Acceptability and Perceived Benefits and Risks of Public and Patient Involvement in Health Care Policy: A Delphi Survey in Belgian Stakeholders

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ABSTRACT

Background: In systems with public health insurance, coverage decisions should reflect social values. Deliberation among stakeholders could achieve this goal, but rarely involves patients and citizens directly. Objectives: This study aimed at evaluating the acceptability, and the perceived benefits and risks, of public and patient involvement (PPI) in coverage decision making to Belgian stakeholders. Methods: A two-round Delphi survey was conducted among all stakeholder groups. The survey was constructed on the basis of interviews with 10 key stakeholders and a review of the literature on participation models. Consensus was defined as 65% or more of the respondents agreeing with a statement and less than 15% disagreeing. Eighty stakeholders participated in both rounds. They were defined as the Delphi panel. Results: Belgian stakeholders are open toward PPI in coverage decision processes. Beneﬁts is acceptable to Belgian stakeholders, be it in different ways for different types of decisions. Benefits are expected to outweigh risks. Conclusions: PPI in coverage decision-making processes is acceptable to Belgian stakeholders, it be in different ways for different types of decisions. Benefits are expected to outweigh risks.

Keywords: Belgium, coverage decisions, patient participation, policy, public involvement.

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Introduction

Involvement of the general public and patients in the resource allocation decision-making process is a way to incorporate societal values in decisions. Involvement is “the spectrum of processes and activities that bring the public into the decision-making process” and is associated with activities beyond routine democratic processes [1]. Public and patient involvement (PPI) in health care decision making helps in legitimating decisions [2-4] and in dealing with societal and economic evolutions, such as increasing demand for health care and higher patient expectations in a context of budgetary constraints [5]. Moreover, it could engender the trust and confidence in the health system [6] and engage communities and individuals in health action [3,7].

Public involvement in coverage decisions implies a shift from professional dominance of technocratic experts in decision-making processes toward more empowerment of lay people [8].

In deliberation-driven models, as in Belgium and Austria, health care coverage decisions are prepared by a multistakeholder appraisal committee, consisting of scientists, sickness funds, pharmaceutical industry, medical professionals, health care institution representatives, and politicians. Patients or citizens are usually not directly represented in the committees. Nevertheless, the committees are deemed to take balanced decisions in the best interest of the citizens and patients, taking resource constraints into account.

It is unclear to what extent the committees would value PPI in decision-making processes, in which cases, and in which way
Nevertheless, there seems to be an interest in the subject at different levels: the strategic level, relating to global priorities for health care resource allocation, and the operational level, relating to the reimbursement of individual products or services. This study assesses the acceptability to stakeholders of PPI in health care resource allocation decision-making processes, possible reasons for PPI, and perceived benefits and risks of such involvement.

Methods

General Design: Delphi Approach

The aim of assessing the opinions of stakeholders in health care coverage regarding PPI calls for a qualitative research approach. We used a two-round Delphi approach, combining elements from the modified Delphi approach and elements from the policy Delphi approach [12], to survey a group of Belgian stakeholders currently involved or not (yet) involved in decision-making processes. Patient organizations are, for example, not involved (yet) in Belgium [13].

The Delphi approach uses a series of sequential questionnaires or “rounds,” interspersed by controlled feedback, that seek to gain the most reliable consensus of opinion of an “expert panel” [15]. As in the modified Delphi approach, we first performed face-to-face interviews to construct the survey for the first Delphi round. As in a policy Delphi approach, we invited policymakers and other stakeholders to participate in a two-round survey. The research protocol followed the guidelines for qualitative research of the Belgian Health Care Knowledge Centre [14]. Only those respondents who participated in both Delphi rounds were considered part of the Delphi panel. Consensus was defined as at least 65% of the participants agreeing with a statement and a maximum of 15% disagreeing. The Delphi survey was performed by e-mail to avoid direct confrontation and the risk of excessive influence of powerful stakeholder groups. Figure 1 presents the consecutive steps of our Delphi process.

