Conclusions and discussion

Under embargo
In this Chapter, I present the conclusions of this thesis research which was guided by the following main research question:

*How can knowledge co-production processes be structured so that patients’ knowledge is effectively articulated and integrated with knowledge of researchers and health professionals, and can be sustained in health research, policy and care practice?*

I have described and analyzed knowledge co-production processes on health-related decision making by conducting four case studies. These case studies provide insights into effective strategies, facilitating factors or barriers for knowledge articulation, integration and embedding. To achieve this, the main research question is answered using the findings of the four case studies for each study question, as formulated in Chapter 3:

1. What strategies can best be employed to articulate the knowledge of researchers, health professionals and, in particular, patients?
2. How can patients’ knowledge be effectively integrated with the knowledge of researchers and health professionals?
3. How can the embedding of knowledge co-production processes in health research, policy and care practice be enhanced?

In the last sections of this Chapter, I discuss methodological considerations, followed by suggestions for future research on knowledge co-production in health-related decision making.

### 10.1 Strategies for knowledge articulation

In three of the four case studies, knowledge articulation was studied, namely the case studies concerning the policy advisory process (Chapter 4), clinical guideline development (Chapter 5) and clinical trials (Chapters 6 and 7).

*Process of knowledge articulation*

In the cases, specific attention is paid to the articulation of the experiential knowledge of patients. As their experiential knowledge is often implicit, patients need to become aware of their perspectives and corresponding needs and preferences (Abma and Broerse 2010; Nierse and Abma 2011). To achieve this, interviews and focus group discussions were designed in such a way that they started with identifying problems and concerns in patients’ daily lives. Subsequently, these problems and concerns were converted into suitable inputs for integration; (1) needs for medical products, (2) solutions and improvement of current practice for resumption of activities and employment after gynaecological surgery and ideas for an e-health intervention, and (3) potential improvement of clinical trials and possibilities for patient involvement in design and conduct of clinical trials. To convert the experiences into suitable input for knowledge integration, several steps were taken. This was particularly important in the policy advisory process because it had a relatively narrow focus on medical products, while patients’ interests generally cover a wide variety of issues. During the focus group discussions and in the
interviews, patients were asked to identify the medical products for their disease with which they were already familiar. This led to a better understanding of the broad range of current medical products and their meaning in daily life. To acknowledge the presence of wider issues (e.g. communication between patient and clinicians, societal participation, health financing) the so-called ‘parking spot’ was used. The issues on the parking spot were included in the research report and provided context to the advice. In this way, patients felt heard and were motivated to discuss their needs for medical products. In the clinical trials case, patients found it difficult to provide ideas for patient involvement because they were not familiar with the concept. Clear explanation of the concept was necessary for good understanding of the topic among patients, although it was still difficult to come up with concrete ideas for patient involvement, because many participants lacked experience in this area. In particular, focus group discussions were considered valuable for knowledge articulation, because they facilitated co-construction of patients’ views by sharing, acquiring and contesting knowledge (Lehoux et al. 2006). Interviews were often used to complement the focus group discussions because they provided input to focus group design, validated the findings of the focus group discussions and facilitated a greater understanding of the results. The expert knowledge of health professionals is constructed by their scientific background and their experiences with care practice. Especially, the latter part of the expert knowledge is also often implicit, and the scientific background of health professionals may even come from particular perspectives of which they are not fully conscious. To this end, attention of the articulation of expert knowledge is also important. In the cases of the policy advisory process and the clinical trials special attention was paid to the articulation of expert knowledge of health professionals, in the same way as for patients. The focus group discussions and the interviews did start with the experiences of health professionals in their care practice. Subsequently, these experiences were converted into suitable inputs for integration.

Knowledge articulation of researchers and health professionals occurred in various ways. In the policy advisory process, medical specialists, general practitioners and nurses were consulted by means of focus group discussions. This consultation of health professionals is not described in Chapter 4, but is incorporated in the background study (Gezondheidsraad 2010) and in the advice of the GR (Gezondheidsraad 2011). In the clinical guideline development, scientific knowledge was derived from scientific literature and expert knowledge by means of a Delphi Study (Vonk Noordegraaf et al. 2011). In the Delphi Study, 12 health professionals from the relevant disciplines (five gynaecologists, five occupational physicians and two general practitioners) were involved. In the clinical trials case, health professionals were consulted via interviews and focus group discussions. A distinction was made between clinicians (who also were researchers) and research nurses, since the perspectives of nurses also included elements of experiential knowledge.

**Developing a ‘we-voice’**

In the three cases, patients were only consulted using qualitative methods (e.g. semi-structured interviews and focus group discussions). In general, quantitative methods, like questionnaires, are used to validate the insights obtained from interviews and focus group discussions and to maximize representation and diversity. Some scholars argue that the use of quantitative methods, in addition to qualitative methods, is essential for establishing scientific rigour (Hamberg et al. 1994). However, the case studies demonstrate that the use of only qualitative methods can generate relevant and legitimate data, as is also mentioned by other scholars (Mays and Pope 2000; Malterud 2001). In these three cases, successful attempts have been made to convert the ‘I-voice’ of patients into a ‘we-voice’ by involving both ‘lay-patients’ and ‘patient representatives’. In general, lay-patients were included for obtaining a broad inventory of experiences and ideas. Patient representatives were included to broaden and deepen the findings obtained from consultation with lay-patients as they are familiar with the experiences of peers and are therefore able to tell a ‘we-story’, which transcends the ‘I-story’. The inclusion of both types of patients in
knowledge articulation is also emphasized in the literature because they complement each other and thereby contribute to increased representation of the patient community (Caron-Flinterman et al. 2005; Tritter and McCallum 2006; Schipper 2012).

