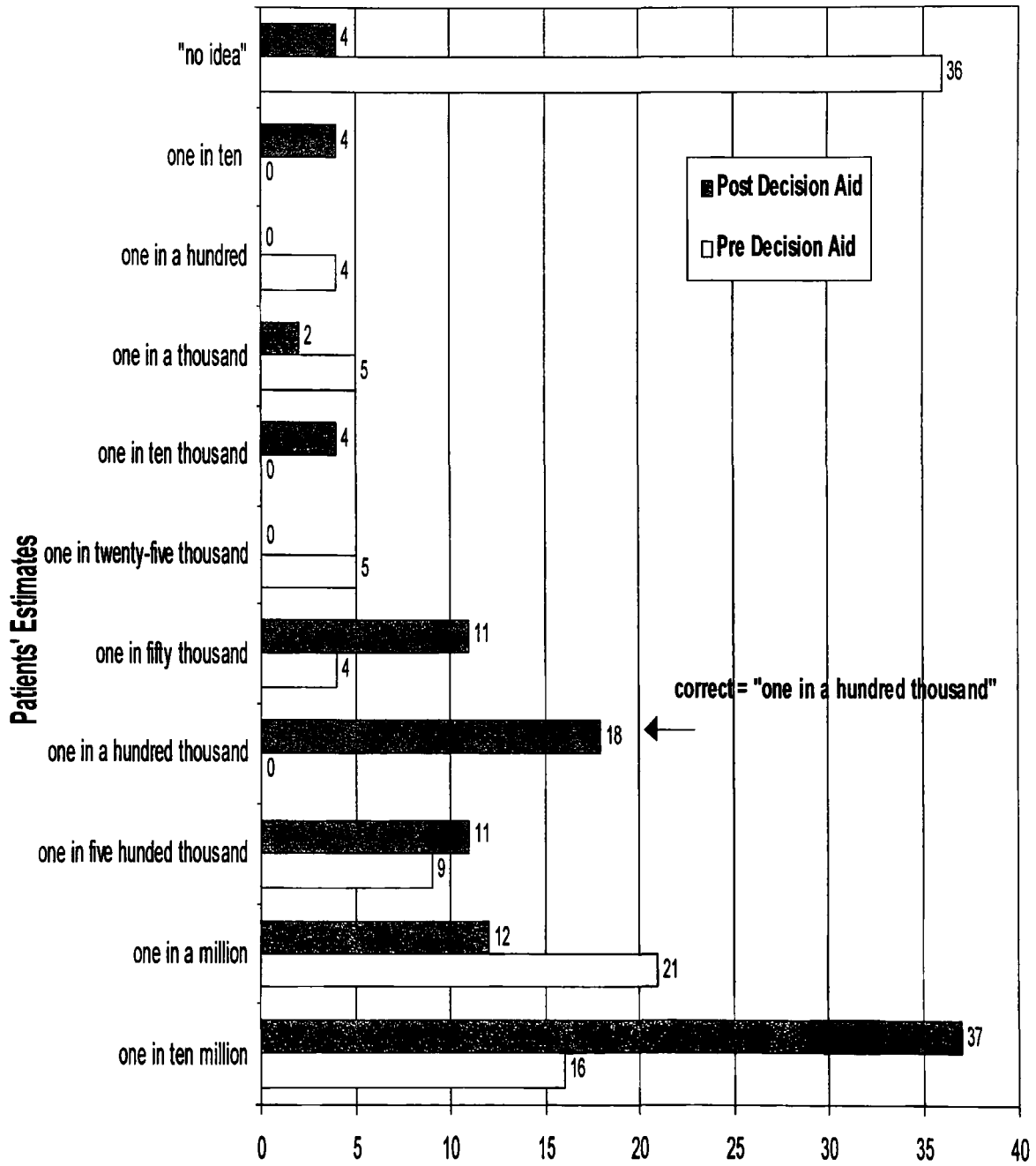
**Figure 5. Patients' Estimates of the Chance of AIDS with Self-Donated Blood Choice, Pre and Post Decision Aid**



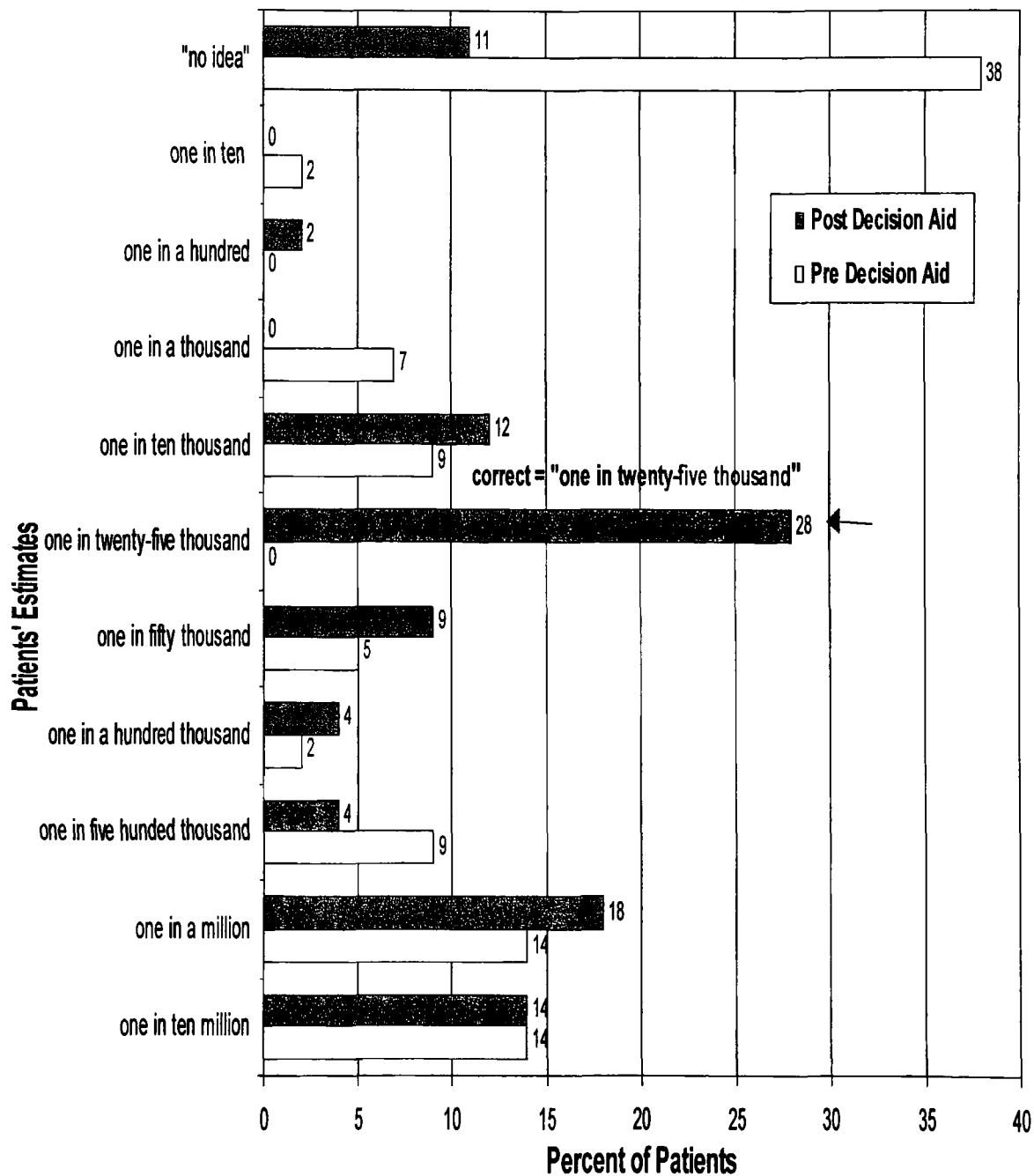
**Figure 6. Patients' Estimates of Chance of Hepatitis with Volunteer-Donated Blood Choice, Pre and Post Decision Aid**



