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Early Health Technology Assessment of E-health

by

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The papers are referred to by their Roman umbers in the text.

LIST OF ABBREVIATIONS

HTA	Health Technology Assessment
Early HTA	Early Health Technology Assessment
HB-HTA	Hospital Based Health Technology Assessment
OECD	The Organisation for Economic Co-operation and Development
GDP	Gross Domestic Product
EUnetHTA	European Network for Health Technology Assessment
ICT	Information and Communication Technology
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
C3	Centre for Connected Care
IPLOS	Individual-based health and care statistics
EPR	Electronic Patient Record
Diff-in-diff analysis	Difference-in-difference analysis
PACT	Patient-Centred Team
WHO	World Health Organisation
UN	United Nations

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SUMMARY

In line with international trends, the public healthcare system in Norway is under increasing pressure. The composition of the population is changing and the number of elderly is rising, resulting in a growing need for health and care services. New technology enables the refinement and personalisation of existing health care practices; this has the potential to prevent grave diseases and save more lives. Although the technological revolution in the health care sector shows great potential, not all technological innovations serve their purposes [1]. Documenting the effects of innovation in health care is therefore essential to assist prioritising in adequate technology implementation. To improve the pace and efficiency of the development and assessment of health innovation, new methods for early health technology assessment (early HTA) are emerging in the literature [29]. Early HTA is a form of HTA that evaluates technologies still in development, and can be defined as the early examination of the medical, economic, social, and ethical implications of a health intervention to determine the potential of its incremental value in health care [30, 31].

The purpose of this thesis was to study methods for early HTA of innovative technologies and explore the value of behavioural data in the assessment of usability of e-health solutions.

Paper I found that research is emerging in the literature on altering and adopting methods for HTA to earlier phases of decision making. The use of methods has a tendency to change by stage of innovation. Stakeholder analysis was highlighted as a prominent method of collecting data in the three innovation stages. This applies particularly in the earliest stage of innovation, the developmental stage, since later stages involve greater availability of data and allows for more advanced methods and models. There were barriers to the identified methods in all the innovation stages related to lack of data and much uncertainty. Early assessment may address

clinical value and risk, but due to short investigation periods, obtaining concluding evidence is challenging.

Although user or patient involvement in the early stages of innovation is recommended in the literature, there is a shortage of studies in this review that effectively involves them. Paper II showed that early health assessment may be applied in the conceptual phase to address quality outcomes that can be used for benchmarking purposes in the further development and implementation. Early assessment by means of stakeholder analysis and scenario drafting identified potential benefits both for the patients, the home care service as well as socioeconomic benefits of implementing the web-based platform DigiHelse.

Paper III showed that including behavioural data provide an important source to assess usability. Behavioural data from the study indicates that the low adoption rate may, at least in part, explain the inability of the DigiHelse pilot to perform as expected; meet the citizens' needs. This study points to early assessment of behavioural data as an opportunity to identify inefficiencies and direct digital development in the right direction. Implementing e-health solutions is known to be challenging and time consuming. To ensure adoption, effective diffusion strategies are needed, including user training programs. For DigiHelse, learning strategies may be targeted to increase adoption in the next phase.

This thesis points to early assessment of health innovation as a method to identify drivers and barriers at an early stage, and decide on anticipated outcome measures to meet the users' needs. The application of early HTA methodology may provide decision makers with stepwise decision support, particularly needed in e-health solutions to ensure sustainable implementation.

Paper I presents various terms that acquires definition. Firstly, identified studies included in paper I were categorised in theoretical and empirical studies. In this paper we defined theoretical studies as studies presenting a theoretical framework, or expressing a need or solution to early HTA. This category did not include studies based on applications of existing methods. Although every empirical study builds on theory and aim to produce new theory, an empirical study was defined in paper I as a study preforming an assessment in practice.

Further, the studies in paper I were categorized as strategic, economic, or clinical analyses or a combination. This categorization was based on the purpose of the assessment in terms of outcomes. For example, an analysis was deemed strategic if its core outcome was to determine the acceptance rate of a technology to plan future implementation, or deemed economic if the core outcome was to determine socioeconomic value through a Markov model. A clinical analysis may typically be a bench study on clinical efficacy. In paper I, this outcome measure was described as the purpose of the analysis and not on the analytical approach used. However, this definition may cause confusion as analysis is part of the methods used in an assessment and this outcome variable rather describes the purpose of the assessment which would be the objective of the study.

1. INTRODUCTION

1.1 Future Needs of the Norwegian Health Care System

Health care constitutes a significant part of public sector expenditure. Total government expenditures among OECD countries was 41% of GDP in 2015 (in Norway: 49%), and health typically accounts for around 20% of these expenditures [2]. In Norway the public healthcare system is under increasing pressure. The composition of the population is changing and the number of elderly is rising, resulting in a growing need for health and care services. The clinical picture shows a higher rate of chronic and complex diseases. In addition to the social and demographic changes, citizens have higher demands and expectations for public services and its delivery [3]. The average citizen today requires more from public services in terms of accessibility and influence than was found a generation ago [3].

Current government systems, including health care, have been built to ensure efficiency, predictability and stability in the shape of mass delivery. Although treatment is customised patients' health and diagnosis, the health care system struggles to meet flexible adaptation to individual users' needs beyond disease related issues, which is now being called for [4]. These numbers and trends make innovation imperative if the health care sector is to solve societal problems efficiently [5, 6]. The Worlds Health Organisation (WHO) defines health innovation as new or improved health policies, systems, products and technologies, and services and delivery methods that improve people's health and wellbeing [7]. The "Action plan for the Health&Care21 Strategy", Norway's first national research and innovation strategy for the health and care services, and the "Long-term plan for research and higher education 2015–2024" (Ministry of Education and Research, 2014) both call for more cohesive, coordinated cooperation on research, innovation and industrial development [8, 9]. Important breakthroughs in knowledge, however, often fail to be translated into medical practice. There is a clear lack of adoption, diffusion and knowledge transfer of given solutions at local, regional, national and European levels of health care development [10, 11].

The comprehensive framework for priority settings laid out by the third Norwegian Committee on Priority Settings in the Health Sector in November 2014 discussed the need for innovation in the health care service [12]. Based on the current methodology at the time, the Committee (Norheimutvalget) meant there was not sufficient basis for recommending a separate innovation criterion for prioritising health. But, to ensure efficient and effective services, "(St. melding) no. 34 Values in the patient's health service- Announcement of prioritisation" [13] emphasises that clear priorities are needed to deliver fair and equitable distributed health care within available resources. As such, we see a gap between how health care is prioritised in Norway, not based on innovation, and the need for more innovation to meet future challenges. To improve the quality of decision-making concerning innovation, both assessment of potential value of the innovation and assessment of future impact at different levels, i.e. local and national, are needed. Early dialogue with stakeholders affected by the innovation in question, may be useful in the mapping of possible implications in terms of potential hurdles and value creation. In this, efforts should be employed to build a structured model which enables a process for continuous dialogue among stakeholders. The Ministry of Health and Care Services' Health&Care21 strategy and white paper (St. melding) no. 11 National health and hospital plan (2016-2019) [8, 14] emphasise the importance of service innovation and of moving services closer to the end-user. There is also political agreement concerning the need to focus efforts on employing technological development in changing health services.

Even though Health Technology Assessment (HTA) of new methods in medicine has been important in the prioritising of the introduction of new pharmaceuticals and health technologies, the method is not really adjusted and suitable for impact assessments in early-stage of an innovation [15]. So far it has not been mandatory to perform HTA in local clinical practice at the hospital level in Norway when introducing a new service. The system has two levels; a national level where decisions based on HTAs are made by the four regional health authorities, and a local or a hospital level where decisions are made based on the mini-HTAs performed locally in each hospital [16]. The type of method and its designated authorised area of use, help determine the suitable level for assessment. New ways of looking at current challenges and increased evidence- based thinking are necessary, not only when we implement new solutions but also at a much earlier step on the service innovation ladder. This may influence the outcome and secure solutions that bring commerce into the loop at an earlier stage, all for the greater good of health care services. This know-how is limited today or at the best, in its infancy. If successful implementation of new solutions may reduce costs and improve services to the public, these innovations may potentially have a large catchment area, as the health care sector in most countries constitutes a large part of national budgets and provides essential services to the citizens. Not surprisingly, the OECD has emphasised the importance of innovation in the public sector [2].

1.2 The History of Health Technology Assessment

The costs associated with the introduction of new health technology rose in the 1970s and the need for thorough decision-making became necessary. This laid the foundation for the development of the Health Technology Assessment (HTA). The conceptualisation of HTA began in the United States around 1975 and then spread to Europe and to the rest of the world. The main motivation for using HTA methodology was the synthesis of evidence for decision support in specific policy areas, such as pharmaceutical regulations. The general term for HTA was then "a form of policy research for evaluating social consequences associated with the implementation of a new technology in the short and long term" [17]. HTA methodology developed over the next 10 years, especially in Europe. From 1985 the focus shifted to be more about efficacy, or when possible effectiveness, safety and cost-savings when introducing new technology at a national level. Towards the end of the 90s, HTA was used by clinicians and hospital management as an important instrument in the implementation of new innovations [18]. Internationally, different organisations emerged alongside a greater need for prioritisation in healthcare. There was a growing mismatch between what was medically possible, and available resources across Europe. The European network for HTA (EUnetHTA) [19], a network established to create an effective and sustainable network for HTA work across Europe, introduced a structure called "HTA Core Model" [20]. The model was based on years of HTA evaluations and consisted of nine key domains for evaluation. Over the past 50 years, HTA has contributed to decision-making around the world. HTA is now defined as an interdisciplinary process for synthesising information on medical, social, economic and ethical issues related to the introduction of a new health technology " [21, 22]. The term technology encompasses everything from new medical procedures to organizational services.

Although HTA methods and approaches have been subject to significant improvements over time, several challenges remain in the field [23, 24]. HTA is deemed as a robust method for technology in the later phases of national implementation. In its current form, it continues to lack the incentive to promote innovation, include local considerations for decision-making at an institutional level, and express the value of dynamic interactions with private businesses. This challenges HTA in showing the whole value chain to promote value-based health care.

In 2012 the consortium AdHopHTA was founded in Europe with the aim of solving some of the challenges related to local management benefits of HTA. The consortium aims at strengthening the use and impact of excellent quality HTA results in hospital settings, making available pragmatic knowledge and tools to boost adoption of hospital based HTA initiatives.

The collaboration resulted in a new approach to HTA named Hospital based HTA (HB-HTA). The approach is based on HTA activities tailored to the hospital context to inform managerial decisions on different health technologies. It includes the process and methods used to produce HTA reports in and for hospitals [25, 26]. Although AdhopHTA succeeded in creating a management tool for decision makers in hospitals, the latest report from the consortium emphasised that more research is needed to identify sustainable innovative ideas and products in the healthcare system [27]. The research focus should be on methods and mechanisms to promote innovative health technology through the use of HTA [25]. An article from the international network EuroScan supports this conclusion [28]. The article states that early awareness is becoming an increasingly important component of decision making, implementation and dissemination of new health technology [29]. EuroScan is a collaborative network for information exchange on new medicines, equipment, procedures, services and organization in the healthcare system. The network is currently working to evaluate the consequences of early-phase HTA in relation to the spread of new technology in the health care system [29].

1.3 Early Health Technology Assessment

As the importance of innovative technology expands in the health care sector, new practices and organisations are constantly evolving. New technology enables the refinement and personalisation of existing health care practices; this has the potential to prevent grave diseases and save more lives [30]. Although the technological revolution in the health care sector shows great potential, not all technological innovations serve their purposes [1]. Paper I, emphasises that documenting the effects of innovation in health care is therefore essential to assess prioritising in adequate technology implementation [31]. Unlike the product cycle of pharmaceuticals, where the timeframe from development to implementation can take several years, new technology and organisational innovation in the health care sector move at a much faster pace [15]. The methods for value assessment and priority settings therefore need to be adapted to a faster product cycle with a greater diversity of products. In promoting innovation in the health care sector, research should be dedicated to methods and approaches for early assessment in order to allocate public support effectively and produce the most beneficial technology for society.

To improve the pace and efficiency of the development and assessment of health innovation, new methods for early HTA are emerging in the literature [32]. Early HTA is a form of HTA that evaluates technologies still in development, and can be defined as the early examination of the medical, economic, social, and ethical implications of a health intervention to determine the potential of its incremental value in health care [33, 34]. Several of the studies on early HTA found in the literature take an industry perspective, emphasising on market entry and reimbursement [35]. Both individual studies and review papers broach the subject of early assessment of medical technology [36, 37]. Fasterholdt et al. [37] provide an overview of early assessment of medical technology and discuss which models hold the most promise for hospital decision makers. However, early decision support for organisational innovation in a health care setting is less embodied in the literature [31]. A service innovation can consist of both a technology-enabled reorganisation of the health care supply or simply an organisational innovation. A mobile application for the registration of blood sugar levels for diabetic patients can change patient pathways and create a new service, which is an example of a technology-enabled service innovation. However, reorganising the health care supply such that a health care worker measures blood sugar levels at the patients’ homes would also be a service innovation in terms of an organisational innovation. A standard model for early

HTA is yet to be established; accordingly research is needed to validate the proposed approaches to early HTA emerging in the literature [38].

1.4 Innovation in health care and e-Health adoptions

Innovation in health care is a broad and complex phenomenon. Innovation activities occur not only in specific units with designated resources to develop and deploy new solutions, but across multiple units, levels of the organisation and areas of service. The use of complexity reducing mechanisms in large organisations, such as hierarchies and silos, are found to be effective barriers to innovation [39]. The capacity of organisations to manage both exploration (i.e. search and innovation activities) and exploitation (i.e. value appropriation and regular operations), is studied under the label 'organisational ambidexterity'[1]. Cultural complexities are well known in health care, mainly stemming from highly specialised and powerful professional cultures [39]. In the different knowledge cultures people work, innovate and collaborate in very different ways, based on different practices and values, hence making interdisciplinary collaboration challenging [40, 41]. Innovation culture may be enhanced by motivating and enabling creativity by making available 'slack resources' [42], facilitating circulation of people and ideas across the organisation [39], and organising for trial and error learning. In practice, exploration is about creative interactions with the 'real world' to determine whether and how innovative ideas may be realised. Such learning processes will, by definition, lead to other insights than those initially proposed with stakeholders. Hence, controversies between stakeholders' interests and the innovation process are likely to occur [43].

Although innovation in health care is increasingly a shared ambition, there is still uncertainty about what kinds of innovation activities are more important and how to manage innovation activities. A report by the Norwegian Directorate of Health [44] sets out to clarify priorities and to select instruments to support innovation in health in Norway. Overall, the report claims that the attention to innovation varies substantially among the health institutions. Moreover, the report claims that there is lack of knowledge of innovation among leaders in the health care system and limited capacity to carry out and diffuse innovation across the health care system. Further the report emphasises the lack of arenas to involve stakeholders in innovation activities, and finally a lack of economic incentives across all levels of the health care system. The report argues for increased attention to strategic leadership of innovation within the organisation. This includes building competences and capacity through arenas for knowledge exchange and involvement across groups of employees as well as external participants and patients. Available resources and incentives may increasingly involve health care workers and departments in innovation activities. In sum, the Norwegian health authorities argue for increased emphasis on innovation to cope with the challenges ahead. At the same time, they argue that the healthcare system lacks innovation competence, capacity and leadership.

Studies have found that breakthroughs in knowledge often fail to be translated into practice in healthcare, due to lack of alignment with established practices, the need to bridge organisational and knowledge boundaries, and established power relations [40]. Thus, to move innovations from development settings into settings of widespread use in healthcare may be demanding [45]. Centralisation of decision making may increase professional resistance [46]. Decentralised approaches, such as project work to enhance local experimentation, is useful, but may lead to 'pilotism' and make implementation and scaling of innovations difficult [47]. Hoholm et al. (2018) suggest that increased innovation in health care requires a combination of attention management, boundary work, early stage evaluation methods, and systematic cross-case learning over time [43].