In the three cases, lay-patients and patient representatives were involved in different ways for the conversion of the ‘I-voice’ into a ‘we-voice’. In the clinical trials case, the development of a ‘we-voice’ was most explicit. In the consultation phase, experiences and ideas of a broad group of lay-patients (and professionals) were collected. This provided a general overview of directions for patient involvement, but lacked in-depth and concrete details. Patients were not familiar with the concept patient involvement and experienced consequently constraints in the operationalization of the concept. Therefore, an advisory board of seven patient representatives broadened and deepened the overview of the consultation of lay-patients and made it more concrete. Their familiarity with experiences of peers made it possible to bring in perspectives of specific patient groups, like the perspectives of women with young children or women in the palliative phase (broadening) and to add details to the issues which were identified in the consultation phase (deepening). In the clinical guideline development case, three focus group discussions with lay-patients were organized in addition to the inclusion of a patient representative in the advisory committee. The patient representative was familiar, in general, with perspectives of surgical patients who were resuming activities and employment but was not acquainted with the specific experiences of gynaecological patients. For the policy advisory process, patient representatives were involved to further specify the needs for medical products identified by lay-patients. For the six disease domains with a research agenda, knowledge articulation of lay-patients had already taken place. Needs for medical products were further specified by means of semi-structured interviews with patient representatives. For the nine disease domains without a prior research agenda, one or two focus group discussions, several interviews and feedback rounds were organized with a mix of lay-patients and patient representatives. Lay-patients were only involved in the focus group discussions while patient representatives were involved in both focus group discussions and interviews. Additional interviews were held with patient representatives when the focus group discussions did not yield clear priorities for future medical products. Patient representatives were, in particular, involved in the focus group discussions for disease domains demonstrating great diversity, for example orphan diseases and rheumatic diseases.

*Diversity and saturation*

For legitimate knowledge articulation all perspectives within an actor group should be included. However, within actor groups there is considerable diversity. For instance, various types of health professionals can be distinguished, e.g. medical specialists (working in different health disciplines), general practitioners, research nurses, physiotherapists. There is still more diversity among patients. Patients have varied experiences with diseases differing in severity and duration. Moreover, patients are represented among all ages, have different socio-economic status and cultural backgrounds. In a knowledge co-production process that is constrained by time and money, it is a complex task to include all different perspectives. This creates a dilemma regarding the realization of legitimate knowledge articulation. Attention should be paid to maximizing diversity and representation of the actor groups within the boundaries set by available resources (e.g. money and time).

This dilemma is evident in all three cases. In every case, choices were made regarding the inclusion of actors, which were transparently communicated. It was determined which perspectives within an actor group were relevant for the end-product, and what was feasible (e.g. number of focus group discussions) in the context of available resources. Regarding patients, in all cases it was decided to exclude children and patients who were not able to attend focus group discussions or to be interviewed (such as seriously ill patients). Furthermore, in the policy advisory process, conditions were set to justify the selection of the fifteen disease domains. Regarding
health professionals, in the policy advisory process it was decided to include three types of health professionals, namely medical specialists, general practitioners and nurses, to cover a broad range of expert knowledge (from ‘professional’ expert knowledge to more ‘practical’ expert knowledge). In the clinical trial case, for the same reason, the decision was made to include both clinicians and research nurses.

Despite the constraints in articulating knowledge, in the three cases several attempts were made to maximize diversity and representation of the patient community, and thereby enhance the legitimacy of knowledge articulation. First, interviews and focus group discussions were organized until saturation of data was obtained. Second, patient representatives were consulted to tell a ‘we-story’, which transcends the ‘I-story’, and in doing so include, to a certain extent, perspectives of patient groups which were not individually consulted. For health professionals, the dilemma was less significant as the knowledge of health professionals is more readymade (explicit) and researchers are more familiar with the perspectives of their peers by publications in scientific journals.

Empowerment

The scientific literature argues that involvement of patients in knowledge articulation can facilitate empowerment of patients (e.g. Schipper, 2012; and others). In this context, empowerment should not be considered as a process of power shift but, rather, as a process which emerges through interaction with others (Schipper 2012). For example, patients can empower each other by recognizing each other’s experiences. In the cases studied, patients were empowered by the recognition of their experiences in the focus group discussions. In the policy advisory process, this relational empowerment was clearly visible. As a result of involvement in the process, knowledge exchange between patients, and seeing the results of their advice to the GR, patients began to place greater value on their own experiential knowledge. As a result, several patient organizations took their own follow-up actions (such as developing their own research agenda). In the clinical trials case, the members of the advisory board, in particular, were empowered. They gained insights into the value of their joint experiences with breast cancer and clinical trials. As a result, the members (with only one exception) who were not already active as patient representatives became active members of the patient organization.

Content and value of articulated knowledge

Insights were also developed in terms of content and additional value of the articulated knowledge. The knowledge of patients, health professionals and researchers overlapped on several issues, but also complemented each other by providing additional insights or further specifications of issues.

In the policy advisory process, articulated needs of both health professionals (presented in the advice of the GR Committee and the background study) and patients related to early and accurate diagnoses (Gezondheidsraad 2010; Gezondheidsraad 2011). Furthermore, general practitioners, as well as patients, indicated a need for medical products which address issues affecting the quality of life (e.g. pain, fatigue). Needs for medical products which complemented each other were related to prevention (articulated by health professionals) and medicines based on individual characteristics (articulated by patients). In the clinical guideline development, health professionals and patients, for the most part, complemented each other. Health professionals and scientific literature provided the content of the recommendations for resumption of activities and employment which was mainly focused on isolated physical movements (Vonk Noordegraaf et al. 2011). Patients indicated that recommendations for resumption of activities and employment should not only focus on isolated physical movements but also on more complex daily activities like vacuum cleaning and climbing the stairs. In the clinical trials case, the ideas for
improvement and possibilities for patient involvement articulated by health professionals were mainly an elaboration of the ideas of patients with a focus on feasibility in daily practice. For instance, they emphasized the importance of clearly defining roles, tasks and expectations when involving patients in designing and conducting clinical trials. Furthermore, patients’ input mainly focused on improvement of daily functioning. For instance, they indicated that outcome measures should also focus on quality of life. Patients also identified new topics that are relatively easy to bring into practice but had not been considered by health professionals, such as sending a ‘thank-you’ letter to patients who participated in a clinical trial.

Patients’ input, however, also focused on specific medical topics (such as biomarkers for early recognition of complications in diabetic patients) and patients considered the feasibility of their articulated needs and desires. For example, in articulating needs for medical products, patients were well aware that the need for cure could not be satisfied in the short term. In the clinical trials case, the advisory board considered the feasibility of patient involvement and acknowledged that appointing patient research partners for every clinical trial would not be realistic.