Preliminary Phase: Interviews with Key Stakeholders and Literature Review

The preliminary phase of our Delphi process consisted of semi-structured interviews with 10 stakeholders and a narrative review of the literature on PPI in resource allocation decision making. The aim of the stakeholder interviews was to identify contextual factors and experiences with PPI that were important to know for the construction of the first Delphi survey and for the interpretation of its results. An interview guide consisting of three parts was used. Part 1 consisted of nine questions relating to experience with PPI and the presumed purpose of PPI. Part 2 included six questions relating to ways to involve the public and patients. In part 3, the interviewees were asked to give examples of PPI from Belgium or elsewhere, followed by semi-structured discussion about these examples.

All interviewees had a key role in the current health care system. They consisted of politicians, civil servants, representatives of the medical profession and care institutions, patient organizations, and sickness funds. They were selected because of their expected general overview of concerns and sensitivities of stakeholders with respect to PPI in decision making. The interviewees were not excluded from the Delphi panel. After the interview, they were treated in the same way as other invited stakeholders.

The literature review was performed to be able to describe different implementation models for PPI in health care resource allocation policy. We started from existing reviews on PPI [1,5,7,15] and applied the snowballing principle to the reference lists of these reviews to select additional articles for full-text review. Articles were included if they added new information or fresh insights. These included studies on PPI and consultation methods, practice and evaluation, and theoretical and conceptual frameworks of the design and evaluation of PPI processes. The review identified the dimensions of involvement and the pros and cons of different implementation models. The dimensions used for describing PPI models were level or type of the decision [16–18], role of the citizen or patient representative [16,19,20], intensity of involvement [5,16,18,21–23], and involvement modalities.

The level of the decision can be the strategic or the operational level. The strategic level refers to general priority setting for resource allocation. It relates to questions such as “should we, as a society, give priority to the expansion of home care services for chronically ill elderly patients or to more effective curative treatments for cancer patients when allocating our limited public resources for health care?” The operational level relates to the coverage of specific products or services for the entire population, a subgroup of patients, or individual patients. They refer, for instance, to decisions regarding the coverage of a new insulin analog for the treatment of diabetes.

The role of the public or patient representative can be that of a tax and social contributions payer (citizen), or that of an expert by experience (patient). This simplified presentation of possible roles was chosen to avoid confusion among the participants in the Delphi panel. It should be acknowledged, however, that the distinction between public and patient is in a way artificial because the public includes past and current as well as future patients. In addition, individuals easily move between roles [16,19]. We did not, as some authors do, define patient involvement as referring to “decisions about one’s own care” only [20].

The intensity of involvement refers to “the extent to which individuals have control over the decision-making process” [16]. A broad range of levels of involvement has been documented in the literature [5,16,18,21–23]. We used the spectrum of the International Association for Public Participation (IAP2), but adapted the labels to avoid confusion with the general term.
“involvement,” which encompasses all levels of intensity in our framework. The most basic level of involvement is to inform the public or patients, which mean they are attributed no power. The highest degree of power transfer happens when decisions are actually taken by the public, labeled as “public decides” in our framework instead of “empower” in the IAP2 spectrum. Consultation, debate (instead of involvement), and codetermination (instead of “collaboration”) are intermediate levels of involvement, in increasing order of power transfer.

Dimensions relating to the modalities of PPI encompass where the involvement takes place (inside current decision-making organs [e.g., expert committees] or outside existing organs [e.g., in a specifically established consultative commission]); when the public and patients are involved (at all deliberations, only at milestones during the decision-making process, only at the end of the process, or only just before or after a decision is taken); how many citizens and patients are involved (only one or more representatives), duration of representation (fixed or a changing representation), and how the involvement is organized (by written and/or oral contributions, face-to-face, or from a distance). Also, the impact of the involvement on the decision is considered, that is, should the advice be binding or nonbinding, and if nonbinding, should deviations from the public’s and patients’ advice be justified.

