NoTeB
Nordic Test Beds

How to assess **value and benefits** of innovation

C3 CENTRE FOR CONNECTED CARE

Nordic Innovation

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NOTEB- nordic test bed

The NoTeB project was set up to create a health product and service testing collaboration between companies, research institutes and health care professionals in Nordic health living labs connected to university hospitals.

The project participants include Innovation Skåne, Innovation Akademiska at Uppsala University Hospital, Aalborg University Hospital at North Denmark Region, Centre for Connected Care (C3) at Oslo University Hospital, Oulu Health Labs at Oulu University Hospital, Business Oulu and Centre for Health and Technology at University of Oulu. There are two main aims for each partner in the Noteb project (1) common testing among the Nordic countries, and (2) delivering on the individual work packages.

It was identified a need to strengthen the Nordic level of strategic and operational cooperation in the health care field. The Nordic health care systems vary in their service production and operational procedures from country to country, and also the test beds operate with different methods and practices. Moreover, the companies and developers of health and welfare solutions within the Nordic region have indicated that they do not have a sufficient understanding of the needs of the public sector healthcare actors. NoTeB addresses these challenges by joining experiences and know-how of Nordic university hospitals and innovation centers in order to create efficient Nordic test bed cooperation ecosystem and common best practices.

Overall, the project hopes to have impact on public health by generating new products and supporting the professionals through the need driven innovations.

Oslo University Hospital has been responsible for work package 7 (WP7):

"Health value, efficiency gains and best practices".

WP 7 aims to suggest common methodology for testing of non-invasive hospital technologies and services. The methods used at Oslo University Hospital are based on experience from 10 years of testing from "Idepoliklinikken" at Oslo University Hospital. In addition, we have been collecting testing procedures from all our partners to compare methods and approaches.

Starting 2016, the NoTeb partnership was moved to the new consortium for innovation C3 – Centre for Connected Care - a Centre for research-based innovation – SFI. C3 have put a large effort into developing and refining testing and assigned a PhD student for the method development.

Writing this innovation tool has been a joint venture between the Innovation Unit and C3 - Centre for Connected Care at Oslo University Hospital. To account for differences in working habits in the Nordic we gathered all partners for a workshop late fall.

Enjoy!

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Oslo May 2018

SUMMARY

We always start with the challenge

In the present user guide for evaluation of innovation in a healthcare setting we use a project assessed at Oslo University Hospital to provide the reader with concrete examples. The project is Outreach Wound Team and was assessed by the innovation unit during the first pilot. Although this project serves as an example on how effect measurements can be carried out in an innovation assessment, the project did not get implemented at the hospital. We believe that stepwise evaluation starting from a concept stage of an innovation can help steer the innovation process such that the new service meets it predefined intent. As an introduction to this user guide we will provide you with what could be done at an early stage to redefine and adjust an innovation to enhance implementation.

What if we had approached the outreach wound team before the innovators had decided on a permanent solution of the problem at hand?

We would have used the **logic model methodology** described at page 9 and most likely identified the following question:

What outpatient or mobile wound treatment service is best for the patient, employees, the hospital and society at large?

After the first logic model workshop, there are three questions to answer:

1. What is the most important bottleneck in the identified issue? (A bottleneck mapping comes next/ Detailed process flowchart mapping)

2. Which stakeholders are affected by a change, and what approach should we use at this stage to obtain the information necessary to further develop the idea? (Workshop, focus groups, interviews with experts – what is most expedient)

3. On the basis of the problem we want to solve: what already exists? It is important to enlist help in conducting a good and systematic literature search and map existing alternatives/products

Logic model for the measurement

On the basis of the first logic model, we introduce a new logic model that now focuses on how to document and highlight the value of the specific issue we choose to address. We now need to create a new logic model – **a logic model for measurement**

When we use a logic model for measurements, we will have sufficient information from stakeholders (different types of insight work), more accurate specification of bottlenecks (process flowchart mapping), and knowledge of what already exists (literature search).

A logic model for measurements helps us to focus, prioritise our wishes and obtain information about and facilitate the collection of good documentation which address what we need in the initial phase (problem clarification, objective specification, detailed process flowchart mapping, including exchange of information, document flow and patient pathway flow, selection of sub-item measurements).

Choosing a measurement method

As regards the choice of method, the initial phase will be characterised by investigations of functioning and user-friendliness. In most cases, it is both desirable and necessary to test the innovation on a small group several times so that we can make the adaptations that the users indicate are necessary if the innovation is to be fully implemented.

These tools are useful in order to make the right adaptations and to highlight good innovations, as well as for the people who will use them for measurements and studies later.

While design in the conceptual and early phases will include feasibility methodology (utility, acceptability and usability), later phases will include more classical epidemiological designs; pre-post sampling, case-control studies etc.

In this phase, it is natural and important to cooperate with method communities to make the right choices.

Benefit is what is best for the service, patients, employees, the hospital and society

We recommend using the following eight categories to find out whether your innovation is useful. We should always use the following eight categories…
Patient benefit, benefits to employees, financial effects locally for a hospital or health unit and nationally for the health sector, treatment effect/health effect, the risk associated with starting to use new things, organisational consequences in the form of improved flow within and between departments. The stakeholders participating in the design of the project define what should be registered in each category. This will depend on the type of innovation and the objective.

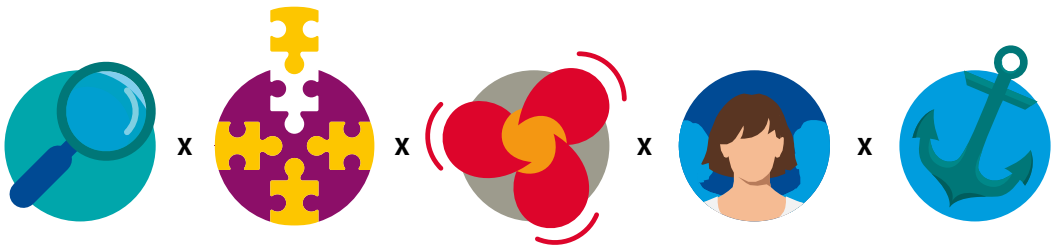
C3 DOMAINS

DOMAIN	TOOL	CATEGORIES
Patient	Validated questionnaires (SF36, EQ5D) Semi-structured surveys Focus groups	Patient benefit Benefits to employees
Economic	Simulation models	Local effects National effects
Clinical	Structured literature studies with the help of a librarian or university college	Treatment / health effects Risk
Organisational	Flowcharts with all affected players	Local bottlenecks Transferred bottlenecks

Before you begin, check that you have everything in place

There are five factors that must be in place if the innovation is to become a lasting solution and for the implementation to succeed. Sit down and think about who should participate. It is a good idea to include this figure in the work after having discussed the challenges/ problems (points I and II), and no later than at this time. It is well worth noting that if you cannot tick all the boxes here, the project will become difficult to implement.

How to succeed with innovations?



Need
What is the needs to fulfill?

Solution
Does the solution give value for money?

Promoter
Is the project driven by a promoter?

Team
Is it a team helping the promoter? Are the participants on the same team?

Management commitment
Who should be involved from management? Who is crucial for success?

It is worth noting that if any of the elements is non existing, innovation is doomed to fail.
Source: Stanford Research Institute International, 2006

Introduction

This user guide is meant for people working with innovation projects within the healthcare sector, and who is in need of checking the value of their innovation project. We define innovation as "something new and useful that is intended to be taken into permanent use. The innovations can be a new service, new practice or new product. In larger organisations, such as hospitals, innovations should be developed through a controlled process (Cooper, 2008). [1] The process should consist of different phases with clear decision points (stage gates) before the next phase begins. At the same time, it is important to be open for changes, i.e. take a step back and/or move further in a new direction. The innovation process is an iterative process.

Many people are struggling with showing the benefits of their innovation project. Good innovative solutions often end up not being taken into permanent use. Others projects should have been changed during the process and still others should have been stopped at an earlier stage. Knowledge concerning costs and benefits will help you and your colleagues taking right decisions. This knowledge also helps for ensuring that the final solution really solves the actually problem.

The user guide describes some of the important principles doing cost benefit analyses, and it can be used as a checklist for these kinds of studies. The intention is to enable you and your colleagues to do these kinds of studies yourselves. However, it can be necessary to engage assistance from experts in the respective fields.

The method applied here is based on recognised research methodology. The **methodology** is interdisciplinary and is based on 'Health Technology Assessment - HTA' (Phillips et.al. 2006)[2] (Kristensen et al., 2009).[3] HTA combines elements from 'cost-effect analysis' (Drummond 2005)[4] with concepts such as 'benefits realisation' and socio-economic analyses (the Norwegian Government Agency for Financial Management, 2014).[5] For a more detailed description of the HTA logic, see page 28. In this user guide, the HTA methodology is simplified and adapted for measurements also at later stages of the innovation process.

Why measure effects?

