

Societal Research Evaluation

UMC Utrecht

Members of societal stakeholder committee:

Anke Vervoord (chair)
Sigrid Attema
Gorrit-Jan Blonk
Jasper Boomker
Dominique Hamerlijnck
Kim Holtzer
Martin de Kleine
Judith van de Meerakker
Jacqueliën Noordhoek
Jan van Veldhoven
David Verschoor
Jop de Vrieze

October 2019

Facilitated by: Anne-Floor Schölvinck
(Scholvinck Advies)

Executive summary

2

As part of the UMC Utrecht external research evaluation for the period 2013-2018 (SEP), a societal stakeholder committee has evaluated the societal value and patient involvement of the research performed in that period. This societal research evaluation aimed to; *map the efforts (policy and activities) regarding patient involvement and the societal value of research at the UMC Utrecht; evaluate these activities regarding the process and the outcome; in order to formulate recommendations for more and/or "better" societal value and patient involvement in future research.*

Generally, the societal stakeholder committee agrees that there is an abundance of activities to make societal impact and to involve patients in research at the UMC Utrecht. However, the strategic research programs reflect little on these activities and their outcomes. From the self-evaluations it is often unclear what the activities aimed for, whether that aim was achieved, on which aspects the activities did not succeed, or how those involved experienced the activities.

Additionally, the committee did not find an overarching policy regarding either patient involvement or societal impact. Without a strategic framework or vision, the committee had difficulties to determine whether any preset goals had been achieved.

In many strategic research programs, there were large differences regarding the amount and quality of patient involvement and societal value activities between the research lines. This added to the impression that activities are not embedded in the strategic research program, but rather dependent on the enthusiasm of individual researchers and their connection with a few patient representatives.

The societal stakeholder committee formulates the following general recommendations;

- ❖ Define the societal value which the UMC Utrecht aims for, determine objectives and organize activities that contribute to these objectives;
- ❖ Implement a policy on patient involvement regarding representation, reimbursement, remuneration, training, communication and feedback;
- ❖ Provide more opportunities for researchers to learn from each other, both within and across strategic research programs, on patient involvement practices and efforts to enhance societal impact.

Additionally, for each of the six strategic research programs specific recommendations are formulated.

Table of contents

Executive summary	2
1. Background, Goal and Scope	4
2. Approach.....	5
3. Findings	6
Overall findings.....	6
Observations regarding the self-evaluation.....	7
4. Recommendations	8
Overall recommendations	8
Brain	9
Cancer	10
Child Health	10
Circulatory Health	10
Infection & Immunity	11
Regenerative Medicine & Stem Cells	11
Appendix A. Members of the societal stakeholder committee	12
Appendix B. Evaluation criteria	13
Appendix C. Contextual background	15
Appendix D. Presenters	16

3

1. Background, Goal and Scope

4 At UMC Utrecht, the impact of research is of paramount importance: research must not only be of high scientific quality, the results must also actually contribute to improving (the quality of) patients' lives. Involving patients in a meaningful and structural way in research can contribute to such impact.

There are three arguments advocating the involvement of patients in research. First, the experience of illness makes patients valuable discussion partners in health research, as they have a different perspective from healthcare professionals and researchers. Second, one can argue that it is patients' democratic right to be involved in research, as they are the ones most directly affected by health research. Third, involving patients in health research increases the support for research amongst patients, thereby increasing the chance of implementation of the results ¹.

The societal impact of research can take many different forms. Research can change (care) practice, be economically valued, improve public health, and / or improve the lives of patients in a broader sense.

The centrality of the societal value of research and patient involvement at the UMC Utrecht justify its evaluation adjacent to the 6-yearly research evaluation in the Standard Evaluation Protocol (SEP). Therefore, a societal stakeholder committee² (henceforth: the committee) has been asked to evaluate the societal value and patient involvement of the research performed at the UMC Utrecht. The purpose of this societal research evaluation is to;

- *map the efforts (policy and activities) regarding patient involvement and the societal value of research at the UMC Utrecht;*
- *evaluate these activities regarding the process and the outcome;*
- *in order to formulate recommendations for more and/or "better" societal value and patient involvement in future research.*

This report contains the findings and recommendations of the committee with regard to the societal value and patient involvement of the research performed in the strategic research programs of the UMC Utrecht. The integral program on patient participation, led by prof. dr. Hans van Delden and prof. dr. Jim van Os, was not included in this evaluation. This program has been running since 2018, which the UMC Utrecht deemed too short to evaluate effectively. Additionally, this program focuses on patient involvement in all three core activities of the UMC Utrecht (care, education and research). This combination would have complicated evaluation of purely patient involvement in the research domain.