Innovations based on the development of e-health solutions are entering the health care marked with high speed. Paper III, emphasises that the era of digital health and the demand for health information technology (HIT) brings opportunities, for both patients and professional users [48, 49]. While HIT defines the technology, E-health is defined as the interaction between medical informatics, public health and businesses referring to health services and information delivered or enhanced through the Internet and related technologies [50]. One promise of e-health solutions is that, through enhanced communication and patient involvement, increased efficiency and reduced cost for the health care service may be achieved [50]. Further, it is assumed that e-health may enhance quality of care by increasing transparency and availability between different health supplies. There is however discrepancy between the expected value of such interventions and the empirically demonstrated benefits [51, 52]. More research is needed on case studies demonstrating the assumed cost-effectiveness and efficacy of e-health solutions, and research to promote value based health care in this field has been requested [51, 53, 54].

A health service characterised by efficiency and high quality can only be achieved if patient outcomes and costs of delivery are addressed [55]. When facing the complex healthcare system, not only technical and legal issues appear, but organisational, economic and social aspects need to be taken into account [48]. User-centric design can be employed from the earliest exploratory stages to help understand and design for the needs, goals, limitations, capabilities, and preferences of all stakeholders [56]. The landscape of technological development is changing constantly, and continuous technological adoptions are challenging the identification of valid outcome measures for assessment of cost and patient benefits [57]. Such evaluative challenges in the field of effective implementation of e-health interventions may be addressed by including the whole development cycle in the assessment of potential value. The earlier stages of the development cycle, such as concept stages of innovation, may however suffer from lack of valid data sources; this may explain the heterogeneity in the evidence concerning the effect of e-health interventions in the literature [51, 54, 58].

The digitalisation of services in health care provides a new, potentially valuable data source as real-time data, at any time can be extracted and analysed [59]. According to the Lean Startup framework, behavioural data from initial testing may provide essential information on how the market will respond to a service or a product [60]. Through collecting behavioural data from users testing a prototype, the product is self may be shaped based on the needs of its intended user group, prior to commissioning a final product. Measuring quantifiable behavioural data outcomes provides an opportunity to assess utility [61]. Qualitative information on the directions of the developmental improvements of the service can then be assembled from the same study sample. This allows for iterative modifications and adaptations at the initial project phase to avoid implementation of ineffective services. Through this process, the likelihood of developing a user centric service which complies with market expectations may increase as the early assessment of behavioural data provides the ability to test whether the service meets its initial intent and contribute to value based health care [60].

1.5 Digital development in Norwegian municipalities

Norway has succeeded in many areas of public digitalised services [62]. Governmental organs and municipalities offer an increasing amount of digital solutions and the use of services are increasing considerable. The use of public services online has increased by 235 per cent from 2010 to 2015 [63]. Still the United Nations' (UN) report on e-governance lists Norway as number fourteen on the ranking over countries best equipped for digitalisation in public sector [64]. Norwegian municipalities are independent management levels, and are not part of the hierarchical state administration. The municipal sector has an independent responsibility towards its inhabitants to solve tasks, provide services, operate community development and exercise authority. The municipality must carry out suitable digitisation and development measures in their areas of responsibility. Norwegian municipalities have a broad and complex nature of tasks in their portfolio, that contribute to a large number specialised ICT professional systems. This gives a high degree of complexity in managing and digitising tasks. An average municipality has between 180 and 200 different ICT systems [65]. For health care, The Directorate of e-Health was established 1st of January 2016. The Directorate aims to be a driving force in the development of digital services in the health and care sector. As such, the Directorate recommends common, national solutions for health and care services in Norway. In a report the Directorate points out that existing digital solutions in the municipal sector has significant functional deficiencies, and that lack of capacity and competence make it challenging for the municipalities individually to solve their needs [65].

The eHealth Directorate will have a key role in identifying the need for new common solutions, and how existing common solutions can be expanded to support new needs [62]. However, even with increased emphasis on national solutions, it does not mean that all activity takes place in central government. To ensure that these national solutions meet the needs of the health care sector, the municipalities, who will use the solutions, must define, prioritise and order functionality requirements. Central government will not be able to fully finance solutions that may have significant impact for the primary health care, and municipalities must contribute in financing and management of national ICT solutions. Paper II, emphasises that addressing quality of care, patients safety and economic aspects is of importance when promoting new services [66, 67]. The funding scheme for municipality care services in Norway is partially based on local investments though the country's 422 municipalities [66]. A number of relatively small municipalities in Norway struggle to meet national requirements for service provision and economic growth. As thus, 119 municipalities will be combined to become 47 new municipalities, and on January 1st 2020 the country will have 356 municipalities. It provides larger and stronger municipalities that can provide better services and develop business and local communities. Still, to strengthen primary care nationally, benefits in terms of potential socioeconomics are a prerequisite to acquire funding for development and implementation. To ensure municipal resource allocation for digitalisation projects, there is a need to select interventions that produce the greatest benefits and document why they should be prioritised for funding [68] . Defying this logic, large-scale digitalisation projects in the health and welfare sector are not always accompanied by rigorously designed research projects to assess effects, in terms of implications on cross-sector coordination, inclusion, coherence and empowerment [69]. Methodology for stepwise assessment and adjustment of digitalised services are therefore needed.

"Digihelse" is a nationwide digitalisation project initiated by the Norwegian Directorate of Ehealth [70]. Its main purpose is to enable a digital dialogue between the Norwegian home care service and the recipients, introducing the following three platform features: digital messages between resident and the service, visualise agreed and completed visits with associated information, and the option to cancel visits and final notifications of completed visits. DigiHelse is designed to become a public and national service for the home service, gradually implemented and offered to residents in Norwegian municipalities. DigiHelse is an example of an e-health intervention still in development and has the opportunity to perform assessment on different stages of the development cycle. To ensure that the final solution meets the needs of the end users, a stepwise decision process with several evaluation points and iterative adoptions of the solution has been incorporated in the implementation plan.

2. AIMS OF THE STUDY

The overall objective of this thesis was to study methods for early HTA of innovative technologies in health care and explore the predictive value of behavioural data in the assessment of usability of e-health solutions.

Specific aims for each paper were:

I. Paper 1: To identify methods and discuss the analytical approaches applied for the early assessment of innovation in a health care setting.

II. Paper 2: To assess how Digihelse should be designed and developed to ensure increased quality and value for recipients, the home care service and the society.

III. Paper 3: to test the usability and economic feasibility of adopting DigiHelse in four districts in Oslo by applying registry and behavioural data collected throughout a one-year pilot.

3. MATERIALS AND METHODS

In this chapter, the study designs, samples, recruitment procedure, definition of therminology, data collection, ethical considerations, analyses and statistics and sample size are presented.

3.1 Study design

This thesis consists of three different papers using three different study designs.

Systematic review (Paper I)

In Paper I, a knowledge synthesis based on a structured search and thematic analysis was conducted in 2017 to identify early assessment methods used to evaluate innovations in the healthcare sector. The review was structured according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) [71]. The review of the articles was accomplished in two consecutive screenings based on the inclusion and exclusion criteria in table I.

Proof of Concept analysis (Paper II)

A proof of concept analysis was designed to assess the feasibility and the potential value of the project DigiHelse in 2017. The Digihelse project applied for funding from the Agency for Public Management and eGovernment (Difi) in 2016. Regretfully, the project was declined funding due to lack of ability to show value for money as this first application mainly highlighted qualitative outcomes. As a result, the next year the candidate of this thesis was invited to participate in the design and analysis of a trial to show potential monetary value of implementing Digihelse nationally and reapply for Difi funding. The candidate of this thesis made accordance with the project to conduct the evaluation of the potential value of Digihelse with the core team consisting of the project manager and an economist for KS, in exchange for the possibility to publish the results as part of this thesis. As such, the candidate of this thesis became part of the core team for the evaluation of DigiHelse. Based on the findings from the concept stage simulations on potential monetary value of Digihelse, the project received Difi funding in 2017. The written application is available at KS home page presented at present as a report on potential socioeconomic value [70]. The work done in this Difi application is the basis for the outcomes presented in paper II and partially paper III.

In absence of empirical data foundation, this proof of concept analysis was elaborated prior to Digihelse's first pilot. The design of this study hence was based on stakeholder insight and scenario drafting to ensure primary data sources to complete the analysis [31]. Stakeholder insight was collected through four main workshops assessing the consequence of implementing the following three digital features for the home care service and its recipients: 1) digital messages between resident and the service, 2) visualize agreed and completed visits with associated information, and 3) the option to cancel visits and final notifications of completed visits. Scenarios were drafted by the stakeholders to identify potential value in terms of costs and effects of the intervention over 10 years. We adhered to the Cheers checklist when the economic evaluations were reported.

Pilot study (Paper III)

A pilot study was designed in Oslo in 2017 to reassess the potential value of DigiHelse estimated in the proof of concept analysis. To reassess its potential value, all recipients of home care services in four districts in Oslo were offered DigiHelse, in addition to regular services, in a one-year pilot project in the period from autumn 2017 to the next year. The utilisation of DigiHelse was completely voluntary. A control group was established in a district in Oslo that did not offer the intervention. We adhered to the CONSORT-EHEALTH checklist when reporting on this e-health trial.

3.2 Samples

In the knowledge synthesis, studies were included if they reported on methods for early assessment of innovative technology in a health care setting. In the proof of concept study, participants were professionals and recipients of home care services in Norway. Finally, the participants in the pilot study were professionals and recipients in four intervention districts and one control district in Oslo. Inclusion and exclusion criteria are presented in Table 1.

Table 1 Inclusion and exclusion criteria

Study	Data collection	Inclusion criteria	Exclusion criteria
Knowledge synthesis	The studies included in the knowledge synthesis	Articles reporting on the early assessment of innovation in the health sector and articles reporting on methods or practices for the early assessment of health innovations	Articles were excluded if they did not report on assessment in the healthcare sector, for instance, if the evaluation only took place in the industry and articles were excluded if they did not report on the early assessment of technology-enabled or organisational innovation
Proof of concept analysis	Stakeholder insight and scenario drafting	Health value categories for recipients, the home care service and for society	Health value categories for the secondary health care sector
Pilot study	The home care service in four intervention districts, and one control district in Oslo	Health value categories for recipients, the home care service and for society	Health value categories for the secondary health care sector

Table 1. The table presents type of study, data sources, and inclusion and exclusion criteria for each paper.

3.3 Recruitment procedure

Knowledge synthesis (Paper I)

Eligible studies for the knowledge synthesis were identified through an extensive search by an experienced librarian of the following databases: MEDLINE, Embase, Cochrane Library; these databases were searched in January and February 2017. The inclusion criteria for the studies were: 1) all studies with ISBN and ISSN numbers in English, Norwegian or Danish; 2) Studies evaluating non-invasive technology and organisational innovation; 3) Methods for early assessment and assessment related to the health care sector; and 4) reported outcomes of methods (theoretical or empirical) for early assessment of health innovation: strategic analysis, economic analysis, clinical analysis.

Proof of Concept analysis (Paper II)

To determine and quantify potential effects of the project DigiHelse in the concept stage of innovation, stakeholder insight and scenario drafting were applied. The project steering group identified stakeholders from different parts and professions in the home care service. They were to represent a holistic view of potential effects in terms of improved quality, efficiency and safety. The following areas of expertise were included in the project group: professional system managers from Oslo, leading professionals in home based services from Oslo and Bergen, health economists from the municipality board and Centre for Connected Care (C3) at the University Hospital in Oslo, resources from the e-Health Directorate, and project manager from Oslo municipality. The stakeholders represented an expert opinion from each field of the service, including recipients.

Pilot Study (Paper III)

The inclusion of the intervention districts for the yearlong pilot of DigiHelse in Oslo was determined by the project's steering group to ensure diversity in the pilot in terms of the demographic distribution. Four districts were included in the study, and the use of DigiHelse was completely voluntary in the intervention districts. A control districts was also appointed by the steering group to best match the demographic distribution the intervention districts. The demography for each district is presented in table 2.

Table 2 Demography of the districts included

District	Demography
1	Population: 57 000 12.2 % over retirement age 28% immigrants
2	Population 36 000 5.1% over retirement age 35% immigrants
3	Population: 49 200 11.8 % over retirement age 35% immigrants
4	Population: 49 800 13.7 % over retirement age 18% immigrants
Control	Population: 51 400 5.6% over retirement age 39% immigrants

Table 2. The table presents information on the demography of each district included in paper III

3.4 Data collection

In this thesis, several data collection methods were used. In paper I data collection was completed though a knowledge synthesis and categorised in a thematic analysis describing the data from the included studies in categories such as stage of innovation, type of innovation, type of study, study design, type of analysis, methods, main target audience. Data on the included studies were collected and analysed in an excel document, including all the agreed upon study parameters of the thematic analysis (stage of innovation, type of innovation etc.), and each included study was apprised accordingly.

In paper II, to assess the potential socioeconomic value of implementing DigiHelse nationally, the project group aimed at comparing the current situation in the home care service with a future scenario where DigiHelse is implemented. As the project was in its concept stage at the time of the assessment, potential socioeconomic value was estimated in four interdisciplinary workshops in the period from January to March 2017

Workshop participants

To determine and quantify potential effects of the project, the project steering group identified stakeholders from different parts and professions in the home care service. The participants were selected based on their stakes in the implementation of Digihelse, as well as interest and availability. They were to represent a holistic view of potential effects in terms of improved quality, efficiency and safety. The following areas of expertise were included in the project group: professional system managers from Oslo, leading professionals in home based services from Oslo and Bergen, health economists from the municipality board and Centre for Connected Care (C3) at the University Hospital in Oslo, resources from the e-Health Directorate, and project manager from Oslo municipality.

Workshop 1 Mapping and estimating potential benefits

Brief introduction and summary of previous work: The project applied for funding in 2016 and the application was declined due to lack of quantitative outcome measures. However, the project group successfully identified a number of potential qualitative outcome measures. Prior to the evaluation of socioeconomic value of DigiHelse the stakeholder in the project group had identified nine main health value categories to address quality of care and patient safety aspects of implementing DigiHelse. A total of 29 outcome measures were included in the following nine health value categories: predictability and coping, accessibility and cooperation with the service, privacy and information security, easier task management, better cooperation with residents, basis for further digitisation of citizens' services, increased prevention, better use of community resources and E-health and digitisation. In order to estimate the potential socioeconomic value of DigiHelse, the aim of the workshops was to identify which of the 29 outcome measures that may be quantified and priced.

Review and quantification of potential gains: The qualitative outcome measures from the previous application were reviewed by the interdisciplinary group of stakeholders and the value of each outcome measure was discussed in plenum. Further, new outcome measures for monetary value of DigiHelse were suggested and documented in the workshop.

Further work and data collection: A primary list of relevant outcome measures was agreed up on by the interdisciplinary group of stakeholders. The stakeholders were asked to take part in different tasks in the data collection depending on their area of expertise.

Workshop 2 Baseline measurements

In order to compare the current situation in the home care service with a situation where DigiHelse was implemented nationally, the second workshop facilitated a plan for data collection on baseline data from the service. Stakeholders were asked to provide baseline data from different parts of the service. This data was either collected throughout the workshop and discussed in plenum, such as figures from the Iplos register, or given as a task to be collected after the workshop, such as phone call survey in Oslo and Bergen. Further, a plan for identifying the costs associated with investing in DigiHelse was agreed upon.

Workshop 3 Scenario drafting

Scenarios on potential outcomes of implementing DigiHelse were elaborated by the core project team, consisting of the project manager, an economist from the municipality board (KS) and the candidate of this thesis. All scenarios were discussed with the stakeholders in the project group according to the data collected. In case of lacking data, the stakeholders represented an expert opinion from each field of the service, including recipients. Of the originally identified 29 outcome measures of implementing DigiHelse the following six outcome measures were deemed eligible for quantification through scenario building by the stakeholders: increased predictability for recipients, increased involvement from relatives and volunteers, increased predictability for the home care service, greater efficiency with dialogue with citizens and better time management, reduce phone inquiries, and provide technical basis for developing digital services.

