

**PROJECT PROPOSAL (BP2) /
GOVERNANCE DOCUMENTATION (BP3 AND BP4)
FOR
MHEALTH**

Case number in 360: 14/9116-1	Version number: 1.0	
Approval date: 01.10.2014	Approved by Project Owner: Roar Olsen	Created by: Helge T Blindheim / Astrid Nyeng / Per Hasvold / Thor Steffensen

Changelog

Version	Date	Change	Producer	Approved
0.1	10.09.14	Document created	Astrid Nyeng	
0.9	01.10.14	Document to approval – Roar Olsen	Helge T Blindheim	01.10.14
1.0	01.10.14	Document delivered to the Ministry of Health and Care Services	Helge T Blindheim	01.10.14

Distribution list

Units/Organisations
Project owner (Roar Olsen)
Project responsible (Helge T. Blindheim)
Project manager (Astrid Nyeng)
Project research responsible (Per Hasvold, NST)

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PROJECT BACKGROUND AND MOTIVATION

The project proposal described in this document is a response to the mission stated by the Ministry of Health and Care Services to the Norwegian Directorate of Health dated 28th of May 2014 with the Ministry reference 13/4505. The project will be part of the 4 year WHO-ITU joint initiative on mHealth for noncommunicable diseases (NCDs): Be He@lthy – Be Mobile (see Attachment 1). The overall objective is the global goal based on the World Health Assembly strategy from 2012 to reduce early death caused by NCDs by 25% within 2025. This project will leverage mHealth as one tool for accomplishing this goal.

WHO: World Health Organization, ITU: International Telecommunication Union

Definition

The project proposal is focused on mHealth and noncommunicable diseases (NCDs). In this document mHealth is an abbreviation for mobile health, a term used for the practice of medicine and public health supported by mobile devices and applications. In the Norwegian context, mHealth is to be understood as a sub-segment of eHealth and as an extension of the area of technology assisted living (Norwegian: Velferdsteknologi).

mHealth involves mobile devices that people carry, wear and in other ways bring with them when they move around. Examples are smart phones and tablets with device accessories, sensors and software appliances as apps and server side services. Users fall into different categories: Consumers, patients and health care professionals. mHealth is also a contextual move towards more personal health systems and services, since the mobile devices are personal, and carried with the user for the larger part of the day. mHealth empowers the patient. There is a distinctive difference between devices and solutions chosen by the individual and used in a personal context, and equipment referred to and used by health service providers in clinical practices. This will imply different approaches with regards to responsibility and regulatory compliance.

Background

There is significant momentum in health oriented technology development. Earlier, dedicated health care solution providers and established suppliers of technology to the health care sector dominated this market alone. With the emergence of fitness and wellness applications, global consumer and business technology innovators like Apple, Google, Samsung, Microsoft and others are now a driving force in the market space. From their wellness and lifestyle base, these innovators are rapidly moving their solutions and platforms towards health and clinical oriented applications. Their focus on user friendly mobile and home devices with related services generate popular demand. In Norway, this is supported by widespread access to the internet through fixed and mobile connectivity, combined with a relatively high purchasing power in the population.

The number of commonly available mobile health technologies is rapidly increasing. This development, and the corresponding public adoption, is happening outside the scope and influence of government health care services (see [Norwegian Board of Technology](#)).

The project this document describes addresses the issue of how the government led health care services in Norway should relate to and make use of the mHealth momentum. The basic assumption is that there are potentially significant benefits for public health and quality and cost in health care by embracing and integrating mHealth in health care services. Demographic development in the next decades, documented in multiple other contexts, clarifies the need to develop new methods and identify new tools in health

care. mHealth is one such potent tool. This project aims to identify how, in which context, what benefits of mHealth can be exploited.

The current use of mHealth for NCDs by Norwegian healthcare is fragmented and mostly through local initiatives or projects. A small number of vendors and service providers have products and services for NCDs, and there are a few ongoing research projects addressing COPD and diabetes in particular. Prevention and secondary prevention through self management apps and services are increasing in numbers, but are mostly initiated and administered by citizens themselves.

The systemic use of mHealth prescribed to a patient, advised by a healthcare professional, is still not very common beyond ECG (Holter) monitoring. Care professionals use mobile health information systems within home care to record observations and actions out in the field, as well as using imaging services for leg ulcer follow up.

Present situation

The use of mHealth in health and care services today is limited. Health care professionals does not have tools nor legal support for accepting and knowing how to relate to data from consumer equipment that patients may be using. The development empowers patients and relatives, but there are no mechanisms in place to secure quality and evidence based practices. No guidelines or methods exists to secure quality in technology, clinical practice or patient outcome specific for mHealth. Because of this, neither health care professionals, their organisations, nor patients and their relatives are able to separate the wheat from the chaff in an open market with tens of thousands of mHealth apps and appliances.

Hence, mHealth today does not provide the health care sector with any structural benefits. Public adoption of mHealth may in fact be experienced as a nuisance by health care professionals due to the fact that patients may develop confidence in their own judgement based on mHealth tools and information that is not subject to any quality assurance. This may lead to high and specific expectations that professionals must spend time and energy to counter.