The growing challenges within the healthcare sector make it important to ensure that new methods,-solutions and -practices are implemented in areas where they really can make a difference. It is important to know how the innovation will affect the patients, their relatives, the healthcare workers, the hospital, the municipality and the society as such. There are several important arguments for measuring the effects of your idea/innovation. The most important are listed below.

1. It is important to make early cost- benefit analysis before deciding if it's worthwhile starting an innovation development process. The analysis should give important input to the content of the innovation and add quality to the development process.

2. To **check if you are on the right path.** Evaluations following the development process will make it possible to improve or reject the solution during the process. This will avoid using time andresources on projects heading the wrong directions. It will also increase the likelihood of better results (maximising the effects), which can in turn increase the likelihood of the solution being implemented and spread to others.

3. To **help staff members understand the purpose of the innovation**. This might reduce resistance against change, and help in transforming existing practice to new practice. Highlighting the benefits will also make it easier for other actors implementing the innovation.

4. To **create an innovative culture and a learning organisation.** It is easier to communicate the importance of the innovation to the stakeholders doing this kind of analysis.

5. To **improve communication** with the people involved, both within the project team, with management and with other stakeholders.

6. To **help the management make decisions in starting the development process, making changes throughout the process, and improving the possibility of implementation.** The cost- benefit analysis can ensure support for starting the innovation project,ensure support for changes during the process and ensure support implementing the project into operations. It can help managers to prioritise the resources for procurement and reorganisation, increase the likelihood of successful implementation, and reduce the risks. The analysis could also be of help getting funding and support when needed during the development process, and ensuring implemented innovations support also in the next budgeting process.

How to carry out measurements

In order to measure the effects of your innovation project, the measurement process must also follow the innovation process. This is illustrated in figure 1, where the different phases of the innovation process are shown in the blue circles and the corresponding measurement processes in the rectangles below.

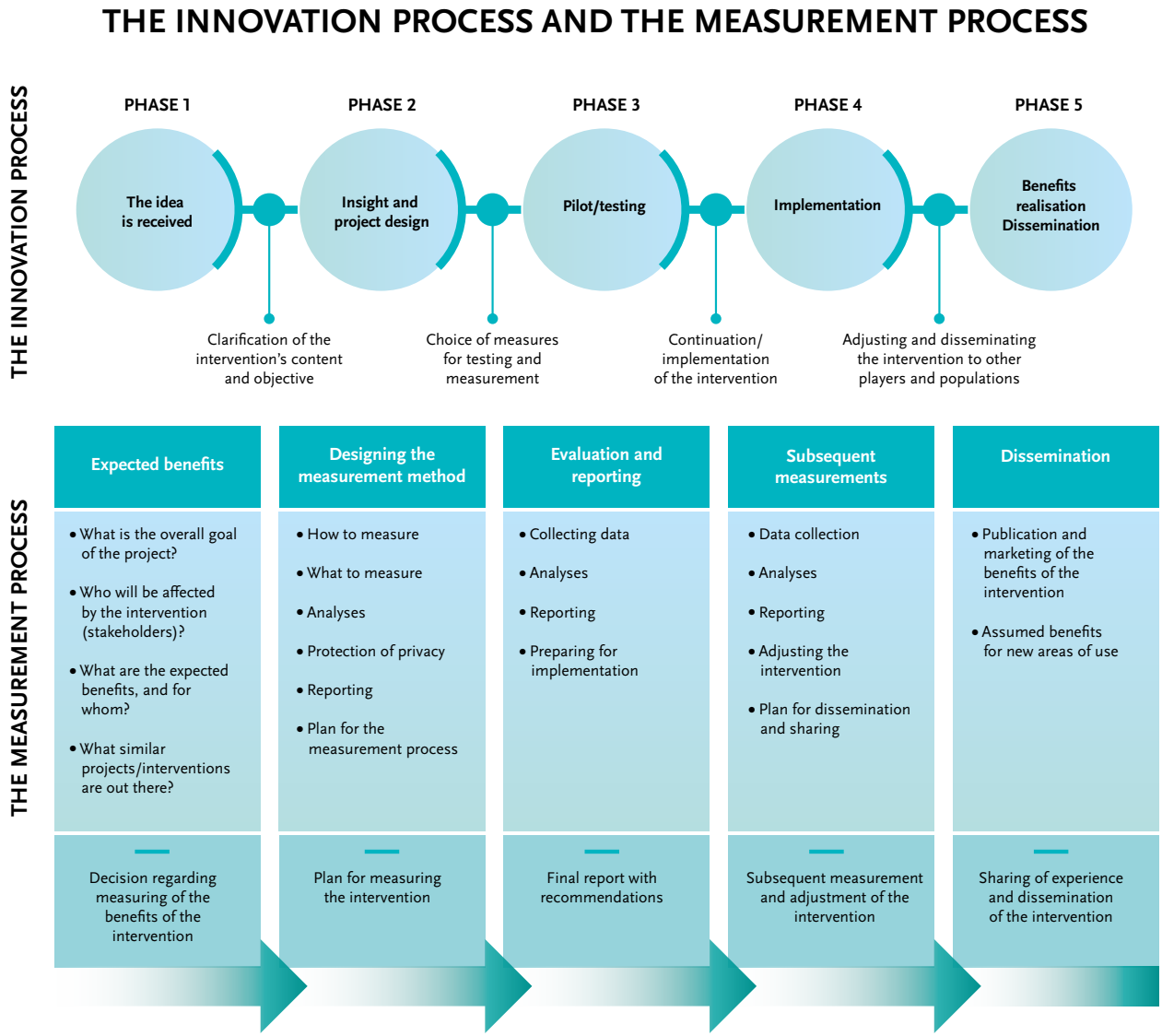


Figure 1. The innovation process and process for measuring effects

An innovation process often consists of five phases. Each phase should consist of purposeful work to reach defined goals. The phases should be concluded by a decision concerning the road ahead. Should the project continue to the next phase, or should the project or its conditions be modified? Should the project be discontinued? The innovation process and the corresponding points of measurement are as follows:

Phase 1 The idea is received: This phase often starts with an idea owner registering the idea with a unit within the organisation, e.g. the Innovation Department or the organisation's TTO (Technology Transfer Office). It is important that the main objective of the innovation is clearly defined when it is registered. The expected effects for the different stakeholders should be described based on this objective. During this phase, it is also important to gain information and experience from comparable studies or similar innovations.

Phase 2 Insight and project design: In this phase, the idea is described and developed until it is ready to be tested. This phase concludes with a plan for testing. The plan must be appropriate to the development and testing of the innovation, and include the chosen measurement method. This includes specifying what data to be collected, when to collect them and who is responsible for collecting them. Project participants are often very keen to start work on the innovation once they have acquired some insight. This can lead to changes being made or measures being implemented outside the project's control. It is therefore important to start the measurements as soon as possible after the insight phase. One important part of gaining insight is to conduct a literature study and/or obtain knowledge from similar innovations if it's not already done in the first phase. It is important to set up a plan for carrying out the effect measurements.

Phase 3 Piloting/testing: The measurements should be concluded by a final report containing recommendations, e.g. project adjustments, project stop or implementation. Subsequent measurements should be planned for projects that are implemented. These subsequent measurements should increase reliability and validity of the results and analysis, and in addition give and visualize important learning points.

Phase 4 Implementation: In this phase, the innovation project will be put into practice. Experience shows that very few innovation projects are implemented. They are often kept as continuing projects until they are eventually discontinued, even if they are useful to all stakeholders. An initial implementation plan should be prepared already in phase 2. This plan should then be revised in phase 4 on the basis of, among other things, the results of the cost benefit analysis. It is sensible to plan measurements to adjust the innovation also after the project has been implemented, for example as part of continuous improvements (lean-process).

Phase 5 Benefits realisation and dissemination: In this phase, the innovation is ready to be shared and diffused to other internal and external stakeholders. The subsequent measurements in phase 4 may form the basis for diffusion and sharing of the innovation with other internal and external parties.

It is important to note that the innovation process and measurement process often build on each other, and that the processes may change as the project progresses. Sometimes, it is necessary to take a few steps back before moving the process forward again (iterate between phases).

The measurement is normally conducted before, and after the pilot has been initiated. How often data should be collected and how long before and after the innovation process they should be collected may vary, and can, among other things, depend on the resources available for implementation and how demanding it is to collect the data. For some of the parameters it can be relevant to collect data point-by-point, e.g. by means of observations, interviews and questionnaires. For other parameters, data can be collected on a more continuous basis or at regular intervals, e.g. through various healthcare registers (see figure 2). The analyses often compare data from the various periods, forming the basis for estimating changes.

Reporting on measurements and analyses during the process should be planned in order to ensure the involvement of important decision makers, and as a tool for adjustments of the innovation and the measurement process.