Workshop 4 Pricing of quantitative effects and risk assessment

The core project team priced the quantitative effects resulting from the agreed upon scenarios and discussed the outcomes with the stakeholders in the project group. This crucial exercise was helpful in clarifying misunderstandings and from the scenario analysis, and provided a deeper understanding of structural issues of the home care service. The priced quantitative effects were then applied in a model for present value calculation over 10 years with a calculation rate of 4% and weighted against the identified costs. Finally, the stakeholders in the project group identified potential risk elements to both the implementation of Digihelse and the present evaluation. The identified risk elements were scored by the same group on a scale form low to medium to high.

Individual-based health and care statistics (Iplos) is the legal health record which forms the basis for national statistics for the home care service [72]. The Iplos register contains information on persons who have applied for or received health care services from their municipality during the period 2007-2019. In this analysis Iplos provides the number of recipients enlisted in home care service, the need for assistance and the average number of hours the service devotes to home care, practical assistance and both. Based on this register, and data and information about the average length of each visit from tender documents in Oslo municipality, the average number of visits per week was estimated on a national basis. Interviews with professionals from the service were used to map the administrative workload that could be limited by digitalisation of the service. Data from a survey in Oslo municipality (special extract from the electronic patient record (EPR) system in Oslo municipality) and findings from the municipality's price model for home services were used to estimate the amount of unnecessary journeys for the home service. Finally, the project also registered phone calls to the home service in Oslo municipality to study the percentage of the inquiries that could potentially be replaced by the digital communication. Employees carried out a telephone counting in Oslo (Østensjø district) and in Bergen. For the municipality of Oslo, the count applies to home nursing and for the municipality of Bergen it applies to practical assistance. The number of phone calls was mapped out to identify the areas of expertise where the web-based platform may contribute to fewer phone calls. Employees have registered telephone inquiries in the following categories: 1) Inquiries on whether the visit is performed, 2) Inquiries on when the recipient will receive the visit, 3) Recipient or relatives change or cancel appointment for visits, and 4) Other. The hypothesis was that the implementation of DigiHelse may reduce the number of visits within categories 1-3.

In Paper III, data collection was performed at the following three measure points: at baseline (the week before intervention), short period (15 weeks after intervention), and total study period (52 weeks after intervention). Data was collected in the four intervention districts and one control district. To assess if the intervention may give an incentive to increased involvement from relatives and volunteers in the care of recipients, data was collected on the number of visits for the home service to the recipient. Further, to assess if the option to cancel unwanted visits in the digital portal, may result in a reduced number of unnecessary trips and increased predictability for the service, the number of unnecessary trips by the home care service to the recipient was also registered. An unnecessary trip is defined as an incident when the home service arrives at a recipient's home for a planned visit and the recipient does not answer the door. Finally, to study if the digital dialogue may reduce the number of phone calls to the home service, phone calls to the service were registered on the three measurement points in the five districts according to the procedure mention above.

In this pilot assessment descriptive behavioural data from the web based platform was collected to study the usability of the platform. Data points such as number of digital users, digital inquiries and active users were retrieved form the platform's server. Aggregated data from the electronic patient record (EPR) system Gerica was retrieved to study changes in health consumption in the home care service in four intervention districts and one control district in Oslo.

3.5 Definitions of terminology

Paper I presents various terms that acquires definition. Firstly, identified studies included in paper I were categorised in theoretical and empirical studies. In this paper we defined theoretical studies as studies presenting a theoretical framework, or expressing a need or solution to early HTA. This category did not include studies based on applications of existing methods. Although every empirical study builds on theory and aim to produce new theory, an empirical study was defined in paper I as a study preforming an assessment in practice.

Further, the studies in paper I were categorized as strategic, economic, or clinical analyses or a combination. This categorization was based on the purpose of the assessment in terms of outcomes. For example, an analysis was deemed strategic if its core outcome was to determine the acceptance rate of a technology to plan future implementation, or deemed economic if the core outcome was to determine socioeconomic value through a Markov model. A clinical analysis may typically be a bench study on clinical efficacy. In paper I, this outcome measure was described as the purpose of the analysis and not on the analytical approach used. However, this definition may cause confusion as analysis is part of the methods used in an assessment and this outcome variable rather describes the purpose of the assessment which would be the objective of the study.

Following are a selection of definitions of the terminology for this thesis:

Stakeholder analysis is typically a qualitative analysis and is the process of identifying stakeholders and assessing a decision's impact on relevant parties and the parties impact on the decision, by considering and prioritising all of the competing demands [73]. This analysis may be valuable in assisting a decision process, however it is subjective and time-limited and should be complemented by other analytical approaches [74].

Scenario analysis can be based on both qualitative and quantitative analysis and defines the process of identifying and analysing hypothetical sequences of events by considering alternative plausible future outcomes, combining more and less probable processes and points of decisions [75]. Barriers to scenario analysis are the possible loss of information and that scenarios do not cover all outcomes in a real world system.

Cost-effectiveness analysis is a quantitative analysis that aims to compare the costs and effects of one treatment to a relevant alternative [76]. Early assessment often suffer from small data sets that lack the power to control for variables that could explain the observed effect, and short investigation periods make it difficult to identify changes in outcome.

Expert elicitation is a qualitative analysis used to address uncertainty or insufficient data through a structured approach of consulting experts on a subject [77]. There is no universal method for expert elicitation and different approaches may lead to different results.

Sensitivity analysis is a quantitative analysis which studies how the uncertainty in the output of a model can be apportioned to different sources of uncertainty the model's inputs [78]. Sensitivity analysis prove complex and time consuming when dealing with a large number of uncertain inputs as there often are in early assessment.

Constructive technology assessment is based on both qualitative and quantitative analyses which emphasises the involvement and interaction of diverse participants to facilitate and anticipate possible impacts of technology, and account for the social problems surrounding technology design and implementation [79]. This framework has been criticised for its lack of structure in including sufficient public participation, as patients or users, in the decision process.

Bayesian modelling is based on quantitative analysis that estimates the structure of the world via a rational probabilistic procedure, Bayesian probabilities [80]. These models require data, competence and can be difficult to implement in practice. It can be challenging to define a prior.

Markov modelling is a quantitative analysis based on a stochastic model used to model progression over time across a finite set of states were future events depend on current states in the model [81]. Markov models may be problematic at short time intervals. These models suffer from the precision required for data input. Such potential sources of data could be challenging to acquire at an early stage.

Value of information analysis is a quantitative analysis of the value of reducing uncertainty through investing in more research prior to making a decision [82]. Innovation deals with both parameter and structural uncertainty, accounting for all these uncertainties in the estimation a price of knowing a priori can be challenging.

Real option analysis is a quantitative analysis of delaying an investment pending on more information, typically a trade-off of investing in development of more research [83]. In this, the investment must be well defined and understood in considering a series of decision points over an investment horizon. Data issues may arise in an early stage of innovation.

PEST (Political, economic, socio-cultural, and technological analysis) analysis employs a framework for strategic decision making and evaluates macro-environmental factors qualitatively [84]. This analysis may be resource intensive as it requires a great amount of data and its durability in time is limited.

SWOT analysis is a qualitative study of internal strengths and weaknesses in an organisation, as well as its external opportunities and threats [85]. This analysis does not reveal adoptable factors nor does it shed much light on the sustainability of advantages and the persistence of disadvantages.

3.6 Outcome measures for each study

Knowledge synthesis (Paper I)

Stage of innovation: In paper I the innovation process was divided into the following three stages: 1) the developmental stage, 2) the introduction stage, and 3) the early diffusion stage. The developmental stage is the concept phase of development. The introduction stage is when innovation is piloted on a cohort. A pilot study is normally a small test with a few patients in which the recruitment procedures, research design and methods for data collection are tested. The early diffusion stage begins when the pilot becomes transferred or extended to other populations or locations.

Type of innovation: The studies which formed the knowledge basis for paper I were categorised based on the innovation studied. Studies were divided in two; technology-enabled innovation or organisational innovation, as service innovation may consist of both a technology-enabled reorganisation of the health care supply or simply an organisational innovation.

Type of study: Studies were categorised in empirical or theoretical studies based on whether the study explored a method through a case or in theory.

Type of analysis: Studies were distinguished in strategic, economic, and clinical analysis based on the purpose of the analysis and not on the analytical approach used, as one analytical approach can be used for different purposes.

Study design: Type of study design for the articles was listed in the thematic analysis.

Methods: Based on the methods for data collection and assessment, studies were categorised in qualitative, quantitative or both.

Main target audience: In paper I the audience of assessment was categorised in the following groups: decision makers, patients/users, healthcare personnel, or innovators. The main target audience of the evaluation was based on the authors' interpretation of who are likely to benefit the most from the assessment.

Proof of Concept analysis (Paper II)

Based on statistics from Iplos and information about the average length of each visit from tender documents from the municipalities Oslo and Bærum, the average number of visits per week was estimated on a national basis [70]. Estimated outcome for 2015 has been characterised in three groups according to assistance need.

- Some or limited assistance need: 76 000 recipients have an average of 3 visits per week
- Medium or large aid needs: 70 000 recipients have an average of 9 visits per week
- Extensive aid needs: 26 000 recipients have extensive needs and can have up to 64 visits per week
- 7800 users have reserved themselves for registration in Iplos

Increased predictability for recipients: Through the digital platform the recipient will have a better overview over visits from the home service. Arrivals and delays will be displayed in the portal and the recipient can cancel unwanted visits. The stakeholders in the project group believed that this feature may potentially reduce waiting and provide the recipient with more freedom to do other things. Unpredictability has ripple effects beyond the individual's perceived coping and freedom, and can also cause delays for relatives who wait with the recipient.

The hypothesis is that predictability gives higher quality of life and that it is possible to estimate the value of the time the recipients can use on other tasks than waiting.

Based on Iplos statistics from 2015, we estimated that 179 800 recipients have six visits a week nationally. The home care service informed the stakeholders in the project group that employed recipients receive their visits on time hence this group was excluded from the cohort. The unemployment rate from the Norwegian Labour and Welfare Administration of 30 euro an hour was used to calculate the value of the recipients' free time. The home service uses time slots of two hours per visit. If the recipients could know exactly the arrival of the home service, the assumption is that this can release about one hour per visit. This was applied for 50% of the recipients.

More predictability gives in this scenario an annual value of 408,4 mill. euro a year for this group of recipients.

This value was not included in the present value calculation, as the value of free time is debatable.

Increased involvement from relatives and volunteers: An ambition for the home services is that to provide good and effective services, relatives and volunteers must be included [62]. In this interaction there are both quality gains, but also opportunities to restructure and modernise how the home service work.

The stakeholders in the project group built a scenario where recipients who are relatively self-sufficient receive help from relatives or volunteers sometimes a year. The scenario was therefore based on recipients who have an average of three visits a week. Assumedly, relatives or volunteers can carry out one visit per month in average for this group of recipients.

There are 76 000 recipients having an average of 3 visits per week. With good communication between relatives or volunteers and the service, these recipients can receive a visit less per month by the home service. A visit lasts an average of 20 minutes. So by replacing one visit a month with the care of relatives or volunteers, 20 minutes of effective time saving can be accomplished per recipient per month for this group.

For this recipient group, increased involvement from relatives or volunteers can results in savings for the home service of 13.8 million euro per year.

Increased predictability for the home care service: The proposed intervention may reduce the number of unnecessary trips for the home service as it will be easier to report changes to planned visits for both the recipients and the relatives through the digital dialogue. In addition, it reduces the risk of analogue messages disappearing or getting misinterpreted. An unnecessary trip is when the home service arrives at a recipient’s home for a planned visit and the recipient does not answer the door. A survey on unnecessary trips for the home care service was performed in Oslo municipality through a special extract from the EPJ system in 2014 and findings from the municipality's price model for home services (2014). If was estimated that the home service have 553 000 unnecessary journeys per year on a national basis. Based on the survey the unnecessary trips consisted of 0.4% in home nursing care and 0.8% in practical assistance. In a scenario where the digital platform can reduce the number of unnecessary journeys with 30% of today's amount, the home service will have 46 000 less unnecessary journeys nationwide. The hourly rate was set to 48 euro and time spent per unnecessary journey was on average 30 minutes.

A reduction of 30% wasted journeys will result in savings for the home service of 3.8 million euro per year.

More efficiency with dialogue with citizens and better time management: Digital communication may allow for more efficient planning of daily work chores and less interruptions for the home care service. In this, DigiHelse may reduce the work load of administrative tasks. The outcome measure of a digital dialogue with citizens was based on the value of increased time to complete care tasks for the home care service. Through interviews with professionals from the home services (a total of four coordinators form districts in Oslo, Bergen and Romerike) the project group estimated potential time savings of 30 minutes per day with digital communication. The interviews were performed by the core team and the coordinators were identified by the stakeholders in the project group. As this type of communication is mainly directed to the coordinators in the home service, the project group estimated the number of coordinates to be approximately 1350 nationwide. This gives an annual saving of 7.1 million euro a year.

Reduce phone inquiries: The home service currently receives several phone calls related to both planned and completed visits, as well as recipients and relatives wishing to move or cancel visits. The digital platform establishes solutions for recipients to get an overview over planned and completed visits, and they can be notified by SMS before and after the visit. The platform also provides the possibility to cancel a visit.

To assess whether the intervention may reduce phone inquiries, that otherwise could be solved digitally, a phone survey was conducted in Oslo and in Bergen for a week.

The employees registered phone inquiries for one week in the following categories:

• Category 1 – Is the visit completed?

• Category 2 – What time is the visit?

• Category 3- Change or cancel visit

• Category 4 - Other

The stakeholder group believed that the digital platform may reduce the number of phone inquiries within categories 1-3. After analysing the outcome from the phone survey in the home service a scenario where digital communication may reduce the phone inquiries to the home service with 40% was built. The estimated impact of this measure will amount to 1 million euro per year on a national basis.

Provide technical basis for developing digital services: A large proportion of the municipalities will have to undertake procurement of a digital infrastructure for home services if the present project is not implemented.

In Norway there are 365 municipalities with ICT cooperation. The smallest municipalities will probably never acquire this type of solution. Therefore, the assumption is that 50% of the municipalities will acquire solutions on their own. In this scenario an acquisition cost of approximately 100 000 euro with procurement, infrastructure, licenses / rent etc. was included. The effect of 182.5 municipalities that each consumes 100 000 euro, results in a one-time saving of 18.25 million euro.

This effect was not included in the present value calculation because digitalisation of home services is still not statutory.

Prerequisites for cost impact: In the estimation of both potential cost and savings in paper II and paper III we used average rates from Statistic Norway 2017, presented in table 3. These cost units are the basis for the net present value calculation. The input variables on the cost side of the 10 year present value calculation of implementing DigiHelse nationally includes investment costs, the expected implementation pace, number of full-time equivalents and average unit costs for investments in digital infrastructure, training and technical support was based on national statistics (Statistics Norway).

Summary of costs		Comment
Full time equivalents in hours a year	1695	(Statistics Norway)
Hourly rate of the home service in Euro	48	Internal human resources, time spent on training in municipalities (Statistics Norway)
Hourly rate of consultancy in Euro	107	System development, planning and implementation costs (Statistics Norway)
Increase in the proportion of full-time equivalents for technical operation of the solution per operating unit	10%	10% the first two years, then 5% (Estimates stakeholders)
Training needs of new service staff, hours per employee	3	(Estimates stakeholders)
Number of employees in need of training in the new service	5	(Estimates stakeholders)
Training in basic electronic messaging, number of hours per employee	15	(Estimates stakeholders)
Number of employees per operating unit / municipality, including operating supplier, receiving training in basic electronic messaging	5	(Estimates stakeholders)
Average increase in annual license / maintenance cost to EMR per operating unit in Euro	1 677	(Estimates stakeholders)
Number of full-time equivalents within the care service	67 000	Statistics Norway 2014 (134,000 employees). We have assumed that 50% need training
Time spent on planning organizational changes	225	Hours per municipality (Estimates stakeholders)
Time spent on staff training / organizational changes in hours	2	(Estimates stakeholders)
Time usage training of recipients in hours	0,5	(Estimates stakeholders)
Number of active users	89 000	We have assumed that 50% of users need training. (Estimates stakeholders)
Other operating and maintenance costs at Norsk Helsenett, health authorities and 800HELSE in Euro a year	262 055-817 610	Increases in pace with the implementation (Estimates stakeholders)
Implementation pace in years	5	365 ICT operating units (Statistics Norway)
Lifecycle in years:	10	The life cycle of professional systems is considerably longer than the standard life of ICT equipment (Estimates stakeholders)

Implementation pace	2018	2019	2020	2021	2022
Number of operating units (cost driver)	3	26	91	243	365
Share of population (effect driver)	*18 %*	42 %	69 %	90 %	100 %

Table 3 shows the input variables on the cost side of the present value calculation investment, the expected implementation pace, number of full-time equivalents and average unit costs for investments in digital infrastructure, training and technical support was based on national statistics.