10.2 Effective knowledge integration

Knowledge integration was studied in the first three cases: the policy advisory process (Chapter 4), clinical guideline development (Chapter 5) and clinical trials (Chapters 6 and 7). Knowledge integration followed knowledge articulation. In these three cases, knowledge integration occurred in different ways and also the outcomes were constructed in various manners, as presented in Table 10.1.

Table 10.1. Overview of knowledge integration process for the three case studies

<table>
<thead>
<tr>
<th>ID</th>
<th>Topics</th>
<th>Knowledge integration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Policy advisory process</td>
<td>By a working group, including a patient representative</td>
</tr>
<tr>
<td>2</td>
<td>Clinical guideline development</td>
<td>By an independent process facilitator</td>
</tr>
<tr>
<td>3</td>
<td>Clinical trials</td>
<td>By a dialogue meeting, including patient representatives from the advisory group, researchers, representatives of patient organizations, the funding agency and the organization coordinating breast cancer clinical trials</td>
</tr>
</tbody>
</table>

For clinical guideline development, integration was performed by an independent process facilitator. For the policy advisory process and the clinical trials case, knowledge integration was performed by representatives of the actor groups involved. For the policy advisory process, integration was done by a working group (the GR committee), comprising twelve members of which six were professors in different medical disciplines, two were representatives of the industry, three were representatives of the government, two were member of the GR staff and one was a patient representative. These members had not been directly involved in the knowledge articulation process but were representatives of the different actor groups. Although the role of the patient representative in the GR committee was not specifically studied in this research, one could argue that the patient representative preserved patients’ perspectives, given the outcome of the knowledge integration process. In the clinical trials case, integration took place during a dialogue meeting with representatives of the actor groups, including members of the advisory board; policy makers from patient organizations; representatives of the Dutch Breast Cancer Trialists Group (BOOG) and the Dutch Cancer Society (KWF); and professors involved in breast cancer clinical trials who were highly respected in the field and had experience with patient involvement in clinical trials. The members of
the advisory board and the professors were also involved in the process of knowledge articulation. The other participants were part of the project team.

**Interaction between actors and learning processes**

Although the international literature reports that patient involvement at the level of collaboration (which implies interaction between actors) is increasing (Oliver et al. 2004; Tritter and McCallum 2006), this is not directly reflected in the three case studies. With the exception of the clinical trials case, interaction between actor groups was restricted. However, interaction is necessary because it stimulates learning processes required to embed integrated knowledge in practices, activities and use (Regeer 2009; Abma and Broerse 2010; Roelofsen et al. 2011). Interaction is needed if actors are to adjust their beliefs, assumptions and behaviours, and develop competences for knowledge co-production in practice (Loeber et al. 2007; Roelofsen et al. 2011). Without interaction, learning tends to be restricted to single-loop learning in which assumptions are not questioned and compared with perspectives and values of other actors (Guston 1999; Irvin and Stansbury 2004; Caron-Flinterman et al. 2007), as is the case for double-loop learning (Argyris and Schön 1978). Double-loop learning stimulates creativity and critical thinking. It implies that actors change in the process and reflect on their perspectives and routines. This is reinforced by learning in a group which creates the possibility to generate a broad set of perspectives and to get acquainted with each other’s underlying assumptions (Levine and Moreland 2004). Triple-loop learning occurs when the dynamics of the interaction are discussed after a research.

Reflecting on the process of knowledge integration, it should first be stressed that generally all actors in the different cases were satisfied with the process of knowledge integration; they particularly appreciated the transparency of the process and supported the outcome. Regarding the occurrence of learning, it could be argued that mainly single-loop learning occurred during clinical guideline development because there was no interaction between actors, and little vicarious learning took place. For the policy advisory process, vicarious learning was observed. The members of the GR committee received extensive summaries of the knowledge articulation process and its (intermediary) outcomes and a few committee members observed focus group discussions with patients. Moreover, at the end of the process a feedback meeting to discuss, disseminate and implement the advice was organized. Many of the actors involved in the knowledge articulation process also attended this meeting. Therefore, they gained, to some extent, insights into each other’s perspectives and into the process of knowledge co-production (double-loop learning). In the clinical trials case, double-loop learning (in a group) was clearly evident. Double-loop learning was already initiated during the process of knowledge articulation and further reinforced during the dialogue meeting in which a shared vision for patient involvement was developed. During knowledge articulation focus group discussions with health professionals and research nurses were organized, parallel to the working sessions of the advisory board of patient representatives. In the focus group discussions and the working sessions the ideas for patient involvement, formulated by the other actor groups, were presented and health professionals and patients reflected on them. Thereby, health professionals and patients already gained insight into each other’s perspectives and underlying assumptions. As a result, at the start of the dialogue meeting there was already general agreement on the content of the outcomes. Therefore, during the dialogue meeting considerable attention could be paid to the feasibility of the advice and follow-up steps. In the case for clinical trials, triple-loop learning was observed to some extent during the dialogue meeting. In this meeting, the several participants reflected with each other on the followed process and the interaction that occurred between the different consulted actor groups.
Consensus-building

As described in Chapter 2, the end-product of knowledge integration is constructed during the previously mentioned process of reflexive learning followed by consensus building in which consensus represents general agreement on an issue (a shared vision and action plan). Joint construction of knowledge is not restricted to the harmonization of perspectives, ideas and opinions, and the symmetrical integration of different types of equally valid knowledge. It can, for instance, also result in the formation of a coalition of ideas, in a dominant design in which the perspective of one actor group dominates or in a situation in which knowledge integration leads to intensification of contrasts (Boon 2008). The integrated knowledge is most ‘socially robust’ when actors agree on both the content of the knowledge as well as on the underlying values and assumptions (Boon 2008).

In the three cases, all actors agreed on the end-product and were satisfied. However, the joint construction of knowledge differed between the cases, each with different advantages. In the previous section – strategies for knowledge articulation – the extent to which the knowledge of the actors differed has been described. In clinical guideline development, knowledge integration was not symmetrical. Although the process facilitator took the involvement of patients seriously, the experiential knowledge of patients was not considered to have the same validity as expert and scientific knowledge. The medical content of the recommendations for resumption of activities and employment was determined by the health professionals and scientific literature. However, patients’ input influenced the formulation of the recommendations because patients indicated that recommendations should not only focus on isolated physical movements but also on more complex daily activities. As a consequence, knowledge integration led to synergy in which joint construction resulted in an end-product of better quality. The testing of the web-based patient version demonstrated that patients agreed on the content of the recommendations. Given that no interaction between actors occurred and little vicarious learning activities were undertaken, it is unlikely that underlying assumptions have changed due to the knowledge co-production process.