Based on concepts of the informed and active patient, and the informed and pro-active health team, The Coordination Reform in Norway emphasizes prevention and secondary prevention as a key focus areas for meeting challenges of the future healthcare services in an aging population. The “One Citizen – One Health Record” Government Report outlines how electronic health records (EHRs) are key elements in communication within the health and care services, as well as between the patient and the health services. The Norwegian Strategy for NCDs (2013-2017) has four key strategic elements: primary prevention, secondary prevention, improved identification of persons at risk of NCDs, and improved treatment for those with an NCD. The goal is to reduce deaths from NCDs by 25% by 2025. The recent Government Report “HelseOmsorg 21” puts emphasis on the person-centered care and the importance of involving the patient in the care processes. mHealth holds promise of being a key element to answer these policy documents, as mHealth enables involvement of the citizen as well as providing a platform for prevention, early identification of risk, and improved treatment.

18% of Norwegians reports to have used a health app [REF: [e-helse i Norge 2013, Sørensen, Andreassen, Wangberg. NST Rapport 2013](#)]. In a Scandinavian context the distinction between eHealth and mHealth is blurred as the high proliferation of smart-phones means that most people can access eHealth services on their mobile phone device. 78% of the respondents reported to have used the Internet for health issues.

No-go consequences

If this project is not executed, these consequences are likely to follow:

- mHealth technology and public adoption continues its fast track development, and will result in ever more patients being empowered on what health care professionals will identify as questionable grounds. mHealth risks obstructing health care services rather than supporting it.
- The benefits of mHealth will not be possible to exploit structurally and systematically by the health care services. mHealth may provide more quality health care with less person to person interaction between health care professional and patients, and thus enable more quality health care for the same or reduced cost. If this assumption is correct, each health care professional will be able to provide quality health care for a higher number of patients than today. In addition to reducing the number of deaths related to noncommunicable diseases, mHealth may be one building block to counter the challenges of demographic change in the next decades.
- mHealth will remain a tool for the resourceful individual, and will in practice not be available for large groups of patients that potentially have much to gain.
- Health care professionals will not be able to provide patients with beneficial tools for quality patient outcomes. In the long run they risk losing credibility with mHealth empowered patients.
- Evidence based knowledge from effect research will not be obtained, so the benefits or challenges with mHealth will still be subject for speculation.
- The healthcare sector risks being perceived as old fashioned and outdated, thus reducing the trust and confidence in the public health and care services.
- The Norwegian Strategy for NCDs (2013-2017) promising a 25% reduction in deaths from NCDs by 2025 will be harder to accomplish.
- The demographic change will reduce the number of available hands in the health and care services compared to the needs in the population. This challenge will be harder to address if mHealth is not developed.

Be He@lthy – Be Mobile

The WHO-ITU joint initiative, Be He@lthy – Be Mobile, is an international mHealth framework project that will run over the next 4 years. Se Attachment 1 for more information.

Norway will participate in this program, together with 7 other countries. The program encourages national projects and programs with international sharing of skill-sets, experiences, research results and solutions where intellectual property rights support such sharing.

The Norwegian mHealth project will, as part of the WHO-ITU joint initiative, stay focused on deliveries in Norway, as described in this document. The participation in the Be He@lthy – Be Mobile program will mean that deliverables in Norway will be transformed and adjusted to value and content relevant in WHO-ITU-enabled contexts. This will also mean participation in and potential hosting of events that support adoption of mHealth in international arenas. The mutual exchange of partner relationships to enhance value in projects will be taken into account. The WHO-ITU project encourages partnerships between government, private sector, academia, and non government organisations (NGOs). The Norwegian project will do the same.

An additional dimension to be evaluated is the question of hosting a Nordic/Scandinavian oriented mHealth innovation hub. This will be discussed in the Project description of the Innovation track.

PROJECT GOALS AND DELIVERABLES

This mHealth project aims to describe, document and demonstrate which benefits there are in mHealth, how to exploit them, and what requirements needs to be met to integrate mHealth into clinical practices while securing good patient outcomes. This approach to mHealth also implies the ambition to clarify what limitations may exist for mHealth efficiency, and areas where mHealth might not represent the best available toolkit.

When the project is finished, these will be the major outcomes:

- A few mHealth solutions will be implemented and put into normal use in a national deployment context.
- The health care services has identified how to relate to and exploit benefits of mHealth, and has created guidelines, methods and tools for achieving this. Including how the use of mHealth can be financed through the activity- or quality based financing system.
- Research has been done to document what benefits mHealth provide, the context in which they can be achieved, and the requirements that needs to be met to secure them.
- mHealth innovation is spurred by the facilitation of arenas that encourage innovation in technology, clinical practices, patient experiences and incentive models.

In total, the project will deliver input for a national strategy for mHealth, where the role of mHealth in terms of reaching the stated national goals of 25% reduction in deaths from NCDs within 2025 can be described.

PROJECT DESCRIPTION

Project tracks

The project will be executed with 4 distinctively different but operationally integrated and interdependent tracks:

- Health care services
- Solutions
- Research
- Innovation

Health care services track

What

The health care services track is about integrating mHealth in the provision of health services. mHealth provides the health services with similar opportunities and challenges as technology assisted living. These areas of technology are overlapping, though in the Norwegian context technology assisted living is often understood as home-oriented eHealth (smart houses with health appliances).