Pilot Study (Paper III)

Increased involvement from relatives and volunteers: To study if relatives and volunteers would become more active in the care of recipients once planned visits becomes available in the web-based platform, the outcome measure of increased involvement from relatives and volunteers was amount of visits to the recipient. The rate of visits to the recipients in the intervention group was compared to the rate of visits in the control group. Amount of visits increased in the intervention group compared to the control group with a rate of 1.04 after a year. With an increase of 4% the intervention group the estimated savings from the concept stage evaluation will be reduced with 7 mill euro a year as 76 000 recipients will receive 6.24 more visits a year on a national basis.

Increased predictability for the home care service: To assess if the option to cancel unwanted trips in the portal may result in less unnecessary trips, the outcome measure of increased predictability for the home care service was the rate of unnecessary trips. The rate of unnecessary trips in the intervention group was compared to the rate of unnecessary trips in the control district after a year. The amount of unnecessary trips increased in the intervention group compared to the control group with a rate of 1.37 after a year. With an increase of 37% unnecessary trips for the home care in the intervention group the estimated savings from the concept stage evaluation will be reduced with 4.7 mill euro a year on a national basis.

Reduced phone inquiries: To study if the digital dialogue may reduce the number of phone calls to the home service, the outcome measure of reduced phone inquiries was the rate of phone calls regarding management of visits. The rate of phone calls in the intervention group was compared to the rate in the control group. Amount of phone calls increased in the intervention group compared to the control group with a rate of 1.24 after a year. Whit an increase of 24% phone calls in the intervention district the estimated savings from the concept stage evaluation will be reduced with 3.3 mill euro a year on a national basis.

Increased predictability for recipients: This variable was held constant from the concept stage evaluation on 408.4 a year on a national basis.

More efficiency with dialogue with citizens and better time management: This variable was held constant from the concept stage evaluation on 7.1 a year on a national basis.

Provide technical basis for developing digital services: This variable was held constant from the concept stage evaluation on 19.1 a year on a national basis.

Number of active users: Behavioural data from the platforms server was collected to study the percentage of users in the platform. All recipients in the intervention districts were offered to log into the platform and create a profile. Number of active users is defined as the amount of users who, not only created a profile, but also had interactions with the home care service in the platform. Number of active user of DigiHelse was 3-4% after a year.

An increase in unnecessary tips, number of visits and number of phone calls were found when the intervention group was compared to the control group trend. The column for the early assessment in the concept stage (CS) is based on stakeholder analysis and the pilot stage column (PS) is built on the analysis with empirical pilot data. Leaving the three outcome measures Increased predictability for recipients, Greater efficiency with dialogue with citizens and better time management, and Provide technical basis for the development of digital services from the concept analysis unchanged. Table 4 shows how the effect of adding empirical data to the remaining three outcome measures Increased involvement from relatives and volunteers, Increased predictability for the home care service and Reduce phone inquiries reduced the potential value of the estimation such that the return of investment becomes negative. The net present value of the intervention after adding data form the pilot is reduced by 241.8 million Euro over 10 years form the first assessment, resulting in a loss of 62.2 million Euro over 10 years. Due to the low adoption rate showed above, a sensitivity analysis was not carried out.

Table 4. Summary of priced effects in the concept phase and after the pilot phase

Priced effect measures	**Euro**	**Early assessment in a concept stage of innovation (CS)**	**Early assessment after the one year pilot (PS)**	**Data sources**
For residents				
Increased predictability for recipients	Meur pr. year	(408,4)	(408,4)	(Estimates stakeholders, Iplos, NAV, EPJ)
Increased involvement from relatives and volunteers	Meur. pr. year	13.8	-7	(Estimates stakeholders, Iplos, Statistics Norway)
For the home care service				
Increased predictability for the home care service	Meur. pr. year	3.8	-4.7	(Survey EPJ unnecessary trips, Estimates stakeholders, Statistics Norway)
More effective of dialogue with citizens and better time management	Meur. pr. year	(7.1)	(7.1)	(Interviews coordinators, Estimates stakeholders, Statistics Norway)
Reduce phone inquiries	Meur. pr. year	1	-3.3	(Phone survey, Statistics Norway, Estimates stakeholders)
Provide technical basis for the development of digital services	Meur. pr. year	(19.1)	(19.1)	(Statistics Norway, Estimates stakeholders)
Total	Meur. pr. year	25.7	-7.9	
Net present value of the intervention	Meur	179.6	-62.2	
Present value investment cost in the public sector	Meur	5.5	5.5	
Net present value per invested Euro in the public sector	Euro	3.2	-1	

Table 4. compares the results for the early assessment in the concept stage (CS) with the assessment performed with data from the pilot (PS) and the difference between the two (CS-PS). The table presents yearly estimates for the six outcome measures, net present value, present value investment costs and net present value per invested Euro in the public sector over 10 years. Values in parenthesis are not included in the present value calculation.

3.6 Ethical considerations

No ethical considerations are necessary for this thesis as data sources are based on published articles, national statistics, expert opinion and aggregated register and server data. The Regional Committee for Medical Research Ethics, Region Eastern Norway provided information that consent was not needed.

3.7 Analyses and statistics

Knowledge synthesis (Paper I)

Table 1 shows the final inclusion and exclusion criteria agreed to by the review team. References from each database search were imported into database-specific folders in EndNote version X7 and duplicates were eliminated. Abstracts were first assessed by L.N.S using the selection criteria listed in Table 1 and then each of the full-text articles was appraised independently by two reviewers (L.N.S. and K.J.K.). Disagreements were solved by means of discussions or referred to a third author (K.K.). The data was initially extracted by L.N.S. and then discussed with K.J.K. A framework based on the assessed literature was agreed upon and core themes to answer the research issue were identified. This framework was set up in an excel document, including all the agreed upon study parameters of the thematic analysis (stage of innovation, type of innovation etc.), and each included study was apprised accordingly. When there was a disagreement among the authors as to the appropriate theme, the article was discussed until agreement was achieved. Bibliographic data and study content were collected and analysed using templates developed iteratively with feedback from the other authors (K.K. and T.M.).

Proof of Concept Study (Paper II)

A 10-year present value calculation with a calculation rate of 4% was used for the estimates. The potential value of the six priced effect measures was calculated based on scenarios elaborated by the stakeholders and data collected from expert opinion and national statistics. The benefits were also weighed against costs; initial investments in infrastructure, maintenance costs, sequential implementation rate and costs associated with training. An assessment of the risk related to the interventions feasibility and potential socioeconomic value was carried out by the stakeholders and evaluated on a three point scale (low, medium, high)

Pilot Study (Paper III)

A 10-year present value calculation model with a discount rate of 4% was used to estimate the potential value of the intervention. Potential value was first estimated on a yearly basis, and by employing the cost of investment, training and implementation pace the overall value was calculated over 10 years. The assumption of 10 year life cycle is based on national recommendations from the Directorate for Financial Management [86].

To update the present value calculation in paper III, the data from the intervention and control group was analysed using the quasi-experimental difference-in-difference design to estimate the casual effect. Such a design may be used to estimate the effect of an intervention by comparing the changes in outcomes over time between a population exposed to the intervention (intervention group) and a population not exposed (control group) [87]. A Poisson regression analysis was used to fit the model, as the dependent variables are counts of events.

First, to test for an effect of the intervention, interaction models with dummy variables were used for the intervention and the time period. To assess both short term and long term effects, analyses were done separately for time points 1 week before intervention vs. 15 weeks after and before intervention vs. 52 weeks after. The number of exposed in the model corresponded to the number of home care recipients (user base) in each group, this due to the fact that all recipients in the intervention group had in principle access to DigiHelse and all analyses are based on aggregate data. The interaction coefficient between the intervention and the time period dummies indicates the effect of the intervention.

Second, to assess the effect of proportion of active users in the intervention districts, an interaction model with continuous time and continuous rate of digital users was used in each district. Different rates of active digital users were then extrapolated to assess how this would influence the rates for visits, unnecessary trips and phone calls and thereby the costs in the present value analysis. All calculations were done in NOK and converted in Euro based on the exchange rate from May 2018: 9.54 [88]. All analyses were performed in Stata 15.1 and Microsoft Excel 2010.

4. SYNOPSIS OF THE PRESENT STUDY

Paper I: Early Assessment of Innovation in a Health Care Setting

The aim of the present study is to identify methods and discuss the analytical approaches applied for the early assessment of innovation in a health care setting. Knowledge synthesis based on a structured search (using MEDLINE, Embase, and Cochrane databases) and thematic analysis were conducted. An analytical framework based on the stage of innovation (developmental, introduction, or early diffusion) was applied to assess whether methods vary according to stage. Themes (type of innovation, study, analysis, study design, method, and main target audience) were then identified by the authors. The search identified a total of 1064 articles and 39 articles matched the inclusion criteria. A majority of the studies used a mixed method approach to assessment, including both qualitative and quantitative methods to data collection and analysis. The identified methods of assessment had a tendency to change according to stage of innovation. Stakeholder analysis was a notable method for data collection in all innovation stages, in particular in the earlier stages (developmental), when empirical data from testing is still lacking. In the introduction and early diffusion stages, methods for validating the available data was identified, such as simulations based on Bayesian techniques and Markov modelling. Barriers to the identified methods were however also found, as all the innovation stages suffered from lack of data and substantial uncertainty.

Paper II: Evaluating the design of a digital communication platform for recipients of home-care services to improve municipal care services: a proof of concept study

The aim of the present study was to assess how Digihelse should be designed and developed to ensure increased quality and value for recipients, the home care service and the society. Early health technology assessment with stakeholder insights and scenario drafting was applied to identify health quality gains and address patient safety issues, define relevant outcome measures and compare the new solution to the current situation. Outcome measures were quantified priced and analysed using a 10-year present value calculation with a calculation rate of 4%. A risk analysis was also carried out. In addition to addressing quality and safety outcomes, the present value calculation estimated savings equal to 172.6 million euro, with present value investments costs of 5.5 million euro over 10 years. This resulted in net present value per invested Euro in the public sector equal to 3.2. Overall risk assessment related to the intervention's socioeconomic profitability was deemed average.

Paper III: A Web-Based Communication Platform to Improve Home Care Services in Norway (DigiHelse): Pilot Study

The aim of the study was to test the usability and feasibility of adopting DigiHelse in four districts in Oslo applying registry and behavioural data collected throughout a one-year pilot. Outcome measures identified in the project's concept phase by stakeholder insights and scenario drafting, were used to assess quality gains and patient safety issues in a present value calculation on socioeconomic benefits. In this follow-up study, aggregated data was collected to assess changes in health consumption. Descriptive behavioural data from the digital platform was applied to assess the usability of the platform. A significant gap was found between the estimated value of DigiHelse in the concept phase of the project and after the one-year pilot. In the present pilot assessment costs are expected to exceed potential savings with 67 million Euro over ten years, as compared to the corresponding concept estimates with a potential gains of 172.6 million Euro. Interestingly, behavioural data from the digital platform revealed that only 3-4% of recipients used the platform actively after one year.

5. GENERAL DISCUSSION

In the literature on early HTA both qualitative and quantitative approaches to data collection and analysis were present, and the major parts of the studies identified applied a mixed method approach to the assessment of health innovation. Stakeholder analysis was presented as a method for data collection in all innovation stages. Early HTA was applied in a concept stage of innovation to guide the design and development of the national digitalisation project DigiHelse, where stakeholder insight and scenario drafting was used as the main data source for economic modelling. When empirical data from a later pilot of the project was included in the economic model, discrepancy in the outcomes between the two models was found. Although the concept assessment contributed with the formalisation of anticipated outcome measures, uncertainty in the input variables made it challenging to conclude on the value of the concept model as early as in the first pilot. The application of behavioural data in early health technology modelling was however found to be an important data source to assess usability, and information on lack of adoption may be central in adjusting the new service to achieve successful implementation. We believe that stepwise decision support may help reduce risk and show potential value of health innovation.

5.1 Methodological issues

There are two types of errors that can affect quantitative or epidemiological studies: random errors and systematic errors. Systematic errors are classified in selection bias, information bias and confounding factors. By eliminating systematic errors we are left with random errors.

Random errors

Random errors are due to variability in the data that we cannot easily explain [89]. If the study is large, the estimation process will be relatively accurate and there would be small amount of random error in the estimation. If there is a small amount of random error in the study, the precision is high. Confidence intervals are used to indicate the amount of random error in the estimate. A wide confidence interval indicates low precision, and narrow intervals indicate high precision. Due to relatively short study periods and the use of small data sets, random errors in paper II and III cannot be excluded. Random errors may have occurred in the aggregation of the registry data. Paper III showed wide confidence intervals and no statistically significant findings. However, both papers based their analyses on aggregated data sets and not individual data, which supply a larger data foundation than typical pilot studies, with a limited number of included study subjects. Nevertheless, as early assessment studies are often based on small datasets, random errors may affect the precision of the estimates on effects.

Systematic error

Another term for systematic error is bias. A study may be biased due to the way participants are selected, the way the study variables are measured, or whether any confounding factors may have affected the results and not been controlled.

Selection bias

For this thesis, avoiding selection bias is important both in the sense of identifying all relevant papers in the knowledge synthesis (paper I), in the inclusion of stakeholders (paper II) and in collecting quantitative data (papers II and III).

Recognised bias in literature searches are those related to selection and publication bias [90]. Publication bias is failure to publish results that go against the direction of the researcher or funder of a study, such as unfavourable or negative findings, which may lead to an incorrect vision of the reality. The knowledge synthesis (paper I) may not have identified all published studies on the early assessment of health innovation, in particular the grey literature, such as material produced outside traditional commercial or academic publishing. A structured search with clear exclusion and inclusion criteria was prepared to analyse the literature on the topic. It has been argued that the systematic review process reduces systematic error, thus reducing confounding variables and ensuring high internal validity [91]. Despite attempts to adjust the search strategy to several different terms previously used in the literature to describe similar methodologies, other terms may also exist.

Although three comprehensive health databases were included in the search (MEDLINE, Embase, and Cochrane), searching other databases may have included additional published studies. Our search included only studies in English, Norwegian, and Danish, although only English terms were used in the search. Furthermore, no consultations from stakeholders or experts were included in this review, thus results are only based on the content of the included literature and views of further development in the field may have been missed. Finally, although the method was systematically adhered to by the reviewers, each reviewer subjectively included studies based on the study criteria. The classification and interpretation of the results may also be subject to reviewer bias. Paper I highlights and describes different methods found in the included literature on early HTA. After extracting data form the included studies, the authors selected the most frequent used methods in the literature and discussed enablers and barriers of these methods in light of early assessment. The presentation of eligible methods of early assessment may have been subject to reviewer bias, and valuable methods for early HTA may not have been highlighted and described in paper I.

Paper II used stakeholder insight as a method to collect data. Stakeholders were included by the steering group of the project to ensure a multidisciplinary approach to assessment. In such process selection bias cannot be excluded, and stakeholders commonly may be positively biased towards the value of the technology in which they have a particular interest [92]. This may have led to over-optimistic estimates on potential value. In addition, different methods for including stakeholders in such processes may result in different outcomes, as no standard inclusion process was found in the literature.

