

1 **Ethical Challenges Related to Patient Involvement in Health Technology Assessment**

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34 **Abstract**

35 Including information and values from patients in HTA has the potential to improve both the
36 process and outcomes of health technology policy decisions. Accordingly, funding and structural
37 incentives to include patients in HTA activities have increased over the past several years.
38 Unfortunately, these incentives have not yet been accompanied by a corresponding increase in
39 resources, time, or commitment to responsiveness. In this Perspectives piece, we reflect on our
40 collective experiences participating in, conducting, and overseeing patient engagement activities
41 within HTA to highlight the ethical challenges associated with this area of activity. While we
42 remain committed to the idea that patient engagement activities strengthen the findings,
43 relevance, and legitimacy of health technology policy, we are deeply concerned about the
44 potential for these activities to do ethical harm. We use this analysis to call for action to
45 introduce strong protections against ethical violations that may harm patients participating in
46 HTA engagement activities.

47 **Keywords:** Patient Engagement, Patient Involvement, Patient participation, Ethics, Health
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60 Ethical Challenges Related to Patient Involvement in Health Technology Assessment

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62 Introduction

63 Engaging patients in health technology assessment (HTA) may enrich health policy
64 decisions by strengthening the legitimacy and efficacy of this process (1). Recent years have seen
65 a rise in funding and structural incentives to include patients in HTA, reflecting growing
66 recognition of the importance of ensuring that policy decisions are relevant to consumers. As
67 more agencies strive to involve patients, the rush to inclusion may create an environment where
68 thoughtful engagement is reduced to check-box forms of involvement that approach tokenism
69 (2). This is not always intentional, and we acknowledge the significant efforts of many agencies
70 to meaningfully involve patients. However, the current focus on methods and processes
71 sometimes overlooks the ethical issues inherent in involving patients, or fails to acknowledge the
72 vulnerability of patients and the potential for harm in HTA participation.

73 In this Perspectives article, we highlight three ethical challenges related to patient
74 involvement in HTA. We do this by using ethical theories to critically reflect on our own
75 experiences as patients, researchers, patient engagement facilitators, ethicists and staff at
76 agencies in Canada, Norway, and transnational HTA organizations. While we recognize that there
77 are many ways of involving patients in HTA, we focus on the forms of involvement which directly
78 solicit new information from patients to inform decisions made by expert committees and
79 agency personnel throughout the full HTA process.(1) This form of involvement is distinct from

80 evidence created by gathering or synthesizing information collected from patients outside of the
81 HTA process.(3)

82 **Three Ethical Challenges of Patient Involvement:**

83 *Recognizing and re-balancing risk and benefit for all HTA participants*

84 Many patient involvement activities increasingly resemble research, and expose patient
85 participants to similar potential harms. For example, we have observed a growing pressure to
86 conduct more numerous and more detailed interviews with patients. Patient interviewees are
87 typically limited to describing their experiences in response to prepared questions, and may not
88 have the opportunity to direct the conversation to topics they deem relevant to the policy
89 decision, such as the trade-off between cost and improvement in quality of life. Patient-
90 contributed information is analyzed cumulatively and presented in a written report, mediated
91 through the perspective and priorities of the analysts and report authors. Dissenting views may
92 or may not be included. As the report is discussed, patient participants have little opportunity to
93 respond, react and offer an alternative vision.

94 This form of patient involvement is qualitatively different from the way other experts are
95 engaged, and very closely resembles research participation. Research has a rich history of ethical
96 theory guiding the recognition and re-balancing of cost and benefit. These ethical principles can
97 guide patient involvement in HTA, under the principle that we should work to “do good”
98 throughout the entire process of the HTA and not only at its conclusion (4). This means that we
99 must strive to maximize benefit and minimize harm to patient participants throughout their

