CADTH Optimal Use Report

Pilot Project: Ethical Assessment: Open versus Restricted Access and Optimal Use of Solvent/Detergent-Treated Human Plasma (Octaplas)

May 2011

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Ethical Assessment: Open versus Restricted Access and Optimal Use of Solvent/Detergent-Treated Human Plasma (Octaplas)

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May 2011
## TABLE OF CONTENTS

1  PREFACE................................................................................................................................. 1

2  INTRODUCTION ...................................................................................................................... 1

3  METHODOLOGICAL CONSIDERATIONS.............................................................................. 3

4  CONSIDERATIONS: OPEN ACCESS TO SOLVENT/DETERGENT-TREATED HUMAN PLASMA.................................................................................................................. 8

5  CONSIDERATIONS: RESTRICTED ACCESS TO SOLVENT/DETERGENT-TREATED HUMAN PLASMA............................................................................................................. 9

6  KEY ETHICAL CONSIDERATIONS .......................................................................................... 9

7  REFERENCES.......................................................................................................................... 10
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The authors have no scientific or economic conflicts of interest to disclose.

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**ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>A4R</td>
<td>Accountability for Reasonableness</td>
</tr>
<tr>
<td>CADTH</td>
<td>Canadian Agency for Drugs and Technologies in Health</td>
</tr>
<tr>
<td>CBS</td>
<td>Canadian Blood Services</td>
</tr>
<tr>
<td>FFP</td>
<td>fresh-frozen plasma</td>
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<tr>
<td>HRQoL</td>
<td>health-related quality of life</td>
</tr>
<tr>
<td>NAC</td>
<td>National Advisory Committee on Blood and Blood Products</td>
</tr>
<tr>
<td>QALY</td>
<td>quality-adjusted life-year</td>
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<tr>
<td>S/D plasma</td>
<td>solvent/detergent-treated human plasma</td>
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1  PREFACE

The purpose of this ethical assessment is to identify and discuss ethical issues related to optimal use recommendations for solvent/detergent-treated human plasma (Octaplas) (S/D plasma) — a blood product derivative — in Canada. This assessment compliments a set of clinical and cost-effectiveness analyses done for the purpose of informing a reasonable funding decision on S/D plasma.

Before analyzing the ethical issues relevant to an ethical assessment regarding open versus restricted access to S/D plasma in Canada, certain observations should be noted.

We reviewed the scientific material which was produced for the original 2009/2010 funding recommendations on S/D plasma. We acknowledge that there may not be agreement between all parties (Canadian Blood Services [CBS], Canadian Agency for Drugs and Technology in Health [CADTH], and the Octaplas manufacturer — Octapharma Canada) on all clinical and cost-effectiveness findings, as well as on the ultimate budgetary impact to the jurisdictions that might adopt S/D plasma. It appears reasonable for the purpose of this ethical assessment, however, to assume that S/D plasma provides a greater level of safety than fresh-frozen plasma (FFP). Similarly, it seems reasonable to assume that S/D plasma is more expensive than FFP. Although they arrive at substantially different views as to how much more S/D plasma would cost the health care system if utilized, CADTH and CBS have both suggested that the cost would increase should the product replace FFP either totally or partially. This ethical assessment is therefore premised on the following assumptions:

- that S/D plasma will indeed cost more
- that it increases the safety of blood products for transfusion
- that the financial resources of the Canadian health care system are limited.

If it were the case that S/D plasma was less expensive than FFP, or should financial resource limitations disappear, there would be no need to conduct an ethical analysis.¹ Most certainly, the considerations contained in this assessment would become less relevant in any discussion where the product is less expensive and/or more risky than the current products in use.

2  INTRODUCTION

2.1  History and Philosophical Context

In the context of direct patient care, health care ethics typically focus on the individual, and looks to established moral principles as guides to ethical decision-making. The four principles that are most generally appealed to are:

- autonomy (self-government)
- beneficence (obligation to do good)
- non-maleficence (obligation to do no harm)
- justice (both procedural, and distributive).

² There appears to be a consensus in the Western health care ethics community that this form of principlism currently represents one of the best approaches to making ethical decisions in health care.

¹
Generally, the principle of autonomy is prioritized above all the others when addressing individuals in health care. In provider interactions with individual patients, the providers seek to maximize and respect autonomous decisions. They also attempt to be beneficent, non-maleficent, and just in the process. In the case of justice, an attempt is always made to be as just as possible from both a procedural and distributive perspective. Procedurally, health care providers seek to treat like cases alike in the process of decision-making and, when considering distributive justice, they attempt to allocate goods and services in as fair and equitable a manner as possible.