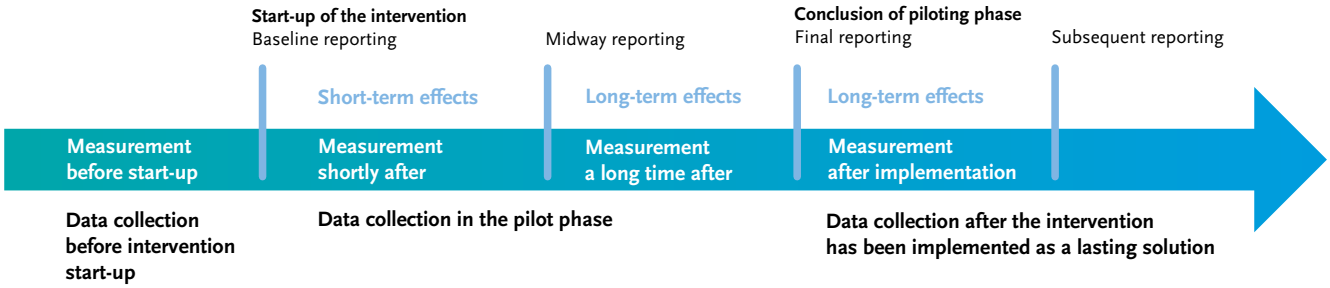


Figure 2 – Prior and subsequent analyses of effects

Expected value and benefits of the innovation

The expected effects are closely related to the objective of the innovation, and mainly consist of listing the assumed benefits for the parties affected by the innovation. Some important questions to ask at the start of the measurement process are:

What is the overall goal of the innovation and the project?

First, a clear and verifiable overriding goal must be defined. This can be the objective of the innovation itself and not necessarily the goal of the project. For example, the innovation's goal can be 'To improve the treatment of elderly nursing home patients with chronic wounds in nursing homes', while the project's goal can be 'To implement a pilot project from May to December to adapt and test a new practice in the treatment of elderly nursing home patients with chronic wounds.

The overriding goals can be divided into more specific operational goals. This means goals that can be verified. For example, what does 'improved treatment' entail? Does it mean that the treatment should lead to fewer admissions, fewer outpatient check-ups, fewer doctor's appointments and/or more satisfied patients or health personnel?

Defining the right goals can be a difficult task. You may need some help, for example from service designers, to define what you actually want to achieve with the innovation. It is important to spend some time on this insight phase to really bring to light the innovation's direct and indirect consequences for the involved parties.

One useful tool in this context can be to set up a logic model where the important elements and the connection between them can be schematically presented, see figure 3. Such a logic model for measurements can help you to get an overall picture of the measurement work, and, on this basis, to focus and prioritise the most important measurement points and activities.

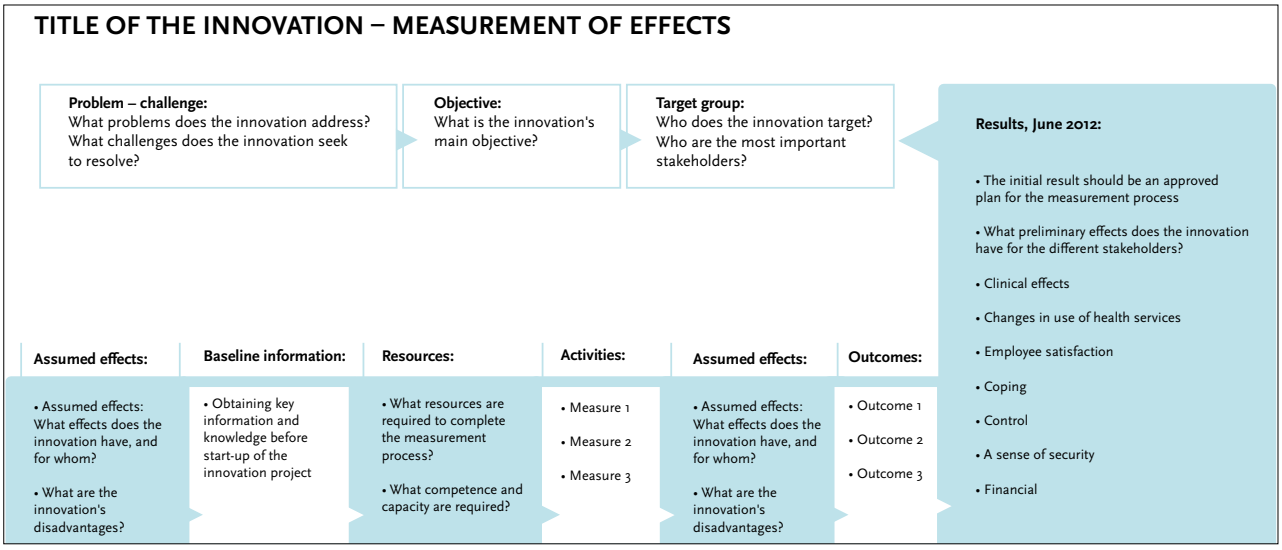


Figure 3 – Early-phase mapping of important elements for measuring innovation

The model can be used dynamically. You can obtain new information and reach new insights that change conditions – conditions that affect all elements.

We have chosen to follow a case through this guide to clarify some important elements of measuring the effects of innovation projects. The outreach wound team is based at Oslo University Hospital. The innovation consisted of establishing an outreach (mobile) wound team comprising a specialist doctor and specialist nurse. The team was to go to nursing homes after receiving a referral to examine and treat immobile patients with chronic wounds. Bed-side teaching of the nursing home nurses and immediate hand-over of the discharge summary and wound procedure were part of the innovation; see Appendix 2 where the effects of the innovation are summarised. For this case, the team gathered to fill in an initial version of a logic model for the measurement process. The most important result of this introductory exercise was that the team agreed on a plan for the measurement, including who was responsible for doing what and when. One important task was to search for similar innovations and conducting a literature search. Figure 4 shows the content of the measurement process immediately after the testing of the innovation had begun (the pilot project).

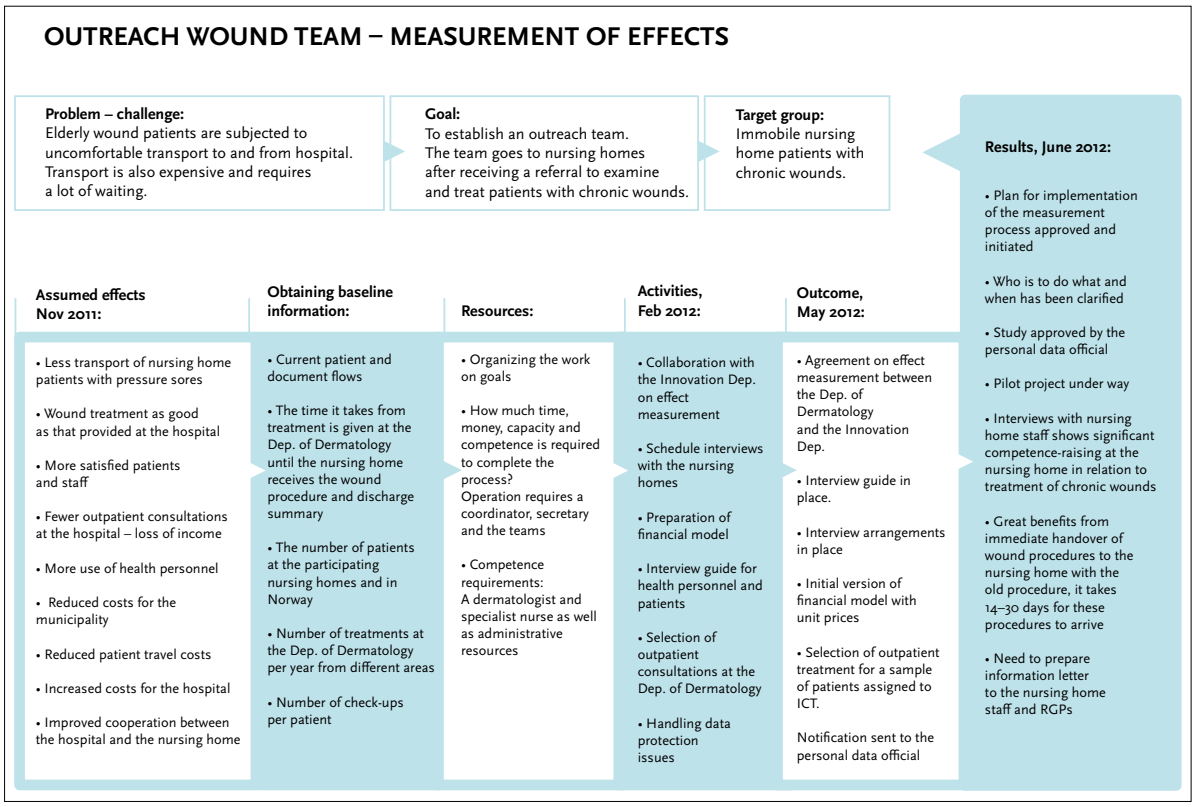


Figure 4 – Important elements of the measurement work after the testing of the outreach wound team had begun.