In the policy advisory process, it was decided to present patients’ needs for future medical products separately from those of health professionals in the advice to the Minister of Health. To this end, patients’ priorities were visibly incorporated into the advice, giving patients an inclusive, non-tokenistic experience of involvement and making patients’ perspectives and underlying values and assumptions visible. Subsequently, the GR committee prioritized patients’ priorities based on three criteria: societal relevance, market failure and the presence of a good knowledge base, using scientific and expert knowledge (Gezondheidsraad 2011). In the clinical trials case, the perspective of patients was dominant in the design. The dialogue meeting mainly discussed the feasibility of the potential improvements and possibilities for patient involvement identified by patients. In this way, actors became familiar with each other’s underlying values and assumptions, resulting in a shared action plan for future implementation of patient involvement in clinical trials. For example, patients understood why some of their ideas were not feasible in practice in the short-term, such as appointing patient research partners for every clinical trial or deleting the insurance section in Patient Information Sheets because it is a legal obligation. On the other hand, some of the patients’ ideas were ‘eye-openers’ to the other actors, like a ‘thank-you’ letter or the potential willingness of patients in the palliative phase to be involved in research. Moreover, the participants agreed to start with the implementation of tasks that are relatively easy to integrate in existing structures and procedures. To this end, they consciously sought for ‘quick-wins’.

Some scholars are worried that patients might overly align themselves to the perspectives of researchers and health professionals in interactions. They attribute this to the higher status accorded to all actors, including patients, and to scientific and expert knowledge (Van De Bovenkamp et al. 2008; Elberse et al. 2011). To minimize the risk that patients might take on the perspectives of researchers and health professionals, patients were involved in making their experiential knowledge explicit, during knowledge articulation, in a process known as
During the knowledge integration process in the different cases, we did not observe that patients aligned with the perspectives of researchers and health professionals, while neglecting their own perspective. Firstly, there was no direct interaction between patients and professionals in clinical guideline development, and the needs for future medical products for each actor group were incorporated into the advice separately. Secondly, in the clinical trials case, attention was paid to ‘enclave deliberation’ and the development of intermediated trust, and the members of the advisory board articulated their preferences specifically. Furthermore, the dialogue meeting was facilitated in a directive manner, something that I will reflect upon in more detail below.

Facilitation of knowledge integration

In knowledge integration, an important task of the facilitator is to create trust between actors (Broerse 1998). At the start of the knowledge co-production process, the level of trust is usually low because actors generally have no experience with knowledge co-production processes. Initially, the facilitator as an independent actor can enhance ‘intermediated trust’, making the actor groups familiar with each other’s perspectives and removing preconceptions. As a result, individual actors are already better prepared for dialogue. During the dialogue, the facilitator facilitates the exchange of perspectives between actors and supports development of mutual trust. The development of both intermediated and mutual trust was most clearly visible in the clinical trials case. Prior to the dialogue meeting, all participants received the advice of the patient advisory board, an overview of the results of the consultation of health professionals, and a review of the scientific literature. In the working sessions of the advisory board, the perspectives of health professionals and the scientific literature had already been discussed, as described earlier. During the dialogue meeting, the development of trust was enhanced by first presenting the perspectives of individual actor groups followed by a reflection by each actor group on the findings. For the dialogue in the clinical trials case, the facilitator relied on the use of various inclusion strategies to overcome the tendency to exclusion resulting from the asymmetrical relationships between researchers, health professionals and patients, caused by differences in social status and the lower value assigned to experiential knowledge (Callaghan and Wistow 2006; Dewey 2008). In addition, considerable attention was paid to the creation of conducive social conditions (openness, respect, inclusion and engagement) (Abma and Broerse 2010). For example, a neutral and central location was chosen, and the facilitator treated all participants with equal respect and did not use academic and medical titles. All actor groups received equal time to share their perspectives and, when necessary, the facilitator created time for patients to voice their opinions.

Trust was, to some extent, also developed in the policy advisory process. Although the involvement of patients was considered important by the members of the GR committee, there was also some reluctance to value patients’ knowledge equally. Most focus group discussions were observed by one or two members of the GR committee and staff. As a consequence, they gained firsthand insights into patients’ perspectives. They indicated that this contributed to increased insights into the value of experiential knowledge. In this way, trust was developed by the GR committee and staff. The feedback meeting at the end of the process contributed to development of mutual trust because consulted patients gained more insights into how their articulated needs for future medical products were incorporated in the advice. They also had the opportunity to ask for explanations and clarifications. Given that patients had no influence on the advice or follow-up activities, mutual trust was only developed to a limited extent.

Involvement of patients in knowledge articulation can already contribute to increased empowerment. In interaction with other actors, this empowerment can be reinforced during knowledge integration because patients are then allowed to express their articulated knowledge in dialogue with others (Schipper 2012). Unlike
empowerment during knowledge articulation, a power shift could occur during knowledge integration because patients could influence outcomes and health-related decision making. Empowerment during both knowledge articulation and integration was particularly visible in the clinical trials case among the members of the advisory board. These patients observed the development of their experiences into specific potential improvements and possibilities for patient involvement while concrete follow-up activities were also discussed during the dialogue meeting, based on their advice. They experienced first-hand the impact that their experiential knowledge may have on the design and conduct of clinical trials.

10.3 Enhancing knowledge embedding

Although knowledge embedding was explicitly studied in the nine cases of evaluation of follow-up activities after agenda setting (Chapters 8 and 9), the other three cases also provided interesting insights into how attention was paid to this element of the knowledge co-production process.

In general, patient involvement in the phases of knowledge articulation and integration was organized in the context of a project, facilitated by an academic institute. After the end-product (the outcome of knowledge integration) was established, in three of the four cases (excluding the case on clinical guideline development) external financing ceased. It was assumed that knowledge embedding would follow naturally. However, the case studies reveal that knowledge embedding is not easy and straightforward. The case on the nine cases on research agenda setting provided detailed insights into factors influencing this embedding of knowledge, and resulted in the identification of strategies to stimulate knowledge embedding in future patient involvement initiatives. The findings of this case were further strengthened and complemented by observations from the other three case studies.