While this prioritization of autonomy over other principles holds in general circumstances, it may not be possible or logical when discussing the optimal use of limited resources. In the context of priority setting (which is a public policy decision requiring the engagement of the entire society), it may be necessary to adopt a broader, more collective conception of ethical decision-making that might apply to decisions of individual treatment. Regarding the principlist approach, the notion of distributive justice becomes an overriding concern when allocating scarce resources. When determining optimal use of resources, attempts are made to maximize the aggregate good for the greatest number of people (i.e., an ethically consequentialist or utilitarian approach) rather than focusing exclusively on individuals and their rights per se (which constitutes an ethically deontological approach). Although priority-setting decisions should not come at the expense of individual rights and obligations, there may be circumstances where these rights and obligations will become secondary to the needs of greater society. As such, new sets of moral issues and tensions arise.

The use of quality-adjusted life-years (QALYs) as a methodological tool, which is used by CBS and CADTH to make their assessments of S/D plasma, represents a utilitarian approach. Historically, patient-centered approaches to health care ethics are concerned with the process of decision-making, and the ways in which that process can be enhanced. With societal concerns related to resource allocation, the focus shifts to the outcomes, or the consequences, of decision-making. While utilitarianism is not an ideal system, it may indeed be the most intuitive guide to ethical decision-making in the context of priority setting. Use of QALYs, however, should nonetheless be used with a degree of caution. Research by Nord et al. has suggested that patients value criteria other than utility, such as equity, or freedom from severe disability. This research indicates that the appropriateness and validity of QALYs is not given.

One of the challenges of resource allocation issues in a public health context is to make decisions as fairly and justly as possible given the circumstances and limitations present. It is important to remember that the need to make resource allocation decisions which will enhance the health of the greatest number of people does not obviate the obligation to install and maintain as fair, just, and defensible a process of decision-making as possible. Therefore, in terms of principles, a focus should be maintained not only on distributive justice, but, to the extent possible, on procedural justice, the importance of autonomy, beneficence, and non-maleficence. As it relates to QALYs, enhancement of the decision-making process may include consultation with appropriate stakeholders, transparent acknowledgement, and disclosure of any limitations inherent to the methodology, confirmation of a factual knowledge base, and so on. Despite the inability of a publicly funded health care system to satisfy everyone’s preferences when resources are finite, individual rights should always be respected to the greatest extent possible. Utilizing a recognized ethical framework, as will be seen in section 4.3, can add legitimacy to difficult
decisions, including the one addressed by this assessment: the choice between open and restricted access to S/D plasma.

3 METHODOLOGICAL CONSIDERATIONS

3.1 Ethical Issues Related to Quality-Adjusted Life-Years

As previously stated, QALYs represent a utilitarian methodology for calculating the potential outcomes of a given decision. From the QALY perspective, the action that produces the most QALYs at the lowest cost is likely the most appropriate and cost-effective use of resources. In practice, the notion that one can and should calculate QALYs is extremely similar to the “felicific calculus” that was originally proposed by the father of utilitarianism, Jeremy Bentham (1746-1832). Like any utilitarian analysis of consequences or outcomes, the use of QALYs presents several ethical challenges that will subsequently be discussed in this ethical assessment.

3.1.1 Individual rights

Traditionally, one of the main criticisms of utilitarian theory has been that it prioritizes collective good over individual rights. Because an action’s moral merit is proportional to the degree to which it maximizes an aggregate amount of utility, the individual is not relevant per se. As a result, utilitarianism can sometimes lead to counterintuitive results. Consider the following example:

- Ten people require a variety of organs for transplantation to save their lives and restore their health. It is determined that one clinically depressed individual would be a perfect organ donor to these ten individuals. Should this individual’s organs be harvested without consent?

According to the basic precepts of utilitarianism, the answer to this question would be yes. However, it would be unacceptable to violate an individual’s moral rights to liberty and autonomy in this fashion for the benefit of a greater number of people. This is one of the inherent flaws of utilitarian theory, and is one that can also be seen with the use of QALYs in certain circumstances. Consider another example:

- It is determined that a certain public health intervention would result in a very slight increase in QALYs for the entire population of Canada, with the price per QALY being projected at $50,000. It is expected that each individual will gain five minutes of QALYs as a result of this intervention. It is at the same time determined that another public health intervention will benefit only 100 Canadians but will do so in a much more significant way. Each of these 100 individuals can be expected to gain many QALYs, but the aggregated price per QALY is judged to be $55,500.