Who is affected by the innovation?

The intention behind the innovations is to create lasting positive effects. The effects can be positive for some, while having the opposite effect for others. To be able to say something about the big picture, everyone who is affected by the new innovation must be identified. These are the innovation's stakeholders. There could be many stakeholder, and it can be difficult to involve all the groups in a study. In such cases, it is important that the most important groups are chosen to take part in a study. It may be a good idea to organise a workshop with colleagues (insight workshop) to identify the stakeholders.

What are the expected benefits, and for whom?

Before you start, it is important to identify those who will be affected by the changes:

1. Who will be affected by the innovation?

2. What consequences will the innovation have for the affected parties?

Choose the measurements that are necessary to answer these two questions. If practically possible, the effect of all the innovation's measures for all stakeholders should be assessed. In many cases, it can be difficult to carry out measurements. Collecting data can be time-consuming, expensive and difficult because of considerations relating to the protection of privacy, the time aspect, requirements for control groups and sample sizes. One option can be to choose the most important change(s) and stakeholder(s).

The effects of the innovation can normally be measured in:

- Patient benefit, including improved clinical effect, improved patient satisfaction
- Health effects, including better treatment and/ or lower risk
- Benefits to employees, e.g. increased job satisfaction.
- Organisational effects, e.g. removing bottlenecks or transferring bottlenecks to others
- Financial effects for one or more stakeholders, e.g. cost savings for the patient and the hospital
- National financial effects through socio-economic gains.

For the outreach wound team, the assumption was that the Department of Dermatology at Oslo University Hospital would lose money on the innovation due to reduced income, whereas it would result in cost savings for the nursing homes. Patients would not have to pay patient charges or travel to the hospital and back. The assumption was also that the innovation would not have any effect, positive or negative, on healing.

To identify such benefits, it can be a good idea to include it in an insight workshop. Such workshops typically include:

- A description of the innovation
- Brainstorming: Who is affected by the innovation?
- Specification and structuring of stakeholder groups
- Assumed effects (positive and negative) for the different groups
- Ranking of groups in relation to how much they will be affected

Another tool that can be useful to describe and visualise the innovation is a flowchart. The flowchart should set out everything that happens from the start to the end of the innovation, marking important details and tasks. In the outreach wound team project, two flowcharts were made. One showed the flow before the innovation, and one after the innovation, see Appendix 1. The flowchart is also well suited for mapping details concerning bottlenecks for existing practice and for the innovation.

Literature search before you get started: What similar projects or innovations exist?

Systematic literature searches are a routine part of quality projects and research projects. The same standard should be applied to innovation projects. Remember that there will often be other innovations or studies that are similar to your innovation or study. Have a librarian help you to define and carry out a good search.

For the outreach wound team, it turned out that there was already a similar outreach service, namely a mobile X-ray service. Here, a radiologist travelled to nursing homes, among other places, to x-ray suspected fractures in persons in need of nursing. This innovation provided input on which groups of stakeholders were important, what method could be suitable for collecting and analysing data, as well as challenges relating to the measurements.

Insight obtained from comparable innovations and literature searches can also provide useful input to the design of the innovation itself. It is therefore important to carry out such activities as early as possible in the innovation and measurement process.

Designing the measurement method and implementation

Once you know who the stakeholders are and which benefits you want to achieve, you must find a method that is feasible and cost-efficient, i.e. that interferes with the day-to-day work tasks as little as possible. When measuring innovation, you start by conducting a pilot, i.e. a test of the innovation. Pilots are suitable for small samples with a brief data collection phase.

Some important issues relating to the work of choosing a method are described below.

How to measure

Once you have decided what you need to measure, you will need help finding out which analyses are expedient and how to collect your data. You will need to cooperate with other persons in your organisation on this. One example relating to financial data could be unit costs such as salary, fees, investments, licence costs and travel expenses.

Register data can be used to measure healthcare expenditure and can be collected from several sources, for example registers of the use of hospital services, regular GP (RPG) services, care services, medication or unit costs. Some examples are provided in table 1.

Interviews, observations and/or questionnaires are some means of gaining insight into the stakeholders' opinions and attitudes. The interviews can be organised as open conversations, but should normally be conducted as structured or semi-structured interviews. In many cases, it may be sensible to conduct focus interviews, which means gathering a group of experts and/or patients and interviewing them as a group. The interview should normally be semi-structured. For some innovation projects, it can be a good idea to obtain data through observation, for example by seeing how patients react to a measure, whether they understand what is to be done, how they handle new equipment or what alternatives they choose.

Table 1 – Example of registers containing health data

EXAMPLE OF REGISTERS	CONTENTS
Statistics Norway	This is an extensive register that, among other things, contains aggregate data on demographic developments, wage growth, health and death
The Norwegian Patient Registry – NPR	This is a register of, among other things, patients' use of outpatient consultations, the number of admissions and the number of bed days from all the hospitals where a patient has received care.
Local hospital registers (registers of patient records)	These registers provide the same information as NPR, but only in relation to the patient's use of services from the local hospital.
Individual-Based Nursing and Care Statistics (IPLOS)	This register provides an overview of people's use of municipal care services.
Local municipal health registers	These registers provide the same information as IPLOS, but often with more details as regards the real use of services
The Norwegian Health Economic Administration (HELFO)	Here you can, among other things, gain access to patients' use of RGP services broken down by different service categories, patient charges and reimbursement rates.
The Norwegian Prescription Database	Among other things, this register contains information about the number of users of a specific drug or group of drugs.

In many cases, it can also be a good idea to obtain information through questionnaires, preferably with a combination of open-ended and closed-ended questions. With closed-ended questions, we can also conduct quantitative analyses, provided that the sample is of a certain size.

The outreach wound team collected data through:

- Semi-structured interviews with nursing home staff and staff at the Department of Dermatology at OUS.
- OUS's hospital register (PASDOK) concerning the number of outpatient treatments
- A pilot project. Time spent per wound treatment, including planning and travel, was logged as part of the pilot project. A total of 27 treatments were logged during the pilot period.
- Statistics Norway. Costs data, e.g. wage statistics, were collected from Statistics Norway and the hospital's accounting system and through interviews with hospital staff. Data on costs of material were collected from staff and the hospital's accounting data.

Selecting respondents. It is rarely expedient to collect data from the whole population when considering the effect of an innovation. Normally, a sample will be sufficient; see figure 5. A sample is the subset of the population that is actually observed, or, for questionnaire surveys, those who are actually asked (respondents). It is important that the sample is as representative of the population as possible; see the illustration to the right in figure 5.

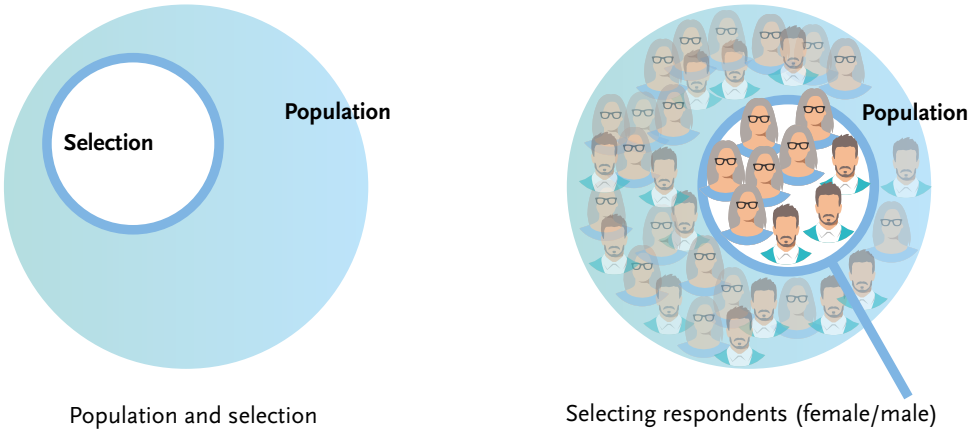


Figure 5 – Selecting respondents – from spørreundersøkelser.no

Ideally, we want to compare our sample with a control group. Health-oriented innovation projects often test and adjust the innovation through a pilot to see whether the innovation is feasible, to identify challenges and to collect data in order to measure effects, among other things. User-friendliness and feasibility must be clarified first. Later in the pilot project, it can be a good idea to select a group that does not participate in the innovation – what is known as a control group. This group can then be used as a reference for comparison with the main group, where the innovation is implemented. In effect measurements, conducting studies with control groups can often be time-consuming and demanding in terms of resources. In many cases, it is also difficult to select representative control groups.

In figure 6, the green curve represents a sample of patients in the innovation group, and the blue curve a sample that does not participate in the innovation. The two group's use of RGP services is about the same as before the innovation. After the innovation, the average use of RPG services is lower in the innovation group than in the control group.