As of today, the health care sector does not relate to health data created on devices in solutions that they have not initiated themselves. For mHealth to be relevant and possible, there are numerous questions to be answered and challenges to be solved. The health care services track will involve resources from primary care, public health, specialist health care, finance, regulation and patient and health care professional organisations. The objective is to study, debate and answer these. The goal is to identify how mHealth is to be part of the health care services in the future, i.e. to produce a national strategy for mHealth.

The following is a list, though not complete, of issues to be addressed:

- What mechanisms for ensuring quality in equipment and solutions and patient safety are necessary?
- What methods and work practices does health care professional and their institutions need to provide treatment and follow up of patients with mHealth tools?
- What frameworks, guidelines, standards, quality assurance processes are needed to support mHealth as an integrated part of health services provision?
- What does mHealth demand or require from the patient and relatives?
- How does mHealth influence health professional work processes and health institution practices?
- How does mHealth influence patient treatment processes?

- How can the independence mHealth provides to the individual be leveraged to increase quality and care, since patient location and time of activity is not reliant on immediate health professional access?
- What possibilities and possible limitations does present regulation pose for use of mHealth?
- How should the large amounts of data that mHealth is expected to produce be treated? Under what regulatory area does it fall and in which context does this apply?

How

The health care services track will make extensive use of relevant representation to cast light on necessary issues. See more about involvement and how the process is to be designed in the project organisation section of this document.

The project will focus on five different perspectives:

- The user perspective
- The health care professional perspective
- The health care institution perspective
- The solution provider perspective
- The government perspective

The user perspective seeks to identify the experience and the need the user has regarding mHealth tools. The user is the patient or the patient's relatives. For example: The user will be focused on her particular situation, wanting an mHealth solution that is as dedicated to all aspects of her health profile and treatment needs as possible. The health care professional will need methods and tools to refer to or advise mHealth, and will have her professional skill-set and responsibilities as a background to do this in a secure manner. The health care institution must focus on its structural responsibilities regarding information management and role as a health care provider. The solution provider focuses on time to market, who the customer is, business models and volume. The government develops policies, regulation, ensures compliance and supports practices with financial incentives.

With these perspectives as a background, the project will identify a number of specific user- and role-driven scenarios. Some of these will correspond directly with the user scenarios the solution track will deliver upon. The scenarios will describe every day situations where mHealth is relevant, and show how the different perspectives meet and interact. This method will ensure that the issues to be addressed will be relevant and realistic and not only of theoretical value.

Hence, the perspective analysis will provide the holistic view of the challenges, and seek to identify similarities between scenarios that will support policy and work process development. The scenario analysis will focus on the potential daily use of mHealth and thus clarify realistic dilemmas that is expected to occur.

Attachment 2 represents a preliminary description of a couple of perspective analysis and several user scenarios.

Why

If it is not made clear how mHealth is to be integrated with the health care services to secure quality in process and patient outcome, mHealth will not be leveraged according to its potential. It is to be expected that the incentive models in the health care system at the minimum must be updated, possibly even rehailed, to accommodate for systematic use of mHealth. The incentive models inside health care, whether they remain as today or are made subject to development, will have large impact on the innovation pace, business models and the direction chosen in the private sector. The vast amount of new

information created through mHealth appliances address the need for updated practices regarding privacy and information security. More or new regulation may be needed.

The issues identified inside the health care services track are vital if one is to accomplish anything in this area at all.

Solution track

What

The solution-track is focused on putting a limited number of mHealth solutions into normal use in a context that can be nationally deployed. Focus will be on choosing at least one solution from three categories:

- **mHealth solutions in the consumer space.** Solutions in this category are identified by technology that is readily available for consumers. They address the question of how the health care services should relate to such appliances, how they influence health professional work process and use by patients, what incentive and business models are needed, how to identify quality in solutions and requirements for integrating such solutions successfully in health care. Solutions in this category will often be of the preventive type.
- **mHealth solutions in the treatment space.** A patient with a noncommunicable disease will need support for every day life and treatment to keep the disease in check. Solutions in this category will be chosen by the health service provider the patient is referred to, or the provider will direct the patient to the solution but leave the patient to decide for himself. This category addresses the question of what requirements a solution, and potentially its producer, must fulfil to be referred to by health care services in one way or another. Solutions in this category will be used directly in patient care, and will because of this be subject to medical equipment regulations.
- **National integration infrastructure for mHealth.** The project will focus on establishing a national integration infrastructure for integrating mHealth with health care administrative solutions (see figure 1 below). Pilot projects in the mHealth area often face complicated and cost driving integration challenges to enable interaction with implicated government administrative solutions. Technology assisted living projects faces the same challenge. Data from mHealth or smart home solutions is generated outside health institutions. Such data, though not all, need to be securely transported into relevant systems on the health service side, i.e. electronic patient records. mHealth solutions may generate very large amounts of data, creating the need to filter, aggregate and add value to the data before or during transportation to the back end systems. Traditionally, integrating external solutions with health care provider solutions inside the health network (Norwegian: Helsenettet) is a daunting task. For mHealth to be relevant, mechanisms must be identified to make the proper data flow to and from back end systems easy to implement and maintain. The Norwegian strategy for eGovernment and eHealth has provided Norway with existing infrastructure that may be leveraged and expanded for this purpose. Building on the existing base of solutions, new national integration infrastructure will be limited in scope and scalable in character. It will provide a “bridge” between the internet and the health network where data will flow in and potentially out based on pre-defined rules supported in general legislation and the code of conduct for information security in the health care sector (Norwegian: Normen). A solution in this category will be in line with existing national eGovernment and eHealth strategies, and will represent a strong new mechanism to deliver standardisation and regulation compliance.