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a Theoretically, the felicific calculus would calculate the pleasures and pains resulting from a decision. The concept of utility is not fixed. In some circumstances, utility substitutes for concepts such as “happiness,” or “pleasure.” In the case of QALYs, utility substitutes for health outcomes, as determined by quality and quantity of life combined into one piece of numerical data.
If a person were to make an assessment utilizing only the numbers, one would be compelled to choose the intervention that gains the most QALYs at the least expensive price. In this instance, it might be the case that it would be more cost-effective to purchase the QALYs that will impact every Canadian for a very short amount of time, versus purchasing the QALYs for a much smaller group of individuals who will benefit greatly on an individual basis and at a slightly higher price. As in the former example, this would seem to be counterintuitive, as the individual is not taken directly into account in the operation of QALYs. As long as the greatest good is achieved for the greatest number of individuals, the theoretical utilitarian analysis is sound.

To account for the de-prioritization of individual rights, utilitarian theorists have conceptualized a refined version of their theory, which they call “rule utilitarianism.” Rule utilitarianism aims to avoid the problem of rights by incorporating the concept of moral rules into the calculation itself. Based on rule utilitarianism, an act is ethical insofar as it complies with defined rules. A moral rule is chosen if it “will maximize social utility if it is followed by everybody in this kind of situation.” Applying this approach, imagine how the previous example of the unwilling organ donor would change. Presumably, it would be a moral rule that organs are not to be harvested from anyone without informed consent, because doing so would not maximize social utility in any way. This could also be stated in a more general form: It could be a moral rule that the rights of other individuals are not to be violated unless the circumstances are exceptional, well-defined, and publicly agreed upon.” This would, theoretically, maximize social utility by creating trust, cooperation, defined freedoms, structure, and by reducing fear. Thus, it would be inappropriate to obtain the organs from an unwilling donor.

It is not clear whether QALYs are able to incorporate any meaningful moral rules into their equation. One could perhaps say that a proposed intervention is meaningful only after a certain threshold of QALYs is gained by each individual in a given calculation. In this sense, one might say that only gains in QALYs of one month or more will be considered. One might similarly propose a moral rule saying that those individuals who are expected to gain the most QALYs should be prioritized, regardless of the aggregate amount of gain. Based on these types of rules, the inclination would be to choose the second intervention in the second previous example, even though it is less cost-effective and might create less overall QALYs. But these hypothetical moral rules aren’t self-evident in the same sense as the rule that organs are not to be removed from unwilling donors by force. It is much more difficult to determine which gain in QALYs is superior to another, and for what reason. Indeed, the variability in the sources, calculation, and analyses of QALYs and the notion of cost-effectiveness has been the subject of much debate and scrutiny.

It may well be that some of these problems may be because of issues around allocating scarce resources at large, rather than the way in which those resources are allocated in particular. It appears to be the case, for example, that any allocation of scarce resources will result in at least some number of people not having their preferences satisfied. Given the finite financial resources in the Canadian health care system, decisions on which beneficial interventions will be funded and which will not must be made, and no theory can completely eliminate the dissatisfaction resulting from those decisions. However, this does not obviate the need to create a system that is as just and fair as possible, and to be transparent about the limitations of the method used. QALYs present several challenges, perhaps the most important of which is the promotion of the collective good over the preferences of individual patients. It is perhaps most ethically appropriate to utilize QALYs as only one piece of
information among others, and to not be bound by purely numerical calculations that can create counterintuitive results.

A final point should be made about QALYs as a method of determining which interventions are the most cost-effective. In other resource allocation scenarios, such as pandemic planning, broad public consultation is undertaken to ascertain the views and values of Canadians. In the context of pandemic planning, this public consultation has demonstrated that, for the most part, Canadians would favour a utilitarian approach to rationing of scarce resources. It is not clear to the authors of this assessment that this type of public consultation around the use of QALYs as a method for determining cost-effectiveness and influencing health care spending decisions in non-crisis or emergency circumstances has occurred. It is recommended that this type of consultation occurs transparently before presuming that Canadians would fully accept QALYs as the preferred method for determining the value of an intervention.