WHAT CAN WE LEARN FROM A CONTROL GROUP?

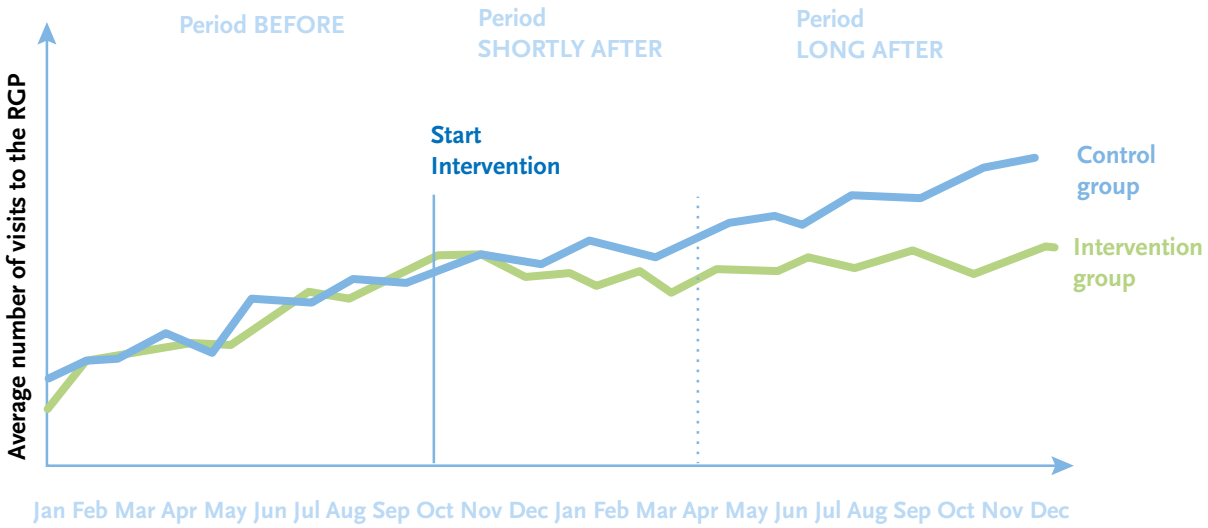


Figure 6 – An innovation group's use of RGP services compared with a control group

Another example from OUS can illustrate the benefit of using control groups:
Players in the City of Oslo and the Department of Dermatology at OUS identified a need to increase the home care services' competence on wounds. This competence should benefit the patients and help to prevent unnecessary referrals and check-ups of wound patients at the hospital. A pilot project was initiated in May 2002 after a process had been set up to measure the innovation. The pilot period ran until the end of June 2013. During the period, three wound contacts from each of the participating city districts were given chief responsibility for wound treatment in their respective city district. They took on the role of experts in relation to the rest of the nursing staff in the city district and were the point of contact between the home nursing care service and OUS/the Department of Dermatology. The innovation's main measures were training, dedicated responsibility and systematic follow-up. In order to measure how much of a wound had healed during a specified period, when the wound was completely healed and the financial aspects, a group from the participating city districts (32 patients) was compared to another group (21 patients) who did not participate in the innovation. The clinical results showed better healing of the wounds of the patients participating in the innovation group compared with the control

group. After three months, 47% of the wounds had healed in the innovation group. The corresponding figure for the control group was 24%. The financial analyses showed that the Department of Dermatology can achieve costs savings of NOK 7,557 per wound patient per year. At the same time, the city districts would save NOK 32,377 per wound patient per year, and society would save NOK 39,934 per patient per year.

It is a good idea to cooperate with experts when conducting such analyses, for example specialist doctors, statisticians and health economists.

What to measure

The parameters and elements that are best suited for measuring the effects of an innovation depend on the innovation's content and objective. Suitability is often related to whether the parameters actually say anything about the effect of the innovation – that they are valid (validity) and the extent to which the measurements can be trusted (reliability). Typical measurement parameters for different stakeholders are set out in table 2.

Table 2 – Typical measurement parameters for different shareholders

WHO	PATIENT & NEXT-OF-KIN	STAFF	HOSPITAL & MUNICIPALITY	SOCIETY
What	• Use of health services • State of health • Sense of security, coping and well-being • Knowledge • Physical activity • Finances	• Satisfaction • Time spent • Workload • Safety • Knowledge	• Use of health services • Time spent • Quality • Finances	• Finances • State of health
When	• Intervals or a measurement point BEFORE and AFTER the pilot has been initiated	• Intervals or a measurement point BEFORE and AFTER the pilot has been initiated	• One period BEFORE and one or more periods after the pilot has been initiated	• One period BEFORE and one or more periods after the pilot has been initiated
How	• Individual interviews • Focus interviews • Questionnaires • Register data • Calculations	• Individual interviews • Focus interviews • Questionnaires • Register data	• Register data • Calculation based on financial models	• Register data • Calculation based on financial models

The outreach team primarily collected its data through semi-structured interviews. Such interviews were conducted with a sample of staff from the seven participating nursing homes, wound teams and the project management. Data were also collected regarding the time it took to register the discharge summary before and after the innovation, as well as cost data; see table 3.

Table 3 – measurement parameters for the outreach wound team project

WHO	PATIENT	STAFF	HOSPITAL & MUNICIPALITY	SOCIETY
What	• Clinically, a change in the number of check-ups performed in hospital • Financially, less travel and a reduction in patient charges • Patient satisfaction	• The nursing home's wound treatment competence • Time spent on making wound procedures and discharge summaries available • Understanding of wound procedures	• The nursing home's wound treatment competence • Time spent on making wound procedures and discharge summaries available • Understanding of wound procedures • The nursing home's and hospital's costs and financial benefits	• Finances
When	• Number of check-ups in a period before, during and after the pilot project	• Collection of data during the pilot project through log keeping • Semi-structured interviews in the final phase of the pilot project	• One period BEFORE and one or more periods after the pilot has been initiated	• After the pilot project
How	• Information about the number of check-ups was retrieved through the hospital's PASDOK register • Semi-structured interviews after treatment	• Individual interviews • Registration of time spent by the wound team on each patient	• Information about the number of check-ups was retrieved through the hospital's PASDOK register • Calculations on the basis of financial models and collected unit data from Statistics Norway, among others.	• Cost-benefit calculations based on financial models • PASDOK data, SSB data and log

Analyses

In this phase, you may need to obtain expert help. The analysis work starts as the data start to come in. This often entails looking for trends, patterns and changes in the collected data. The work often involves literature studies, qualitative, quantitative and financial analyses. Relevant expert assistance in this context is typically provided by analysts, statisticians and health economists.

WHAT CAN WE LEARN FROM A CONTROL GROUP?

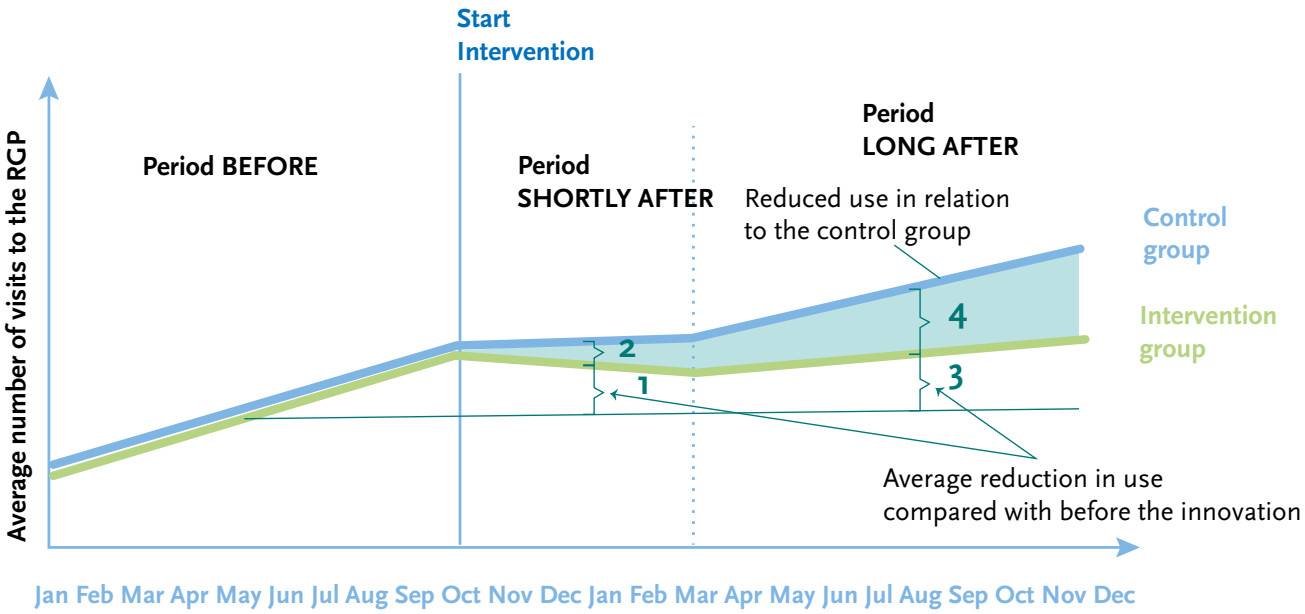


Figure 7 – Calculation of the change in the use of RGP services

One possible method for calculating the changes is to start with the average use in the two groups in each of the periods and compare them with each other. As shown in the figure, the change shortly after the innovation was implemented is 2 + 1, and 4 + 3 for the period a long time after it was implemented.