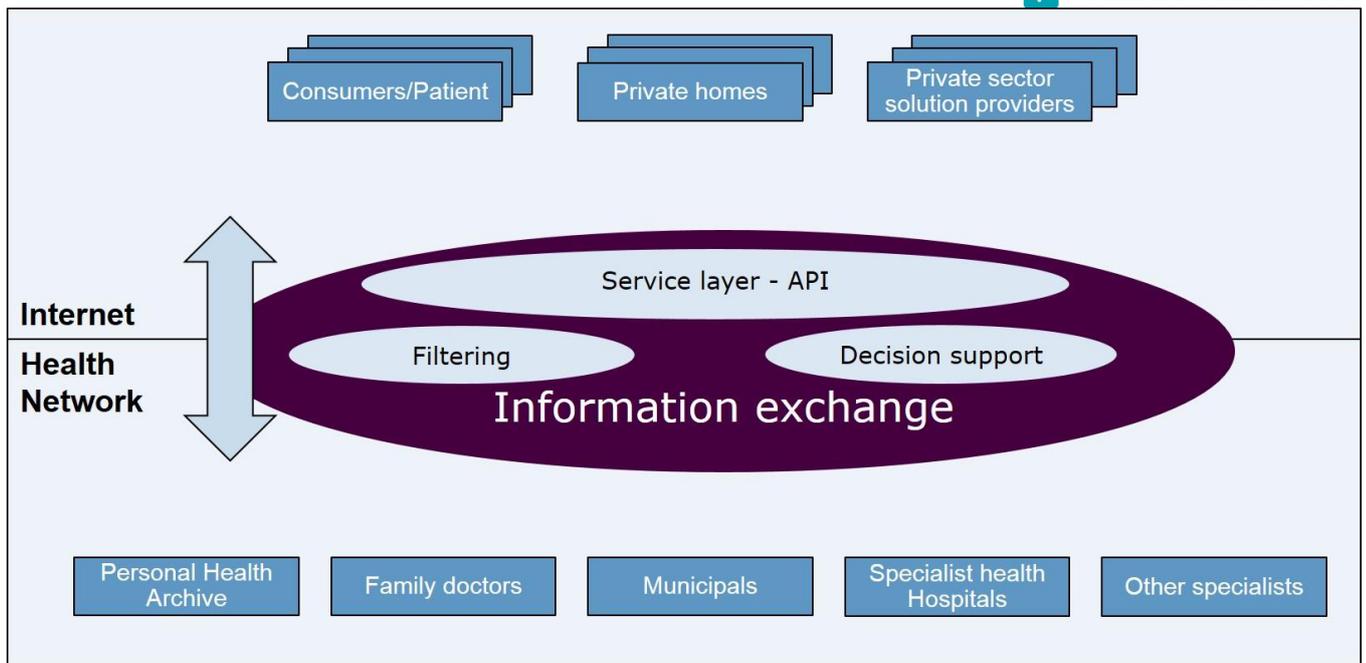


Figure 1: Architecture concept for national integration infrastructure

How

This track will be run as a technology development and implementation project with involvement of all parties necessary to make it relevant. The goal is to put solutions into normal use in a national context.

Priority will be to choose one or a few mHealth solutions and secure their deployment rather than piloting many. Choosing which mHealth solutions to implement will be a task for the first part of the project. The following factors will be prioritised when evaluating different solutions:

- **Solution and solution provider must be able to support national deployment.** The mHealth project is not another pilot or research project. The goal is national deployment. This requires a certain robustness in the technology of the solution and the solution provider itself.
- **Solution and its business model must comply with present regulations.** Solutions that are to be put into use today must comply with all relevant regulatory requirements. Solutions that challenge these belong to the innovation track.
- **Existing solution with existing implementation.** The solution track of the project will prioritise solutions that are locally or regionally implemented or under implementation today. The goal will be to implement, deploy and put the solution into normal use in a national context. This also means that the solution in question has demonstrated a level of credibility by already passing existing decision making in the health care sector. New solutions may be submitted to the innovation track for follow up in an innovation context.
- **Solution provider should have an export strategy.** Solutions and providers that are prepared for export through properties in their technology and their business model will be preferred. Export need not be present today, however. Innovators that does not meet this requirement may submit their candidacy for the innovation track to visualise how mHealth innovation in Norway should support startups and innovators in establishing themselves internationally. This factor is in place also because the chosen solutions should be as applicable as possible for the other WHO-ITU project participants.

The solution track will have deliverables to the health care services track. Among these are questions and dilemmas regarding the health service with mHealth solutions, showstoppers or challenges for the project presented through work process, incentive systems and more. The solution track also needs input from the health services track. Regulation, work practices etc may and will provide guiding principles the solution track must follow. Hence, the project tracks need to be integrated.

The solution track will also have deliverables and need input from the research track. Base line analysis needs to be designed and performed, and implementation of solutions will be subject to follow- and effect research. The research track will provide a set of reporting parameters and set conditions for both technology implementation and patient/health care professional involvement.