The multiple case study revealed that factors influencing knowledge embedding are primarily related to the context of follow-up activities: attitude towards patient involvement, relations between actors, characteristics of organizations (e.g. available resources, presence of expertise, structures and procedures), and availability of time for embedding of the research agendas. These factors are presented in Table 10.2. The international literature also highlights the importance of these factors to the success of knowledge embedding (Barber et al. 2011). It stresses that structural patient involvement requires adjustment of structures and procedures, the establishment of long-term relationships between stakeholders, the building of competences, and willingness to involve patients (Howe et al. 2006; Thompson et al. 2009; Elberse et al. 2011).

<table>
<thead>
<tr>
<th>Context</th>
<th>Attitude</th>
<th>Relations between stakeholders</th>
<th>Characteristics of the organization</th>
<th>Time</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Willingness to cooperate and openness to each other’s perspectives</td>
<td>Presence of existing (informal) relations</td>
<td>Available resources for translation of patient topics into a funding</td>
<td>Habitation</td>
</tr>
<tr>
<td></td>
<td>Tension between stakeholders</td>
<td></td>
<td></td>
<td>Timing (e.g. available time between agenda setting &amp; call for)</td>
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</tbody>
</table>
During the different agenda setting projects, little attention was paid to the factors responsible for knowledge embedding (see Figure 10.2) because knowledge embedding was seen as a separate phase of agenda setting after the research agenda had been set. To counteract this trend, it is therefore suggested by many of the interviewees/participants that knowledge embedding should become a more integral part of projects for research agenda setting. At the start of a knowledge co-production processes the factors influencing knowledge embedding should already be anticipated on, as suggested in Chapter 9. This anticipation should continue in knowledge articulation and integration. To bring this about, support should be provided to improve attitudes to patient involvement, to build competences of actors, to develop enduring partnerships between actors and to adjust procedures and structures for patient involvement. The inclusion of activities related to knowledge embedding in an early stage of knowledge co-production processes is also expected to result in outcomes which better align with their use in daily practice. In response, proposals were made during the multiple case study to pay attention to these factors during early phases of the Dialogue Model.

The possibility and potential benefit of including knowledge embedding in early phases of knowledge co-production processes are illustrated in the clinical guideline development case. By the development of a web-based patient version of the clinical guideline in a parallel process involving patients, knowledge embedding became an integral part of the knowledge co-production process. The three elements of knowledge co-production follow each other sequentially in most patient involvement initiatives, something which is also inherent to the design of most participatory approaches (Broerse and Bunders 2000; Oliver et al. 2004; Titter and McCallum 2006; Abma and Broerse 2010; Boote et al. 2011). However, in this case, the embedding already started at the beginning of the process. The parallel development of the recommendations for resumption of employment and activities and the web-based patient version was expected to provide better alignment of the integrated knowledge in practice.

Developing ‘know-how’

The multiple case study revealed that the limited knowledge embedding observed in many of the single research agenda setting cases is partly related to lack of ‘know-how’ among actors and the absence of financial resources, captured in the factor characteristics of organizations. After a result is obtained from the process of knowledge articulation and integration, financial resources, as well as persons with know-how, are often no longer available. Therefore, a need for continued facilitation after knowledge integration was identified in the case on research agenda setting; actors should receive support in competence building for involving patients. In the single agenda setting cases, many participants from funding agencies and patient organizations also indicated that they were in
great need of practical guidelines with detailed instructions for involving patients in their procedures and structures, for organizing and designing participatory meetings (e.g. focus groups, dialogue meetings) and for developing and sustaining partnerships. As a result, guidelines were developed to assist policy makers of funding agencies and patient organizations in programming and implementation of patient involvement activities. In some other knowledge co-production projects (not part of the case studies in this thesis), the initiative was also taken to bundle the lessons-learned in a handbook or guideline. For example; insights obtained from the structural involvement of patient research partners in rheumatology research are described in a handbook (Visser et al. 2013, forthcoming), as are strategies and methods of patient involvement in clinical guideline development (Broerse et al. 2010; de Lange et al. forthcoming). However, these guidelines and handbooks are often poorly disseminated and, consequently, the acquired knowledge will be lost. As a result, the Netherlands Organization for Health Research and Development (ZonMw) took the initiative to collect and disseminate the lessons learned from patient involvement initiatives on an online platform, in collaboration with the independent network organization for non-governmental organizations (PGO Support)\(^1\). On this platform, actors can share their knowledge and experiences, and find information about involving patients in health research, policy or care practice. This idea is not new (see for example www.participedia.net), and is based on the understanding that knowledge should be shared through an open global knowledge community for actors in the field of patient involvement.

The abovementioned strategies for developing ‘know-how’ indicate that organizations should continue experimenting with involving patients in health-related decisions. This further stimulates reflexive learning processes, which contributes to competence building among actors and the realization of an ongoing means of knowledge co-production. Ideally, the learning process is monitored and evaluated by an academic institute for optimal results. The single case studies on (the revision of) the research agenda for Asthma/COPD shows that the Lung Foundation continued to experiment with involving patients in their research policy. Through several learning cycles they improved and expanded their patient involvement activities, which is amongst others, revealed by the revision and extension of the research agenda, the development of specific assessment criteria from a patient perspective, and the involvement of patients in the appraisal of research proposals. Both policy makers of the Lung Foundation and patient representatives developed ‘know-how’. To this end, both the process and the outcomes of knowledge co-production are embedded in the Lung Foundation.

**Change agents**

Change agents are persons or organizations who could be considered ‘frontrunners’ in the change process (Loorbach 2007). Change agents are characterized by their motivation for change and their willingness to invest resources (Elberse 2012; Essink 2012). The presence of change agents, as part of the factor attitude towards patient involvement, was clearly identified in the multiple case study as having influenced follow-up activities after agenda setting. For instance, the policy maker of the Lung Foundation was able to motivate other actors (e.g. colleagues, researchers); he convinced the scientific advisory board of the importance of patient involvement, and took the lead in implementing the research agenda. In the case of the research agenda for neuromuscular diseases, a professor acted as change agent. His involvement in the project team of the agenda setting project was responsible for a more positive attitude among other researchers. The importance of change agents in promoting change in health systems and stimulating knowledge embedding has also been stressed by various scholars (Geels 2005; Loorbach 2007; Elberse 2012; Essink 2012).