¹ In appendix C, more contextual background is provided about patient involvement in the Netherlands.

² Please see appendix A for the members of the societal stakeholder committee, their affiliations and on which strategic research program they focused on.

2. Approach

5

The societal stakeholder committee has based its findings and recommendations on two primary sources of information: the self-evaluation written by the six strategic research programs of the UMC Utrecht, and six presentations of best practices in which a researcher and patient (representative) have collaborated successfully in a research project. The committee has met twice for an afternoon (on October 2nd and October 16th 2019) to discuss their findings and recommendations.

Self-evaluation of strategic research programs

Each of the six strategic research programs have written a self-evaluation for the SEP-evaluation. From these evaluations, relevant passages were selected in which the efforts to involve patients and maximize societal value were described.

For each strategic research program, two members of the committee assessed these relevant passages of the self-evaluation, structuring their judgement according to a set of predetermined evaluation criteria³. They discussed their findings first amongst themselves in a facilitated preparatory meeting. Subsequently, they presented and discussed their joint assessment with the other members of the committee to formulate both overall recommendations, and recommendations specific for each strategic research program.

Presentations of best practices

During the meetings of the committee, 6 duos of researchers and patients (representatives) presented their collaboration during a 10 minute presentation followed by 10 minutes of discussion⁴. Each strategic research program was represented in one showcase. The committee discussed the collaboration with the involved patient representatives and the involved researchers.

³ This set of evaluation criteria is described in appendix B

⁴ See Appendix D for list of presenters

3. Findings

First, the overarching findings of the societal stakeholder committee are presented. Subsequently, the committee has a few observations about the format of the self-evaluation and how it has influenced their advisory role.

6

Overall findings

Generally, the committee agrees that **there is an abundance of activities to make societal impact and to involve patients** in research at the UMC Utrecht. The committee has the impression that many researchers at the UMC Utrecht collaborate with patients with great drive and passion to improve their lives. The strategic research programs provide an comprehensive listing of activities involving patients or fostering societal value.

However, in the self-evaluations the strategic research programs **reflect little** on the activities and their outcomes. From the documentation, it was often unclear what consequences the activities aimed for, whether that aim was achieved, in which parts the activities did not succeed, or how those involved experienced the activities.

In line with the above findings, the committee had the impression that **an overarching policy and definition regarding patient involvement or societal impact** was either lacking in the self-evaluations, or not being implemented by the strategic research programs. Societal value was not defined, and a policy fleshing out patient involvement in research was missed. This gave the self-evaluations a rather fragmented impression. On the other hand, the committee had the impression that the UMC Utrecht provides ample flexibility for researchers to organize patient involvement in creative ways. Without a strategic framework or vision, the committee had difficulties to determine whether any preset goals had been achieved.

In many strategic research programs, there were **large differences regarding the amount and quality of patient involvement and societal value activities between the research lines** (both within and across strategic research programs). This added to the impression of the committee that activities are not embedded in the strategic research program, but rather dependent on the enthusiasm of individual researchers and a few patients or patient representatives. The committee found few indications that sharing of best practices or learning experiences is encouraged between researchers across different research lines, divisions, and/or strategic research programs.

The committee noted that **the amount and quality of patient involvement taking place at the UMC Utrecht seemed partly dependent on external or contextual factors**. For example, how well patients were involved in research is influenced by: how well the condition and the patient group is defined, whether and how well the relevant patient organizations are organized, and the complexity of the stakeholder-landscape.

Observations regarding the self-evaluation

The committee agrees that the organization of this societal research evaluation by the UMC Utrecht is commendable in itself. It demonstrates the importance that the UMC Utrecht places on patient involvement and the societal value of its research.

7

According to the committee, **the format of the self-evaluation might have been partially responsible for the limited level of reflection** of the strategic research programs in these documents. The strategic research programs extensively listed their activities, paying great attention to completeness. However, the format provided little opportunity to reflect on the intended and achieved outcomes of these activities, unintended consequences, learning experiences, etc.

Similarly, **a definition and framework of what the strategic research programs aimed for** regarding patient involvement and societal value was lacking in the self-evaluations. This information would have helped the committee to assess whether they met their goals.

Additionally, the committee missed a **quantitative overview** of all the research projects in the strategic research program, with a clear indication if (and if so, when and how) patients were involved in the research. This complicated the assessment of how well patient involvement is embedded in the research of the UMC Utrecht; were the highlighted projects in which patients were involved the only showcases around, or are patients involved in research by default?