3.1.2 Calculating utilities

Another challenge to utilitarian theory is the notion that one can calculate utilities accurately, if at all. It has been suggested that it is not possible to accurately assign numerical values to ambiguous concepts such as happiness, pleasure, and, in the case of QALYs, quality of life. This is precisely what QALYs attempt to do, and many have questioned their validity on this basis. As Räsänen et al. noted in their 2006 study, a great variety of health-related quality of life (HRQoL) tools are used to calculate QALYs, and many are obtained from “vaguely defined sources or estimated by healthcare professionals.” Similar issues are reported by Bravo Vergel and Sculpher, and Hirth et al. in their respective articles. These criticisms indicate that QALYs should be used with some caution, and should be based on information that has been reported by patients themselves. Based on the principle of autonomy, patients should be able to reflect on and report their own HRQoL. By obtaining information from patients, QALY data can become more meaningful, and appear less arbitrary.

It nonetheless remains difficult to assign a perfectly accurate numerical value to the quality of health states that individual patients might experience as a result of an intervention. Ethically speaking, it would be questionable to reduce something as complex as quality of life to a purely numerical metric. Different patients evaluate their HRQoL from different points of reference, and the inability of QALYs to directly account for this fact should be kept in mind when assessing any recommendations based upon them.

3.1.3 QALYs of elderly and disabled persons

In a 1987 article titled “QALYfying the Value of Life,” John Harris suggests that the use of QALYs necessarily discriminates against elderly and disabled persons. This is a very important critique to consider in the context of a product such as S/D plasma.

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\[\text{See, for example, the CanPREP Policy Briefs, p. 20-21.}\]

\[\text{As an example, consider patients who might find great value in continued quantity of life, regardless of quality. The somewhat famous 2008 case of Samuel Golubchuk, an orthodox Jewish patient in Winnipeg, is an example of this issue.} \]

On the basis of his religious beliefs, Mr. Golubchuk’s substitute decision-makers demanded ongoing aggressive measures in an intensive care unit for many months. In this case, QALYs completely fail to take these types of contextual features into consideration, which might result in inaccurate or irrelevant data.
According to Harris, elderly persons are given less consideration when calculating QALYs simply because they are not capable of experiencing as many QALYs as younger persons. Because elderly persons cannot be expected to have as many added life-years (and, hence, as many QALYs), Harris suggests that QALYs will de-prioritize care for this population in favour of younger individuals. This issue may be reflected in the CADTH report, where the cost per QALY for younger recipients is lower and therefore theoretically more attractive for policymakers ($822,900.00) for 35 year-old individuals than for 65 year-old individuals ($1,307,800.00). From an ethics perspective, the question would be whether QALYs are biased toward younger individuals and, if so, what the justification for this bias is. It is not morally self-evident that younger individuals should be favoured over more elderly persons who have less life expectancy, and this issue should be reflected upon when making any optimal use recommendations using QALYs.

Similarly, Harris argues that those who have been “victims of a disaster” (i.e., those who have poor health, or those who are otherwise disabled in such a way that they cannot be expected to gain significant QALYs) are also discriminated against through the use of QALYs. Harris calls this the “double jeopardy” feature of QALYs, and considers this to be a significant problem when allocating resources using this tool. Regarding the assessment of S/D plasma, any potential bias against those who are, unfortunately, not able to gain QALYs at a cost-effective rate because of physical disability should be made transparent. Ethically, the question would be: Why would those who are less fit and able to benefit from interventions be less of a priority? Harris also raises similar points about QALYs having the potential to appear racist and sexist, noting that certain groups of people are more susceptible to certain conditions, and that these groups might be less cost-effective to treat than others.

### 3.1.4 Cost-effectiveness standards

A final point that can be made about QALYs is that they are assessed through standards of cost-effectiveness that may be arbitrary. In other words, certain numerical standards are used to determine whether a certain intervention is or is not cost-effective. In the CADTH report, $50,000 and $100,000 are used as willingness-to-pay standards to determine the likelihood of S/D plasma being cost-effective. Questions to be considered here are: Where did these figures come from? How are these figures representative of actual cost-effectiveness? Given that the data produced by these standards may be a key consideration when deciding whether S/D plasma should be offered to all transfusion candidates or just a percentage, it is important to understand how the conclusions were arrived at. It is imperative that these numbers be reflective of meaningful standards of cost-effectiveness and not arbitrary “round-number thresholds.”