Before launching the first round of the Delphi process, a face-to-face meeting was organized to inform all stakeholders who would be invited to participate in the Delphi survey about the Delphi process, and to show some results of the literature review. Participants could ask questions and give suggestions for the study. Sixty-three persons participated in the session.

First Delphi Round

The questionnaire for the first Delphi round was structured in four parts:

- Part 1: General opinion about PPI, including rationale for involvement.
- Part 2: Perceived benefits and risks of PPI.
- Part 3: Preferences with regard to the intensity of PPI.
- Part 4: Preferences with regard to the modalities of PPI.

In parts 3 and 4, a distinction between strategic and operational decisions was made.

Participants were asked to what extent they agreed with a number of statements, how important they considered specific items, or which response option they preferred out of a list of options. For the analysis, each pair of the following response categories was merged to determine whether consensus was reached: “very important” and “important,” “fully agree” and “agree,” “not important” and “not important at all,” and “not agree” and “not agree at all.” For questions in which respondents had to choose their preferred response option, the proportion of respondents choosing each option was calculated. When this proportion was higher than 65%, consensus on that item was assumed.

Invited stakeholders also received a background document, explaining the concepts used and the framework of PPI. This document was kept brief to ensure that participants would read the document before answering the questions. The complete version of the questionnaires and background document are available online in Dutch and French [24,25].

Second Delphi Round

The second Delphi round started after the analysis of responses from the first round. Stakeholders who participated in the first round received a synthesis of the first round results and a second questionnaire. The second questionnaire built further on the elements for which consensus was reached in the first round: it explored the acceptability of practical proposals for involving the public and patients when there already was consensus on the principle or the level of involvement. Proposals related, for instance, to the role and number of representative(s) to be involved (one or more patient and/or citizen), where and when the involvement should take place, and what should be the impact for decision makers, given the acceptance of a minimal level of PPI for strategic and operational decisions. In combination with the other dimensions of involvement, all these practical dimensions make up the involvement models (Fig. 2). In addition, the second round further explored elements for which no consensus was reached in the first round.

The questioning was simplified in the second round and consisted of yes/no answers for most items. New items suggested by respondents in the first round were added if at least two participants had suggested them. Consensus was determined by calculating the proportion of respondents answering “Yes.”

Sampling

Nearly 600 persons representing several stakeholders in Belgium were invited to participate in the first Delphi round. They included representatives of consumer and patient associations, politicians/decision makers at the national level (parliament), high-level civil servants and policymakers at the regional level, and members of the advisory councils and committees at the National Institute for Health and Disability Insurance (NIHDI).

The NIHDI advisory councils and committees prepare decisions for the decision makers (i.e., the ministers). They are composed of several stakeholders in health care decision making: civil servants, representatives of sickness funds, academics, medical professions, care organizations, pharmaceutical companies, manufacturers of medical devices, employer organizations, and trade unions. Consumers’ and patients’ associations are currently not involved in the decision-making processes and were therefore added to our sample. They were invited on the basis of a nominative list of persons who showed interest in the subject, for instance, by participating in earlier events relating to PPI in health care (for patient organizations) or by direct contact (for consumer organizations).

Some individuals belong to several stakeholder groups. For example, an academic can be a medical doctor working in a health care institution; thus, he or she belongs to three different stakeholder groups. People can also be members of several decision-making organs. For example, a representative of the sickness funds can be a member of the insurance council as well as of the drug reimbursement committee at the NIHDI. This makes it difficult to give an overview of the number of people involved in the study per stakeholder group. For this qualitative study, however, this is less of an issue, because the aim was to cover the variety in positions relating to PPI among stakeholders, and not to obtain statistical representativeness of stakeholders’ characteristics [14].