4. Recommendations

On the basis of these findings, the societal stakeholder committee has formulated three general recommendations for all the strategic research programs. Additionally, for each of the six strategic research programs, specific recommendations are presented.

Overall recommendations

- ❖ **Define the intended societal value of the research, determine objectives and organize activities that contribute to these objectives**

Societal value can have multiple definitions or outcome measures. First, research results may be implemented in healthcare practice, for example by drafting or changing care standards or guidelines. Adoption of a new treatment in the benefit packages of healthcare insurance is also part of this aspect of societal impact. Second, societal value can be defined economically; for example by applying for patents or by furthering (pharmaco)therapeutic development. Third, research results could improve public health, for example by improving prevention. Last, the lives of patients can be improved in a broader societal sense, for example when stigma is reduced or psychosocial care in the workplace is improved. Defining what societal impact one aims for in a research project, may help determine what activities should be considered to achieve this goal.

Societal value can be defined either bottom-up or top-down. Each research project or research line can determine the intended impact. Based on these goals, the strategic research programs can define the intended aggregate societal impact. Alternatively, the UMC Utrecht could formulate an overall definition of societal value and translate this into societal impact for each research project. In both cases, this societal impact should inspire the objectives of the research and guide what action should be taken to research these objectives.

In the endeavor of defining the intended societal impact of a research project, patients should be involved. In other words, the 'we' in a vision⁵ must represent both researchers and patients to achieve maximal value.

- ❖ **Determine and implement a policy on patient involvement regarding the aspects representation, reimbursement, remuneration, support, and communication and feedback:**

To reduce the differences in quality of patient involvement within strategic research programs, the drafting and implementation of guidelines regarding patient involvement is necessary. In case such policies already exist, for example in the healthcare domain, the

⁵ The UMC Utrecht often formulates visions or missions as 'we aim to...'. The committee wonders, who is the 'we' in such a sentence?

implementation of these policies should be extended to patient involvement in health research.

The committee advises to involve patients as early on as possible in the research decision-making process – ideally when setting the research agenda of a particular research line or condition.

Regarding the representation of patients, the committee advises to involve the relevant patient organization rather than individual patients whenever possible – that is, in case a relevant organization exists in The Netherlands. Also, when possible, the committee recommends to avoid involving patients who are currently under treatment in the UMC Utrecht, to avoid potential conflicts of interest. Last, the committee thinks it is important to involve a diverse group of patient representatives – to be aware of not only involving the 'professional patient' who is often consulted.

The committee missed the existence or implementation of overall guidelines regarding the reimbursement of travel expenses, provision of fees for patients' involvement, and the offering of training and support opportunities for patient representatives.

Providing feedback to patients who have been involved in research (either as collaborator or as study subject) is pivotal for their commitment. The committee is under the impression that following up on past involvement is not yet standard practice. Also, it is therefore important to consider and evaluate how well information on a research project is translated from medical jargon to laymen's vocabulary, to ensure that the involved patients understand the information that is being conveyed.

❖ **Encourage researchers to learn from each other within and across strategic research programs.**

Cross-pollination between different research projects, research lines, and strategic research programs does not take place automatically. Therefore, ample opportunities need to be created for researchers to share best practices, inspire each other and to support them in their endeavors to cooperate with patients in their research.

Brain

In addition to the overall recommendations, the committee advises the strategic research program Brain to pay attention to the following additional comments;

- ❖ There are large differences in the amount and quality of patient involvement between the research lines. Patient involvement is well organized in the research lines Neuromuscular disorders and Psychosis, while this is less so for the research lines Epilepsy and Developmental disorders. The strategic research program could facilitate learning across these research lines.
- ❖ The ALS collaboration between patients, researchers and fundraisers can be considered a best practice, demonstrating the value of such a partnership. Maintaining pleasant formal and informal relations between all three stakeholders

is pivotal to a fruitful collaboration. It might be worthwhile to consider how this collaboration can function as a blueprint for other disease areas.

Cancer

In addition to the overall recommendations, the committee advises the strategic research program Cancer to pay attention to the following additional comments;

10

- ❖ the research line Prevention & Survivorship involves two quite different audiences from the patients' perspective. The societal impact to be aimed for could therefore also be of a completely different nature. It might be helpful to split the research line Prevention & Survivorship into two separate lines.
- ❖ The transition from research into a cancer type to research into a tumor type is well described in the self-evaluation. It is important to consider how this transition affects patient involvement; do patients feel connected to research into their tumor type, or do they identify themselves more by cancer type? How can patient involvement be continued in this new research era?