100 involvement. "Doing good" is more than just "not doing bad". It means not remaining
101 complacent that if the HTA is done well, the resulting policy decisions will benefit patients and
102 society, but striving to create benefit to the participants of the HTA regardless of the outcome of
103 the assessment. This could be facilitated through the adoption of the principle of patient
104 empowerment as an aim of patient involvement (2, 5), which requires consideration of the
105 principles of self-determination, autonomy, responsiveness and ensuring the 'voice' of
106 participants is at the forefront (6). It means using the principle of respect for autonomy to create
107 strong structures to facilitate the collection of continuous informed consent to participate (7). As
108 we strive not to do harm, we should consider the concept of therapeutic misconception, that is,
109 whether a patient has chosen to participate because she assumes that the results of
110 participating will directly benefit her. This is especially important when engaging patients who
111 use the drug or device being assessed. At a minimum, we should strive to ensure that
112 participation in patient engagement activities does not cause physical, emotional, spiritual or
113 economic harm that outweighs the benefits of participating. Ideally, we should identify some
114 additional benefit to patients, whether that is opportunity for capacity-building, learning, or
115 system change.

116 ***Selecting and engaging patient participants in an ethical way***

117 There are two related parts to this challenge. First, there are many barriers to patient
118 participation in HTA, meaning that only the most strongly motivated are likely to participate (8).
119 Second, when only the most strongly motivated participate, ethical issues related to coercion
120 and selection bias are introduced.

121 Barriers to patient participation in policy decision-making activities have been well-
122 documented (9, 10). Barriers include activities which take place during working hours, absent or
123 limited remuneration for time (11), as well as a requirement to interpret and respond to
124 complex information (9, 12). Other barriers include significant power differentials between
125 patients and other participants (13), and the request to disclose potentially personal information
126 to an audience who is not reciprocating with assistance, or similar levels of disclosure or
127 vulnerability (11). Considering these barriers, it is not surprising that most HTA patient
128 participants tend to be of higher socio-economic status than the general population. By ignoring
129 barriers to participation, we risk excluding all but the most motivated from the knowledge-
130 sharing process (14).

131 What inspires some patients to overcome these barriers, to give up their time and energy
132 and to assume the costs and risks inherent to participation? Research indicates that patients may
133 be motivated to acquire meaningful social roles, overcome stigma, improve the health system
134 and achieve social justice for others (15). Beyond these reasons, we have met participants who
135 are motivated by the unresolved tensions they carry from previous harm experienced within the
136 health care system, and those who participate because they wish to access the technology being
137 assessed. We've met patients who participate at their own cost and others who receive support
138 from industry. All of these reasons for participation may motivate particular behaviours from the
139 individual, prompting fear that bias or coercion may influence the information that person
140 provides.

141 Instead of ignoring or aiming to eliminate bias, we re-conceptualize this issue, believing
142 that the value of patient involvement lies in the unique experience and perspective each person
143 brings (16, 17). Indeed, we are asking for patient participation because of, not in spite of their
144 personal experience. To do this, we must find ways to recognize the value of the variations in
145 experience and perspective and incorporate these variations to support the production of a rich
146 and useful HTA process. The approach of valuing the diversity of lived experience rather than
147 seeking to minimize bias conflicts with the approach taken in areas of the HTA which rely on
148 epidemiological methods and 'objective' data (16). Others have suggested that each individual
149 should carefully manage and support the overlap between their private preferences (self-
150 interest) and understanding of what serves the wider public good (18). One strategy for
151 achieving this is to borrow the concept of reflexivity from qualitative research.(19) Reflexivity is a
152 way to identify, interrogate and communicate the influence of personal perspective on
153 qualitative research decision-making. A reflexive conversation would be useful in HTA at the time
154 of recruitment to check the fit between the person and the activity. Each participant would be
155 informed of the nature and objectives of the activity and asked to reflect on their motivation to
156 contribute, the perspectives they hope to convey during the activity, and the expectations they
157 have for their involvement in the activity and its outcomes. This would not be a one-way
158 conversation; the HTA team would also share their experience, goals, and conflicts relevant to
159 the proposed activities. This conversation could be used to adapt or refine the activity to allow
160 more transparent and effective patient engagement, and be included in analysis and reporting to
161 improve the transparency of the results.

162 Increasing the accessibility and appeal of HTA activities may help ameliorate barriers to
163 participation and the potential for selection bias and coercion when only the most motivated
164 participate. Actions to reduce barriers to participation include: meaningful remuneration,
165 activities outside of normal working hours, and attention to the physical and mental needs of
166 people who may be sick, in pain, or living with functional limitations (20). Constructing activities
167 which don't require high levels of education or verbal eloquence, and those which feel
168 emotionally and psychologically safer will increase accessibility. These actions follow the guiding
169 principles of empowering patients to contribute by respecting and valuing their contributions,
170 creating structures that mitigate potential risks, and ensuring transparency through the
171 accessibility of information.