The solution track also have deliverables to the innovation track. The innovation track will be focused on identifying both innovation supporting and obstructive mechanisms in the process of adopting the solutions in health care.

Why

Implementation of these solutions is meant to provide 1) first hand experience with technology, 2) substance for research to identify potential effects to provide basis for policy creation and further deployment, and 3) demonstrate opportunities and clarify obstacles for mHealth in Norway.

Research track

What

The research track will follow two lines of research:

- Research activities directly related to this particular mHealth project. These research activities must be funded from the mHealth project itself.
- General research related to mHealth, and possibly also specifically targeting noncommunicable diseases. These research activities may rely on the research momentum in other and wider contexts provided by other institutions. The mHealth project may be able to leverage and make use of these activities.

The mHealth project requires research activities to inform about decisions made in the selection of cases and as a foundation for defining effects and expected results. In addition, research is necessary in order to document the implementation processes in the selected cases, in order to learn from the cases and to share systematic descriptions of these cases with the stakeholders and the wider mHealth partnership, also through WHO-ITU internationally. Thirdly, it is important to follow the individual patients to document the clinical outcomes for the mHealth services.

In addition to the research activities specific to the mHealth project, this mHealth initiative can be used as an inspiration to a broader commitment to mHealth systems and services development through research and innovation projects outside the scope of the mHealth project. The Research Council of Norway (RCN) plays an important role through their research funding programs. For research activities outside the scope of mHealth it is necessary to have calls for projects that address the topic of mHealth related to noncommunicable diseases. The Horizon 2020 calls from the EU is an important source for funding for research and for innovation and business networking.

How

Research directly related to the mHealth project needs to be funded as part of the project, and will have four phases:

- **Business Case/Baseline study.** Assessment of state of the art for mHealth and the specific topic (i.e. this type of assessment is necessary for each of the topics targeted by the Norwegian mHealth project). This will typically be in the form of a literature review, as well as an overview of ongoing activities in each of the health regions in Norway, an overview of Norwegian/Nordic/Scandinavian vendors and stakeholders, and a review of current strategies for

mHealth in government papers, in the regional health authorities, the health trusts, as well as the primary care sector.

- **Research scope and design.** This phase describes the definition and approval of the research protocols; approval of the research by regional ethical committees; recruitment of PhD Candidates and/or Post Doc Candidates (if organised as PhD/Post Doc projects); recruitment of patients and healthcare professionals to participate in the project.
- **Study of the implementation.** Studies of the implementation process for each of the cases or topics selected. This will typically be in the form of a longitudinal research process that follows each implementation process and has insight into the discussions and documents that each process uses. It is possible to organise such longitudinal study so that it follows an iterative process where the project is informed about the findings along the way.
- **Outcome studies.** These are the most complex to organise, as they require collecting patient data and financial data that are harder to come by and organise. Patient data might require approval from the regional ethics committees where the data is to be collected. An RCT would provide the highest quality results, but might be difficult to organise due to danger of contamination from use of other mHealth systems and services. A comparative study with equal cohorts from two different regions or a prospective before/after study might be a more viable alternative.

Other research activities relevant for noncommunicable diseases and mHealth:

- Development of mechanisms for adherence.
- Addressing gaps in access (universal design and reaching users who do not have access to smart phones or has cognitive or physical challenges regarding use of smart phones).
- Use of gaming (gamification) and tailoring of user feedback to encourage lifestyle changes.
- Integration of personal health systems with professional health systems; how to turn mHealth and pHealth data into relevant and useful information to the clinician.
- Development of advanced analytics to understand individual health and how lifestyle affects individual longterm health outcomes.
- Social networks (virtual and real) and the effects on health outcomes.
- New mHealth information platforms and cloud services.
- New business models for mHealth for NCDs and other complex health issues (chronic care).
- Development of health services that include the use of mHealth systems and services.
- Privacy and security of mHealth for NCDs.

Why

Research will identify what benefits mHealth can provide, which requirements need to be fulfilled to secure them and in which context they will flourish. Research will also clarify what obstacles there are to realising gains, and limitations to the usefulness of the technology.

Research is vital to acquire a knowledge basis for further policy and strategy development in the mHealth area.

Innovation track

What

Innovation focus in the mHealth project will address innovation both in private sector and in government, technical solutions and business models as well as clinical practice, patient treatment and efficiency.

The innovation track will have three lines of focus. The decision upon how to approach or even execute on the third is not taken, but should be evaluated.

- **Innovation focus in the mHealth project.** All project tracks will have an innovation focus that will be driven forward by the innovation track. Implementation of mHealth technology in the solution track will identify and evaluate requirements for technology innovation, and document challenges that is encountered with regards to this. The health care services track will have a corresponding focus on innovation in work processes, incentive models and government regulatory issues. The motive is to identify a quality focused health care services context for innovation, focusing on how to make use of new technology. The research track should in its research focus adopt these parameters to substantiate the project findings in an evidence based context.
- **Innovation in mixed professional environments.** Innovation in mHealth is not only innovation in technology, but innovation in a context where technology, patients, health care professionals and government regulatory representatives congregate in a think tank oriented manner. The objective is to create out of the box solution scenarios that match their different perspectives into common and realisable directions. The delivery team of this mHealth project is designed to create such a forum. It will seek to identify the innovative players that exist in Norway and deliver information and relationships to existing and new innovation arena.
- **Long term mHealth innovation.** One such potential arena is an mHealth innovation hub. WHO-ITU has asked Norway to evaluate creating a Nordic/Scandinavian innovation hub for mHealth. Such an initiative can be born out of a partnership between relevant research- and expert organisations and private technology clusters. The intent will be to maximise a combination of long term academic innovation approach with time-to-market oriented technology innovation in private sector where business models and return on investment is first in mind.