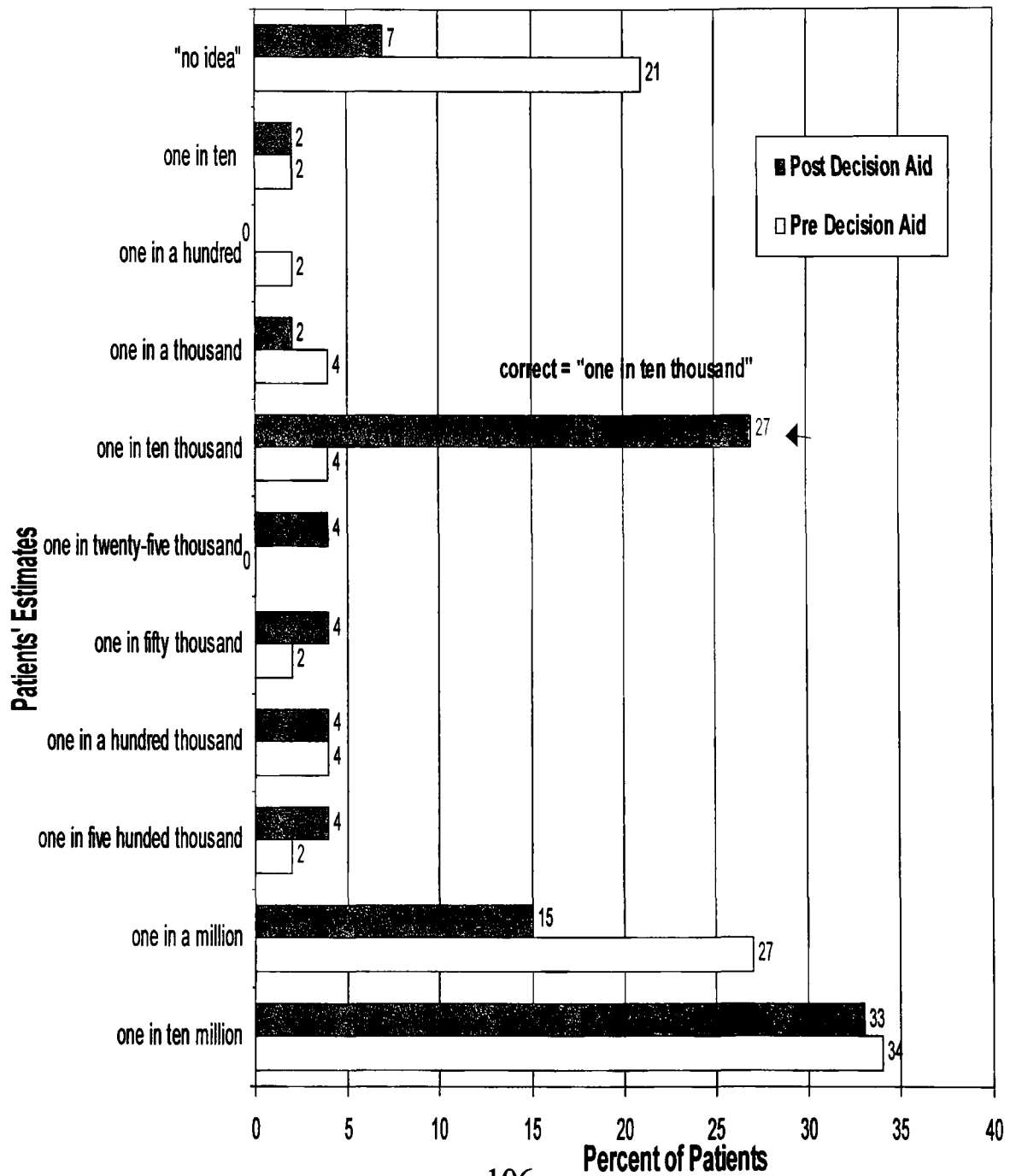
**Figure 7. Patients' Estimates of the Chance of Hepatitis with Self-Donated Blood Choice, Pre and Post Decision Aid**



**Figure 8. Patients' Estimates of Chance of an Immediate Reaction with Volunteer- Donated Blood Choice, Pre and Post Decision Aid**



**Figure 9. Patients' Estimates of the Chance of an Immediate Reaction with Self-Donated Blood Choice, Pre and Post Decision Aid**



## **Appendices**

- 1. Errata- Booklet and questionnaires**
- 2. Decision Aid Booklet: "Making Choices: Blood Transfusion in Heart Surgery"**  
**(reduced in size by 20%)**
- 3. Decision Aid Audiotape Script**
- 4. Patient Information Sheet and Consent Form**
- 5. Baseline Questionnaire**
- 6. Post-Decision Aid Questionnaire**

## Errata

### 1. Decision Aid Booklet

- first page (unnumbered) "press the play button" is repeated
- page 10: "58%" was missing (written by hand)

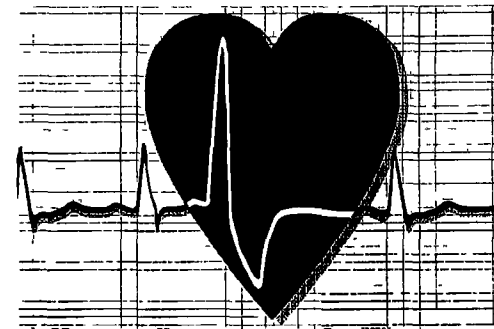
### 2. Baseline questionnaire

- page 14, question 11 should read as follows: "If I choose to accept volunteer-donated blood for use during or after surgery, my chance of having an immediate reaction ( either a wrong blood or an allergic reaction) is:

- page 15, question 12 should read as follows: "If I choose to self-donate blood before surgery, my chance of having an immediate reaction (either a wrong blood or an allergic reaction) is:

- ### 3. Post-Decision Aid questionnaire: The above corrections apply to page 13 (question 11) and page 14 (question 12).

**Making Choices:  
Blood Transfusion in Heart Surgery**



**A DECISION AID FOR PATIENTS**

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## Welcome !

This workbook and cassette tape prepare you for a discussion with your doctor about the pros and cons of two alternatives for blood transfusion at the time of your surgery: donated blood from volunteers and self-donated blood (autologous).

1. Set aside 30 minutes.
2. Have a pencil ready to use.
3. Place the cassette in a tape recorder. Press the play button.
4. Press the play button.
5. Stay on the page until you are asked to turn to the next page.

### Please Note:

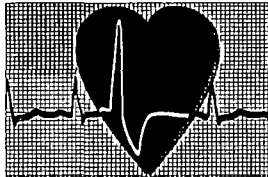
Research studies that support statements are referenced by numbers such as "1". The complete list of references is at the back of this workbook.

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- 1 Overview**
- 2 About Blood and Blood Loss**
- 3 Blood Transfusions**
- 5 Approaches to Replacing Blood Loss**
- 6 #1: Donated Blood from Volunteers**
- 9 #2: Self-donated Blood (autologous)**
- 13 Summary of the Pros and Cons**
- 14 Steps in Decision Making**
- 15 Scientific References**
- 16 Appendix: Calculation of Risks of Transfusion**

## This workbook is for you if you are :

- **having heart surgery** (bypass or valve surgery)
- **wondering about** the approaches to **blood transfusion**
- **wondering which** of the approaches is best for you



## You will learn about

- blood transfusion in surgery;
- the pros and cons of two approaches to replacing blood loss:
  - #1) donated blood from volunteers
  - #2) self-donated blood (autologous)
- steps to decide with your doctor which approach is best for you.

## What does blood do ?

- essential for health;
- carries oxygen to the body;
- oxygen carried by hemoglobin in red blood cells;
- adults have about 5 litres (or nine pints) of blood.

## What happens if I lose blood and it isn't replaced ?

### *If you lose a little blood...*

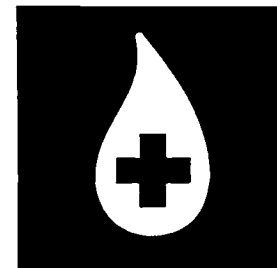
- you may have no reaction

### *If you lose a little more blood...*

- possibly weak and tired

### *If you lose a moderate amount of blood...*

- chest pain
- shortness of breath



### *If you lose a lot of blood...*

- risk of heart attack and death is increased

## What is a blood transfusion ?

- **Transfusions** replace blood lost during **surgery**;
- **given** through a needle into a vein in **your arm** (intravenously);
- measured in units;
- one unit of blood is 300 ml (10 fluid ounces);
- each unit is given in a separate bag and comes from a separate donor.



## How does a blood transfusion help ?

- useful for people who lose a lot of blood;
- reduce your chance of problems from too much blood loss
- people who lose a small amount of blood don't need a blood transfusion.

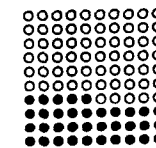
## Will I need a blood transfusion ?

Depends on.

- your health;
- the difficulty of the surgery;
- how much blood you lose; and
- practices in your hospital.

About 35 of every 100 patients having heart surgery need at least one transfusion.

65 out of 100  
will not need  
a transfusion



35 out of 100  
will need a  
transfusion



- those needing transfusion usually get on average 2 units of blood
- no way of knowing before surgery whether **you** will need a blood transfusion

## Approaches to replacing blood loss :

### During surgery, your medical team may use:

- recycling your blood lost during surgery using a cell salvage machine (autotransfusion);
- blood dilution in which blood is removed, IV fluids are given, and blood is returned (hemodilution);  
or
- medications that promote blood clotting (such as aprotinin).



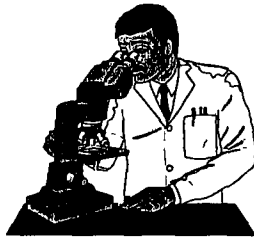
### Before surgery, you may wish to consider:

blood donated from anonymous volunteers;  
or  
donating your own blood a few times in the weeks before surgery.