Selection bias also occurs in data when the relationship between disease and exposure differs in participants and non-participants. An important limitation in case-control studies is that they are vulnerable to this type of selection bias. In a case-control study, it is crucial that the researcher has explicitly defined inclusion and exclusion criteria before choosing a case [93]. Paper III studied the value of scenario analyses based on stakeholder input in predefining outcome measures for assessment, by re-evaluating the DigiHelse case after piloting the project in four districts in Oslo. Choosing the right control group may be one of the most demanding aspects of a case-control study. An important principle is that the distribution in the intervention group should be the same as in the control group; both interventions and controls should originate from the same source population. This may create methodical errors in paper III, as the homogeneity of the districts in the analysis may be questioned, due to variation in the baseline data. Although the demographic data in the intervention districts presented a satisfactory match with the chosen control district, baseline data on health consumption in terms of number of visits and unnecessary trips may indicate lager heterogeneity than assumed in the two groups.

To increase the representativeness of the selected control group, data could preferably have been collected from more than one control district. An increased number of measurement points prior to the intervention would have provided an opportunity to assess trend assumption between the control and intervention group, crucial for diff-in-diff analyses. The adoption rate of DigiHelse in the intervention districts was dramatically low (3-4%), and if the behavioural data had shown a higher adoption rate, both these issues would have been resolved prior to the diff-in-diff analysis. In addition to empirical outcomes on health consumption, the present value model could have been used to predict socioeconomic outcome if the adoption rate was 90%. Although the use of DigiHelse was voluntary, the stakeholders in the project group believed that the adoption rate would arrive at 90% after a few years of implementation. This highlight the potential bias of stakeholder analysis, as stakeholder may be overly enthusiastic to the ability of the innovation under assessment. However, given the unexpected low adoption rate, collecting more measurement points and performing sensitivity analysis of the findings was deemed futile. Only 3-4% active users were registered in the data, which makes it challenging both to predict whether the precision and the fit the concept model was good and to compare the present value calculation with and without empirical pilot data. As such, the analysis in paper III may, at least in part, show that the control district improved over time compared to the intervention districts and that the adoption rate of the intervention was considerably lower than expected.

Another methodological issue in paper III, is that the inclusion and exclusion criteria in the study were non-specific. In the intervention districts, anyone who belongs to the home service will have access to the digital platform, but it is not mandatory to use it. This may cause selection bias, as we do not know what makes some people choose to use the solutions while others do not. It may be assumed that the active users registered in the portal's behavioural data are those with highest technological literacy, which may not be representative for the group, due to the high percentage of people over retirement age in the home care service.

Information skewness and misclassification

Information bias may occur in the results and exposures. Misclassification may have affected the interpretations in the knowledge synthesis (paper I), recall and confirmation bias may occur in the stakeholder elicitation (paper II) and loss of information may occur in the scenario drafting (paper II and III).

Included studies in the knowledge synthesis (paper I) were interpreted and classified in different categories, potentially causing misclassification bias if the studies were pooled in the wrong group in the thematic analysis. However, the classification was discussed and agreed upon by all four authors, which reduces the risk of misclassification. The knowledge synthesis in paper I formed the basis for the methods of data collection and analysis in the case study DigiHelse, which was the subject of paper II and III. Despite the ongoing development of methods within the field, a standardised method for early assessment of health innovations was not found in the literature. Early HTA is challenged by three issues; limited access to data, the fact that small datasets lack the power to control for variables that can explain observed effects, and short investigation periods that make it difficult to identify outcome changes [58, 94, 95]. Stakeholder insights and scenario analysis were identified as valuable approaches to data collection and analysis in a conceptual phase of innovation.

The main data source in paper II was retrieved applying scenario analysis based on surveys, semi-structured interviews and focus groups among stakeholders. Surveys commonly collect data in a simple and practical way which may lead to misclassification. Recall and confirmation bias is also possible as answers are affected by both differences in experience and memory between respondents. For instance, in paper II stakeholders were asked to estimate the potential time reduction in administrative tasks due to the digital communication in DigiHelse. Recall bias may occur both in the estimation on time spent on administrative tasks and in the potential reduction. Confirmation bias is a tendency between participants to interpret or favour information such that it affirms prior beliefs.

Another issue is the loss of information that may arise in scenario analyses, as a scenario does not cover all outcomes in the real world [96, 97]. In paper II, it was assumed a gradual rate of adoption of the DigiHelse, reaching 90% adoption rate at its maximum. In paper III, however, empirical data reflecting real world outcomes showed a much lower adoption rate after a year than the assumptions in the scenario analysis (paper II). Loss of information also applies to expert statements, as different approaches have been used in the literature, which can lead to a variation in outcome [98]. Model inputs may therefore be subject to incorrect formulations and misunderstandings that may have led to sources of uncertainty. Such sources of uncertainty may, for example, be estimated time savings when digitising the service, which may later be corrected with empirical data from piloting.

Main exposures

The aggregate data on number of visits and number of unnecessary trips made available from the EPR systems may be subject to incorrect registration. Number of unnecessary trips and visits per user may be subject to incorrect registrations among the districts studied in paper III. Incorrect registrations may also apply to the count of telephone calls completed in paper II and III. The phone calls were registered in different categories to study the type of inquiries that may be limited by digitalisation of the communication stream, number of phone calls was registered manually by different employees in different locations, and phone calls may have been registered incorrectly. The latter, mat be of the biggest concern in this study, as incorrect registrations is less likely in the EPR systems compared to the manually registered phone calls.

Confounding

Confounding factors may be explained as confounding or mixing of effects; the effect of exposure is mixed with the effect of another variable, thus leading to bias. Several approaches may be considered when deciding how to handle confounding factors in observation studies. For example, one can handle confounding factors by using multiple regression models or stratification. In most observational studies, the possibility of non-measured confounding factors cannot be excluded. The quasi-experimental design, difference-in-difference analysis was used in paper III. This means that many confounders may affect the results, such as other changes over time independent of the intervention, aging in the population and heterogeneity between the intervention and the control group. However, the short investigation period limits the extent to which external confounders may have affected the results. Paper III show that the control district improved for all outcomes (visits, unnecessary trips, phone calls) over time compared to the intervention districts. This does not necessary mean that the intervention has a negative effect on the reduction of health consumption in the home care service. The overall aim of the intervention of reducing unnecessary trips, phone inquiries and visits may have been affected in the control district, as they could be aware of the DigiHelse pilot performed in the intervention districts. The lack of individual data makes it challenging to control for mixed effects on the outcome variable, like for instance the effect of competing interventions in the districts, aging or policy changes.

5.2 Theoretical issues

This thesis extends the knowledge of methodological approaches to early HTA of e-health innovations and reorganisation and highlights the appliance of behavioural data as a new data source to assess usability.

Methods for early assessment of health innovation

In the development and implementation of future health care services, major shares of health care system users as well as costs will be affected. This includes large numbers of people with substantial unmet needs or with huge opportunities to benefit from new ways of supplying and organising healthcare services. To ensure a satisfactory health service that meets global needs, more effective methods and competences are needed in the adaption of health supply. There is still uncertainty surrounding prioritisation of innovative technologies and services in the Norwegian health system, and early assessment methodology may assist decision makers in demonstrating value, addressing risk and provide stage-wise implementation of new health services.

Concerning non-invasive technologies and organisational innovation, both empirical and theoretical approaches for the early HTA were identified in this thesis (paper I). Many different methods for early assessment of innovation were found, and the majority of the articles included a combination of strategic, clinical, and economic analyses with qualitative and quantitative methods. In the earlier innovation stages methods focused on identifying available data sources, while various simulation and analysis methods used in new ways were applied in later stages to increase the impact of the scarce availability of data. However, no article validated a specific method used for early assessment against a technology assessment completed in later phases, with additional data. This finding was important in the formulation of the aim in paper II, to test a method for early assessment in a concept stage of innovation, and in paper III, to retest the method in a later stage with more data.

Markiewicz et al. [99], argues that there is a lack of evidence on how effective methods for early assessment are and that there is a need to develop an agreed-upon method for early assessment. This coincides with the findings in paper I, where the methods identified, approach early assessment using diverse strategies for data collection and analyses; thus choice of method may lead to different outcomes as no universal method was found.

Paper I, however, identified several attempts to fill the evidence gaps on early assessment modelling, and stakeholder analysis and scenario drafting were methods applied in every innovation phase. Recommendations on the use of sophisticated mathematic techniques such as Bayesian techniques or Markov modelling are present on the theoretical side [94, 95, 100, 101]. In early HTA the low availability to robust data sources and the uncertainty in the data available presents methodological weaknesses. As such early assessment cannot be treated as conclusive but rather indicative. The technology, in many cases, has yet not been fully tested in real world practice, and scenarios on costs and effects do not tell the whole story. Sensitivity analyses may however be employed in scenario analysis to analyse the impact of probable variance in the main parameters on the outcome of the analysis. Markov modelling may also be useful when estimating economic outcomes based on different health stages depending on diagnosis and treatment. Early assessment which usually is based on small-sized or short-duration trials may also benefit from Bayesian techniques, as the approach uses existing information on uncertain parameters and update that information as the trial progresses. Such approach is found to be less used in economic evaluations, while may be valuable to inform clinical trial design or data analysis [94, 95, 100, 101]. Empirical models based on scenario drafting and expert elicitation, have also been used to compensate for the lack of data and steer the innovation in the right direction [100, 102-105]. Early assessment may address clinical value and risk, but because of short investigation periods, it is challenging to obtain concluding evidence.

Early HTA may enhance the production of beneficial innovations for the society as the documentation of effects at an early stage is essential in prioritising adequate technology development. However, empirical tests of the precision of early HTA methods needs to be further explored in practice.

In paper I, case studies and reviews of early assessment of non-invasive and organisational innovation formed the bases to identify methods and analytical approaches. As a result, paper I identified several service innovations in a health care setting. Fasterholdt et al. (2017) [37] provided an overview of early assessment of medical technology in hospital setting. The review included early cost effectiveness studies on hospital innovation to identify models for early assessment in different health care institutions. The models were then discussed according to their promise for hospital decision makers. In this, data was collected on decision context, decision problem and description of the model for early assessment. Through this review the authors showed that decision models using familiar methods for cost effectiveness analysis was most applied in hospital decision support, although some showed little promise in a hospital context. The authors however highlighted three usable elements that they recommend being included in a hospital based model for early assessment, and these are strategic issues, evidence mapping, and project management tools.

Another aspect not included in the studies analysed and discussed in paper I was medical pharmaceuticals, as they are deemed invasive. Ijzerman et al. (2017) [106] however identified empirical studies on early assessment methods of medical products, such a pharmaceuticals. The authors identified iterative economic evaluations as a prominent method for medical products to enable market access and launch. Further, in product development headroom analysis was highlighted prominent to inform actors in the industry before investment decisions are made. Finally the authors recommend methodological development combining systems engineering and health economics to manage uncertainty in medical product portfolios.

Although paper I successfully identified methods for early assessment in different innovation stages, it is critical to further explore what methods to recommend for different purposes and decision makers. We found that the majority of the included studies in paper I addressed decision makers on implementation as the main target audience of the assessment, this equals 36 percent of the included studies. Eleven studies targeted innovators as the main target audience, a total of 28 percent. Further 26 percent targeted healthcare providers as the main audience. And finally, only 10 percent of the studies targeted patient/users. Markiewicz et al. (2014) [38] reviewed theoretical and practical studies on early assessment of medical devices to identify assessment methods that help to inform decisions during the development stage. As the medical devices under assessment were typically a prototype or under development, the outcomes of this review addressed an innovators view. As such this review explored potential areas of use and improvement of medical devices and as well as an early assessment framework for innovators. The methods identified in this review aimed at informing strategical, economical and clinical aspects of the innovation. Although several assessment approaches were identified, the authors emphasised the need to develop an agreed up-on framework for easy assessment to enhance secure and efficient development of medical devices.

As for the role of clinicians in early assessment, Smith et al. (2019) [107] explored this in a review on focusing on medical technology. The authors identified four areas were clinicians may participate in early assessments informing stakeholders and suggested an innovation framework for clinical collaboration based on the literature included in the review. The areas recommended for clinicians' contribution were need-based problem solving, co-assessment of medical devices, economic evaluation of medical technology and addressing conflict of interest.

Paper I also discussed barriers of the identified methods for early assessment as we found all innovation stages suffered from lack of data and much uncertainty. Economic modelling was highlighted as promising in helping to steer the implementation process and restrain resource-inefficient technologies. However, the high uncertainty in the input variables in these models may challenge their value. Grutters et al. (2019) [108] reviewed models for health economic evaluations to assess the promise of these models in identifying potentially cost effective health innovation from those who lack this potential for economic benefit. The study also addressed which information these models produce to support decisions on further development, research and implementation. The authors found that early health economic evaluation provides insight in cost effectiveness of health innovation and uncertainty. Further, these models may be applied before and under the development of innovation in health care. The findings from this review showed that early health economic evaluations have the potential to provide knowledge on development and market positioning of innovation, as well as further research to maximize value for money. These results indicates a shift away from traditional health economic modelling focused on exact outcomes, to exploring enablers to increase the value of the technology under assessment. The authors also highlight context-specific assessments to enhance the relevance of the potential value of the innovation and associated uncertainties to inform further research and development.

Design and evaluation of e-health solutions – strengths and limitations of findings

New, radical and plentiful opportunities are emerging for developing new and better technologies, products and services through all kinds of integrated hardware-software solutions, and service application tools in nearly all areas of activity that affect our lives. The design and development of digital interventions presents evaluative challenges, such as obtaining valid outcome measures. This is partly due to the rapidly changing technological landscape [57]. As such, current methods need to be adapted to the way digital health interventions are delivered, and evaluation must be built into the development cycle from the initial concept. Such evaluations maybe demanding, as a concept stage usually lack empirical data on effect [58] .

DigiHelse potentially represent a significant boost for the development of digital services within the municipal health and care sector, with the potential reach to all citizens in Norway. Although the project was in a concept stage at the first time of analysis (paper II), assessment of potential value in terms of quality, safety and efficiency, provided information to reduce uncertainties surrounding decisions on further development [38, 109]. Paper I found that early assessment of health innovation has successfully been used to align stakeholders and show potential value at an early stage [94, 103, 110-112]. The involvement of stakeholders was considered a prominent data source in every innovation stage; development, introduction and early diffusion phases. In accordance with other early assessment literature, we found that stakeholders' views regarding potential benefits may be key contributors for the prioritisation of effects, as they are based on their need to innovation [112].

Evident in the literature are frameworks for assessing technology still in development, applying methods for stakeholder analysis in prioritisation of outcome measures and the use of qualitative scenarios based on expert opinion for data collection in cost-effectiveness modelling [96, 112, 113]. The economic evaluation in paper II was necessary in informing rational decisions about investments in quality improvement as it apprised whether the differential investment is justiciable in face of the differential benefit it produces [114]. The study found a significant potential for socioeconomic value of implementing DigiHelse. As a consequence of the documented health and socioeconomic value the early assessment provided, DigiHelse received funding for further development and implementation. Through a case of early assessment employing empirical data from a pilot, paper III updated effect estimates made in the concept stage of DigiHelse. A significant gap between the estimated value in the concept stage of DigiHelse and the estimated value using empirical data from the one-year pilot was however found (paper III). This may indicate that the stakeholder insight and scenario drafting applied in the concept stage was less precise than expected. In particular, due to the very low adoption rate of DigiHelse, that would not have been discovered without the pilot (paper III).

In line with similar research on the subject, we found that early stage analyses may suffer from loss of information, unable to reflect all possible outcomes [96, 97]. An early innovation stage is often challenged by a small amount of data and high uncertainty. At the time of analysis DigiHelse was in a concept stage prior to its first pilot. Assessment of potential value may provide information to reduce uncertainties surrounding decisions [109]. However the estimated socioeconomic value of the project is based on many assumptions and cannot be translated directly into practice. To highlight uncertainties related to the realization of the project and the estimated effects a risk assessment was carried out for decision support. This risk assessment may however be subject to bias as it was carried out by the same stakeholders evaluating the potential of Digihelse. As discussed above, stakeholders may be prone to promote innovations they have a stake in, and important risk elements of both the evaluation and the project may have been left out and deemed less troublesome than they should.