Child Health

In addition to the overall recommendations, the committee advises the strategic research program Child Health to pay attention to the following additional comments;

- ❖ The formal alliance between the Nederlandse Cystic Fibrosis Stichting (NCFS) and the UMC Utrecht can be considered a best practice of a valuable patient-researcher collaboration. Similarly, the patient advisory group on childhood rheumatism and the VOICE project demonstrate the value of a partnership between patients and researchers. It might be worthwhile to consider how this collaboration can inspire other disease areas within the strategic research program.
- ❖ The UMC Utrecht is a centre of expertise on neonatal neurology. The committee points out that this appointment is not only an opportunity to acquire research funding and a concentration of expertise; it also comes with obligations regarding the involvement of patients and information provision to them

Circulatory Health

In addition to the overall recommendations, the committee advises the strategic research program Circulatory Health to pay attention to the following additional comments;

- ❖ A collaboration with Philips on the Fiber Optic RealShape (FORS) technology is described as a successful endeavour to valorize the research in cardiovascular imaging. The committee is curious whether this is the only successful collaboration with companies set up in this strategic research program, whether other attempts have been made to valorize research economically, and whether the strategic research program could reflect on the factors that made the collaboration with this particular firm a success.

- ❖ The committee regards the SWOT analysis of the strategic research program as an important starting point for improvement of the research in the program. According to the committee, the observations and issues noted in the SWOT-analysis call for further reflection and activities to implement improvements. These proposed actions, especially regarding societal impact and patient involvement, are lacking in the self-evaluation. The committee wonders whether such activities have been undertaken nevertheless.

Infection & Immunity

In addition to the overall recommendations, the committee advises the strategic research program Infection & Immunity to pay attention to the following additional comments;

- ❖ There are large differences in the amount and quality of patient involvement between the research lines. Patient involvement is well organized in the Prevention of inflammation research line. For example, the cooperation in Irritable Bowel Disease provides a clear description of what was done and what the results were. In the other research lines a description of activities was provided, but the impact remained unclear. This gave the impression that the researchers had involved patients in fewer occasions or with less impact.
- ❖ The strategic research program states that learning across the research lines is aimed for, but -apart from a number of researchers and clinicians working on several themes- no activities are described to facilitate such mutual learning.

Regenerative Medicine & Stem Cells

In addition to the overall recommendations, the committee advises the strategic research program Regenerative Medicine & Stem Cells to pay attention to the following additional comments;

- ❖ the valorization and patient involvement activities of the research lines Musculoskeletal tissue regeneration and Heart regeneration are more elaborate than in the research lines Renal regeneration and Stem cell-based therapies. There may be differences between these research domains regarding the fundamental, translational, or clinical nature of the research. For more fundamental research, involving patients or asking them the right questions might be difficult. However, providing researchers the opportunity to learn from each other on how to involve patients and foster societal impact might still be worthwhile.
- ❖ ethical parallel research and efforts to create more transparency in animal experiments (such as preclinicaltrials.eu) are meaningful in itself. However, the outcomes and impact of these efforts remain elusive. A proactive media-strategy might help to promote debate regarding the ethical implications of the RMSC research.

Appendix A. Members of the societal stakeholder committee

The following people were members of this societal stakeholder committee. Although they acted in their personal capacity, many of them are affiliated with a patient organization or funding agency. They were asked to focus on a strategic research program related to their affiliated organization.

12

	Representing organisation or perspective	Focusing on strategic research program
Anke Vervoord (chair)	Harteraad	Circulatory Health
David Verschoor	Hartstichting	Circulatory Health
Judith van de Meerakker	Experiential expert	Brain
Gorrit-Jan Blonk	Stichting ALS Nederland	Brain
Kim Holtzer	NFK	Cancer
Sigrid Attema	KWF Kankerbestrijding	Cancer
Jacqueline Noordhoek (present at 1st meeting)	Nederlandse Cystic Fibrosis Stichting	Child Health
Martin de Kleine	Vereniging Ouders van Couveusekinderen	Child Health
Jop de Vrieze	Sciencejournalist	Infection & Immunity
Dominique Hamerlijnck	LongFonds	Infection & Immunity
Jasper Boomker	Nierstichting	Regenerative Medicine & Stem Cells
Jan van Veldhoven	Reuma Nederland	Regenerative Medicine & Stem Cells

Anne-Floor Schölvinc (Scholvinck Advies) prepared and facilitated the meetings of the committee and drafted the report.

On behalf of the UMC Utrecht, staff advisor Rinze Benedictus from the Research Office and coordinator of the SEP Research Evaluation, was present during the committee meetings.