**#1: DONATED BLOOD FROM  
VOLUNTEERS**

## How is the blood collected and tested ?

- anonymous, unpaid, volunteer donors;
- all potential blood donors have to answer a screening questionnaire, to make sure they are healthy; and
- all donated blood is tested in a laboratory to detect known infectious diseases (such as hepatitis and HIV).



## What are the pros of blood donated from volunteers ?

- widely available and convenient;
- free of charge;
- can be given quickly if you need blood.

## What are the cons of donated blood from volunteers ?

- minor side effects such as fever and chills<sup>1,10,12</sup> (1 in 100 transfusions)
- infections not yet discovered
- complications are described below :

	Chance out of 1 million patients	
	No. getting the complication	No. <u>not</u> getting the complication
<b>Number of Immediate Reactions</b>	43	999,957
<ul style="list-style-type: none"> <li>• wrong blood reaction (37)<sup>13</sup></li> <li>• allergy to blood (5)<sup>8,12</sup></li> <li>• storage infection (1)<sup>7,12,15</sup></li> </ul>		
<b>Deaths from Immediate Reactions</b>	2	
<b>Number of Delayed Infections</b>	20	999,980
<ul style="list-style-type: none"> <li>• Hepatitis- liver disease<sup>5</sup> (18)</li> <li>• HIV-AIDS (1)<sup>6,12</sup></li> <li>• HTLV- leukemia, nerve destruction (1)<sup>5</sup></li> </ul>		
<b>Deaths from Delayed Reactions</b>	3	

Adding all the known risks together, the chance of getting ill after being transfused with blood from volunteers is 63 per million patients having surgery.

The chance of dying immediately from a transfusion is 2 per million and the additional chance of dying from a blood transfusion in the next 10 years is 3 per million<sup>5-15</sup>.

## #2: SELF-DONATED BLOOD (AUTOLOGOUS)



What is it?

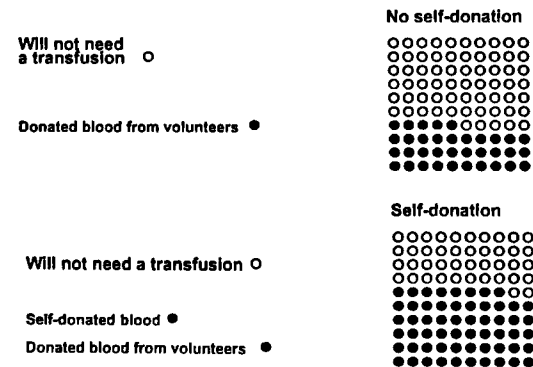
- donate your own blood 1 to 4 times in the weeks before your surgery;
- get your own blood back first.

## Will I get *only* my own blood if I need a transfusion ?

- every effort will be made to use **only** your blood;
- you may need more blood than was collected;
- donated blood from volunteers may also have to be used.

## What are the pros of self-donated blood ?

- free of charge.
- reduces your chance of getting **donated blood from anonymous volunteers** from 35% to 8% in the average hospital;
- but will increase your chances of getting any transfusion (usually your own blood) from 35% to *58%*



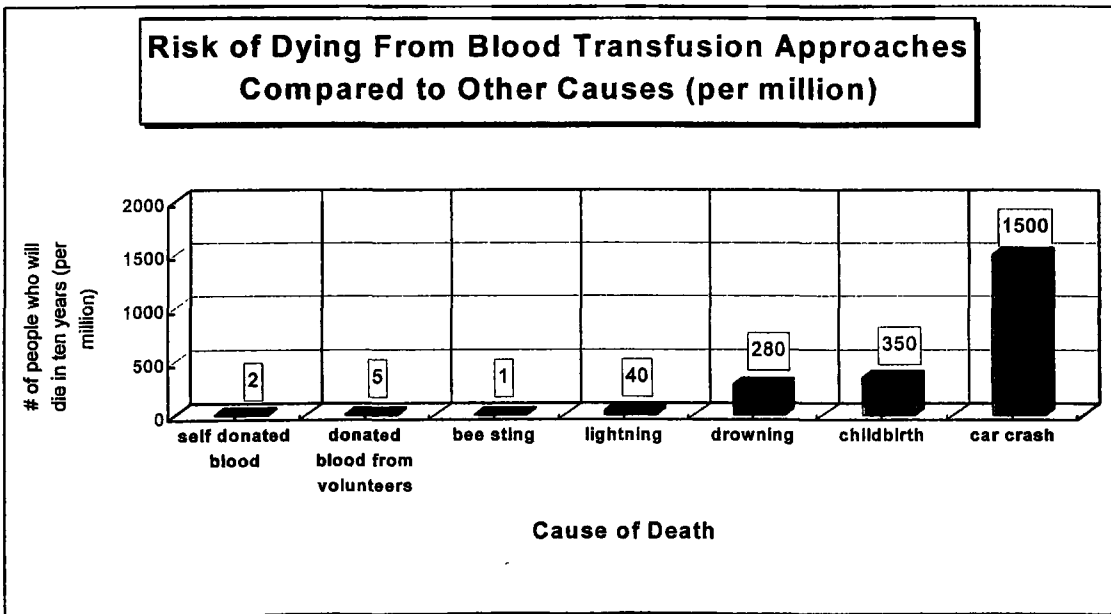
## What are the cons of self-donated blood ?

- inconvenience;
- may need to be hospitalized for fainting or chest pain when donating the blood (40 per million donations).<sup>9</sup>
- complications described below:

	Chance out of 1 million patients getting the complication	No. <u>not</u> getting the complication
<b>Number of Immediate Reactions</b>	71	999,929
<ul style="list-style-type: none"> <li>• wrong blood reaction (69)<sup>13</sup></li> <li>• allergy to blood (1)<sup>6,12</sup></li> <li>• storage infection (1)<sup>7,12,15</sup></li> </ul>		
<b>Deaths from Immediate Reactions</b>	2	
<b>Number of Delayed Infections</b>	5	999,995
<ul style="list-style-type: none"> <li>• Hepatitis- liver disease (5)<sup>5</sup></li> <li>• HIV-AIDS (nearly 0)<sup>6,12</sup></li> <li>• HTLV- leukemia, nerve destruction (nearly 0)<sup>5</sup></li> </ul>		
<b>Deaths from Delayed Infections</b>	nearly 0	

Adding all the known risks together, the chance of getting ill after being transfused is **76 per million** patients having surgery.

The chance of dying immediately from a transfusion is **2 per million** and the additional chance of dying from a blood transfusion in the next 10 years is close to zero.



# Summary of Pros and Cons

Options	Chance of having a transfusion ● donated ○ self-donated ○ no transfusion	Chance of complication per million patients		Chance of death per million patients		Convenience	Cost	Other
		Immediate Reactions	Delayed Infections	Immediate	Delayed			
Donated blood from volunteers	○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ●●●●●●●●●●●● ●●●●●●●●●●●● ●●●●●●●●●●●● ●●●●●●●●●●●●	43	20	2	3	no extra preparation	free	Possible undiscovered infections
Self-donated blood (autologous)	○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ○○○○○○○○○○○ ●●●●●●●●●●●● ●●●●●●●●●●●● ●●●●●●●●●●●● ●●●●●●●●●●●●	71	5	2	nearly zero	trips to centre blood tests	free	possible fainting or chest pain

## STEPS IN DECISION MAKING

### Step 1: My questions and comments

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### Step 2: Who should decide?

- I should, after considering the opinions of my doctor, family, or others
- My doctor and I together
- My doctor
- Unsure

### Step 3: My overall leaning

- Unsure
- Donated blood from volunteers
- Self-donated blood (autologous)

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## Appendix: Calculation of Risks of Transfusion

The authors have based their estimates of risk on studies in the medical literature (references 5-15). The estimates are approximate, and serve as a general guide to making decisions.

### Assumptions:

35% of those who do not pre-donate blood will receive 2 units of blood.

50% of those who pre-donate blood will receive 2 units of their own blood. 8% of those who pre-donate blood will receive 2 units of their own blood and also 2 units of volunteer-donated blood.

### Complications:

wrong blood reaction (risk 1/19,000 fatal 1/800,000) ( ref.13)  
severe allergic reaction (risk 1/150,000 20% fatal) (ref. 8,12)  
hepatitis B (1/63,000) hepatitis C (1/103,000) (ref.5)  
HIV (1/913,000) (ref. 6)  
bacterial infection (1/1,000,000) (ref. 7,12,15)  
donation risk for self-donation (1/16,783) Risks include fainting and chest pain. (ref. 9)

The general form of the risk calculation is :

Number of patients out of a million affected=  
(number of units transfused)(risk per unit)(%transfused/100)  
(1,000,000)

### Example:

number of patients contracting hepatitis B out of a million receiving volunteer-donated blood=(2)(1/63,000)(.35)(1,000,000) =11

## AUDIOTEXT

### MAKING CHOICES: Blood transfusion in heart surgery

Welcome! My name is XXXXX and I'll be guiding you through this workbook. The information in the workbook and cassette tape are designed to prepare you for a discussion with your doctor about the pros and cons of two options for blood transfusion at the time of your surgery: donated blood from volunteers and self-donated blood (also called autologous blood).