Financial analyses. In order to measure the financial effects of the innovation, financial models should be developed that can simulate any savings or increased costs in connection with the implementation of the innovation. The analysis is often organised as a separate process. Such a process is illustrated in figure 8 (Norwegian Government Agency for Financial Management's guide).

Normally, the analysis should begin by establishing a baseline that describes the situation as it will be if the innovation is not introduced. Then, assumptions are entered in the model. These assumptions are replaced by real figures as they are obtained. The final calculations

are carried out on the basis of empirical figures obtained, register data and user data.

The financial analysis should normally say something about:

- **The user effect**: changes in costs for the user as a result of the innovation shortly and a long time after implementation.
- **The municipal financial effect (primary healthcare service)**: changes in costs for the municipality as a result of the innovation shortly and a long time after implementation.
- **The effect for hospitals (the specialist health service)**: changes in costs for the *health trust as a result of the innovation shortly and a long time after implementation.
- **Socio-economic effects:** the overall changes in costs for the above-mentioned parties (municipality, hospital and user).

The wound contact project: The project's financial calculations indicate that the annual savings for Norway as a whole can amount to approximately NOK 554 million if the wound contact scheme is introduced in all the home care services nationwide. By implementing the wound contact scheme, the Department of Dermatology at OUS can save NOK 7,557 per wound patient per year, or NOK 5,187 per wound patient per year if we deduct the loss of income resulting from introducing the scheme. At the same time, the city districts will save NOK 32,377 per wound patient per year, and society as a whole would save NOK 39,934 per patient per year. The patients will also save patient charges calculated to amount to NOK 307 per patient per year because they will have fewer hospital check-ups.

Useful things to know about protection of privacy: Collection, processing and disclosure of data

What are personal data? All data that can be linked to individual persons must be secured in accordance with laws and regulations. Data that can be linked to individual persons either directly or indirectly are deemed to be personal data. Such data are usually anonymised in innovation projects, meaning that the information is indirectly linked to a person through a list of codes. Directly identifiable data may be processed in exceptional cases. Anonymised data are data that cannot in any way be used to identify individual persons.

Health data are sensitive personal data and shall be processed with particular care to safeguard the protection of privacy. Stringent requirements therefore apply to the processing of sensitive data, and all collection, storage and processing of such data require a legal basis.

Legal basis. For research projects, the collection and use of personal data must be supported by and approved internally in the institution, and must also be approved in advance by a Regional Committee for Medical and Health Research Ethics (REK). For

projects that are not covered by the Health Research Act, but where de-identified data will be collected, used and, if relevant, disclosed, it is nevertheless a requirement that the data in question shall be under the data controller's control. This means that the individual enterprise's internal procedures and systems serve as guidelines for how such data are to be processed and stored.

On 25 May 2018, the EU's new General Data Protection Regulation (GDPR) enters into force, and this will directly affect the rules relating to personal data. In practice, this means that institutions such as hospitals, which are the data controllers for their own patient information, will be given more responsibility for internal control. The consequence of this increased responsibility is that each institution must have a data protection official charged with safeguarding data security. In addition, more specific requirements will be stipulated for data processing agreements when data are disclosed.

Until the GDPR enters into force, the Norwegian Data Protection Authority grants licences for the use and creation of individual registers. Enterprises that have their own data protection official must notify the Norwegian Data Protection Authority via this body.

Consent is the legal basis for collecting, processing and disclosing sensitive data in projects. As a rule, the hospital cannot use or disclose data without consent, except in cases where the appropriate authority grants a dispensation.

In other words, the **collection and use** of personal data shall be approved and supported internally in the enterprise that is the data controller.

The **disclosure** of data to another enterprise for processing (for example for storage with TSD (Services for sensitive data)) shall be based on an internal approval and security assessment, and must be regulated in a data processing agreement. The party that processes data on behalf on an institution will be the data processor, and will be subject to the same requirements regarding responsibility as the data controller.

The **disclosure and sharing of data** in collaboration projects involving several enterprises must be approved internally. For research projects that fall under the Health Research Act, such disclosure must also be approved by REK. All disclosure of data shall be based on a disclosure agreement.

Reporting

It is important to disseminate the results in order to share them with colleagues and other contributors and to gain the support of important stakeholders, such as the management (responsible for decisions) and staff (who will be implementing the change).

The initial reporting often takes place prior to the pilot project and shows the situation before the innovation has been implemented. The term 'baseline data' is often applied to the data collected in this phase. There should normally be several reporting points in the

course of the measurement process. The number and scope of reports should be adapted to the scope and importance of the innovation, as well as to the resources available for carrying out the measurement process. In the first phases, a one-page summary is usually sufficient. For bigger and more important innovations, a baseline report, midway report and final report are recommended. The final report should typically contain:

- **Summary.** It can be a good idea to prepare a one-page summary of the findings from the benefit assessment. An example from the outreach wound team has been enclosed as appendix 2.
- **A description of the innovation.** The issues with the current solutions or practice should be described here. The issues described should lead up to a description of the content and objective of the innovation.
- **Literature study.** It is important to find out whether similar innovations or studies exist that can provide useful experience. Such input can be important to the innovation process, the content of the innovation and the measurement process.
- **Measurement method.** Here, data sources and measurement tools should be described, as well as the sample and how the protection of privacy is safeguarded.
- **Analysis and results.** The object of measurement defines what analyses can be carried out. The analyses should lead up to a description of what effects the innovation will have for the sample.
- **Discussion.** This part should contain a reflection on whether the results can be generalised to a larger population. Any uncertainties relating to the measurements and any interfering factors should be described. Typical interfering factors include other events and measures that affect the sample during the pilot project.
- **Recommendation.** The report should conclude with a recommendation. It can be conditional, and will often contain proposals for changes.
- **Implementation plan.** For projects where implementation is recommended, a proposal for an implementation plan should be submitted.

Subsequent measurement can also be important in some innovation projects. In such case, the purpose is to obtain input on improvements, preferably in relation to a continuous improvement process. The knowledge from subsequent measurements may also form the basis for dissemination to others in connection with similar use of the innovation or other areas of use.

The earlier the better – value-based decision-making

Implementation is the challenge, which means that it is important that we are able to secure support and provide support for the innovation at the earliest possible stage. This will help the innovator to complete a product that the health service wants, and it reduces the risk for the party in charge of changing a health service, introducing a new product or changing a treatment. Current health technology assessment is considered a robust method of supporting decisions in later phases of the innovation process, when the technology has been well tested in clinical environments and a large amount of data has been collected. However, ongoing research on altering and adopting these methods to earlier phases of decision-making is currently emerging in literature. We have seen how previous studies have used existing methods in new ways in order to make full use of the available data, and attempts have also been made to find new sources of data in the early phases. Early technology assessment has the ability to reduce decision uncertainty already in the concept stage of innovation, and enhances the implementation of suitable interventions that meet their predefined purpose.

Ideally, we should simply start using something new when we have documented that it works. But that is not what happens. There are two important reasons for this.[1]

1 **Most new health technologies are technology-enabled services, rather than products.**

Firstly, although the technology itself is thoroughly described and evaluated, descriptions or evaluations of the ecosystem surrounding that technology, such as human support and organisational factors, are seldom given. It is therefore self-evident that we will hesitate to start using something before we know whether it will be useful in our setting.

2 **The goals and strategies of the service, the role of the provider, and the technology itself must all be designed and evaluated simultaneously as an integrated service.**

Today, most new innovations are either combined products and organisational changes, or just organisational changes. Standardised care pathways in cancer treatment is one such example, long-distance follow-up with telemedicine and welfare technology in the home are others. The implementation of such innovations involve many parties. Such transformation requires interaction between people and technology and that we are able to see the big picture. We need to develop a robust methodology for this. While health technology assessments (HTA) is the golden standard for mature technologies, EARLY methodology and pragmatic study designs are needed since early and repeated stakeholder insight is a prerequisite for diffusion. It is therefore useful to be familiar with the existing knowledge on how it is believed that early evaluation of innovations can help us to proceed.

1 Lancaster, G. A. (2015). "Pilot and feasibility studies come of age!" Pilot Feasibility Stud 1(1): 1.Marzano, L., et al. (2015). "The application of mHealth to mental health: opportunities and challenges." The Lancet Psychiatry 2(10): 942-948. Mohr, D. C., et al. (2017). "Three Problems With Current Digital Mental Health Research... and Three Things We Can Do About Them." Psychiatric Services: appi. ps. 201600541.