Results

Description of the Delphi Panel

One-hundred seven stakeholders participated in the first Delphi round. Eighty stakeholders participated in both the first and second Delphi rounds (Table 1). All types of stakeholders were represented in the Delphi panel. The majority was active as full member or substitute in an advisory organ of the NIHDI.
Rationale for Citizen and Patient Participation

More than 70% of the respondents considered PPI in health care decision making (very) important. Eight percent of the respondents who did not consider PPI important came from diverse categories of stakeholders.

Reasons why PPI was considered important were multiple and fitted with several theoretical rationales for PPI described in the literature. The consequentialist, technocratic, or consumer rationale considers PPI as a means to achieve policy goals such as efficiency, accessibility, and quality of care [26]. In the empowerment, emancipating, or democratic rationale, PPI is an end in itself, focusing on the basic right of citizens to participate in decision-making processes [6,16,26,27]. The individualistic, capacity-building rationale sees PPI as a means to give the population the opportunity to take up responsibility for its own choices [28–40].

The only possible reason for PPI that did not reach consensus was to render the health care system more demand driven instead of supply driven. In a demand-driven system, decisions about supply are driven by health care needs, whereas in a supply-driven system, decisions are reactive, that is, following a provider’s decision to supply a new product or service.

Table 1 – Description of participants in the Delphi survey.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Round 2</th>
<th>Round 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (%)</td>
<td>N = 107</td>
<td>N = 80</td>
</tr>
<tr>
<td>Male</td>
<td>57.0</td>
<td>55.0</td>
</tr>
<tr>
<td>Female</td>
<td>43.0</td>
<td>45.0</td>
</tr>
<tr>
<td>Stakeholder category (multiple answers possible) (%)</td>
<td>N = 107</td>
<td>N = 80</td>
</tr>
<tr>
<td>Politicians, members of cabinets</td>
<td>13.1</td>
<td>10.0</td>
</tr>
<tr>
<td>Patient organizations</td>
<td>26.1</td>
<td>21.3</td>
</tr>
<tr>
<td>Sickness funds</td>
<td>27.1</td>
<td>22.5</td>
</tr>
<tr>
<td>Federal, regional, or community institutions</td>
<td>15.9</td>
<td>20.0</td>
</tr>
<tr>
<td>Representatives of medical professions or care institutions</td>
<td>27.1</td>
<td>27.5</td>
</tr>
<tr>
<td>Organizations from the associative world</td>
<td>10.3</td>
<td>7.5</td>
</tr>
<tr>
<td>University/research</td>
<td>15.0</td>
<td>15.0</td>
</tr>
<tr>
<td>Other</td>
<td>8.4</td>
<td>11.3</td>
</tr>
<tr>
<td>Membership of advisory organs of the NIHDI (%)</td>
<td>N = 105</td>
<td>N = 80</td>
</tr>
<tr>
<td>Active member</td>
<td>57.1</td>
<td>53.7</td>
</tr>
<tr>
<td>Former members</td>
<td>5.7</td>
<td>3.7</td>
</tr>
<tr>
<td>Never been members</td>
<td>37.1</td>
<td>42.5</td>
</tr>
</tbody>
</table>

NIHDI, National Institute for Health and Disability Insurance.

* Under this heading are grouped organizations from civil society that are membership based and not directly linked to the health sector.

These are mainly the employer and employee representative organizations.
**Benefits and Risks of Citizen and Patient Involvement**

According to the respondents, involving citizens and patients in the decision-making process has two important advantages. A first advantage is a more in-depth understanding by the experts of issues relating to quality of life and difficulties met by patients. It brings expertise by experience from patients in the decision-making process. A second presumed advantage is an increased public awareness of the challenges, costs, and opportunity costs of health care, potentially leading to an increasing individual and collective responsibility. There was no consensus on the following potential advantages of PPI: the possibility to develop a counter-weight for the traditional lobbies and decision makers and the possibility to get approval of potentially unpopular decisions.