It will take about 30 minutes to listen to the tape and review the workbook. You should have a pencil ready to use. Please stay on each page until you are asked to turn to the next page. If you have any questions that the workbook doesn't answer, you can write them down and discuss them when you next visit your doctor.

When you hear the following sound...

**“SOUND”**

...please turn to the next page in your workbook. You can stop the tape at any time if you're **not** ready to go to the next page.

Let's start by turning to page 1, the page right after the Table of Contents. This page is entitled "This workbook is for you if you are".

**Page 1:**

This workbook is for you if you're:

- having heart bypass or valve surgery.

- you're wondering about the options available for blood transfusion, and
- you're wondering which of the options is best for you.

In this workbook, you'll learn about:

- blood transfusion in surgery,
- the pros and cons of two options to replace blood loss: donated blood from volunteers and autologous or self-donated blood  
and
- steps to decide with your doctor which option is best for you.

Let's start by talking about blood and blood transfusions...

## "SOUND"

### Page 2:

Blood is essential for health and carries oxygen to the body. The oxygen is carried by the hemoglobin in your red blood cells. Adults have about 5 litres (or nine pints) of blood in their bodies.

If you lose blood and it isn't replaced your body may not get enough oxygen; the symptoms depend on how much blood you lose:

- **If you lose a little blood.....**you may have no reaction;
- **If you lose a little more blood.....**you may feel weak and tired;
- **If you lose a moderate amount of blood.....**you may have chest pain, shortness of breath;
- **If you lose a lot of blood and it isn't replaced.....**you may have a heart attack and death is a possibility.

**Page 3:**

Blood transfusions replace some of the blood lost during surgery. They are given through a needle into a vein in your arm (intravenously) and are measured in units. One unit of blood is 300 ml (10 fluid ounces) and each unit is given in a separate bag and comes from a separate donor.

Blood transfusions help when you lose blood by giving back the blood cells that have been lost so that your blood can carry more oxygen again. They reduce your chance of problems from too much blood loss. People who lose only a small amount of blood don't need a transfusion.

**“SOUND”****Page 4:**

Not everyone needs a blood transfusion. The chance that you'll need a blood transfusion depends on your health, the difficulty of the surgery, how much blood you lose and the practices in your hospital.

In most hospitals, about 35 of every 100 patients having heart surgery need at least one transfusion. This is shown by the block of 100 circles. Each block contains 100 circles, representing 100 people who have heart surgery. The black circles show how many of these people will need at least one blood transfusion.

Another way of saying the same thing is that 65 out of 100 people having heart surgery will not need a blood transfusion.

Most people who get transfused are given an average of two units of blood, although

some can need lots more. There is no way of knowing before surgery whether you'll need a transfusion or how many units you'll need.

### Page 5:

There are several ways to reduce the chance that you'll need a blood transfusion. Some of these options are used **during** surgery and others **before** surgery.

There are three methods that can be used during your surgery to reduce your chance of needing a blood transfusion. Your surgical team will decide which one is best for you, depending on your condition.

- recycling your lost blood during surgery using a cell salvage machine (called autotransfusion); the blood that you lose from your surgery will be saved and given back to you after the operation.
- blood dilution in which blood is removed at the time of surgery, intravenous fluids are given, and blood is returned after surgery (called hemodilution); or
- medications that promote blood clotting (such as aprotinin); they help you to lose less blood because you stop bleeding sooner

Each of these methods has its advantages and side effects. Your doctor will be able to tell you which, if any, of these methods are used in your hospital.

Even with these procedures, you may still need a transfusion during surgery. There are two options you may consider **before surgery**:

- choosing to use only blood donated from anonymous volunteers;
- or
- donating your own blood a few times in the weeks before your surgery (also called autologous donation).

**“SOUND”**

**Page 6:**

The first option is to use donated blood from volunteers and not pre donate your own blood.

**Page 7:**

These blood transfusions are from anonymous, unpaid, volunteer donors.

To keep the supply of blood safe:

- all potential blood donors have to answer a screening questionnaire to check that they are healthy, and
- all the donated blood is tested in a laboratory to detect known infectious diseases (such as hepatitis and HIV).

Donated blood is widely available in Canada and you don't have to pay for it. Blood transfusions can be given quickly if you need them.

Despite the extra measures that are in place to keep the blood supply safe, donated blood will never be totally risk-free.

Although the vast majority of transfusions of donated blood cause no harmful effects, they can cause side effects, blood reactions and infections. On the next page we present a table that summarizes the pros and cons of using donated blood.

**“SOUND”**

**Page 8/9:**

The most common side effects with transfusion of donated blood, are fever and chills. These side effects occur in about one of every 100 people transfused. Usually, they only last for one or two hours and then resolve completely. There are no long-term effects to your health from these reactions. In addition to the complications mentioned in the table in front of you , there may be other infections that appear in the future that have not yet been discovered. There is no way of knowing for sure whether new infections will develop and what the risks from these new infections will be .

The table in front of you summarizes the risks of donated blood, including what happens and the chance that the complications will occur.

The complications are divided into immediate reactions - problems that can occur almost immediately after receiving the blood, and delayed infections - problems that can occur some time later. Let's look at the **immediate reactions** first. A total of 43 out of one million patients having heart surgery might have some kind of immediate reaction to their transfusion. On the other hand, 999,957 patients would **not** have any reaction at all. However, there are three possible immediate complications that could occur.

Incompatible blood reactions occur if you are accidentally given the wrong type of blood. This usually occurs because of an error in the lab or on the ward. Your body attacks and destroys the donated blood cells. This happens to 37 out of every million patients having surgery. The symptoms include back and chest pain, nausea, vomiting, fever, low blood pressure, kidney failure, and internal bleeding. There is a 98% chance of surviving the reaction, without long-term effects to your health.

People can be allergic to someone else's blood. This happens to 5 out of every million

patients. The symptoms include a skin rash, itching, tongue swelling, abdominal pain, difficulty breathing, low blood pressure, and (sometimes) loss of consciousness. There is an 80% chance of surviving the reaction, with no long-term effects to your health.

One in one million patients might contract a bacterial infection from their transfused blood. This could happen because the blood became infected while it was being stored. This can cause fever and low blood pressure and can be fatal.

Now let's consider the **delayed infections** that might occur as a result of having a transfusion of donated blood. Most people (999,980 out of one million) will have no delayed infections at all. However, 20 out of one million patients receiving a transfusion of donated blood might experience one of the following delayed infections.

Hepatitis viruses which can be spread in blood transfusions include: hepatitis B, hepatitis C, and non-ABC hepatitis. These viruses occur in about 18 out of every million patients having transfusions for heart surgery and can cause an inflammation of the liver and symptoms that include nausea, loss of appetite, abdominal pain, or jaundice (which is yellowing of the skin). Some patients also develop joint pain, a rash, or itchy skin. Symptoms occur weeks to months after the transfusion.

Although most patients with hepatitis get better in a few weeks and return to normal, some (about one in every six) will develop chronic liver disease (or cirrhosis). The symptoms of cirrhosis include easy bruising and bleeding problems, yellow discoloration of the skin (jaundice), and swelling of the belly (ascites). Cirrhosis can be a fatal condition and has no known cure.

Human Immunodeficiency Virus (HIV) causes Acquired Immunodeficiency Syndrome (or AIDS), a disease that destroys the immune system and results in infections and tumours in the affected person. This happens in one out of every million patients .

Although there are now some treatments for AIDS, it's still a fatal disease. If someone gets HIV infection from a blood transfusion, they may feel well for 10 years before clinical AIDS appears

Human T-cell Lymphoproliferative Virus (HTLV) I and II can cause two diseases. The first condition, leukemia, is a cancer of the blood cells. The symptoms include fatigue, easy bruising and bleeding, swollen lymph nodes, and increased infections. The second condition, tropical spastic paraparesis, is a progressive destruction of the nerves to the arms and legs that causes weakness, tingling, and pains in the limbs. These viruses can occur in one out of every million patients having transfusions for heart surgery.

Adding all of the known risks together, your risk of getting ill after being transfused with blood from volunteers is 63 PER MILLION. The chance of dying immediately from a transfusion is 2 per million patients and the additional chance of dying from a transfusion related cause in the next ten years is 3 per million.

## **“SOUND”**

### **Page 10:**

The next option for blood transfusion is to donate your own blood, also called autologous donation.

In this option you would donate your own blood 1 to 4 times in the weeks before your surgery. If you need a transfusion during surgery, you'll get your own blood back first.

### **Page 11:**

While every effort will be made to use only your blood, it is possible that you may still

need more blood than was collected from you, and donated blood from volunteers may have to be used as well.

Self-donation is available free of charge.

Donating your own blood reduces your chance of getting donated blood from anonymous volunteers from 35% to 8% in the average hospital.