Appendix B. Evaluation criteria

The evaluation criteria below were used by the committee as a guide for interpreting the self-evaluations of the strategic research programs.

13

Overarching policy on societal value and patient involvement

Policy measures can enhance the societal value of research and embed patient involvement in research at the strategic research program. Ask yourself the question;

- ❖ What is the overarching policy of the strategic research program in terms of the societal value of, and patient involvement in, research?
 - what could others learn from this?
 - how could the strategic research program improve on this aspect?


Societal value of research

Research can have societal value in a number of ways; research results can change (care) practice, be economically valorized, improve public health, and/or improve the lives of patients in a broader societal sense. This evaluation focuses on both the societal value itself and on the efforts of the strategic research program to maximize that impact. Ask yourself the questions;

- ❖ What is the societal value of the research of this strategic research program?
 - Have research results been implemented in healthcare practice, for example by drafting or changing care standards or guidelines?
 - Have results been economically valorized, for example by applying for patents or by furthering (pharmaco)therapeutic development?
 - Have results improved public health, for example by improving prevention or has the burden of disease decreased?
 - Have results improved the lives of patients in a broader societal sense?
- ❖ What efforts have the strategic research program made to maximize the societal value of the research results?
 - what could others learn from this?
 - how could the strategic research program improve on this?

Patient involvement

Patients can be involved in various phases of research; when setting the agenda, conducting the research and implementing the results. They can also be involved at different levels; experiential experts can be mainly information providers, think along about the research, make decisions together with the researchers, or even determine the research direction. However, more participation is not by definition better: when the involvement of patients is just window-dressing, one can say their involvement is not meaningful. To evaluate whether patient participation is meaningful, one can consider both the process and the outcome of the involvement. Ask yourself the questions;



- ❖ To what extent and how were patients involved in research in such a way that their contribution could be useful?

- what could others learn from this?
- how could the strategic research program improve on this?

14

- ❖ To what extent and how did patients' involvement influence the research performed at the strategic research program?

- what could others learn from this?
- how could the strategic research program improve on this?

Appendix C. Contextual background

This appendix provides some additional background information about (the reasoning behind) patient involvement. For some readers it might be redundant, for others it might be helpful to put the goal of this societal evaluation in perspective.

15

Patient involvement in health research is about involving patients in decision-making in the scientific research regarding their disease. Traditionally, patients have mainly played a passive role in this research, for example as research subjects in clinical trials. However, patients can also play a more active role in all stages of the research cycle. For example, patients may ask and prioritize research questions that are relevant to them, they can indicate which research outcome measures actually matter to them, or they can be asked to estimate the burden of an experimental treatment on their lives and thereby determine the feasibility of a study from the patients' perspective. Last but not least, patients can contribute to the dissemination and implementation of research results.

Three arguments are generally used to advocate patient involvement:

- the *substantive* argument: patients live every day with (the consequences of) their illness. Their illness experience is not limited to outpatient consultations or hospital admissions, but extends to all aspects of their lives. This experiential knowledge makes patients and their representatives valuable discussion partners in decision making in health research. They can shed a different light on, for example, the relevance of a research question, the feasibility of a study and the implementation of results.
- the *normative* argument: patients are the ones for whom health research is done - the result of research usually has the greatest effect on their body and life. In the case of clinical research, they are even asked to contribute to the research by, for example, undergoing an experimental treatment. Patients participating in health research can therefore be considered as a democratic right.
- the *political* argument: involving patients in health research increases support for research by patients, thereby improving the recruitment of subjects in clinical studies and increasing the chance of implementation of the results.

In the Netherlands, involving patients in health research decision-making is growing. Several major research funding agencies ask patient (representatives) to evaluate grant proposals by patient reviewers on criteria which are relevant to them. In the research funded by these agencies, patient involvement is also often required during research conduct. Moreover, patients are increasingly involved in setting the research agendas for their condition.

Patient involvement is, however, not yet institutionalized nor embedded in all health research, and may remain tokenistic when implemented in purely technocratic ways.

Appendix D. Presenters

16

Presenters	Strategic research program
Leonard vd Berg Vincent Cornelissen (ALS Patients Connected)	Brain
Gerlof Valk Jan de Jong (belangengroep MEN)	Cancer
Louis Bont Nicole Derksen (RSV Patient Network)	Child Health
Renee Maas Annette Klinkert (Stichting PLN)	Circulatory Health
Moniek de Witte Cécile van Dierendonck & Rian Visser (Hematon)	Infection & Immunity
Anne Karien Marijnissen Sjouke Dekker (Patiëntenraad APPROACH)	Regenerative Medicine & Stem Cells