The Delphi panel identified the following risks and problems of PPI: insufficient human and financial means of citizens and patients to participate effectively, the difficulty in finding an adequate representation to express a collective opinion, the risk for patients to be misused to speed up, slow down, or manipulate the process, and the lobbying or power games of other stakeholders. There is also a perceived risk of subjectivity. For several risks, no consensus was reached, although the proportion of respondents who considered them as (very) important was still near to or up to 50%. These were the manipulation of the patient by the industry, the diversity and multiplication of existing representations for different diseases, the risk that more weight will be given to the personal benefits than to the common good, the domination of protest voices, the diversity and multiplication of existing representations on a geographical level (national, regional, local…), and the risk of slowing down the decision-making process.

Despite the risks identified, there was consensus among the participants that the benefits of PPI would outweigh the risks; 18% considered they would be equal and 15% considered the risks would be superior to the benefits.

**Type of Decision and Role of Citizens or Patients Involved**

The Delphi panel judged that for strategic decisions the involvement of a citizen’s representative is the most appropriate. For operational decisions, patient involvement was considered more appropriate.

Patient involvement was considered especially relevant for coverage decisions relating to high-cost pharmaceuticals, high-volume pharmaceuticals, new diagnostic technologies, invasive medical devices, and products and services that are today at the charge of the patient. No consensus was reached on the relevance of PPI for decisions for high-cost pharmaceuticals with low added therapeutic value.

**Intensity of Involvement**

The preferred minimum level of involvement intensity and the role of the representative depended on the type of decision. Consensus was reached on the following:

- For setting global budgetary priorities in health care, the citizen representative should at least be informed and consulted.
- For decisions about the coverage of particular products, the patient representative should at least be informed and consulted.
- For decisions related to the coverage of health care products for individual patients, there was no consensus on whether citizens or patients should be involved at all.

Although there was consensus that consultation should be the minimum level of involvement for both setting global priorities and specific coverage decisions, there was no consensus on what should be the maximum level of involvement. About 24% of the participants explicitly opposed the option of participation of citizens in the debate about health care priorities, and 25% opposed the option of participation in the debate for decisions about the coverage of products and services. The remainder, that is, 76% and 75%, respectively, considered participation in the debate to be an acceptable, though not the preferred, level of involvement. Decision making by citizens and patients alone was explicitly rejected as an option for all types of decision making. No single participant chose this option as being acceptable.

**Modalities of Involvement**

For the two levels of involvement identified in round 1 as being minimally required for each type of decision, the acceptability of several practical dimensions was assessed in round 2 (Fig. 2): who should be involved, by how many representatives, what should be the intensity of the involvement, what should be the impact on decision makers, where should involvement take place, and when should it take place. In combination with the other dimensions of involvement, they make up the involvement models.

For both types of decisions, the preferred involvement model was to consult the public and patients within the existing decision-making organs and at specific milestones in the decision-making process. More than one representative of the public and patients was preferred to only one representative, and changing representatives was preferred over a fixed representation of citizens and patients. There was consensus among the participants that decisions ought to be justified whenever they differed from the advice provided by the public and patients representatives.

**Success Factors of PPI**

The Delphi panel reached a consensus on the following success factors for PPI: 1) training of public and patients and other stakeholders to be able to contribute effectively to the decisions; 2) procedural transparency of the decision-making process; 3) formal recognition and funding of individual patient organizations; and 4) development of a participation culture and a code of conduct for the individuals as well as the participating associations. The respondents also agreed that a legal basis for PPI should be developed. Finally, there was an overall perceived need for a careful selection of the persons who would participate.

Procedural transparency refers to making explicit the role of the citizens and patients in the decision-making process and making transparent how their input is taken into account.

**Discussion**

To our knowledge, this is the first study to investigate the acceptability of PPI in health care resource allocation decisions for stakeholders. Even though there was consensus that PPI in health care resource allocation decisions is important, our Delphi panel did not unanimously agree on the importance of PPI, nor the appropriate level of involvement. This explains at least partly why PPI is not systematically embedded yet in decision-making processes across the globe, despite the actual popularity of the subject.