How

The innovation track will use the mHealth project delivery momentum and the accompanying research to identify favourable variables and ingredients in an mHealth innovation culture. The project delivery team will be designed in such a way that representatives from the different professional areas meet in a delivery and solution oriented environment. This creates a context where technology innovation and the patient empowerment ambition does not live separate lives, far away from the constraints health care professional and regulatory bodies have to relate to. At the same time, the customary routines and work processes of health care, existing incentive- and financial models and present regulatory environment, will be – and need to be – challenged by opportunities driven by technology and public adoption of it. The tension between these conditions make up the energy and drive for innovation.

The project will invite all parties, non government as well as government, to identify themselves as mHealth stakeholders with their solutions, skill-sets or other deliverables. This will supplement and fulfil existing overviews of stakeholders and be put to use nationally and internationally as a network building tool. If work with an mHealth innovation hub is started, this will represent input for that particular initiative.

Attachment 3 represents preliminary suggestions as to what considerations an innovation hub should accommodate.

Why

mHealth does not have an obvious sustainable market in Norway. Norway has a small population, hence volume for solutions focusing on noncommunicable diseases are small. The country is long stretched, the cost level is high and the complexities in health care challenging. Business models for mHealth are not obvious since identifying the customer – who will pay the bill – is not always easy. When customers are identified, the government purchasing processes demand resourceful organisations that has staying power through the whole process and the ability to match robust government requirements. This discriminates smaller innovators, especially startups, and favours large suppliers with established solutions and the ability to provide tailored projects.

To create innovation and sustain a dynamic market for mHealth solutions in Norway, it is vital to create arenas for efficient mix of professions to secure exchange of competencies and reduce the time to market for solutions as much as possible. In addition to this it is important to create platforms for innovators to market themselves to potential investors and partners nationally and internationally.

Innovating solutions with potential volume of sales implies an extended market in at least the Nordic or Scandinavian region. Cultural preferences and regulatory environment is comparable and technology adaption possible to overcome.

PROJECT STAGES AND MILESTONES

Stages

The project stages (phases), milestones and decision points are based on the project model “Prosjektveiviseren” from the Agency for Public Management and eGovernment (DIFI) and are also in accordance with PRINCE2.

Figure 2 below illustrates the main stages:

- The pre-project stage (concept phase), where the main delivery is the project proposal (this document)
- The initiation stage (planning phase), where the user scenarios are elaborated, the technical solution is decided upon based on the chosen scenarios, and test of the solution is planned. Also, a detailed plan for the first delivery stage is developed.
- The delivery stages are
 - Stage 1: test of the concept
 - Stage 2: pilot execution
 - Stage 3: improvement and rollout
- The final delivery stage (the closing phase):
 - Delivery of the project results in normal operation and maintenance – the final stage of the project.

The figure below shows how these stages are timelined for the different parts of the project described in the Project description chapter. The dates are preliminary, and the duration of the delivery stages are most likely to be changed as they are planned from stage to stage. The Project Board authorises the project to continue to the next stage and approves the detailed plan for the next stage at the decision points.

The project plan signals start up in Januar 2015. It is possible to jump start phase 1 in all tracks in the last quarter of 2014 to create extra momentum for deliveries in 2015.