People who donate their own blood often have a lower than normal blood count before surgery. Therefore, although they are less likely to need blood donated by volunteers, they are more likely to need their own blood back. Thus, people who donate their own blood are actually more likely to need a transfusion than those who do not donate their own blood. However, the transfusion is most likely to be their own blood. They have a 50 out of 100 chance of receiving their own blood, 8 out of 100 of receiving donated blood from volunteers and a 42 out of 100 chance of needing no blood.

### “SOUND”

#### Page 12/13:

There are some other cons to self-donation. Self-donating blood can be inconvenient. You'd need to come in to the blood collection centre before your surgery to have blood collected. This involves the insertion of a needle into a vein in your arm and removal of some of your blood. You might feel weak and light headed as a result of this procedure. You'd also need more blood tests before your surgery to monitor your blood. It's possible that you would need to be hospitalized for fainting or chest pain when donating the blood. There are no long term effects to your health once you recover. This could happen 40 times for every million units donated.

Now let us consider the more serious consequences of self-donation. These occur

because self-donated blood is not without risk. As was the case with volunteer donated blood, the possible complications are divided into immediate reactions and delayed infections. When you look at the **immediate reactions**, you can see that the risk of these reactions is actually higher in people who pre donate their own blood than in those who decide not to pre donate. This is because people who pre donate their own blood are more likely to receive a transfusion (as we just discussed). A total of 71 out of one million patients might have some kind of immediate reaction to their transfusion. On the other hand, 999,929 patients would **not** have any reaction at all. The possibility of experiencing an incompatible reaction from being given the wrong blood is 69 per million patients. However, the chance of an allergic reaction is nearly zero, compared to 5 per million patients who use volunteer donated blood. The risk of an infection from bacteria introduced in the storage process is the same as volunteer donated blood: one in one million patients having surgery. If you now look at the **delayed infections**, you can see that the risks of these infections are lower in people who pre donate because this sort of infection is not transmitted by self-donated blood. Most people (999,996 out of one million) will have no delayed infections at all. Only 4 out of one million patients receiving a transfusion might experience any kind of delayed infection. The risk of contracting hepatitis decreases from 18 to 4 per million patients and the chance of contracting HIV or HTLV is nearly zero.

Adding all the known risks together, your risk of getting ill after being transfused is 76 per million patients having surgery. The chance of dying immediately from a transfusion is 2 per million and the additional chance of dying from a blood transfusion in the next ten years is close to zero.

**“SOUND”**

**Page 14/15:**

This bar chart summarizes your chances of dying in the next ten years from both of the transfusion options and compares these risks to other causes of death. These figures combine the chances of death from immediate reactions and delayed infections. Starting at the left, you can see that the chance of dying within ten years from predonating blood is 2 per million patients, while for volunteer donated blood it is 5 per million. These are compared to deaths from other causes such as bee sting (1 per million), lightning (40 per million), childbirth (350 per million) and death from a car crash (1500 per million).

**“SOUND”**

**Page 16/17**

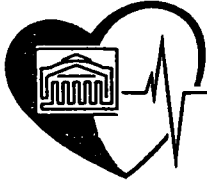
In summary, people who have heart surgery may require a blood transfusion to replace blood lost during the surgery. There are two options available for blood transfusions for you to consider.

One option is to use donated blood from volunteers. If you choose this option you would have a 35 out of 100 chance of needing a transfusion and getting blood from volunteers. Forty-three out of one million patients may have an immediate reaction to donated blood, and 20 out of one million may have a delayed infection as a result of being transfused. The chances of dying immediately from donated blood is about 2 per million patients. The chances of dying within 10 years from transfusion related causes is about 3 per million patients. Donated blood from volunteers is convenient: it requires no extra preparation before you go in for your surgery. It is free of charge,

however, there may be infections associated with this option that have not yet been discovered and which may appear in the future.

The other option is to use self-donated blood. If you choose to self-donate you would reduce your chance of receiving donated blood from volunteers from 35 to 8 out of 100. Seventy-one out of one million patients may have an immediate reaction to predonated blood, but only 5 out of one million may have a delayed infection as a result of being transfused. The chances of dying immediately from predonated blood is about 2 per million patients. The chances of dying within 10 years from transfusion related causes is nearly zero. If you chose to predonate, you would need to make a number of trips to the blood collection centre to collect your blood and you would need more blood tests. There are no costs associated with this option, but you might experience fainting or chest pain as a result of the blood collection procedure.

Take time to consider the information contained in this table. Feel free to review the tape and/or booklet. Then take a few moments to complete the three steps in decision making described on the next page of the booklet. Of course, you will want to discuss the options with your doctor before you make a final decision, but try to decide which way you are leaning. For those who wish to have more information, a list of references is included at the end of the booklet. The method of calculating risks is included in the Appendix. Remember, any choice you make is a reasonable one.



## **Patient Information Sheet and Consent Form**

### **Validation of a Decision Aid for the Choice of Allogeneic versus Autologous Transfusion in Patients Undergoing Open Heart Surgery**

**Principal Investigators: Dr. Fraser Rubens  
Dr. James Robblee**

**Co-investigators/Supervisors Dr. F. Curry Grant (MSc Candidate)  
Dr. Andreas Laupacis  
Dr. Annette O'Connor  
Dr. Phil Wells**

#### **Introduction:**

You have been invited to participate in a research project entitled: **A Validation of a Decision Aid for the Choice of Allogeneic versus Autologous Transfusion in Patients Undergoing Open Heart Surgery.** The purpose of this study is to evaluate a booklet and audiotape which have been designed to inform patients about the risks and benefits of the two methods of transfusion: self donating your own blood before surgery or receiving blood donated by volunteers. You will read the booklet while listening to an explanation on an audiotape and learn about the pros and cons of the two choices. We hope that the information in this decision aid will clarify the risks and benefits of each method, and make this difficult decision easier for you.

#### **Procedure:**

The total time required will be about 1 1/4 hours, including an interview for 20 minutes, listening to the tape and reading to booklet for 2 hour, and a second interview for 20 minutes. The second interview may be conducted by telephone or in person at a clinic follow-up visit. You will not be required to make a special trip to the Heart Institute for this study. We will interview you before and after you use the tape and booklet to determine how it affects your understanding of the risks and benefits of transfusion methods, your choice, your opinions about the choice and your opinions about the booklet and tape.

The decision aid was developed by Doctors Fraser Rubens and Jim Robblee from the Ottawa Heart Institute, and Doctors Andreas Laupacis, Annette O'Connor, Phil Wells and Finlay McAlister from the Clinical Epidemiology Unit of the Ottawa Hospital.

The results of this pilot study will help us improve the decision aid before it is tested on a larger number of patients.

**Risks and Discomforts of Participation:**

There is no risk or discomfort involved in participation in this study. There are no extra medical tests or procedures. The only requirement is the small amount of time to respond to the questionnaires and to read and listen to the booklet and tape.

**Benefits of Participation:**

You may gain knowledge of the risks and benefits of transfusion methods. You will be contributing to our knowledge of how patients make decisions, and how health practitioners can help them to make appropriate decisions.

**Compensation/Remuneration:**

There will be no payment for participating in this research. You will be reimbursed for parking costs.

By participating in this study and signing this consent form, you are not waiving your legal rights.

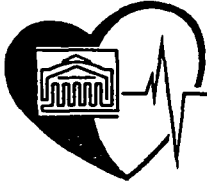
**Confidentiality:**

Information gathered from you and the questionnaires completed by you will be kept confidential. Your health records will be reviewed only to see which transfusion method you choose. We will need to record the information on your hospital card to be able to contact you for the follow-up questionnaire, and to describe in general the group of patients who participated, with respect to areas such as age, sex and education. The questionnaires will be numbered, and your name will not be known by those analysing the data. Your records will be kept in a secure place under lock and key. You will not be identified in any publications or presentations. No identifying information will leave the hospital.

**Participation:**

**Participation in research is completely voluntary.** You are free to choose to participate or not to participate in this research study. If you agree to participate in this study, you may choose to withdraw your participation at any time. This will not affect your present or future care at this hospital. You may also refuse to answer any specific questions.

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## University of Ottawa Heart Institute

### Consent to Participate in Research

I understand that I am being asked to participate in a research study to evaluate a decision aid for heart patients faced with the choice of receiving volunteer-donated blood or self-donated blood. I have read this Information Sheet and Consent Form. I understand that participation is voluntary. All possible risks and benefits have been explained. I may withdraw at any time at my discretion, and refusal to participate will not jeopardize future treatment. My identity will be kept confidential. All my questions at this time have been answered to my satisfaction. If I or any of my family members have any further questions about this study, we may contact Dr. Fraser Rubens at (613)-761-4720.

**This protocol has been approved by the Human Research Ethics Committee of the University of Ottawa Heart Institute. The Committee considers the ethical aspects of all Institute research projects using human subjects. If you wish, you may talk to the Chair of the Human Research Ethics Committee at 761-4885.**

I have read and understand this consent form. I will receive a signed copy of this consent form.

I voluntarily agree to participate in this study.

**Patient's Name**

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**Patient's Signature**

---

**Date**

---

**Witness Signature**

---

**Investigator's Signature**

---

**Date**

---

Please Do This First!