### 3.2 Issues Raised in the Preface Regarding Evidence

As mentioned in the preface, it is crucial that a working set of factual data be established and agreed upon by the relevant parties. In reading the reports produced by the various groups, it is clear that there is considerable disagreement regarding the efficacy and cost-effectiveness of S/D plasma. It also appears as though there is disagreement concerning what is pragmatically possible in terms of open access to S/D plasma. In the 2010 CBS report, it is stated that even replacing 20% of current FFP demand with S/D plasma (as recommended by the National Advisory Committee on Blood and Blood Products) would likely require modification to existing storage facilities (Assessment: Initiating the distribution of Octaplas (S/D Plasma). Ottawa: Canadian Blood Services: unpublished data, 2010 Apr 7 (Redacted)).
Consequently, it is not clear whether it would even be possible or realistic to replace 100% of current demand with S/D plasma from an infrastructure perspective (as CADTH contemplates in its calculations). As is often stated in ethics, *ought implies can*. It would be problematic to state that S/D plasma ought to replace 100% of demand when doing so might be logistically impossible. Any ethical obligation exists only so far as one is actually able to fulfill it in some reasonable sense, and these differing reports on cost-effectiveness and efficacy suggest a need to build a consensus on the relevant facts and possibilities.

### 3.3 The “Accountability for Reasonableness” Framework

Norman Daniels has established a process for priority setting called “Accountability for Reasonableness” (A4R) that can enhance the ethical quality of optimal use decisions in health care. This framework has been used frequently in Canadian pandemic planning, and evidence suggests that those making decisions find the framework to be solid and acceptable. Given that the decision of whether or not to access to S/D plasma should be open or restricted is a priority-setting decision, this framework is applicable and should be considered. (See Table 1.)

<table>
<thead>
<tr>
<th>Value</th>
<th>Description</th>
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<tbody>
<tr>
<td>Accountability</td>
<td>There should be mechanisms in place to ensure that ethical decision-making is sustained.</td>
</tr>
<tr>
<td>Inclusiveness</td>
<td>Decisions should be made explicitly with stakeholder views in mind and there should be opportunities for stakeholders to be engaged in the decision-making process.</td>
</tr>
<tr>
<td>Openness and Transparency</td>
<td>Decisions should be publicly defensible. That means the process by which decisions are made must be open to scrutiny and the basis upon which decisions are made should be publicly accessible to affected stakeholders.</td>
</tr>
<tr>
<td>Reasonableness</td>
<td>Decisions should be based on reasons (i.e., evidence, principles, values) that stakeholders can agree are relevant to meeting health needs...and they should be made by people who are credible and accountable.</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>There should be opportunities to revisit and revise decisions as new information emerges...as well as mechanisms to address disputes and complaints.</td>
</tr>
</tbody>
</table>
Inclusiveness: How have the views of relevant stakeholders, including patients who will be impacted by these decisions, been accounted for? Has consultation been done with the groups who will be affected by the final decision?

Openness and Transparency: Are these considerations being shared with those who will be affected by the decision? Can affected stakeholders access these reports and scrutinize or contest them? In this instance, it could be argued that the entire Canadian populace is a relevant stakeholder.

Reasonableness: Do the relevant stakeholders (who also fund our universal health care system) agree on the methodology used to arrive at determinations of cost-effectiveness? Research by Nord et al., for example, has suggested that patients may value equity over utility in allocation decisions. What are the values of our relevant stakeholders?

Responsiveness: Will we ensure that there are opportunities to revise decisions based on new evidence? How will we address any complaints or disputes that might originate from patients? Is there an appeals mechanism?

This list of questions is by no means exhaustive, and should serve only as a basic starting point in reflecting on the process of decision-making. Given the potential controversies attached to the use of QALYs, it is important that the decision-making process be as fair and just as possible. Use of the A4R framework can help to enhance this process by drawing attention to the five broad aforementioned values.