Paper II used stakeholder analysis and scenario drafting to give input to a net present value analysis of the potential socioeconomic value of DigiHelse. Stakeholder insight and scenario analysis were applied to supplement the poor availability to data when evaluating the project's potential socioeconomic value. Three of the outcome measures from this analysis were transferred to paper III and re-analysed using register data. Both papers however compare the current situation in the home care service with a theoretical future scenario where DigiHelse is implemented nationally. Such exercises are present in the literature in providing decision support in an early innovation stage [115-117]. Stakeholder data can be applied in scenario analysis to give necessary outcome overviews and direct and accelerate the procurement process [113]. Through integrating qualitative scenarios from the perspective of stakeholders and experts into a cost-effectiveness model, the potential value of the innovation can be estimated in an early phase [96]. Retel et al. [96] developed a framework for the assessment of technology still in development by means of scenario drafting to determine the effects, costs and cost-effectiveness of possible future diffusion patterns.

Further, paper II used stakeholder insight as an expert opinion to compensate for lacking data. Such approach to data collection can also be found in the literature [118, 119]. Huygens et al (2020) based input parameters on the analysis of questionnaire data from an expert panel in the early assessment of estimate costs of magnetic resonance-guided high intensity focused ultrasound ablation, compared to breast conserving treatment [118]. Further, Kluytmans et al (2019) used multi-stakeholder analysis to identify current problems of meniscus surgery in the Netherlands [119]. In the literature of early HTA, stakeholder insight is used to assess potential benefit of health innovation [94, 110-112]. Harris-Roxas and Harris [112] found that stakeholder' views about potential benefits are central in assisting the assessment of an innovation, but also in the prioritisation of effects. Such data may potentially ease adoption and diffusion through steering the intervention to achieve value-based innovation [97].

The model approach used in both paper II and III is also evident in the literature on early assessment of health innovation [120-123]. Although, net present value calculation may provide a simple and powerful approach to investment decisions [121], the model is only as good as it's input parameters. As the input parameters largely in paper II and partially paper III are based on stakeholder insight, which may lead to both bias and uncertainty, the power of the model is reduced. Dando et al (2020), studied the use of net present value analysis in early HTA and highlight the models ability to reflect future cash flows and reduce risk in an early stage [120]. However, the authors underline several limitations to the use of these models in an early development stage such as the fact that opportunities from an innovation may not be apparent at the start of development and the underestimation of real costs of development.

Net present value analysis uses the discount rate to account for research and development risk. Based on recommendations form the Ministry of Finance of Norway [124] on public investment projects a discount rate of 4 % was used to calculate the net present value of implementing DigiHelse over 10 years in paper II and III. A higher discount rate may however have been more appropriate as the input variables in the model were highly uncertain. Stasior et al (2018) recommends using discount rates over 30% in early stage evaluations of pharmaceuticals, to not underestimate the risk during the earlier phases of development. Similarly, a study on net present value analysis in innovation projects states that typical discount rates used for corporate projects range from 10 percent to 15 percent, while investors in high-tech start-ups can use rates of up to 25 percent to 30 percent [123]. This may compromise the trustworthiness of findings in paper II and III, and may contribute to explain large amount of savings estimated in paper II.

Both paper II and paper III were based on an implementation process decided by the project group, as thus the design of these studies do not comply with rigours research designs typical for case-control studies or RCTs. The studies however present a real life case on implementation of a public health care service. This introduces various methodological limitations, due to the fact that the design of the studies follows the structure of the project. However, an advantage of paper III was the availability of concept stage (paper II) assumptions and identified anticipated outcome measures based on stakeholder insights and scenario drafting when empirical data from the pilot were collected. Further, the study provided an empirical test of the model for early assessment used in the concept stage, as requested in the literature.

Paper II presented a large amount of potential savings if DigiHelse was to be implemented over a 10 year period weighted against investment costs. Outcomes from paper II also formed the basis for the initial estimations in paper III. The trustworthiness of these outcomes may however be questioned due to stakeholder bias, high uncertainty in the scenario drafting and the use of a relatively low discount rate which may not entirely reflect the risk elements in this model. An example is the assumption of 90% adoption rate of DigiHelse although the use was voluntary. The stakeholders believed that the adoption rate would arrive at 90% after a few years of implementation, and this may reflect the bias of stakeholder analysis in being overly enthusiastic to the ability of the innovation under assessment. The research in paper II was however not included in the decision process and the overall objectives for the project. Further, the project group did not have a learning curve and lack of use as an issue or identified problem area in its structural plan for implementation.

This may indicate that another approach to assessment in paper III would have been more appropriate, such as comparing total costs of the control area with those of the intervention areas. The aim of paper III was to test the usability and economic feasibility of adopting DigiHelse in four districts in Oslo by applying registry and behavioural data collected throughout a one-year pilot study. However, although not implicitly expressed in objectives, the authors also aimed at viewing the assessment in paper III in light of the previous assessment in paper II and highlight the uncertainty of stakeholder insight in covering all scenarios in the real world. Further the authors wished to show this by emphasising on the gap in the net present value when three of the parameters were updated with empirical data form a test. As such paper III show that the stakeholders had been too optimistic with concern to the adoption rate of DigiHelse and this may have major implications on the potential value of the project.

Although the result of the assessment of DigiHelse is still not conclusive, this stepwise decision process, following the development of the technology, provided important information regarding the lack of adoption of the intervention. Furthermore, early HTA may be applied in the conceptual phase to address quality outcomes that can be used for benchmarking purposes in the further development and implementation.

Implementation of e-health solutions - Opportunities and challenges

The global technological revolution in information technology is a powerful driver for change in almost all areas of economic, social and cultural activities through the rolling out of new global as well as national and sectoral ICT infrastructures. However, the change processes required to move them into widespread use are complicated in many dimensions and involve challenging interdependent development processes at multiple parallel development frontiers. Equally important in Norway is the need to integrate such infrastructures across the state organised, specialised and the municipally organised primary care systems. Hence, the ability to develop, to implement, to execute and to spread and scale new and better services are both system dependent and dependent on engaged cross-public as well as private-public collaboration on integration of systems.

Implementing e-health solutions is known to be challenging and time consuming. To ensure adoption, effective diffusion strategies are needed, including user training programs. In paper II, stakeholder insight and scenario drafting was employed to provide information on costs and benefits to ensure that the final solution of DigiHelse meets the need of the population and solves the actually problem [1]. Such data may ease adoption and diffusion through steering the intervention to achieve value-based innovation [97]. The low adoption rate fund among the users in the intervention group may explain the inability of the DigiHelse pilot to perform as expected: meet the citizens' needs. Another explanation may be, at least in part, suboptimal pilot implementation, as adoption and diffusion of e-health solutions requires significant adaption of work practices [125].

While the low adoption rate among recipients of the home care service was an important concern found in paper III, other studies addressing acceptance of e-health solutions tested in clinical settings have indicated high patient acceptability rates [126-128]. But it is still unclear how the adoption rate of e-health solutions may be affected once the technology is moved outside the boundaries of the clinic and are implemented in the users homes. Discrepancies in access to internet and technological literacy in different subgroups may influence the adoption rate and thus the estimated improvement in efficiency and cost reduction expected from implementation of e-health [129-131].

The integration of behavioural data from e-health solutions in early planning and assessment provides an opportunity to address implementation challenges and user adherence, where early HTA-modelling has a purpose [59]. It provides valuable information on the usability of a digitalised service and its corresponding population, and hence may determine whether the predefined intent of the new service is met. Paper III, points to early assessment of behavioural data has an opportunity to identify inefficiencies and direct digital development in the right direction, and thus ensure successful implementation.

All societies have limited resources and must, according to politically determined priorities, provide funds for health care in competition with funds for education, defence, agriculture and others. The availability to limited funds requires making choices. These choices reflect the overall political commitment to health and should, as far as possible, be based on an objective assessment of cost and benefits [22]. All countries, regardless of their income level, may take steps to reduce inefficiency, something that requires an initial assessment of the nature and causes of local inefficiencies. In order to effectively reject or promote methods for prevention, diagnostics and treatment, documentation on costs and benefits must be provided for rigorous evaluation [105].

Increased emphasis on research and testing in the public sector may contribute to innovation [132]. By trying out new solutions in defined areas, uncertainty may be reduced for a decision maker, as well as costs. The undertaking of such assessments may also produce effect measures that may be transferred to other parts of the public sector. Innovation can be complex and may contain several risk elements. To deal with these aspects of innovation, trials should be conducted within a defined timeframe and area, where effects of new solutions are tested in a realistic environment [132].

Early HTA may be integrated in the innovation process to shape and refine an innovation, and inform research and development decisions [108]. Iterative assessments of an innovation from an early stage may help shape and develop health technology and guide evidence generation. This process may inform both innovators and decision makers [38] . Compared to traditional HTA, early HTA often have greater emphasis on qualitative methods than is customary in conventional HTAs [133] .

Changes in work processes in a health care involve risk. The risk may however be reduced if adequate preparations and documentation is acquired before testing a new technology or services. Quality and patient safety must be ensured, and stakeholders must be aware of how a new solution will benefit patients and staff. Good preparation and insight may also enable predictions on economic and organizational adjustments.

Applying value-based thinking at an early stage may provide an opportunity to influence and change the health technology alongside of the development and implementation, such that the final solution truly meets an unmet need in the population.

Through applying early HTA thinking in an innovation process a milestone plan may be compiled where stakeholders agree on criteria that must be met to move forward in the development. This creates predictability, both for the innovators and the decision makers, and increases the likelihood of funding the development and implementation of successful innovation.

Changes in the way health services are organised affect several stakeholders. There is no lack of innovative ideas in health care, however how do we ensure that the ideas meet a need worth solving? And, do all stakeholders understand the challenge in the same way?

Uniting relevant stakeholders to discuss and prioritize what challenges to solve may bring benefits from an early innovation stage [107, 119]. Firstly, this may provide a common idea of the challenge. Secondly, unmet needs may be discovered, across occupational groups and the roles. By mapping out the current situation bottlenecks may be addressed and discussed. Often, we are not even aware of gaps and shortcomings in the way we solve tasks today. This is the first phase in the process of defining and agreeing on measures to implement in order to achieve a better solution than the current situation.

After defining challenges and goals, and ensuring that all stakeholders has the same view of the innovation, a plan to assess the associated effects must be set in place. To ensure that all relevant aspects of the innovation are being covered by the planned evaluation, the stakeholders should discuss outcome measures, resources available for the assessment and concur on a plan for the assessment. In this way, a common understanding of both the innovation's goals and how to document the effects may be achieved.

An early HTA provide an early measure of the potential value of innovation. The potential of the innovation may be evaluated during the development, and necessary changes to the innovation may be applied before the innovation is complete.

Unsuccessful implementation of an innovation may occur when key stakeholders have different perspectives of the challenges and needs in the population [134]. When an innovation fails to produce the expected benefits, the return of investment is negative, and large costs may eventually accrue to society. To ensure that the innovation addresses unmet needs in the population, three important questions may be asked: i) What is the most important bottleneck in the identified problem? ii) Which stakeholders will be affected by the innovation, and what approach should be used to provide the information needed to further develop the idea? iii) Given the problem that needs solving: what already exists?

In an early phase of innovation, collecting empirical data from a test of the intervention may be challenging. Semi-structured interviews with clinicians and / or other experts can provide good indications of the effects that can expect from the intervention [118, 119] . The experts have important information about the health system as a whole and how small changes in practice can affect their field.

In order to identify and evaluate changes in health provision due to eventual implementation of an innovation, it is important to explore user experiences, from both employees and patients as well as next of kin [135]. This may provide valuable insight into the effect of the intervention. Semi-structured interviews or focus groups may provide a good starting point. Key issues can provide important input to the intervention itself, and also provide users and relatives with the opportunity to communicate what they consider most important for further development.

A literature search may supply relevant experience from other environments and projects and help avoid duplications. In addition to mapping relevant projects, a knowledge summary of international studies within the subject can be conducted.

Economic modelling is necessary part of early HTA, and may be facilitated by collection of observational data, such as the data mentioned above, parallel to the development process. The data basis for these models should include both resources and outcome for alternative innovation strategies as well as reflecting the baseline information on the current situation. One such approach could be scenario analysis [115-117].

An early HTA may provide important decision support. By implementing innovation projects in a stepwise process, uncertainty may be reduced and a greater control of costs may be achieved. The early involvement from decision makers has several purposes; clarify risk, agree on milestones in development and what criteria must be met to proceed to the next development phase [136]. In addition, and perhaps most importantly, it provides active ownership and influence of the decision maker on a final solution. This may increase the likelihood of implementing the innovation. From a public decision maker's perspective, early assessment of risk and potential benefits may provide important information and opportunities to change the direction of the innovation project. Risk reduction requires that we define milestones that can be verified in later stages.

An early HTA may provide a suitable basis for decision making moving from an innovation stage to the next. Although early HTAs are designed to reduce uncertainty in the innovation process, they must be used wisely as risk management is not a checklist, but a real interest in the best possible result.

Although early HTA show potential in preventing unsuccessful investments in innovation, the methods are still not integrated in usual health care practice. As such, some challenges need to be addressed. In light of the use of cost-effectiveness models some concerns have been raised. Miquel-Cases et al. (2017) emphasises that in light of the iterative testing recommended for an early HTA, the construction of traditional cost-effectiveness models will become more complex [137]. Further, as early HTAs often employ other study designs than randomised controlled trials, unaddressed ethical and organizational concerns may occur. The authors recommend the development of innovative evaluation framework where rapidly incorporated evidence may be iteratively tested to re-calculate outcomes [137]. Another concern on early HTA is the inability of clinical studies to provide evidence of outcomes, as may often occur in an early stage of innovation [138]. However, statistical extrapolation models may remedy for this lack of clinical outcomes in an early innovation phase.

An early HTA process is designed to reduce futile investments, however the process in itself requires resources as all stakeholders should be involved, including patients. The full integration of these models will therefore require funding. Further, a framework for inclusion of stakeholders and especially patients in the development and evaluation of health innovation must be set in place [139]. Finally, early HTA should emphasise to a larger extent on organisational and service innovation as the implementation of medical devices most often causes changes to services and it is not necessarily the new technology but rather the patient pathway that are being assessed [133].

A classic HTA is a summative evaluation meant to assess whether a finalised intervention provides the right set of cost-benefit to be implemented in a health care system. Early HTA is, however, a formative evaluation of an intervention still under development, which allows for constant alterations to ensure that the intervention meets the needs of the health care system.

The evaluative approach is not necessary different, however the time and purpose of evaluation is. As such, early HTA may not be considered a precise method to measure cost-benefit; however it may be applied as a tool in the innovation process, to provide continuous information of the performance of the intervention in different development and pilot stages. Through a formative evaluation, ineffective solutions may also be rejected at an early stage, making room for innovations that provide most benefit for society.

5.3 Significance of findings

The purpose of this thesis was to study methods for early HTA of innovative technologies and explore the value of behavioural data in the assessment of usability of e-health solutions.

The introduction of e-health solutions and reorganisations of health services occurs with frequency, at both micro and macro levels, without established routines for evaluations of effect before implementing new solutions. Such interventions are often costly, as may be acknowledged summing up every health intervention implemented in Norway throughout times. Thus, starting evaluation and sequel adaptions of health innovation as early as possible is important in order to avoid dedicating scarce health funding on futile solutions. There are no clear guidelines in the literature on how to evaluate heath innovations at an early stage, however there are different suggestions (paper I). One of the most important is stakeholder analysis, which was employed in paper II to evaluate DigiHelse in a concept stage of innovation. Through such approach to early evaluation, the potential economic value of the innovation was presented. Further, more traditional quantitative methods were used on pilot data (paper III) from DigiHelse, which showed that the solution is poorly used by the recipients in the intervention group. However, the estimates from the stakeholder analysis were still updated with the quantitative data, and when comparing results from paper II with paper III, the analysis in paper II seems to be somewhat optimistic. The findings in paper III suggests that by employing sequential testing from an early stage, the implementation of DigiHelse may be improved. However, if these negative results consist after adjusting the implementation strategy it may be an indication that DigiHelse, although great potential for value generation, is not the right solution for the home care service and should therefore be discarded at an early stage. The findings in this thesis generally illustrate how processes for introducing health innovations should be monitored and continuously evaluated towards the implementation phase. Such process may probably result in a lower final cost than investing in several poor solutions.