1

**Patient's Opinion Survey  
About " Making Choices: Blood Transfusion in Heart Surgery  
A Decision Aid for Patients"  
Baseline Questionnaire**

**Study ID Number** \_\_\_\_\_

**Attending Surgeon** \_\_\_\_\_

**Date** \_\_\_\_\_

DD/MM/YY

**Demographic and Clinical Data**  
**“Making Choices: Blood Transfusion in Heart Surgery” Decision**  
**Aid Study**

1. Gender: Female\_\_ Male\_\_
2. Age \_\_\_ years
3. Marital Status
  - Married or common law
  - Single
  - Widowed or widower
  - Divorced or separated
4. Language most frequently spoken
  - English
  - French
  - Italian
  - Chinese
  - German
  - Other- please specify \_\_\_\_\_
5. Highest grade or level of education
  - Less than grade 9
  - Some high school
  - High school diploma
  - Trade certificate/diploma
  - Some college
  - College diploma
  - Some university
  - University degree
6. Type of surgery planned:
  - Coronary Bypass
  - Valve replacement
  - Valve repair
  - Combined bypass and valve surgery
7. Have you ever had heart surgery before?
  - Yes
  - No
8. Have you ever donated your own blood for surgery in the past?
  - Yes
  - No

### A. What do I know about blood transfusion for heart surgery?

**"Self-donated blood" means blood which a patient donates prior to surgery for his or her own later use during or after surgery.**

**"Volunteer-donated blood" means blood donated by a healthy volunteer for use by patients.**

**Please answer "true", "false", or "unsure" for each of the following questions: Circle your response to each question.**

1. All patients having heart surgery are transfused.                    true    false    unsure
2. Transfusions replace blood lost during or after surgery.    true    false    unsure
3. Patients losing a small amount of blood are transfused.    true    false    unsure
4. The advantages of volunteer-donated blood are:
  - a) It is convenient for the patient.                                    true    false    unsure
  - b) It can be given quickly if needed.                                    true    false    unsure
  - c) Serious complications are experienced by fewer than one in ten thousand patients.                                    true    false    unsure
5. The disadvantages of volunteer-donated blood are:
  - a) Infections may be transmitted by blood.                                    true    false    unsure
  - b) The wrong blood may be given in error.                                    true    false    unsure
  - c) Acquired Immune Deficiency Syndrome (AIDS) is a frequent complication.                                    true    false    unsure

6. The advantages of self-donated blood are:

- |   |      |       |        |
|---|------|-------|--------|
| a) It reduces the chance of contracting a viral disease such as AIDS or hepatitis from transfusions.                | true | false | unsure |
| b) There is a lower chance of being transfused with <u>any</u> blood (either my blood or volunteer-donated blood ). | true | false | unsure |
| c) There is no chance of receiving the wrong blood by error.  | true | false | unsure |

7. The disadvantages of self-donated blood are:

- |  |      |       |        |
|--|------|-------|--------|
| a) Donating blood may cause symptoms such as fainting or chest pain. | true | false | unsure |
| b) There is still a chance of receiving volunteer-donated blood.     | true | false | unsure |
| c) Extra blood tests and trips to the Centre will be required.       | true | false | unsure |



### C. My opinion about treatment choices

We would like to know what your opinion is about your transfusion options at present.

**If your doctor asked you right now to make a choice about transfusion methods, please show where you would be on the scale below by placing a check mark in one of the boxes. Show how strongly you feel about your choice by where you place the check mark.**

- If you definitely wish to donate blood for your own use, check the box far to the right.
- If you definitely wish to receive blood donated by a volunteer, check the box far to the left.
- If you are uncertain, check the centre box

--	--	--	--	--	--	--	--	--	--	--

Volunteer-  
donated  
blood

Uncertain

Self-  
donated  
blood

#### D. My difficulty making this choice

Now, thinking about the choice you have just made, please look at the following comments made by some people when making decisions about transfusion methods.

Please show how strongly you agree or disagree with these statements by circling the number from 1 (strongly agree) to 5 (strongly disagree) which best shows how you feel about the choice you just made.

1. This decision is easy for me to make	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2. I'm sure what to do in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3. It's clear what choice is best for me	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4. I'm aware of the options I have in this decision.	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5. I feel I know the pros of <u>volunteer-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
6. I feel I know the pros of <u>self-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

7. I feel I know the cons of <u>volunteer-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
8. I feel I know the cons of <u>self-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
9. I am clear about <u>how important</u> the pros of self-donated blood are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
10. I am clear about <u>how important</u> the cons of self-donated blood are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
11. I am clear about which is <u>more</u> important to me (the pros or the cons)	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
12. I have enough information about what <u>other</u> patients decide	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
13. I am making this choice without any pressure from others	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Agree

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>14. I have the right amount of support from others in making this choice</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>15. I have enough advice about the options</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

The following questions are for those who have made a decision about whether or not to self-donate blood

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>16. I feel I have made an informed choice</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>17. My decision shows what is important to me</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>18. I expect to stick with my decision</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>19. I am satisfied with my decision</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

**E. What I know about the risks associated with transfusions:**

**In the next four questions, please check the answer which shows your opinion about the number of people out of 100 having heart surgery who will need a transfusion.**

1. Out of 100 people who choose to accept volunteer-donated blood, the number needing at least one transfusion during or after heart surgery is:

- |  |  |
|--|--|
| <input type="checkbox"/> 0 out of 100                  | <b>Nobody needs a transfusion</b>              |
| <input type="checkbox"/> 1 to 10 out of 100            |  |
| <input type="checkbox"/> 11 to 20 out of 100           |  |
| <input type="checkbox"/> 21 to 30 out of 100           | <b>About one quarter need a transfusion</b>    |
| <input type="checkbox"/> 31 to 40 out of 100           |  |
| <input type="checkbox"/> 41 to 49 out of 100           |  |
| <input type="checkbox"/> 50 out of 100                 | <b>About one half need a transfusion</b>       |
| <input type="checkbox"/> 51 to 60 out of 100           |  |
| <input type="checkbox"/> 61 to 70 out of 100           |  |
| <input type="checkbox"/> 71 to 80 out of 100           | <b>About three quarters need a transfusion</b> |
| <input type="checkbox"/> 81 to 90 out of 100           |  |
| <input type="checkbox"/> 91 to 99 out of 100           |  |
| <input type="checkbox"/> 100 out of 100                | <b>Everybody needs a transfusion</b>           |
| <br>   |  |
| <input type="checkbox"/> I have no idea of the number. |  |

2. If I choose to accept volunteer-donated blood my chance of being transfused, compared to others who accept volunteer-donated blood is:

- Much lower than other patients' chances
- Lower than other patients' chances
- The same as other patients' chances
- Greater than other patients' chances
- Much greater than other patients' chances

3. Out of 100 people who choose to self-donate blood, the number needing at least one transfusion during or after heart surgery is:

- |  |  |
|--|--|
| <input type="checkbox"/> 0 out of 100                  | <b>Nobody needs a transfusion</b>              |
| <input type="checkbox"/> 1 to 10 out of 100            |  |
| <input type="checkbox"/> 11 to 20 out of 100           |  |
| <input type="checkbox"/> 21 to 30 out of 100           | <b>About one quarter need a transfusion</b>    |
| <input type="checkbox"/> 31 to 40 out of 100           |  |
| <input type="checkbox"/> 41 to 49 out of 100           |  |
| <input type="checkbox"/> 50 out of 100                 | <b>About one half need a transfusion</b>       |
| <input type="checkbox"/> 51 to 60 out of 100           |  |
| <input type="checkbox"/> 61 to 70 out of 100           |  |
| <input type="checkbox"/> 71 to 80 out of 100           | <b>About three quarters need a transfusion</b> |
| <input type="checkbox"/> 81 to 90 out of 100           |  |
| <input type="checkbox"/> 91 to 99 out of 100           |  |
| <input type="checkbox"/> 100 out of 100                | <b>Everybody needs a transfusion</b>           |
| <br>   |  |
| <input type="checkbox"/> I have no idea of the chance. |  |

4. If I choose to self-donate blood, my chance of being transfused, compared to others who self-donate blood is:

- Much lower than other patients' chances
- Lower than other patients' chances
- The same as other patients' chances
- Greater than other patients' chances
- Much greater than other patients' chances

### Thinking About Chances: What the Numbers Mean

In the following questions, you will be asked to give your opinion about the chances of complications in patients having heart surgery. We are considering the chance of a complication happening out of a specific number of patients having heart surgery.

#### Chance of complications

#### For comparison, this is like one person in:

One in ten million patients	Ontario (extremely small chance)
One in a million patients	Ottawa-Hull
One in five hundred thousand	Ottawa plus Kanata and Nepean
One in a hundred thousand patients	A large city such as Nepean
One in fifty thousand patients	A city such as Kanata
One in twenty-five thousand patients	A large sports stadium
One in ten thousand patients	A town such as Hawkesbury
One in a thousand patients	A village such as Chalk River
One in a hundred patients	A movie theatre crowd
One in ten	A sports team (extremely large chance)

In other words, "one in ten million" is a very low chance - it is not very likely to happen, and "one in ten" is a very high chance - it is very likely to happen.