4 CONSIDERATIONS: OPEN ACCESS TO SOLVENT/DETERGENT-TREATED HUMAN PLASMA

Given that any use of S/D plasma will likely result in an increased cost to the Canadian health care system, open access will mean that there will be a more significant impact on the system’s ability to spend on other health care priorities than if a restricted access model is chosen. When using the CBS projections of incremental cost, 100% replacement of demand with S/D plasma will result in a significant increase in health care spending (Assessment: Initiating the distribution of Octaplas (S/D Plasma). Ottawa: Canadian Blood Services: unpublished data, 2010 Apr 7 (Redacted)). Using the 20% replacement of supply figure, which CBS suggests would represent a cap in a restricted-access model (Assessment: Initiating the distribution of Octaplas (S/D Plasma). Ottawa: Canadian Blood Services: unpublished data, 2010 Apr 7 (Redacted)), would limit the budgetary impact of funding S/D plasma, although this approach could potentially be associated with “indication creep” (Briefing note for provinces and territories. Ottawa: Canadian Blood Services: unpublished data, 2010 June 14). In this sense, open-access will cost more than the projected upper-level cost in a restricted access model. Ethically, the residual question is whether this would be an appropriate use of these additional health care funds. For example, are there other health care interventions that can be purchased for that price? Do those same interventions result in greater benefits to Canadians for similar costs? If so, what would the justification be for choosing to spend those excess funds on S/D plasma? These broader questions around distributive and procedural justice need to be considered when making a final decision.
This is not to say that it would be “unethical” to replace 100% of demand with S/D plasma. As the evidence suggests, S/D plasma is safer than FFP, and will result in less transmission of certain diseases. However, it appears as though the risks associated with use of FFP are extremely low already and may or may not constitute an acceptable level of risk. Based on the A4R framework, discussion around these issues can result in greater consensus and ethical legitimacy when making a final decision. Particularly, the notion of “acceptable level of risk” should be reflected on, and those impacted by the risks in question should be consulted, if possible.

5 CONSIDERATIONS: RESTRICTED ACCESS TO SOLVENT/DETERGENT-TREATED HUMAN PLASMA

Restricted access to S/D plasma will raise questions of procedural and distributive justice.

In a restricted access model, certain groups of transfusion patients will be excluded, while others will be given a safer, more effective treatment. Although the approach behind this triage may be sound, it is important to consider the impact on the patients who will not receive S/D plasma. With restricted access, it remains possible that patients who are not eligible to receive S/D plasma will contract the same conditions that S/D plasma eliminates. What would our explanation be to one of these patients who did not benefit from an enhanced treatment being offered to other groups of patients? Are we willing and able to justify acceptance of this risk, given that we may not be willing to accept the risk for other groups of patients? Ethically, these justice and fairness questions are significant.

As well, as the CBS briefing note on Octaplas states, Canada already funds other interventions that have a much more significant cost per QALY than S/D plasma does, with nucleic acid testing of the blood supply for HIV and hepatitis C virus (HCV) costing an approximate $5.8 million per QALY. “The acceptance of such measures is thought to reflect the high value society places on reducing unintentional deaths and injuries, and the depth of public concern about blood safety” (Briefing note for provinces and territories. Ottawa: Canadian Blood Services: unpublished data, 2010 June 14). If this is the case, there would be no question that open access to S/D plasma would be preferable. However, it is not clear that this assumption regarding public preferences is based on actual public consultation. Also, it is not clear what level of safety the public is committed to achieving. Given that FFP already carries extremely low risks, is the public willing to forego open access to S/D plasma? This question must be answered in order for decision-making to be consistent and fair. In the absence of investigating these issues, it will be difficult to justify restricted access to S/D plasma while funding certain procedures that cost many times more.

6 KEY ETHICAL CONSIDERATIONS

In summary, the following key ethical considerations should be considered when developing recommendations on the funding and availability of S/D plasma:

- Is there a meaningful consensus around the data? Ethical considerations will vary depending on the factual evidence. This assessment assumes that S/D plasma is substantially more expensive, and safer, than FFP. There should be agreement around
the efficacy, safety, and incremental costs associated with the purchase of S/D plasma.

- Is there acknowledgement and transparency concerning the challenges associated with the utilization of a QALY methodology? What would be the response to these challenges, particularly from groups that may be disenfranchised, such as people over 65?

- Have the values listed in the A4R framework been considered (i.e., accountability, inclusiveness, openness/transparency, reasonableness, and responsiveness)? Perhaps most importantly, what do the patients who will be impacted by this decision have to say? Although reasonable people may disagree, any final decision that accounts for and is informed by these values will gain moral legitimacy and validity.

- Will it be justifiable to provide S/D plasma to only a percentage of those who require these transfusions and, if so, on what ethical grounds? Have the standards for procedural and distributive justice been met? In a restricted-access model, those who will not receive S/D plasma may become compromised in ways that S/D plasma could prevent. Accepting the risks for some patients while mitigating them for others implies that an acceptable level of risk has already been determined. Is this so?

- What constitutes an acceptable level of risk in Canadian health care? This seems to be a core question in relation to S/D plasma. Given that the risks associated with FFP appear to be extremely low, what price is the system willing to pay for further gains in safety? In terms of consistency, what price is the system already paying for similar gains in safety?

## References