\(^1\)http://www.zonmw.nl/nl/projecten/project-detail/participedia-interactieve-tool-patientenparticipatie/samenvatting/
In the other cases, the presence of change agents was also observed. In the clinical trials case, representatives of BOOG and BVN became very committed to the project and developed a sense of ownership about the advice. Currently, BOOG and BVN are together (factor relationships) setting up a pilot study to put the advice for improvements in breast cancer clinical trials and patient involvement into practice. To ensure the sustainability of the knowledge co-production process, this pilot study will be monitored by an academic institute, which will contribute to the development of know-how as mentioned in the previous section. In addition, a professor who attended the dialogue meeting became inspired to involve patients in the design and conduct of clinical trials. She is stimulating a more positive attitude among other researchers by, amongst other things, publishing short articles about the project (Van der Wall 2012).

For the policy advisory process, ZonMw has been a change agent. In the policy advisory process, the advice for future medical products (Gezondheidsraad 2011) was presented during a feedback meeting, attended by actors involved in the process and potential investors in development of medical products. Subsequently, ZonMw appointed a working group made up of representatives from industry, health foundations, research funds, health professionals and patients organizations to stimulate follow-up of the advice (ZonMw 2012). This resulted, amongst other things, in the establishment of a ZonMw research programme ‘Translational research’, in collaboration with the Cooperative Health Foundations (Samenwerkende Gezondheidsfondsen, SGF), which funds research to meet the needs for medical products2. In addition, a partnership between ZonMw and the Dutch Federation for Patients and Consumers (Nederlandse Patiënten en Consumenten Federatie, NPCF) has been established to enhance the structural involvement of patients in health research3.

‘A normal thing to do’

The cases revealed that adjustments required for structural involvement of patients could hamper knowledge embedding. This can be explained by the fact that every system, including the health system, has fixed routines with clear power relations between stakeholders that structure daily activities. Changes of routines require a transition of the primarily supply-driven health system towards a more needs-oriented health system in which patients have a stronger voice. In this perspective, limited knowledge embedding can also be explained from the perspective of transition theory (Rotmans 2005; Loorbach 2007). Transitions are very slow processes which can take one or two generations. The transition process is not gradual and is often characterized by drastic changes (Rotmans et al. 2001). The knowledge co-production processes in this thesis demonstrate that changes are becoming visible and that an increasing number of actors have positive experiences with involving patients in health-related decision making. However, there is still no profound impact on research, policy and care practices. The multi-level perspective of transition theory distinguishes three levels of social organization of decreasing scale: (1) the landscape (the overall societal setting in which transitions occur), (2) the regime (stable networks of actors with shared assumptions and that interact via a dominant structure, culture and practice) and (3) the niche (spaces outside the regime in which individual actors develop and test new practices and actions) (Berkhout et al. 2003; Rotmans 2005; Loorbach 2007; Bunders et al. 2010). Systemic changes are often initiated at the niche level. At the niche level; new way of organizing, thinking and acting are developed and tested, which sometimes diffuse and scale up to the regime level, thereby changing the dominant structure, culture and practice. The knowledge co-production processes studied in this thesis were initiated at the niche level. They comprise isolated initiatives, often initiated by collaboration between a patient organization and a funding agency. These isolated initiatives

2http://www.zonmw.nl/nl/subsidies/subsidiekalender/detail/item/programma-translatieel-onderzoek/
provided a safe environment to experiment with patient involvement in health-related decision making, to build competences and to adjust procedures. However, these initiatives did not (yet) scale up to the regime level; it usually takes considerable time and deliberate action of many actors to influence the regime level.

Despite the observed constraints and the slow pace of change, the process of knowledge articulation and integration is increasingly embedded in health research, policy and care practice. Funding agencies continue with patient involvement in agenda setting when they consider the current agenda needs to be updated and other funding agencies have developed new agenda setting projects or expanded their patient involvement activities (Elberse 2012). Indeed, involving patients is increasingly considered to be more normal practice. Moreover, health organizations are stimulating sustained knowledge co-production, as demonstrated by ZonMw’s follow-up to the advice for future medical products. Isolated niche experiments, with knowledge co-production, appear to be scaling up to regime level and becoming more embedded in structures, cultures and practices.

10.4 Overall conclusions

The research described in this thesis reveals that the process of knowledge co-production in health-related decision making is complex and not automatic. The four case studies provide insights into how knowledge co-production processes could be more optimally structured by studying the three elements of the process in detail. For the first two elements, suggestions for improvement have been formulated. For the last element, knowledge embedding, insights into limited knowledge embedding have been obtained and strategies have been suggested to enhance embedding in the future. Although the conclusions have been described for each element of the knowledge co-production process, it should be emphasized that knowledge co-production is not a linear process but should be considered as an iterative process with interaction between a wide variety of actors and ongoing learning processes. The conclusions in the previous sections make it possible to formulate the following main conclusions about the effectiveness of knowledge co-production processes in the cases studied. A summary of the conclusions for each element of the knowledge co-production process comprises:

1. **Knowledge articulation:** In the three cases, specific attention was paid to the articulation of experiential knowledge of patients. It revealed that knowledge articulation can be conducted in many ways. The use of interviews and particularly focus group discussions appeared very effective methods for articulation of experiential knowledge. To convert the ‘I-voice’ into a ‘we-voice’, quantitative methods have generally been proposed, but the research in this thesis reveals that qualitative methods involving patient representatives could also be used for the successful conversion of the ‘I-voice’ into a ‘we-voice’. Lay-patients and patient representatives complemented each other, and patient representatives were able to deepen and broaden the experiences of lay-patients, leading to increased diversity and representation of the patient community. However, it is also revealed that in a knowledge co-production process, which is constrained by time and money, it is very complicated to include all different sub-groups within an actor group. This creates a dilemma regarding the realization of legitimate knowledge articulation. Explicit attention should be paid to maximizing diversity and representation of the actor groups within the constraints of time and money. Exclusion of specific groups should be transparently communicated, including the reasons for exclusion.