mHealth Project phases

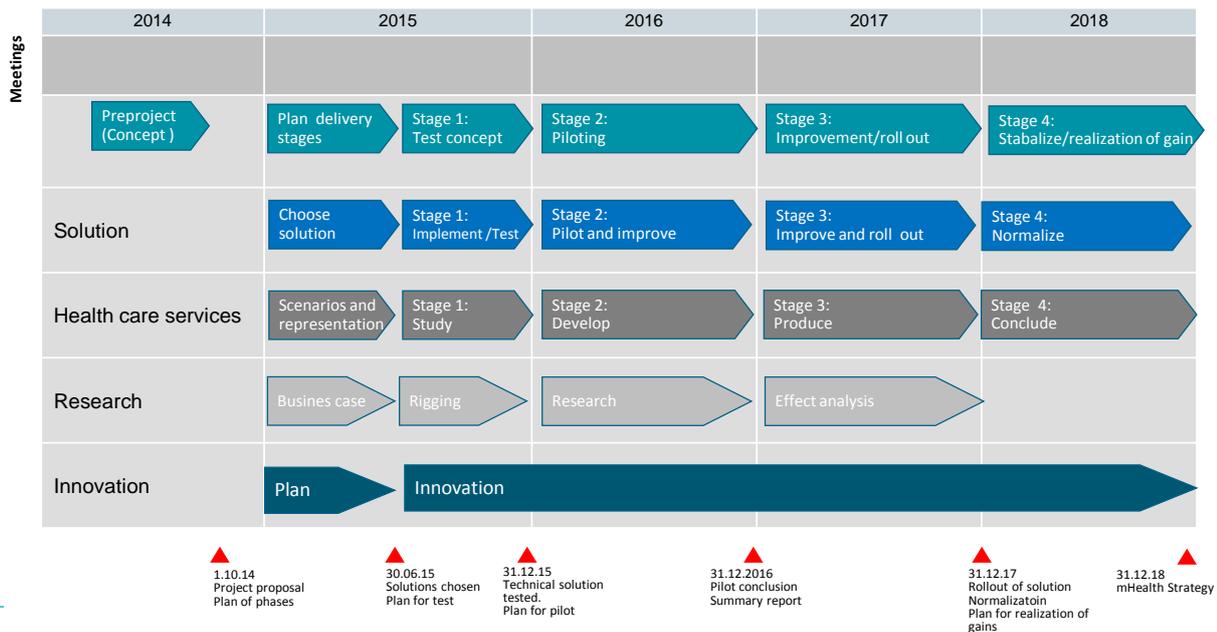


Figure 2: Overview of mHealth Project phases

Milestones

ID	Description of milestones and decision points	Planned date
M0	Project proposal is delivered to the Ministry of Health and Care Services	01.10.2014
BP2	Approval of the project proposal – initiate the planning stage	20.12.2014
M1	Project start up – start of planning stage	01.01.2015
M2	User scenarios and technical solution for pilot are approved	30.06.2015
M3	Test plan is approved	30.06.2015
BP3	Project execution decided	30.06.2015
M4	Technical solution is tested and approved and pilot is planned	31.12.2015
M5	Pilot is finished and experience report is approved	31.12.2016
M6	mHealth solutions are in use at a national level	31.12.2017
BP4	Start of the project closing stage (delivery to normal operation and maintenance)	01.01.2018
BP5	Approval of project completion	31.12.2018
BP6	Approval of plan for realisation of gains	31.12.2018

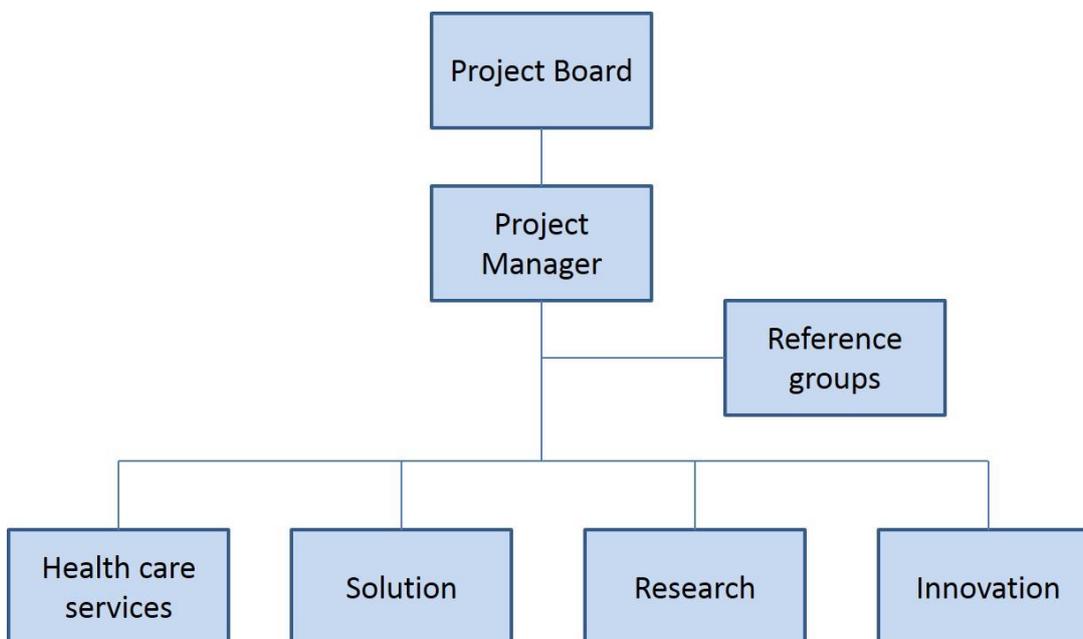
PROJECT ORGANISATION AND ROLES

Ownership

The mHealth project will be owned and run by the Norwegian Directorate of Health, division for eHealth and IT.

Organisational chart

This organisational chart below shows a representation of the organisational structure in this project based on the implementation of PRINCE2® that DIFI is responsible for.



Project Board

This is a national project. Hence, the project board will need to consist of representatives from different organisations in the health care sector:

Role	Organisation
Project executive	Norwegian Directorate of Health, assistant Health director
Operational project owner / "product owner"	Norwegian Directorate of Health, department director
Project manager	Norwegian Directorate of Health
Government	Norwegian Directorate of Health: Primary health, Public health, Specialist health, Finance, Regulation, IT
Specialist health care	National ICT and Regional Health Authorities
Municipality/primary healthcare	Kommit/KS
Userorganisation representatives	Patient organisation Doctors Unions

The Norwegian eHealthgroup (Norwegian: e-helsegruppen) could be considered as a project board for this initiative.