Overview of existing methods for evaluating new health measures and trends compared with new methods for evaluation in earlier phases.

A literature review shows that although this has not yet been implemented in day-to-day operations, much work has been put into identifying methods and discussing analytic approaches for early evaluation of innovation in the health sector, with a particular focus on non-invasive technology and organisational innovation. It is generally about stakeholder analyses, scenario analyses and different simulation methods in the valuation of available data in an early innovation phase. You can read more about this below.

3 Health technology assessment (HTA) – the classic approach to assessing technology

Over the past 50 years, validated methodology like the Health Technology Assessment method (HTA) has contributed to sound decision-making worldwide. HTA is defined as an interdisciplinary process for synthesising information concerning medical, social, financial and ethical issues related to the introduction of new health technology (Kristensen et al., 2009). Although HTA methods and approaches have been subject to significant improvement over time, there are several challenges in the field (Sampietro-Colom, 2012). This includes early assessment of health innovations, decision-making at the institutional level and dynamic interaction with private businesses.

4 Methods of early assessment of health innovations

There are three main approaches to assessments. Methods of early assessment can be categorised into three main analytical approaches:

a) Strategic analysis

Early innovation phases are characterised by a small amount of data and a high degree of uncertainty. Several studies have highlighted that stakeholder insight is an important source of data in the early assessment of the potential benefits of health innovation (Abrishami, Boer, & Horstman, 2015; Bartelmes, Neumann, Luhmann, Schonermark, & Hagen, 2009; Bridges, 2006; Harris-Roxas & Harris, 2007). Such data can potentially ease adoption and diffusion through directing the intervention towards achieving value-based innovation (Kummer, Schafer, & Todorova, 2013). This implies that the innovation should be assessed in the context in which it will be used in order to reveal how it is adopted and used in the real world. Qualitative data on the underlying logic of the intervention are essential in understanding changes in outcome for the target population at an organisational level. Collecting such data from a small study sample can provide valuable information about the potential suitability of the intervention for a larger number of patients (Esposito, Taylor, & Gold, 2009). Qualitative data from various stakeholders can be applied in scenario analyses to give necessary outcome overviews, and direct and accelerate the procurement process (Gantner-Bar et al., 2014). Further, different simulation and analysis methods can be used in new ways to increase the impact of scarce

availability of data in the early innovation phase. Through integrating qualitative scenarios from the perspective of stakeholders into a cost-effectiveness model, the potential value of the innovation can be estimated at an early phase (Retel, Joore, Linn, Rutgers, & van Harten, 2012).

b) Financial analysis

It is believed that an early financial analysis of the innovation's likely cost-effectiveness can help to steer the implementation and restrain resource inefficient technologies (Hartz & John, 2009). Numerous attempts to fill evidence gaps in early cost-effectiveness models and other financial models have been detected in the literature. Expert elicitations by means of scenario drafting can provide qualitative and quantitative data to fill the evidence gaps in early health technology assessment (Retel, Joosten, & van Harten, 2014; Sayres, Allyse, & Cho, 2012). Such approaches to assessment can provide an initial estimate of the cost-effectiveness prior to implementation in clinical practice. They can also forecast the effects of healthcare innovations already in the early research and concept phase to prevent ineffective investments (Gantner-Bar et al., 2014; Kip, Steuten, Koffijberg, MJ, & Kusters, 2016; Steuten, 2016). Scenario drafting can also be useful in identifying critical factors that may affect the speed of adoption (Joosten, Retel, Coupe, van den Heuvel, & van Harten, 2016). To account for the dynamic characteristics of an early innovation future technological development, organisational changes and learning curves should be incorporated into the models (Craig et al., 2015; Girling, Young, Brown, & Lilford, 2010). Several studies point to the use of sensitivity analysis to deal with uncertainty in the interpretation of results and to test the impact of different implementation strategies when the technology is still dynamic (Gaultney, Sanhueza, Janssen, Redekop, & Uyl-de Groot, 2011; Girling et al., 2010; Kip et al., 2016; Markiewicz, van Til, & MJ, 2014; Postmus, de Graaf, Hillege, Steyerberg, & Buskens, 2012; Steuten, 2016). The use of such models in early financial modelling can help to determine what efficacy and clinical performance has to be attained for different cost outcomes (Bartelmes et al., 2009; Craig et al., 2015; Hartz & John, 2009; Retel, Grutters, van Harten, & Joore, 2013)