6. If I choose to accept volunteer-donated blood during or after heart surgery, my chance of getting AIDS (Acquired Immune Deficiency Syndrome) is:  
 \_\_\_\_\_ (please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <input type="checkbox"/> I have no idea of the chance |                           |

7. If I choose to accept volunteer-donated blood during or after heart surgery, my chance of contracting viral hepatitis B or C is:  
 \_\_\_\_\_(please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <br>  |                           |
| <input type="checkbox"/> I have no idea of the chance |                           |

8. If I choose to accept volunteer-donated blood during or after surgery, my chance of contracting AIDS (Acquired Immune Deficiency Syndrome) or viral hepatitis B or C is:

- Much lower than other patients' chances
- Lower than other patients' chances
- The same as other patients' chances
- Greater than other patients' chances
- Much greater than other patients' chances

9. If I choose to self-donate blood, my chance of contracting AIDS (Acquired Immune Deficiency Syndrome) due to receiving additional volunteer-donated blood is:  
 \_\_\_\_\_(please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | very likely to happen     |
| <br>  |                           |
| <input type="checkbox"/> I have no idea of the chance |                           |

10. If I choose to self-donate blood, my chance of contracting viral hepatitis B or C due to receiving additional volunteer-donated blood is closest to:

\_\_\_\_\_ (please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <br>  |                           |
| <input type="checkbox"/> I have no idea of the chance |                           |

11. If I choose to accept volunteer-donated blood before or during surgery, my chance of having an immediate reaction (either a wrong blood or an allergic reaction) is:

\_\_\_\_\_ (please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <br>  |                           |
| <input type="checkbox"/> I have no idea of the chance |                           |

12. If I choose to self-donate blood during or after surgery, my chance of having an immediate reaction (either a wrong blood or an allergic reaction) is:  
 \_\_\_\_\_(please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <br>  |                           |
| <input type="checkbox"/> I have no idea of the chance |                           |

13. The chance of having an immediate (either wrong blood or allergic) reaction is:

- Higher for those who choose volunteer-donated blood
- Higher for those who chose to self-donate blood
- Equal for those who choose self-donated or volunteer-donated blood

14. I have obtained experience about transfusions from the following: (please check all that apply)

- I have previously had one or more transfusion(s).
- I have had a complication of a transfusion
- A relative or close friend has had a transfusion.
- A relative or close friend has had a complication of a transfusion.

15. I have learned about transfusions from: (please check all that apply)

- The news media (newspapers, magazines, television, radio)
- Conversations with friends, relatives or acquaintances
- A health professional (nurse, doctor, pharmacist etc.)
- A personal search for information (library \_\_\_, internet \_\_\_, other (please specify)\_\_\_\_\_)

Thank you for completing the Baseline Questionnaire. You may now, at your convenience, read the booklet while listening to the audiotape. Then, please complete the Post Decision Aid Questionnaire

Please Complete This After Using the  
Decision Aid

**Patient's Opinion Survey**  
**About " Making Choices: Blood Transfusion in Heart Surgery**  
**A Decision Aid for Patients"**  
**Post Decision Aid Questionnaire**

**Study ID Number** \_\_\_\_\_

**Attending Surgeon** \_\_\_\_\_

**Date** \_\_\_\_\_  
DD/MM/YY

### A. What do I know about blood transfusion for heart surgery?

**"Self-donated blood" means blood which a patient donates prior to surgery for his or her own later use during or after surgery.**

**"Volunteer-donated blood" means blood donated by a healthy volunteer for use by patients.**

**Please answer "true", "false", or "unsure" for each of the following questions: Circle your response to each question.**

1. All patients having heart surgery are transfused.                    true    false    unsure
2. Transfusions replace blood lost during or after surgery.    true    false    unsure
3. Patients losing a small amount of blood are transfused.    true    false    unsure
4. The advantages of volunteer-donated blood are:
  - a) It is convenient for the patient.                                    true    false    unsure
  - b) It can be given quickly if needed.                                    true    false    unsure
  - c) Serious complications are experienced by fewer than one in ten thousand patients.                                    true    false    unsure
5. The disadvantages of volunteer-donated blood are:
  - a) Infections may be transmitted by blood.                                    true    false    unsure
  - b) The wrong blood may be given in error.                                    true    false    unsure
  - c) Acquired Immune Deficiency Syndrome (AIDS) is a frequent complication.                                    true    false    unsure

6. The advantages of self-donated blood are:

a) It reduces the chance of contracting a viral disease such as AIDS or hepatitis from transfusions.

true false unsure

b) There is a lower chance of being transfused with any blood (either my blood or volunteer-donated blood ).

true false unsure

c) There is no chance of receiving the wrong blood by error.

true false unsure

7. The disadvantages of self-donated blood are:

a) Donating blood may cause symptoms such as fainting or chest pain.

true false unsure

b) There is still a chance of receiving volunteer-donated blood.

true false unsure

c) Extra blood tests and trips to the Centre will be required.

true false unsure



### C. My opinion about treatment choices

We would like to know what your opinion is about your transfusion options at present.

**If your doctor asked you right now to make a choice about transfusion methods, please show where you would be on the scale below by placing a check mark in one of the boxes. Show how strongly you feel about your choice by where you place the check mark.**

- If you definitely wish to donate blood for your own use, check the box far to the right.
- If you definitely wish to receive blood donated by a volunteer, check the box far to the left.
- If you are uncertain, check the centre box

--	--	--	--	--	--	--	--	--	--	--

Volunteer-  
donated  
blood

Uncertain

Self-  
donated  
blood

#### D. My difficulty making this choice

Now, thinking about the choice you have just made, please look at the following comments made by some people when making decisions about transfusion methods.

Please show how strongly you agree or disagree with these statements by circling the number from 1 (strongly agree) to 5 (strongly disagree) which best shows how you feel about the choice you just made.

1. This decision is easy for me to make	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2. I'm sure what to do in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3. It's clear what choice is best for me	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4. I'm aware of the options I have in this decision.	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5. I feel I know the pros of <u>volunteer-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
6. I feel I know the pros of <u>self-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

7. I feel I know the cons of <u>volunteer-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
8. I feel I know the cons of <u>self-donated</u> blood	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
9. I am clear about <u>how important</u> the pros of self-donated blood are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
10. I am clear about <u>how important</u> the cons of self-donated blood are to me in this decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
11. I am clear about which is <u>more</u> important to me (the pros or the cons)	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
12. I have enough information about what <u>other</u> patients decide	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
13. I am making this choice without any pressure from others	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Agree

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>14. I have the right amount of support from others in making this choice</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>15. I have enough advice about the options</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

The following questions are for those who have made a decision about whether or not to self-donate blood

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>16. I feel I have made an informed choice</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>17. My decision shows what is important to me</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>18. I expect to stick with my decision</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<b>19. I am satisfied with my decision</b>	<b>Strongly Agree</b>	<b>Agree</b>	<b>Neither Agree Nor Disagree</b>	<b>Disagree</b>	<b>Strongly Disagree</b>

**E. What I know about the risks associated with transfusions:**

**In the next four questions, please check the answer which shows your opinion about the number of people out of 100 having heart surgery who will need a transfusion.**

1. Out of 100 people who choose to accept volunteer-donated blood, the number needing at least one transfusion during or after heart surgery is:

- |                          |                               |   |
|--------------------------|-------------------------------|---|
| <input type="checkbox"/> | 0 out of 100                  | <b>Nobody needs a transfusion</b>       |
| <input type="checkbox"/> | 1 to 10 out of 100            |   |
| <input type="checkbox"/> | 11 to 20 out of 100           |   |
| <input type="checkbox"/> | 21 to 30 out of 100           | About one quarter need a transfusion    |
| <input type="checkbox"/> | 31 to 40 out of 100           |   |
| <input type="checkbox"/> | 41 to 49 out of 100           |   |
| <input type="checkbox"/> | 50 out of 100                 | About one half need a transfusion       |
| <input type="checkbox"/> | 51 to 60 out of 100           |   |
| <input type="checkbox"/> | 61 to 70 out of 100           |   |
| <input type="checkbox"/> | 71 to 80 out of 100           | About three quarters need a transfusion |
| <input type="checkbox"/> | 81 to 90 out of 100           |   |
| <input type="checkbox"/> | 91 to 99 out of 100           |   |
| <input type="checkbox"/> | 100 out of 100                | <b>Everybody needs a transfusion</b>    |
| <input type="checkbox"/> |                               |   |
| <input type="checkbox"/> | I have no idea of the number. |   |

2. If I choose to accept volunteer-donated blood my chance of being transfused, compared to others who accept volunteer-donated blood is:

- Much lower than other patients' chances
- Lower than other patients' chances
- The same as other patients' chances
- Greater than other patients' chances
- Much greater than other patients' chances

3. Out of 100 people who choose to self-donate blood, the number needing at least one transfusion during or after heart surgery is:

- |  |  |
|--|--|
| <input type="checkbox"/> 0 out of 100                  | <b>Nobody needs a transfusion</b>        |
| <input type="checkbox"/> 1 to 10 out of 100            |  |
| <input type="checkbox"/> 11 to 20 out of 100           |  |
| <input type="checkbox"/> 21 to 30 out of 100           | About one quarter need a transfusion     |
| <input type="checkbox"/> 31 to 40 out of 100           |  |
| <input type="checkbox"/> 41 to 49 out of 100           |  |
| <input type="checkbox"/> 50 out of 100                 | <b>About one half need a transfusion</b> |
| <input type="checkbox"/> 51 to 60 out of 100           |  |
| <input type="checkbox"/> 61 to 70 out of 100           |  |
| <input type="checkbox"/> 71 to 80 out of 100           | About three quarters need a transfusion  |
| <input type="checkbox"/> 81 to 90 out of 100           |  |
| <input type="checkbox"/> 91 to 99 out of 100           |  |
| <input type="checkbox"/> 100 out of 100                | <b>Everybody needs a transfusion</b>     |
| <input type="checkbox"/>                               |  |
| <input type="checkbox"/> I have no idea of the chance. |  |

4. If I choose to self-donate blood, my chance of being transfused, compared to others who self-donate blood is:

- Much lower than other patients' chances
- Lower than other patients' chances
- The same as other patients' chances
- Greater than other patients' chances
- Much greater than other patients' chances
-

### Thinking About Chances: What the Numbers Mean

In the following questions, you will be asked to give your opinion about the chances of complications in patients having heart surgery. We are considering the chance of a complication happening out of a specific number of patients having heart surgery.

#### Chance of complications

#### For comparison, this is like one person in:

One in ten million patients	Ontario ( <b>extremely small chance</b> )
One in a million patients	Ottawa-Hull
One in five hundred thousand	Ottawa plus Kanata and Nepean
One in a hundred thousand patients	A large city such as Nepean
One in fifty thousand patients	A city such as Kanata
One in twenty-five thousand patients	A large sports stadium
One in ten thousand patients	A town such as Hawkesbury
One in a thousand patients	A village such as Chalk River
One in a hundred patients	A movie theatre crowd
One in ten	A sports team ( <b>extremely large chance</b> )

In other words, "one in ten million" is a very low chance - it is not very likely to happen, and "one in ten" is a very high chance - it is very likely to happen.

6. If I choose to accept volunteer-donated blood during or after heart surgery, my chance of getting AIDS (Acquired Immune Deficiency Syndrome) is:  
 \_\_\_\_\_ (please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <input type="checkbox"/> I have no idea of the chance |                           |

7. If I choose to accept volunteer-donated blood during or after heart surgery, my chance of contracting viral hepatitis B or C is:  
 \_\_\_\_\_(please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <br>  |                           |
| <input type="checkbox"/> I have no idea of the chance |                           |

8. If I choose to accept volunteer-donated blood during or after surgery, my chance of contracting AIDS (Acquired Immune Deficiency Syndrome) or viral hepatitis B or C is:

- Much lower than other patients' chances
- Lower than other patients' chances
- The same as other patients' chances
- Greater than other patients' chances
- Much greater than other patients' chances

9. If I choose to self-donate blood, my chance of contracting AIDS (Acquired Immune Deficiency Syndrome) due to receiving additional volunteer-donated blood is:  
 \_\_\_\_\_(please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | very likely to happen     |
| <br>  |                           |
| <input type="checkbox"/> I have no idea of the chance |                           |

10. If I choose to self-donate blood, my chance of contracting viral hepatitis B or C due to receiving additional volunteer-donated blood is closest to:

\_\_\_\_\_ (please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <input type="checkbox"/> I have no idea of the chance |                           |

11. If I choose to accept volunteer-donated blood before or during surgery, my chance of having an immediate reaction (either a wrong blood or an allergic reaction) is:

\_\_\_\_\_ (please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <input type="checkbox"/> I have no idea of the chance |                           |

12. If I choose to self-donate blood during or after surgery, my chance of having an immediate reaction (either a wrong blood or an allergic reaction) is:  
\_\_\_\_\_ (please fill in)

This is closest to:

- |   |                           |
|---|---------------------------|
| <input type="checkbox"/> one in ten million           | Not very likely to happen |
| <input type="checkbox"/> one in a million             |                           |
| <input type="checkbox"/> one in five hundred thousand |                           |
| <input type="checkbox"/> one in a hundred thousand    |                           |
| <input type="checkbox"/> one in fifty thousand        |                           |
| <input type="checkbox"/> one in twenty-five thousand  |                           |
| <input type="checkbox"/> one in ten thousand          |                           |
| <input type="checkbox"/> one in a thousand            |                           |
| <input type="checkbox"/> one in a hundred             |                           |
| <input type="checkbox"/> one in ten                   | Very likely to happen     |
| <input type="checkbox"/> I have no idea of the chance |                           |

13. The chance of having an immediate (either wrong blood or allergic) reaction is:

- Higher for those who choose volunteer-donated blood
- Higher for those who chose to self-donate blood
- Equal for those who choose self-donated or volunteer-donated blood

**F. My thoughts on the tape and workbook**

1. How would you rate the length of the tape and workbook? Please check one box.

- Much too long
- A little too long
- About right
- Should have been a little longer
- Should have been much longer

2. How would you rate the clarity of the information in the tape and workbook?

- Everything was clear
- Most things were clear
- Some things were unclear
- Many things were unclear

3. What things were unclear?

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4. How balanced and fair did you find the tape and workbook?

- Clearly slanted to volunteer-donated blood transfusion
- Slightly slanted to volunteer-donated blood transfusion
- Completely balanced
- Slightly slanted to self-donated blood transfusion
- Clearly slanted to self-donated blood transfusion

5. How helpful were the tape and workbook in making a decision about the choice of a method of transfusion? Please check one box.

- Very helpful
- Somewhat helpful
- A little helpful
- Not helpful

6. Would you recommend the tape and workbook to other patients who are facing a decision about whether or not to donate blood for their own use? Please check one box.

- I would definitely recommend it.
- I would probably recommend it.
- I would probably not recommend it.
- I would definitely not recommend it

7. What way of presenting small risks do you prefer?

- a) By words, such as "one in a million"
- b) By numbers, such as " 1 in 1,000,000"
- c) By comparisons, such as "like the risk of being struck by lightning"
- d) By a comparison chart such as that on the decision aid page 12
- e) By a combination of methods Please specify : \_\_\_\_\_

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8. Do you have any other suggestions for improving the tape and workbook?

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### G. My thoughts on how other patients decide about self-donating blood

These questions ask about what you think other patients would do when faced with the decision of whether or not to donate their own blood prior to surgery. For each statement, show how much you agree or disagree by circling the number that best shows your opinion.

1. Self-donation of blood is an individual choice, and some patients decide not to self-donate.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

2. There is no right or wrong answer about whether patients should self-donate their own blood.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

3. The decision to self-donate blood depends on a patient's opinion of the pros and cons.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

4. The decision to self-donate blood depends on the doctor's opinions of the pros and cons.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

5. Most patients faced with this decision would choose to self-donate blood.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

6. Most doctors would choose to self-donate their blood if they were having surgery themselves.

1	2	3	4	5
Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree

7. How many patients faced with the same decision do you think would choose to self-donate their blood after they review the audiotape and booklet. Would you say it is...

don't know

- 0 out of 100 **Nobody** chooses to self-donate their blood
- 5 out of 100
- 10 out of 100
- 15 out of 100
- 20 out of 100
- 25 out of 100 **One quarter**
- 30 out of 100
- 35 out of 100
- 40 out of 100
- 45 out of 100
- 50 out of 100 **Half** the patients choose to self-donate their blood
- 55 out of 100
- 60 out of 100
- 65 out of 100
- 70 out of 100
- 75 out of 100 **Three quarters**
- 80 out of 100
- 85 out of 100
- 90 out of 100
- 100 out of 100 **Everybody** chooses to self-donate their blood

8. How much would having information about other patients' choices help you in making your own decision. Would you say it would be...

- essential to have in making your own decision
- helpful to have in making your own decision
- a little helpful in making your own decision
- not at all helpful

9. In your opinion, what do you think your surgeon thinks you should do?

- choose to self-donate my blood
- choose volunteer donated blood transfusions
- my surgeon is neutral about my choice
- I don't know what my surgeon thinks

10. How much has your surgeons' recommendation about what you should do helped you in making your own decision. Would you say it was...

- essential in making my own decision
- helpful , but not essential in making my decision
- a little helpful in making my decision
- not at all helpful

11. How much would having information about other surgeons' recommendations to their patients about what they should do help you in making your own decision. Would you say it would be...

- essential to have in making my own decision
- helpful to have, but not essential in making my decision
- a little helpful in making my decision
- not at all helpful

Thank you very much for your time and patience in evaluating the decision aid, and in filling out the questionnaires. We greatly appreciate your help.