Delivery team

Applying mHealth to health care triggers the need for tight solution oriented dialogue between multiple parties and deliverables from each of them that will be dependent on each other: Innovators in private sector, government representatives, health care professionals, patient representatives and academia. The project team will be established with representation from these parties to secure relevant input and delivery structure.

The suggested project team will consist of the following participants in 2015:

Role	Organisation	Suggested percentage
Project manager	Norwegian Directorate of Health, eHealth and IT division	100
Operational "Product Owner"	Norwegian Directorate of Health	100
Primary health, Public health, Specialist health, Finance, Regulation, IT	Norwegian Directorate of Health	25-50 pr skill area
Research and expert	NST – Norwegian Center for Telemedicine	100
Innovation and mHealth Private Sector	Oslo Medtech	50
Established eHealth businesses	ICT Norway, eHealth-forum	25
Medical equipment and technology assisted living	LFH – the Norwegian Trade Association for Health- and Welfare Technology	25
Patient perspective	Patient organisations relevant for chosen solution	25
Health care professional perspective	Professional organisations relevant for chosen solution	25
Specialist healthcare	Nasjonal IKT	25
Local government	Kommit	25

The private sector representation in the project team consists of Oslo Medtech, ICT Norway and LFH for the following reason: Oslo Medtech is an innovation oriented medtech cluster of companies, hospitals, finance-, knowledge and research institutions focusing on medical technology. Among others, they organise startups and innovators in the mHealth area. The eHealth forum in ICT Norway organises established suppliers of solutions to the health care sector. LFH organises suppliers of medical technical equipment, which is an area closely related to the mHealth field.

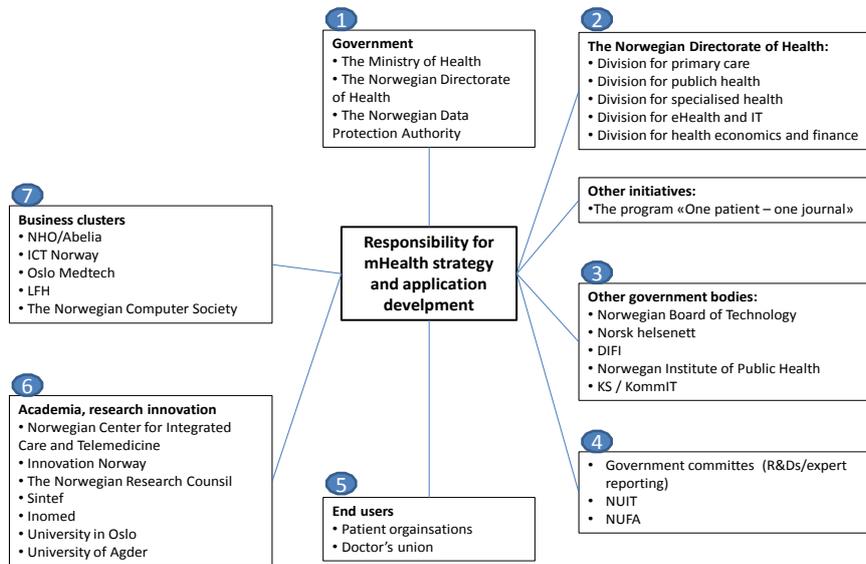
Expert and reference groups

To secure deep enough focus on specific perspectives and subjects than the delivery team will be able to manage itself, the following expert and reference groups will be organised. Relevant stakeholders not in the project team itself will be invited to participate in these:

- Business and technology providers
- Academia and research
- Patient organisations
- Health care professionals
- Privacy and information security

Stakeholders

There will be a large number of stakeholders in an area such as mHealth. Here is an overview that seeks to identify many of these.



Dependencies

- Home hospital or telemedicine projects in specialist health care (regional health authorities)
- The One patient, one journal program
- Projects in the context of Helsenorge, Abstract journal and ePrescription
- The future of care program (Morgendagens omsorg)

Budget proposal for 2015

The project described in this document represents a substantial initiative regarding both mHealth integration in the health care services, solution implementation and research and innovation initiatives.

Observing the complexities involved in the area, the level of funding in such a project will correspond to what results it may deliver. For example:

- Funding up to 6 million NOK pr year will not provide more than a government driven mHealth study with involvement of reference groups.
- Funding between approximately 6 and 12 million NOK pr year will provide the government study, some research and limited mHealth solution deployment in a national context.
- Funding above 12 million NOK pr year will provide the possibility to deliver with substantial national solution deployment and substantial effect research.

The budget proposal below is based on the above described delivery team and the start up of the solution track in 2015.

The first project year will require substantial government resource involvement to work with regulatory issues. Throughout the rest of the project it is expected that the need for resource involvement will change in such a way that the amount of government resources will be reduced, and leverage of external resources (private sector, innovators etc) will increase. The investment in solutions will also likely need to increase after the introduction year of 2015. The project plan forecasts actual start of implementation in the second half of 2015.

The initial planning phase of the project will provide more precise cost estimates for the following phase.

Cost category	Cost driver	Amount in NOK
Government resources	Hours (6 man years)	6.000.000
External resources	Hours (3 man years)	4.000.000
Project costs	Meetings travels and other administrative expenses	500.000
Purchase of solution and implementation project	Possible purchase of mHealth solutions, configuration, development and implementation	2.000.000
Research and innovation	Hours	500.000
	Total	13.000.000