5.4 Future research

To promote innovation and dynamic interaction between health institutions and industry, early HTA is a promising tool to support decision-making. The present thesis studied existing methods for early HTA and explored methodological barriers and opportunities to successfully develop, test, implement and scale health care innovations.

More research is needed to standardise early HTA methodology in varying stages of innovation; on the value of available data, methods and tools to enhance the interactions between different parties. Although paper I identified different methods for early assessment, no single method was highlighted as prominent relative to the robustness of the results or the frequency of use. Firstly, re-assessment of identified outcome measures is needed, to ensure that the final solution has the ability to provide the intended improvement. Further, empirical tests of the precision of early assessment methods and the enhancement of methods to manage lack of data and uncertainty should be performed. Combining existing methods with availability of digital data sources would provide useful, as emphasised by Ijzerman et al. in a recent study of early HTA highlighting observational studies and big data as data sources to allow more detailed analysis in early assessment [106].

The ultimate impact of health innovations depends not only on the effectiveness of the intervention, but also on its reach in the population and the extent to which it is implemented properly [140]. The integration of behavioural data in early planning and assessment provides an opportunity to address implementation challenges and user adherence, where early HTA modelling has a purpose. For DigiHelse, insight into why the recipients in Oslo have not made a greater use of the web-based platform seems to be the next step in ensuring the right improvement measures for the home care service. We encourage more research on the use of behavioural data in case studies as tools to empirically demonstrate e-health interventions benefits.

Research should move focus from separate individual pilot projects to focus on major public procurement projects, systemic development challenges and scaling challenges to third party supplier companies. Further, implementation of evidence-based healthcare interventions and policies, and the de-implementation of those demonstrated to lack clinical benefit should take place. A collaborative initiative to implement remote care in primary care in China provides one such opportunity, exporting Norwegian remote care solutions from Dignio, adjusting its practices to Chinese health care customers and providers. Another ongoing initiative is the Patient-Centred Team (PACT) intervention deigned to stabilise the patient's health situation in the high risk frail multi-morbid elderly, an innovative integrative care model across primary and secondary care. A reduced risk of high-level emergency care and reduced mortality has been documented in an intervention of increased use of low-level planned care. As the project now enters the implementation phase, it provides a unique opportunity to apply early assessment in a longitudinal design to address multi-level barriers and facilitators to the adoption, implementation and scaling and improve delivery of evidence-based interventions.

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APPENDIX

Supplementary Materials (Paper I)

Appendix

Search Strategy Medline Version 2017:

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1 exp Technology Assessment, Biomedical/ and (early* or first-stage or first-phase or horizon or pilot).tw,kf. (538)

2 ((early assessment or early stage assessment or early phase assessment) adj5 (biomedical or medical or health) adj5 (technology or service* or app? or application* or device* or tool*)).tw,kf. (6)

3 (Constructive Technology Assessment* and (early or pilot or forecast*)).tw,kf. (5)

4 ((Early or novel or pilot*) adj5 (hta or health technolog* or technology assess* or technology evaluat* or Health innovation*)).tw,kf. (132)

5 or/1-4 (629)

6 probability/ or bayes theorem/ or markov chains/ (85568)

7 Cost-Benefit Analysis/ (69191)

8 exp models, economic/ (12343)

9 exp Models, Theoretical/ (1498481)

10 exp models, statistical/ (333067)

11 exp decision support techniques/ (68214)

12 exp Risk Assessment/ (214137)

13 exp Uncertainty/ (8842)

14 exp Computer Simulation/ (188970)

15 exp Biomedical Research/ec, mt [Economics, Methods] (31077)

16 (analysis adj3 (cost* or conjoint or Choice or probabalistic)).tw,kf. (25064)

17 analytic* hierarch* process*.tw,kf. (588)

18 (Bayesian adj2 (techniq* or method* or analy*)).tw,kf. (9767)

19 (bench study or bench studies or bench marking).tw,kf. (357)

20 choice-based.tw,kf. (473)

21 clinical trial*.tw,kf. (292412)

22 Conjoint analys*.tw,kf. (560)

23 (decision adj3 (support or modeling or analysis)).tw,kf. (20513)

24 (delphi adj3 (method* or technique*)).tw,kf. (3399)

25 discrete-choice experiment*.tw,kf. (949)

26 early cost-effectiveness.mp. (10)

27 Early Model*.tw,kf. (231)

28 evidence synthesis*.tw,kf. (2409)

29 expected value of perfect information.tw,kf. (143)

30 expected value of sample information.tw,kf. (44)

31 expert panel*.tw,kf. (6906)

32 focus group*.tw,kf. (32514)

33 headroom.tw,kf. (45)

34 health economic modeling.tw,kf. (37)

35 health impact assessment*.tw,kf. (693)

36 horizon scanning.tw,kf. (122)

37 (interview* or focus group* or user* feedback*).tw,kf. (300735)

38 literature review.tw,kf. (64400)

39 (Markov adj3 model*).tw,kf. (10270)

40 multi-criteria decision.tw,kf. (413)

41 Multi-Parameter Evidence Synthesis.tw,kf. (9)

42 payback from research*.tw,kf. (9)

43 preference methods.tw,kf. (55)

44 preliminary market Research.tw,kf. (0)

45 real options analysis.tw,kf. (12)

46 (road-mapping* or multi-path*).tw,kf. (403)

47 return on investment*.tw,kf. (1308)

48 qualitative weighting.tw,kf. (4)

49 Technology profiling.tw,kf. (4)

50 usability test.tw,kf. (94)

51 or/5-50 (2513368)

52 5 and 51 (629)

53 remove duplicates from 52 (623)

54 limit 53 to (danish or english or norwegian or swedish) (583)

Embase and Cochrane Version 2017:

1 exp biomedical technology assessment/ and (early* or first-stage or first-phase or horizon or pilot).tw,kw. (652)

Supplementary Materials (Paper III)

APPENDIX 1

Table 1: Summary of cost units

Summary unit costs		Comment			
Full time equivalents in hours a year	1695				
Hourly rate of the home service in Euro	46	Internal human resources, time spent on training in municipalities			
Hourly rate of consultancy in Euro	107	System development, planning and implementation costs			
Increase in the proportion of full-time equivalents for technical operation of the solution per operating unit	10%	10% the first two years, then 5%			
Training needs of new service staff, hours per employee	3				
Number of employees in need of training in the new service	5				
Training in basic electronic messaging, number of hours per employee	15				
Number of employees per operating unit / municipality, including operating supplier, receiving training in basic electronic messaging	5				
Average increase in annual license / maintenance cost to EMR per operating unit in Euro	1 677				
Number of full-time equivalents within the care service	67 000	Statistics Norway 2014 (134,000 employees). We have assumed that 50% need training			
Time spent on planning organizational changes	225	Hours per municipality			
Time spent on staff training / organizational changes in hours	2				
Time usage training of recipients in hours	0,5				
Number of active users	89 000	We have assumed that 50% of users need training.			
Other operating and maintenance costs at Norsk Helsenett, health authorities and 800HELSE in Euro a year	262 055-817 610	Increases in pace with the implementation			
Implementation pace in years	5	365 ICT operating units			
Lifecycle in years:	10	The life cycle of professional systems is considerably longer than the standard life of ICT equipment			
Implementation pace	**2018**	**2019**	**2020**	**2021**	**2022**
Number of operating units (cost driver)	3	26	91	243	365
Share of population (effect driver)	*18 %*	42 %	69 %	90 %	100 %

Table 1 shows the input variables on the cost side of the present value calculation investment, the expected implementation pace, number of full-time equivalents and average unit costs for investments in digital infrastructure, training and technical support was based on national statistics (Statistics Norway).

APPENDIX 2

An increase in unnecessary tips, number of visits and number of phone calls were found when the intervention group was compared to the control group trend. The column for the early assessment in the concept stage (CS) is based on stakeholder analysis and the pilot stage column (PS) is built on the analysis with empirical pilot data. Leaving the three outcome measures Increased predictability for recipients, Greater efficiency with dialogue with citizens and better time management, and Provide technical basis for the development of digital services from the concept analysis unchanged. Table 1 shows how the effect of adding empirical data to the remaining three outcome measures Increased involvement from relatives and volunteers, Increased predictability for the home care service and Reduce phone inquiries reduced the potential value of the estimation such that the return of investment becomes negative. The column Difference (CS-PS) shows the incremental change in estimated value between the model from the concept stage and the pilot. The net present value of the intervention after adding data form the pilot is reduced by 241.8 million Euro over 10 years form the first assessment, resulting in a loss of 62.2 million Euro over 10 years. Due to the low adoption rate showed above, a sensitivity analysis was not carried out.

Table 1. Summary of priced effects in the concept phase and after the pilot phase

Priced effect measures	**Euro**	**Early assessment in a concept stage of innovation (CS)**	**Early assessment after the one year pilot (PS)**	**Difference (CS-PS)**
For residents				
Increased predictability for recipients	Mill. Euro. pr. year	(408,4)	(408,4)	0
Increased involvement from relatives and volunteers	Mill. Euro. pr. year	13.8	-7	-20.8
For the home care service				
Increased predictability for the home care service	Mill. Euro. pr. year	3.8	-4.7	-8.5

More effective of dialogue with citizens and better time management	Mill. Euro. pr. year	(7.1)	(7.1)	0
Reduce phone inquiries	Mill. Euro. pr. year	1	-3.3	-4.3
Provide technical basis for the development of digital services	Mill. Euro. pr. year	(19.1)	(19.1)	0
Total	Mill. Euro. pr. year	25.7	-7.9	-33.6
Net present value of the intervention	Mill. Euro	179.6	-62.2	-241.8
Present value investment cost in the public sector	Mill. Euro	5.5	5.5	0
Net present value per invested Euro in the public sector	Euro	3.2	-1	-4.2

Table 1 compares the results for the early assessment in the concept stage (CS) with the assessment performed with data from the pilot (PS) and the difference between the two (CS-PS). The table presents yearly estimates for the six outcome measures, net present value, present value investment costs and net present value per invested Euro in the public sector over 10 years. Values in parenthesis are not included in the present value calculation.

II

ECRONICON OPEN ACCESS

EC NURSING AND HEALTHCARE
Research Article

Evaluating the Design of a Digital Communication Platform for Recipients of Home-Care Services to Improve Municipal Care Services: A Proof of Concept Study

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Abstract

Background: The purpose of the project "DigiHelse" is to strengthen the municipality's care services in Norway by offering a digital communication platform to recipients of home-based health services and their dependents. The aim of the present study was to assess how DigiHelse should be designed and developed to ensure increased quality and value for recipients, the home care service and the society.

Methods: Early health assessment with stakeholder insights and scenario drafting was applied to identify health quality gains and address patient safety issues, define relevant outcome measures and compare the new solution to the current situation. Outcome measures were quantified priced and analysed using a 10-year present value calculation with a calculation rate of 4%. A risk analysis was also carried out.

Results: The following outcome measures for recipients, the home care service and the society were identified and assessed to show the potential socioeconomic value of DigiHelse; Increased predictability for recipients, Increased involvement from relatives and volunteers, Increased predictability for the home care service, Greater efficiency with dialogue with citizens and Better time management, Reduce phone inquiries, Provide technical basis for developing digital services. The potential socioeconomic value of selected outcome measures was calculated based on expert opinion and national statistics. In addition to addressing quality and safety outcomes, the present value calculation estimated savings equal to 172.6 million euro, with present value investments costs of 5.5 million euro over 10 years. This resulted in net present value per invested Euro in the public sector equal to 3.2. Overall risk assessment related to the intervention's socioeconomic profitability was deemed average.

Conclusion: This study shows how early health assessment may be applied in the conceptual phase to address quality outcomes that can be used for benchmarking purposes in the further development and implementation. We suggest that early assessment by means of stakeholder analysis and quantification of potential gains has a value from a concept stage of an improvement initiative in health care.

Keywords: *Early Assessment; Health Innovation; Organizational Innovation; Digitalization; Health Technology Assessment*

Abbreviations

HTA: Health Technology Assessment; Early HTA: Early Health Technology Assessment; C3: Centre for Connected Care; IPLOS: Legal Health Register for Municipal Health and Care Services; EMR: Electronic Medical Records; Mill. Euro. pr. year: Million Euro Per Year

Background

The Norwegian health and welfare sector is undergoing large-scale digitalisation programs to transform the delivery of health services and improve quality of care provision [1]. In addition, home care services provided by the municipalities is facing an increased demand [2]. The number recipients in the home care service below retirement age have tripled over the ten last years. Also, due to shorter hospital stays with more day care and outpatient treatment, more demanding user groups with complex medical and psychosocial needs are moved to the municipalities.

A strengthened home service may prevent hospital readmissions and reduce perceived severity among the chronically ill. National guidelines emphasise the need for increased focus on home care services and early efforts, which is identified in several reports and white papers within recent years, such as "Norwegian Ministry of Health and Care Services. Report no. 26 (2014-2015) The primary health and care services of tomorrow - localized and integrated [3], "Report no. 29 (2012-2013) Future Care [1] and Care Plan 2020 The Norwegian Government's plan for the care services field for 2015-2020 [4]. Ultimately, this may optimise the cooperation between municipality care services, voluntary and family-based care and specialist health services [4].

Addressing quality of care, patients safety and economic aspects is of importance when promoting new services [2]. The funding scheme for municipality care services in Norway is partially based on local investments though the country's 426 municipalities. Hence, to strengthen the home care service nationally, benefits in terms of potential socioeconomics are a prerequisite to acquire funding for development and implementation. To ensure municipal resource allocation for digitalisation projects, there is a need to select interventions that produce the greatest benefits and document why they should be prioritized for funding [5].

Defying this logic, large-scale digitalisation projects in the health and welfare sector are not always accompanied by rigorously designed research projects to assess effects, in terms of implications on cross-sector coordination, inclusion, coherence and empowerment [6].

"DigiHelse" is a nationwide digitalisation project initiated by the Norwegian Directorate of E- health. Its main purpose is to enable a digital dialogue between the Norwegian home care service and the recipients, introducing the following three platform features: digital messages between resident and the service, visualize agreed and completed visits with associated information, and the option to cancel visits and final notifications of completed visits.

Aim of the Study

The aim of the present study was to assess how DigiHelse may be designed and developed to ensure increased quality and value for recipients, the home care service and the society.

Methods

Study perspective

DigiHelse is designed to become a public and national service for the home service, gradually implemented and offered to residents in Norwegian municipalities. Early health technology assessment (Early HTA) with stakeholder insights and scenario drafting was applied to identify quality gains and address patient safety issues, define relevant outcome measures and compare the new solution to the current situation. Outcome measures were quantified priced and analysed using a 10-year present value calculation with a calculation rate of 4%. A risk analysis was also carried out.

Population

Recipients of home based services and their relatives were the main target group of the intervention. The present study assessed the consequences of implementing the new service for recipients, health providers and the society.

Setting and location

The study was set in Oslo in February 2017. Primary health care in Norway is provided under the responsibility of Norway's 426 municipalities. This includes General practitioners, primary care nurses, care institutions and home care. Nurses and doctors in preventive and long-term care services are usually employed in municipal health care [7]. Municipalities spend almost one quarter of their total expenditures on health care and still the home care sector in Norway is under constant pressure due to lack of recourses and capacity [8].

The intervention

The purpose of DigiHelse is to strengthen the municipalities' care services by providing digital services to recipients of home services and their relatives. The project is based on the existing "Helsenorge.no" platform from the Norwegian Directorate of e-Health which provides digital health services nationally. The initiative is considered an important step towards achieving a patient centered health care service in Norway, as the main target group for the intervention is both recipients of home-based services and their dependents.