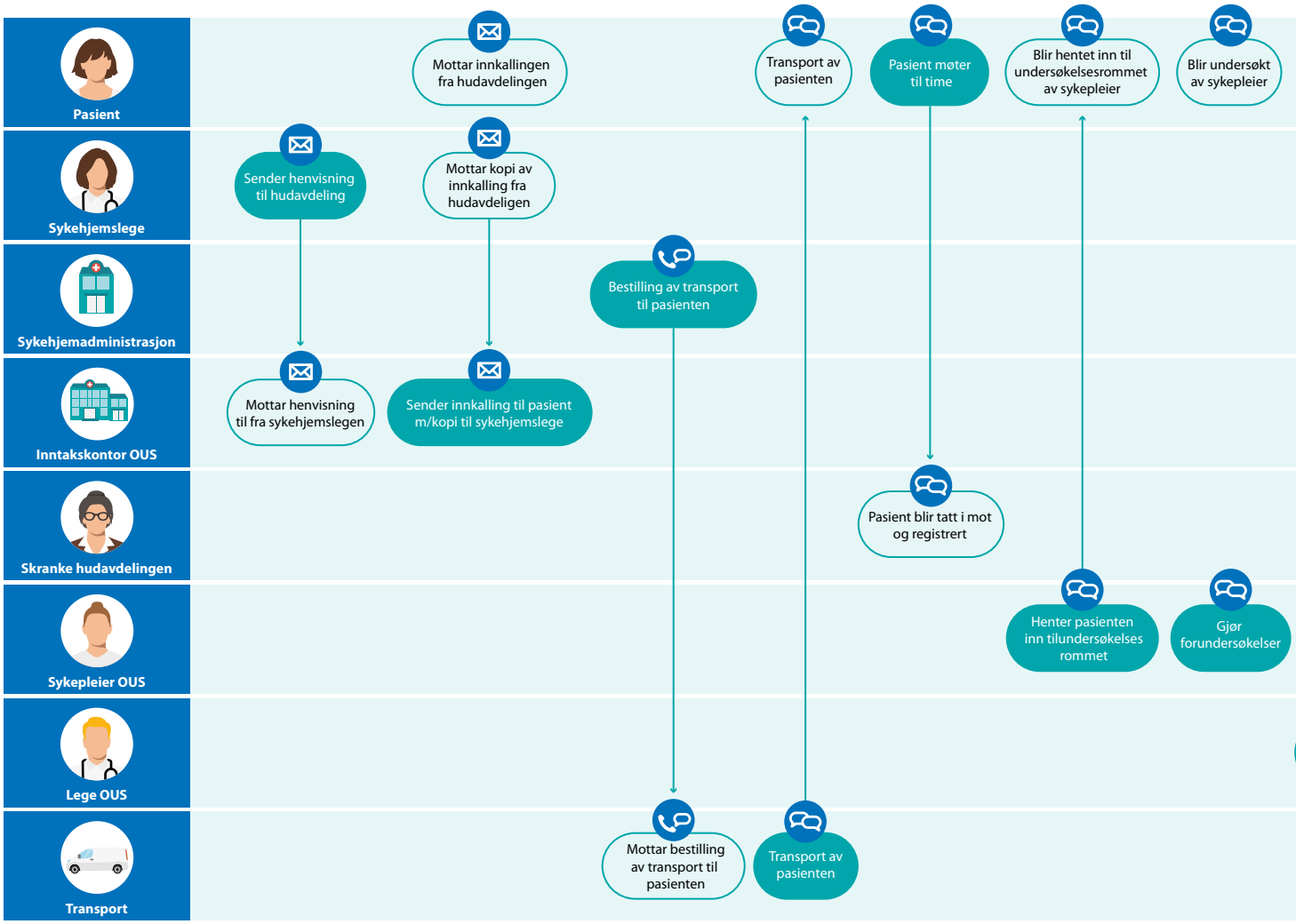
c) Clinical analysis

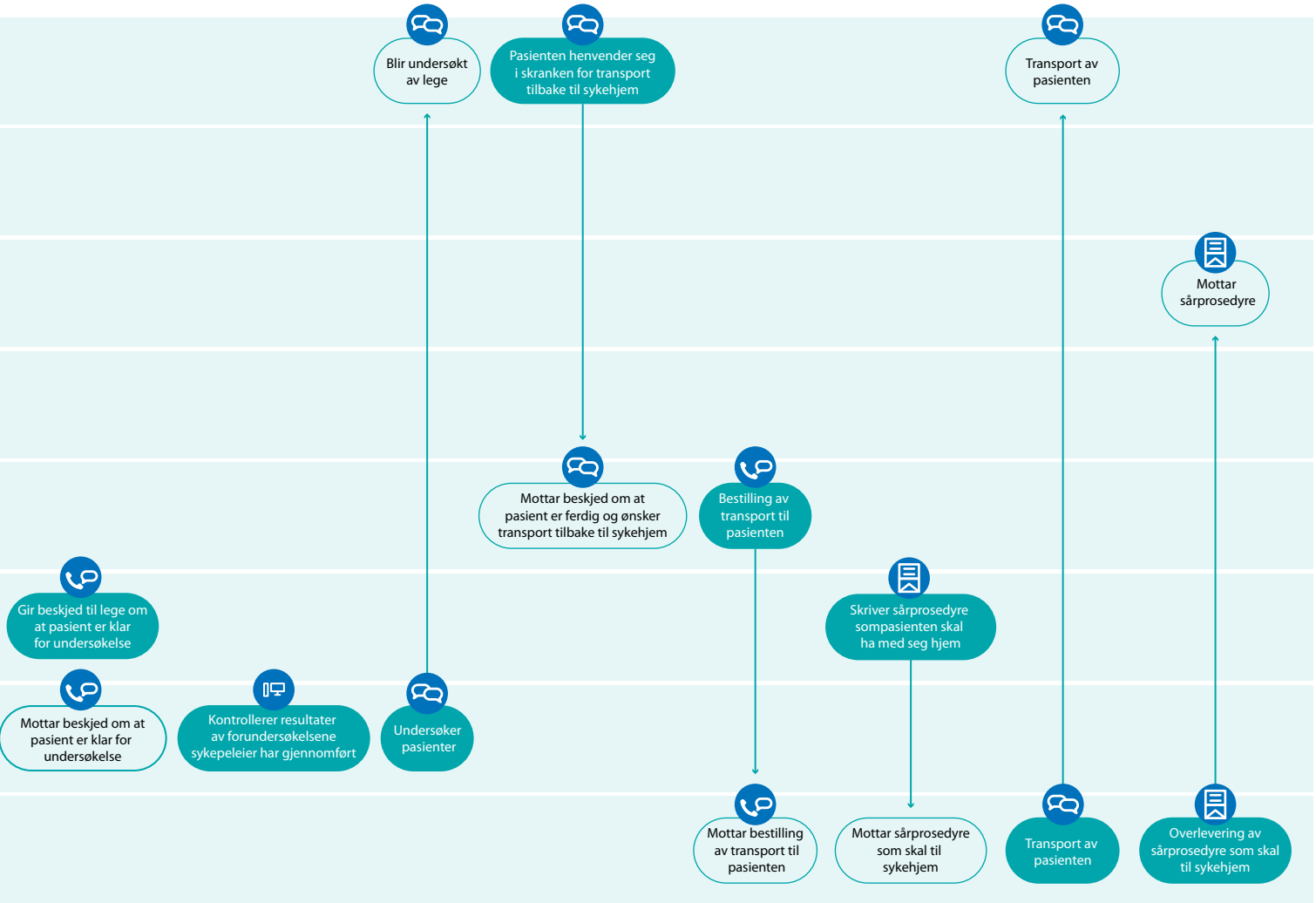
It can be challenging to assess clinical efficacy in early technology assessments. For a long time, randomised clinical trials (RCTs) have been considered the gold standard in assessing clinical outcomes. However, RCT's can be considered to have limitations, especially for the evaluation of early stage interventions (Chang & McLean, 2006). RCTs require a large amount of data and are therefore demanding in terms of time and resources. Difficulties relating to blinding are also evident in literature on the assessment of non-invasive technology and organisational innovation. However, the literature does point out some applicable methods. Clinical trial simulations based on prior clinical outcomes can supply information otherwise unavailable in the early stages of the process (Banta, Gelijns, Griffioen, & Graaff, 1987; Hartz & John, 2009; Ijzerman & Steuten, 2011; Niederlander, Kriza, Wahlster, Djanatliev, & Kolominsky-Rabas, 2013). Input data for clinical simulations can also consist of expert opinions or a structured literature search on clinical outcomes (Gantner-Bar et al., 2014; Girling et al., 2010; Manetti et al., 2015; Steuten, 2016). Clinical trials performed in a controlled laboratory setting, such as bench studies, are also pointed out in the literature as a method of reducing uncertainty on the efficacy of clinical outcomes (Markiewicz et al., 2014).

ILLUSTRATION/SYMBOL

Method	Description
Stakeholder analysis	The process of assessing a decision's impact on relevant parties and the parties' impact on the decision, by weighing and balancing all the competing demands.
Scenario analysis	The process of analysing possible future events by considering alternative possible outcomes, combining optimistic, pessimistic, and more and less likely developments.
Cost-effectiveness analysis	A form of financial analysis that compares the relative costs and outcomes (effects) of different courses of action.
Expert elicitation	The synthesis of the opinions of authorities on a subject about which there is uncertainty due to insufficient data.
Sensitivity analysis	The study of how the uncertainty in the output of a model can be apportioned to different sources of uncertainty in its inputs.

APPENDIX 1: Flowchart for the outreach wound team




Blir undersøkt av lege
Pasienten henvender seg i skranken for transport tilbake til sykehjem
Transport av pasienten
Mottar sårprosedyre
Mottar beskjed om at pasient er ferdig og ønsker transport tilbake til sykehjem
Bestilling av transport til pasienten
Gir beskjed til lege om at pasient er klar for undersøkelse
Skriver sårprosedyre sompasienten skal ha med seg hjem
Mottar beskjed om at pasient er klar for undersøkelse
Kontrollerer resultater av forundersøkelsene sykepeleier har gjennomført
Undersøker pasienter
Mottar bestilling av transport til pasienten
Mottar sårprosedyre som skal til sykehjem
Transport av pasienten
Overlevering av sårprosedyre som skal til sykehjem

APPENDIX 2: A summary of the effect measurements for the outreach wound team

VALUE ASSESSMENT

PROJECT NAME:
Ambulatory wound team

PROJECT MANAGER:
Dr. Kristin Bergersen

DEPARTMENT:
Villa Derma
Department of Dermatology
Oslo University Hospital

DATE:
30.01.2014

REPORT: NV 1-2014

METHOD

Finances:
Cost estimates based on data collected

Organisational:
Interview of employees
(a semi-structured interview guide is used)

Patients:
Interview of employees
(a semi-structured interview guide is used)

Background/Challenge: Elderly wound patients from nursing homes are exposed to uncomfortable transport both to and from the hospital. Transport is also expensive, and requires a lot of waiting. The flow of information between teams for these patients is varied and often inadequate, which has consequences for the quality of treatment.

Innovation: The creation of an ambulatory (mobile) wound team consisting of a specialist doctor and specialist nurse. The team will travel to nursing homes for the examination and treatment of immobile patients with chronic wounds. Bedside teaching and immediate delivery of epicrisis and wound procedure are part of the intervention.

ANALYSIS AND RESULTS

Financials: For nursing homes, the service will result in cost savings of 1.264 NOK per treated patient, and 4.126 NOK per patient treatment overall for the community. Given the same prerequisite as for Oslo, the society as a whole will save ca. 380 million NOK by introducing an ambulatory wound team for wound patients for the country's nursing homes.

Due to today's income system, innovation leads to reduced income for the hospital's Dermatology out-patient clinic. For the hospital, the total cost increase is 894 NOK per patient. The Dermatology out-patient clinic will have increased costs of 1.327 NOK per patient treatment. Patient travels receive a saving of 432 NOK per patient treatment.

Patient benefit: The patient avoids the deductible expense of 266 NOK, and the trip to and from the hospital. Immobile patients who are not otherwise reached will receive adequate treatment. With this settlement the patients will receive faster wound healing, indicated by the reduced number of controls.

Organisational: The assessment of introducing the ambulatory wound team as a new service shows better interaction between hospitals and nursing homes, shorter epicrises time, greater understanding of wound procedures by the nurses, and increased wound skills in the nursing homes.

RECOMMENDATION:
The overall benefit, both economically and non-economically and taking everything into account, for introducing an ambulatory wound team is ready. The **ambulatory wound team provides apparent clinical benefits and satisfied patients, and increased level of interaction and capacity building in the nursing homes.** Furthermore, the assessment shows savings for the hospitals and for society as whole. Oslo University Hospital will lose financially on the agreement, 894 NOK per patient treatment, and the Skin out-patient clinic will lose 1.327 NOK per patient treatment. At the same time, society will have cost reductions of 4.126 NOK per patient treatment.

The Dermatology Department has implemented the innovation from spring 2014.

The Clinic of Innovation – Oslo University Hospital HF
If you want the full report e-mail: Idepoliklinikken@ous-hf.no

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Endnotes

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