Another reason is the lack of evidence with respect to the effectiveness of different PPI models in different health care systems with different types of decision-making procedures. On the one hand, there is a need to formulate principles of involvement that can be generalized and applied across various national
and political environments (standardization), and on the other hand, participation methods need to be sensitive to and adaptable to local circumstances [27]. Therefore, the effectiveness of any PPI initiative should be assessed [23] in terms of both its implementation hurdles and achieving its predefined objectives [16].

Power inequities between actors have been highlighted as a potential threat to the success of PPI in decision-making processes by our Delphi panel. Different actors (e.g., health care professionals vs. patients) have different (power) positions within the health care system, different interests and resources (e.g., knowledge and social capital), and different frames of reference (expert or lay) [41]. The panel concluded that for PPI initiatives to succeed, citizens, patients, and other stakeholders should be trained to contribute effectively to the decisions. It is noted that stakeholders currently involved in decision-making processes—the majority of our Delphi panel—generally seem to expect that citizens and patients acquire the skills to communicate with them, rather than experts and professionals acquire the skills to engage with the public at the public’s level. Because not all citizens and patients will be capable of acquiring the necessary skills, there is a risk of underrepresentation of specific population groups and limited diversity of citizen and patient engagement.

The expectations imposed on the public and patient representatives regarding their skills might bring along the risk of professionalization, creating a distance between participants and those they claim to represent. This is in the literature referred to as the grassroots dilemma [2]. However, lack of education of citizens and patients might increase the risk of manipulation by other stakeholders, which was also identified by the panel as a risk of PPI.

The panel agreed that providing sufficient financial means to individual patient organizations could help to reduce the dependency of patient organizations on private, usually pharmaceutical company, funding. The budgetary implications of this have not been explored, but can be expected to be large if only the umbrella organizations are envisaged.

Our Delphi panel agreed on the fact that there is a need for procedural transparency, recognition, and funding of patient organizations, the development of a participation culture, and support of all stakeholders. This corresponds with the conclusion of Van Bovenkamp et al. [42] that the development of an opportunity structure for PPI is a necessary but not a sufficient condition to make PPI work in practice.

A number of remarks, however, could be made with respect to these findings in the context of the preferred PPI model of the Delphi panel. The agreement that transparency is needed concurs with the preference of the panel for a model in which deviations from the advice of the patients and citizens need to be justified. For coverage decisions, this should happen, according to the panel, in a context in which patients are consulted as experts. In the current Belgian decision-making processes, this could mean that patients are consulted regarding the expected coverage if they are not allowed to really participate in the decision-making processes, although there are still issues that make them reluctant to allow a more intense involvement than consultation. The panel considers PPI important, but at varying levels of intensity and in varying roles depending on the type of decision. They prefer patient consultation as (external) experts for coverage decision of specific products or services and citizen consultation for general priority decisions in the system, in both cases within the current structures.

Conclusions

Belgian stakeholders seem in general to be open toward PPI in resource allocation decision-making processes, although there are still issues that make them reluctant to allow a more intense involvement than consultation. The panel considers PPI important, but at varying levels of intensity and in varying roles depending on the type of decision. They prefer patient consultation as (external) experts for coverage decision of specific products or services and citizen consultation for general priority decisions in the system, in both cases within the current structures.
The success of PPI was considered to depend on adequate training of all stakeholders, procedural transparency, a legal basis for PPI, and sufficient resources for and formal recognition of patient associations. Risk factors essentially relate to the absence of success factors, the imbalance of powers, and not finding the adequate representation to express a collective opinion.

The present study could be a first step in a longer process of PPI. The next steps would be to test the actual implementation of PPI and to evaluate its process and outcomes. PPI is a social process, not a discrete intervention. It requires an ongoing commitment from all stakeholders.

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