2. **Knowledge integration:** The three cases illustrate different approaches to knowledge integration. Integration can be brought about by the actions of an independent facilitator or by means of interaction between actors. Interaction between actors can be operationalized by a working group comprising representatives of the actor groups or by a dialogue meeting between actors. The three cases also showed that the end-product of knowledge integration can be constructed in different ways, although it is desirable that actors agree on the
content and underlying values and assumptions. For this reason, interaction between actors is preferable because it stimulates reflexive learning. It makes different perspectives and underlying assumptions visible. It can broaden and enrich debates, may avoid the exclusion of actors and bring forward creative ideas. Moreover, to ensure acknowledgement and appreciation of experiential knowledge, strong facilitation is necessary to create conducive social conditions and build trust between actors.

3. **Knowledge embedding**: The cases reveal that the process of knowledge embedding is complicated, because of the required systemic changes. Several factors have been identified which particularly influence knowledge embedding: attitude towards patient involvement, relations between actors, characteristics of organizations (e.g. available resources, presence of expertise, structures and procedures), and availability of time for embedding of the research agendas. The cases show that knowledge embedding should become a more integral part of projects for patient involvement and that already at the start of a knowledge co-production process there should be more anticipation on factors influencing knowledge embedding. Also, more attention should be paid to the development of know-how among actors by continuing to experiment with patient involvement in health-related decisions, including ‘quick wins. This further stimulates reflexive learning processes, which contributes to competence building among actors and the realization of an ongoing means of knowledge co-production. Moreover, the presence of change agents can promote change in health systems and stimulate embedding of knowledge. Early identification and support of change agents could enhance knowledge embedding. These insights could contribute to improvement of, not only the Dialogue Model, but also other participatory approaches to knowledge co-production.

10.5 **Validity of the findings**

In this section, issues regarding internal and external validity of the research findings are discussed. With regard to internal validity, the central role of the researcher, representation of actors, and the analytical process will be discussed. In terms of external validity, the relevance of the research for knowledge co-production processes outside health-related decision making is discussed, as well as the validity of the research for others.

**Internal validity**

Researcher bias is particularly an issue when the researchers themselves have played a central role in designing and conducting the experiments and projects, as well as in analyzing the results and evaluating the process. This central role provides researchers with opportunities to examine the data from close proximity and to analyse the data in the context in which it was collected. However, this also implies that the researcher has a central role in the reflection on a (partly) self-designed process. In the policy advisory process and clinical trials cases, the researchers had a central role in designing and conducting the knowledge co-production process. In the clinical guideline development, the monitor did not design the overall knowledge co-production process, but was involved in the organization and conduct of some of the activities involving patients. This implies that to some extent ‘self-evaluation’ took place in these cases. For the evaluation of follow-up activities after agenda setting, researchers were not involved in design and conduct of the knowledge co-production processes. As a consequence, researcher bias was limited in this case.

Various validity checks were used to minimize the risk of researcher bias, as described in Chapter 3 of this thesis. First, data was validated using triangulation. Several data collection methods, such as desk studies, interviews, focus group discussions and observation, were used to improve internal validity. Second, data was documented
extensively to ensure that interpretation occurred within its specific context (rich data). Third, member checks took place among respondents. Also, in all cases, except for the policy advisory process, preliminary findings from the study were presented to and discussed with respondents in later phases of the research in order to validate findings and to minimize misinterpretations and misunderstandings. Fourth, data was analyzed by multiple researchers and, at regular intervals, data was discussed with colleagues and peers not directly involved in the knowledge co-production process (via advisory committees or project teams). They provided an additional check on whether the data was correctly interpreted.

With regard to respondent bias, we often relied on voluntary participation. It was observed that patients with a relatively higher education and with specific experiences were generally more eager to participate than vulnerable patient groups, and therefore over-represented among the respondents. The over-representation of ‘enthusiasts’ seems unavoidable. ‘Enthusiasts’ are actors who already have a positive attitude towards patient involvement and who are willing to contribute to knowledge co-production processes in health-related decision making. However, the involvement of ‘enthusiasts’ does not necessarily have to be a drawback for research. These persons are already motivated and, as mentioned above, change agents and followers are needed to promote change in health systems. ‘Enthusiasts’ could be considered as future followers. Furthermore, in all cases considerable effort was taken to include a broad range of actors.

Internal validity of the research was further enhanced by the analytical process. The analytical process was iterative rather than linear. In other words, study questions were not formulated and answered by one case at the time, but by analysis of all cases together, as is presented in Table 3.1. This meant that the answers to each sub-question were based on conclusions from multiple cases which can also be considered as representing triangulation of data.

Assessing the effectiveness of the process of knowledge co-production and the impact of the outcomes on health-related decision making is not easy (Broerse et al. 2009; Barber et al. 2012). In the literature, various evaluation criteria have been proposed regarding the process of involvement and the generated outcomes (Laird 1993; Webler 1995; Guston 1997; Guston 1999; Rowe and Frewer 2000; Webler and Tuler 2000; Driessen et al. 2001; Abelson et al. 2003; Rowe and Frewer 2004; Abelson and Gauvin 2006; Caron-Flinterman et al. 2006; Broerse et al. 2009). These have led to the development of a monitoring and evaluation framework (see Chapter 2 & 5). Although this framework provides guidelines for assessing effectiveness, it remains difficult to measure implicit but essential outcomes, such as empowerment and learning processes. In addition, it is not easy to determine the influence of patients’ input when decisions have been made together and individual actor perspectives are converged in outcomes (Epstein 2011). To assess the effectiveness of knowledge co-production processes in the case studies, we used a triangulated approach to increase inter-subjectivity. To this end, we studied the intermediary and end-products, statements of participants (formulated in e.g. interviews, focus group discussions) and observations of interactions.

**External validity**

External validity concerns the generalization of the data and whether the findings are transferable to other contexts and to the international literature. The conclusions of this thesis are based on data of four case studies, one of which was a multiple case study of nine different cases. These cases differ in terms of contexts and strategies used for involving patients, and they were conducted within various areas (health research, policy and care practice). The considerable diversity of contexts and strategies means that caution is needed in drawing conclusions about structuring knowledge co-production processes because a different selection of cases might have resulted in other conclusions. However, each case was studied with the same focus – structuring of
knowledge co-production processes – and from one theoretical framework, as described in Chapter 2. Moreover, the iterative character of the analysis allowed the conclusions to be based on results from multiple cases. The different cases revealed that knowledge co-production processes in different contexts in health-related decision making experience similar difficulties and challenges. This indicates that the findings in this thesis might be transferable to other patient involvement initiatives.