172 *Decreasing the influence of power and information differentials between patients and other*
173 *HTA members*

174 There are ethical issues stemming from the different types of information patients and
175 other participants bring to an HTA collaboration and the resulting influence that information has
176 within the assessment and decision-making process. For example, some participants bring
177 clinical or economic research evidence to an HTA, whereas patients often bring information
178 about their lived experience with the technology and health conditions. Differences in how this
179 information is valued can contribute to power differentials between patients and other HTA
180 participants, with the potential to undermine the contributions of patients.

181 Ethical patient involvement should consider how the HTA process will be responsive to
182 the information provided by patients when it contradicts the outcomes suggested by economic

183 and clinical evidence. In our experience, it is an enduring challenge for committees, decision-
184 makers, and researchers to compare and prioritize discrepant messages from clinical, economic,
185 and lived experience information. The challenge of a holistic review of information is at the
186 heart of the HTA endeavour, but all too often we have witnessed committees comment that
187 while the lived experience information is compelling, they must make their decisions based on
188 the clinical or economic evidence. This can be upsetting to patients, who may feel superfluous
189 and betrayed at the previous messages of how important their contributions are (21, 22). They
190 may wonder if the decision-makers ever intended to take their testimony and evidence into
191 account, or whether they are merely being used for their 'patient status' rather than their insight
192 (22).

193 If we are committed to ethical patient involvement, we must be responsive to the
194 information provided by patients. Like other forms of evidence (including synthesized evidence
195 from qualitative studies of patient values and experiences), information gathered through
196 patient involvement activities should be considered essential and authoritative. Lived experience
197 knowledge should not be privileged over other forms of evidence, but it should be equally
198 considered. Hermeneutical marginalization, a type of epistemic injustice, occurs when
199 interpretive resources are organized in a way that privileges one type of knowledge over
200 another, or silences certain groups of people (23). It is disheartening but not surprising that
201 evidence from the direct involvement of patients does not often compete with clinical or
202 economic evidence produced, synthesized, reported and interpreted by people who are deeply
203 embedded in a particular evidentiary system. Dismantling the information differentials requires

204 divergent forms of information to be presented in a way which is understandable and open to
205 critique and response from all participants. This may mean translation of the findings from all
206 HTA reports into plain language, so that those without specialized expertise may critique the
207 assumptions or results of each report.

208 **Conclusion**

209 Patient involvement in HTA can strengthen the findings, relevance, and legitimacy of
210 health technology policy, but it may also do ethical harm. In this analysis, we draw on our
211 collective experience participating in patient engagement to call for the introduction of strong
212 protections against ethical violations that harm patients participating in any phase of an HTA. We
213 identified three broad concerns about fairness in risks and benefits, justice in diversity and
214 accessibility and reducing power differences, reflecting these concerns against ethical theory to
215 suggest tenets that could govern improved conduct of patient engagement activities. If patients
216 are involved more meaningfully in HTA, we should move closer to truly useful HTA products that
217 reflect the context in which the technologies or drugs will be used. This commentary is a starting
218 point, providing only a partial description of the potential ethical issues in this area. Our main
219 objective is to draw attention to the gravity of this issue as demonstrated by our collective
220 Canadian and international experiences in HTA.

221 Raising awareness is only the first step to improving practices of patient engagement
222 within our community. Robillard and Feng (20) suggest that in keeping with the spirit of
223 partnership and collaboration that informs patient involvement, policies and deliberation about
224 the ethics of involving patients should incorporate the needs, perspectives, and wishes of the

225 community (20). All stakeholders (researchers, agencies, and patients) should be involved in the
226 development of guidelines and formal structures that ensure patient involvement within HTA is
227 conducted in a way which minimizes harm. These guidelines are emerging, from organizations
228 such as the European Patients Academy (24). Support from the HTA community for the
229 development and uptake of this work is essential to ensure that future patient involvement
230 activities have stronger potential for benefit than harm.

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