The findings of this thesis may also be extrapolated to the international context. In other countries, notably the UK and Canada, much knowledge on involving patients in health-related decision making is already available. This literature made a valuable contribution to this thesis. The challenges and difficulties identified in this thesis are also reported in these countries (Boote et al. 2002; Stevens et al. 2003; Telford and Faulkner 2004; Hewlett et al. 2006; Oliver et al. 2008; Staniszewska et al. 2008; Ward et al. 2010). As a result, insights from this thesis might also be useful for improvement of patient involvement initiatives in health-related decision making in the countries which already have considerable experience of patient involvement. For countries relatively new in the field of patient involvement, the findings may provide directions for shaping knowledge co-production processes.

The experiences with knowledge co-production in health-related decision making also have a broader relevance. The cases in this thesis provide examples of a process in which the knowledge of different actors is brought together and that is designed to realise decision making. As already mentioned in Chapter 1, the involvement of multiple actors in decision making has been framed in various constructivist areas, like transdisciplinary research (Klein et al. 2001), knowledge co-creation (Regeer and Bunders 2009), post-normal science (Funtowicz and Ravetz 1993), and mode-2 knowledge production (Gibbons 1994). Reflection on the practices and methodologies for these types of processes contributes to a better understanding of possibilities and limitations (Bunders et al. 2010), and provides insights for improvement. This research provides critical reflection on these processes and contributes to increased insights. Moreover, it emphasizes the value of involving multiple actors, including patients, in decision making processes.

10.6 Future research

This research demonstrates that many challenges are experienced in knowledge co-production in health-related decision-making. It opens up a range of questions on how knowledge co-production can be improved. Therefore, additional studies are needed to develop and test improved knowledge co-production processes, which have increased attention for interaction between actors in knowledge integration and new strategies to enhance knowledge embedding. Within the three elements of knowledge co-production – knowledge articulation, integration and embedding – several constraints and challenges have been identified. Many of these have also been reported in the patient involvement literature (e.g. Boote et al. 2002; Stevens et al. 2003; Telford and Faulkner 2004; Hewlett et al. 2006; Oliver et al. 2008; Staniszewska et al. 2008; Bovenkamp and Trappenburg 2009; Elberse et al. 2009; Ward et al. 2010). This thesis has suggested strategies for improvement. These improvements need to be tested within new experiments. These new experiments should also check whether the findings in this thesis are valid for other contexts.

This thesis confirmed that the process of knowledge embedding is very complicated, because of the required systemic changes on different societal levels. Therefore, new experiments should particularly pay attention to the development of strategies which enhance knowledge embedding. The cases already identified various strategies. In an experimental setting these strategies could be further developed, tested and validated. In addition, because knowledge embedding requires systemic changes, insights from transition theory could be used; particularly those
strategies developed in the context of transition management (Loorbach 2007; van den Bosch and Rotmans 2008; van den Bosch 2010). Transition management takes sustainable development as a long-term goal and structures and organizes learning processes to enhance system innovation. In general, transition management stresses the importance of small-scale (niche) experiments, since they could be used as an instrument to explore new structures, cultures and practices (Loorbach 2007). In these experiments three steering mechanisms can be applied to guide the change process: deepening (learning in a specific context), broadening (linking and repeating experiments in different contexts) and scaling up (embedding in the regime level and changing the dominant way of organizing, thinking and acting) (Loorbach 2007; van den Bosch and Rotmans 2008; van den Bosch 2010). The sequence of these mechanisms is iterative involving learning and adaptation. Subsequently, new successful strategies could contribute to improvement of approaches to knowledge co-production. It is important that these new experiments are thoroughly monitored and evaluated.

The international literature also stresses that there is a growing need for systematic evaluation of patient involvement initiatives (Abelson et al. 2003; Mitton et al. 2009; Wright et al. 2010; Barber et al. 2011; Stewart et al. 2011). Systematic evaluations can contribute to increased understanding of the effectiveness of the process of knowledge co-production and the impact of the outcomes on health-related decision making in research, policy and care practice. It can assess whether the improved approaches and new strategies, as suggested in previous paragraph, are effective. Moreover, increased insights will make the added value of patient involvement more explicit. This is essential because many scholars still argue that patient knowledge is too subjective and cannot contribute to health-related decision making (Caron-Flinterman et al. 2005). A ‘solid’ proof of the added value could help to convince people to consider involving patients in their activities and organizations, and thereby create more followers which will contribute to embedding.

As mentioned before, it is difficult to ‘measure’ implicit but essential outcomes, such as empowerment and learning processes, and to determine the influence of patients’ input when decisions have been made together and individual actor perspectives are converged in outcome. The methodology of responsive evaluation (Stake 1975; Guba and Lincoln 1989; Greene 2001; Abma 2005b) could provide in-depth insights because it makes explicit the experiences of different actors and discussion of experiences is facilitated. In combination, the various complementary actor perspectives will lead to a more informed understanding of what is being evaluated. Also Reflexive Monitoring in Action (Grin and Weterings 2005; Regeer et al. 2009) could provide detailed insights because, in this methodology, a monitor closely observes the process and the generation of outcomes, and stimulates learning processes by enhancing reflection and dialogue between actors.

10.7 Concluding remark

The research in this thesis strives to improve knowledge co-production processes by contributing insights on how to overcome challenges and difficulties. Although the thesis focuses mainly on what can still be improved, it is important to stress that patient involvement in health-related decision making has already made considerable progress in the Netherlands. Health organizations, funding agencies, research institutes and patient organizations consider the involvement of patients to represent added value, reflected in the increasing number of initiatives and increased demand for guidelines and approaches. Organizations consider patient involvement to be a ‘normal thing to do’. Although there are still many difficulties facing the design, conduct and impact of patient involvement, I encourage this increased attention. I hope that this thesis contributes to shaping these organizations’ patient involvement initiatives.