Choice of health outcomes

To determine and quantify potential effects of the project, the project steering group identified stakeholders from different parts and professions in the home care service. They were to represent a holistic view of potential effects in terms of improved quality, efficiency and safety. The following areas of expertise were included in the project group: professional system managers from Oslo, leading professionals in home based services from Oslo and Bergen, health economists from the municipality board and Centre for Connected Care (C3) at the University Hospital in Oslo, resources from the e-Health Directorate, and project manager from Oslo municipality. The stakeholders represented an expert opinion from each field of the service, including recipients. Stakeholder insight was collected through four main workshops assessing the consequence of implementing the following three digital features for the home care service and its recipients: digital messages between resident and the service, visualize agreed and completed visits with associated information, and the option to cancel visits and final notifications of completed visits.

Measurement of effectiveness

Addressing quality of care and patient safety aspects, the stakeholders identified nine main health value categories; predictability and coping, accessibility and cooperation with the service, privacy and information security, easier task management, better cooperation with residents, basis for further digitisation of citizens' services, increased prevention, better use of community resources and E-health and digitisation. Priced quantitative, unpriced quantitative and qualitative effects identified by the stakeholders were characterised in three main groups; residents, health care service and society. Grouped in three, the effects for residents, health care service and society are listed in figure 1. Further, the stakeholders identified six effects that could be quantified and priced to be included in the analysis of potential socioeconomic value. The following effect measures are marked with a triangle in figure 1; Increased predictability for recipients, Increased involvement from relatives and volunteers, Increased predictability for the home care service, Greater efficiency with dialogue with citizens and Better time management, Reduce phone inquiries, Provide technical basis for developing digital services.

Data sources and estimation of resources used

The legal health register for municipal health and care services (IPLOS) is the central health register which forms the basis for national statistics for the home care service. In this analysis IPLOS provides the number of recipients enlisted in home care service, the need for assistance and the average number of hours the service devotes to home care, practical assistance and both. Based on this register data and

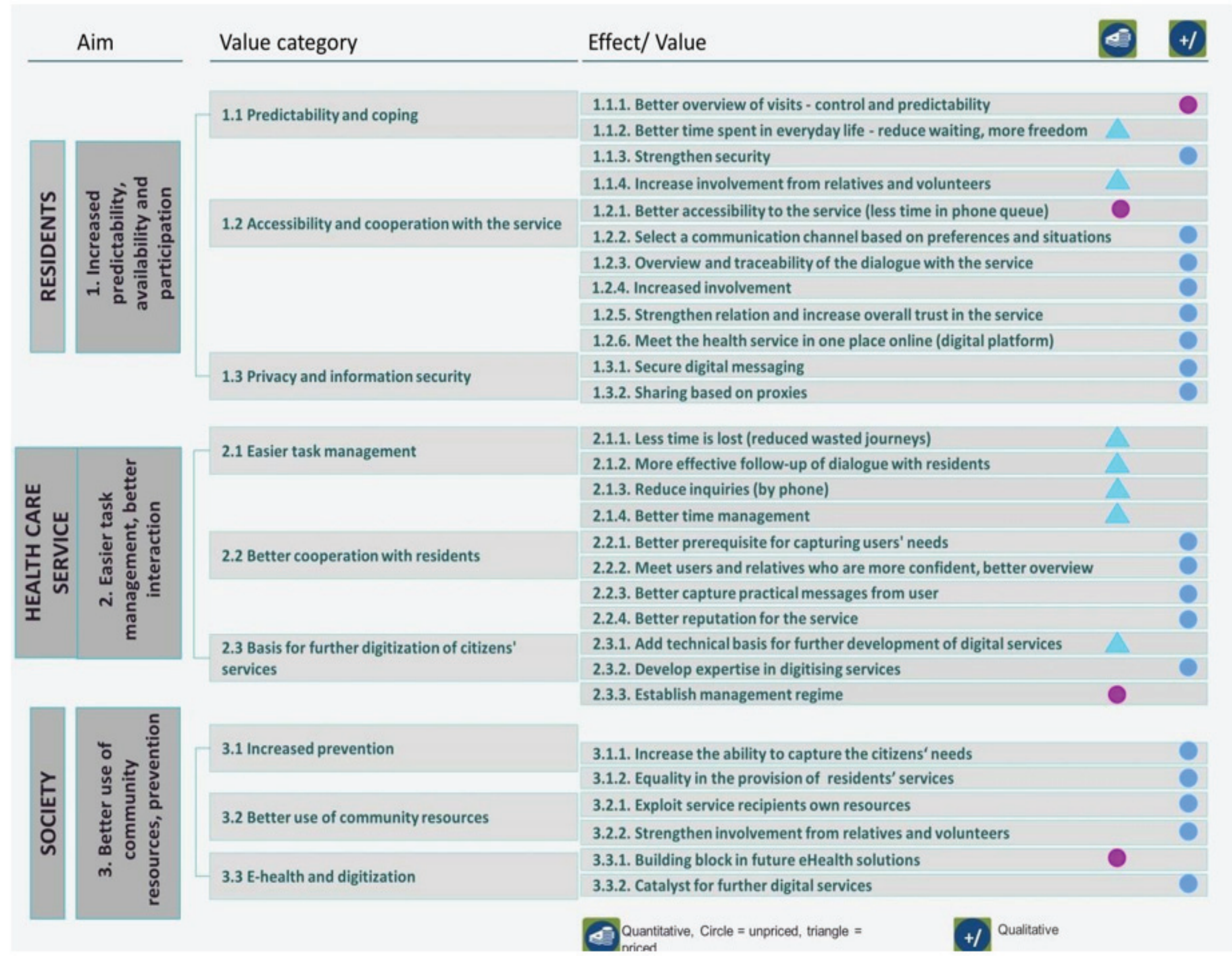

Figure 1: *Potential health value analysis. The figure shows effects for residents, health care service and society. Qualitative effects are marked with a blue circle, unpriced quantitative effects are marked with a pink circle and priced quantitative effects are marked with a triangle.*

information about the average length of each visit from tender documents in Oslo municipality, the average number of visits per week was estimated on a national basis. Interviews with professionals from the service were used to map the administrative workload that could be limited by digitalisation of the service. Data from a survey in Oslo municipality (special extract from the electronic medical record (EMR) system in Oslo municipality) and findings from the municipality's price model for home services were used to estimate the amount of unnecessary journeys for the home service.

Finally, the project also registered phone calls to the home service in Oslo municipality to study the percentage of the inquiries that could potentially be replaced by the digital communication.

Analysis

A 10-year present value calculation with a calculation rate of 4% was used for the estimates. The value of the six priced effect measures was calculated based on scenarios elaborated by the stakeholders and data collected from the sources mentioned above. The benefits were also weighed against costs; initial investments in infrastructure, maintenance costs, sequential implementation rate and costs associated with training.

Risk assessment

There are many risks associated with this assessment due to the early stage of evaluation and lack of data. The estimates of the analysis are built on assumptions and different perspectives of experts in the field. The stakeholders evaluated the risk associated to the potential effects of the digital service on a three point scale; low, medium and high.

Results

Stakeholder insight and scenario drafting

The six scenarios elaborated by the stakeholders to quantify quality and safety outcome measures with the new solution compared with the current situation, are presented below.

Increased predictability for recipients: With the current solution, recipients are not given the exact time of their appointment and dedicate a lot of time waiting for the service. In the digital platform, arrivals and delays will be displayed and the recipient is given the opportunity to cancel visits. The hypothesis was that predictability gives higher quality of life and that it is possible to estimate the value of the time recipients can use on other tasks than waiting.

Increased involvement from relatives and volunteers: An ambition for the home services is that to ensure good and effective services, relatives and volunteers must be included [4]. In this interaction there are both quality gains, but also opportunities to restructure and modernise how the home service works, as some care tasks may be transferred to relatives.

Increased predictability for the home care service: The proposed intervention may increase predictability for the home service, as it will be easier to report changes to planned visits for both the recipients and the relatives through the digital dialogue. Enhanced predictability may improve both quality and safety as the recipient receives necessary treatment, and the service avoids consuming precious time searching for a recipient that does not answer the door for a scheduled visit.

Greater efficiency with dialogue with citizens and Better time management: The home service daily receives inquiries that interrupt work flow. The hypothesis was that digital communication provides a better overview over the work load and allows for more efficient planning of daily work chores for the home service.

Reduce phone inquiries: The home service currently receives several phone calls related to both planned and completed visits, as well as recipients and relatives wishing to move or cancel visits. The digital platform provides recipients with an overview over planned and completed visits, and the possibility to cancel visits.

Provide technical basis for developing digital services: A large proportion of the municipalities will have to undertake procurement of a digital infrastructure for home services if the present project is not implemented.

Potential socioeconomic value of outcome measures

The potential socioeconomic value of the selected outcome measures was calculated based on expert opinion and national statistics. The estimates for each outcome measure are presented below. A related risk assessment of the estimates is presented in table 2.

Increased predictability for recipients: Increased predictability gives in this scenario a possible annual value of 408.4 million Euro per year (Mill. Euro per year). If the recipients knew the exact arrival of the home service, the assumption was that an hour per visit may be saved. This was applied for 50% of recipients which receives 1-6 visits a week (89 900). The home care service informed the stakeholders that employed recipients receive their visits on time; hence this group was excluded from the cohort. The unemployment rate from the Norwegian Labour and Welfare Administration of 30 Euro an hour was used to calculate the value of the recipients' free time. This effect was not included in the present value calculation as the value of free time is debatable.

Increased involvement from relatives and volunteers: In improved communication between relatives and the service this scenario may amount to savings of 13.8 million Euro a year. For relatively self-sufficient recipients, relatives and volunteers may carry out one visit per month on average. There are 76 000 recipients who have an average of 3 visits per week and are considered in need of limited aid. A visit lasts on average for 20 minutes.

Increased predictability for the home care service: With the ability of the user to digitally cancel and postpone visits, a reduction of 30% unnecessary journeys was estimated; savings are estimated to be 3.8 million Euro a year. The estimated saving is based on 46 000 less unnecessary journeys a year, with the hourly rate of 48 euro and a duration of 30 minutes on average.

Greater efficiency with dialogue with citizens and Better time management: Through interviews with professionals from the home services the stakeholders estimated potential time savings of 30 minutes per day with digital communication resulting in savings of 7.1 million Euro a year. As this type of communication is mainly directed to the coordinators, 1350 coordinators will be affected nationwide.

Reduce phone inquiries: The estimated impact of reduced phone inquiries may amount to 1 million Euro per year on a national basis. To assess whether the intervention can reduce phone inquiries, that otherwise could be solved digitally, the project group conducted a phone survey in Oslo and in Bergen. The employees registered phone requests in the following categories: 1) Is the visit completed? 2) What time is the visit? 3) Change or cancelled visit. 4) Other. The stakeholder group believed that the digital platform may reduce the number of phone inquiries within categories 1 - 3. After the survey a scenario where digital communication can reduce the phone inquiries to the home service with 40% was built.

Provide technical basis for developing digital services: Providing a technological basis for developing digital services may results in a one-time saving of 18.25 million Euro. If 50% of the municipalities in Norway each procure their own platform they will on average consume 100 000 Euro each, including procurement, infrastructure, licenses/rent etc. This effect was not included in the present value calculation because digitalisation of home services is still not statutory.

Assessment of risk

An assessment of the risk related to the interventions feasibility and potential socioeconomic value was carried out by the stakeholders and evaluated on a three point scale (low, medium, high) (Table 1). Average risk of the feasibility of the intervention was deemed medium.

Summary of priced effects

Four of six priced effects were included in the present value calculation, which amount to potential savings in resources of 25.8 million euro a year. Table 2 shows the summary of the priced effects in million Euro a year if the digital platform for home services was to be implemented.

Overall socioeconomic value

Table 3 shows the overall socioeconomic value estimated with a net present value calculation over ten years. The net present value of the digital platform taking into account a gradual rate of implementation was estimated to 172.6 million euro over ten years. The overall

Effect	Explanation for the assessment of risk	Assessment of risk
All effects	The value is estimated on a national basis, but it is uncertain whether all municipalities will use the service. However, national and municipal guidelines on digitisation requirements help reduce this risk.	Medium
Effects for the home service	It is demanding to take new work tools and processes into use. The uncertainty may be reduced with robust anchoring in the leadership. Such anchoring is included in the implementation strategy of the project but is challenging given the number of municipalities and districts.	Medium
All effects	The need for local resources may be underestimated. Home services and municipalities must provide resources that can actively contribute to the anchoring of the project and enhance quality before implementation.	Medium
Most effects	Most effects are results of small time-savings in multiple processes. The benefits may be hard to realize in i.e. reduction of staff. It is more likely that these benefits will result in better quality, serving an increase in volume without increase in staff etc.	Medium
Time saving due to fewer phone calls	It may take more time to answer a written inquiry than a phone call and it is uncertain how much dialogue increases when it becomes easier for the recipient to contact the home service via a digital channel 24 hours a day.	Low
Effects for the user	Uncertainly on how large a proportion of recipients have a degree of disability to the extent they are unable to use digital services.	Medium
Effects for the user	If the population does not know about the new service and does not make use of it. When introducing the service, this should be taken into account.	Medium

Table 1: *Summary of risk assessment. The table shows risk elements identified for the effects included in the present value calculation and an explanation of the rating on the three point scale; low, medium and high.*

Priced effect measures	Euro	Included in the present value calculation	Not included in the present value calculation
For residents			
Increased predictability for recipients	Mill. Euro. pr. year		408,4
Increased involvement from relatives and volunteers	Mill. Euro. pr. year	13.8	
For the service			
Increased predictability for the home care service	Mill. Euro. pr. year	3.8	
More effective of dialogue with citizens and Better time management	Mill. Euro. pr. year	7.1	
Reduce phone inquiries	Mill. Euro. pr. year	1	
Provide technical basis for the development of digital services	Mill. Euro. pr. year	19.1	
Total	Mill. Euro. pr. year	25.8	

Table 2: *Summary of priced effects. Estimated resources saved for each of the six priced effect measures. The third column shows the effects included in the present value calculation and the fourth column shows the effects excluded from the present value calculation.*

costs associated with the implementation of the digital platform were 96 million euro over 10 years. The table also shows the assessment of the unpriced quantitative and qualitative effects, rated on a scale from plus to four plus, for impact and range. Present value investment costs for the public sector and net present value per invested euro is also presented in the table. Finally the overall assessment of the risk related to the interventions socioeconomic value is evidenced in table 3.

Net present value of the intervention (in Euro million)	172.6
Assessment of unpriced quantitative effects	+++
Assessment of qualitative effects	+++
Present value investment cost in the public sector (in Euro million)	5.5
Net present value per invested euro in the public sector (in Euro)	3.2
Overall assessment the risk related to the intervention's socioeconomic value	Medium

Table 3: *Summary of potential socioeconomic value. The table shows an overall summary of the evaluations performed on the project. Assessment of unpriced quantitative effects and assessment of qualitative effects are both evaluated on a three point scale where ++++ is the highest score.*

Discussion

This study applied stakeholder insights and scenario drafting to identify health quality gains, socioeconomic benefits and define relevant outcome measures for follow-up. We found that the implementation of DigiHelse may have positive implications on quality, safety and efficiency and provided relevant project outcome measures. A 10-year present value calculation with a calculation rate of 4% estimated the significance of six identified outcomes measures and the overall project risk was deemed medium on a three point scale. Based on findings from this analysis DigiHelse was granted additional funding to further develop the intervention.

The design and development of digital interventions presents evaluative challenges, such as problems obtaining valid outcome measures, due to the rapidly changing technological landscape [9]. As such, current methods need to be adapted to take into account the way digital health interventions are delivered, and evaluation must be built into the development cycle from the initial concept. Such evaluations may, however, be demanding as a concept stage of innovation usually lack empirical data on effect [10]. Health Technology Assessment (HTA) is a well-established method for assessment for health interventions in later phases of implementation. HTA is defined as an interdisciplinary process for synthesizing information regarding medical, social, economic and ethical issues related to the introduction of a new health technology [11]. Currently, additions to the literature on adapting these methods to earlier stages of product and service development is emerging [12]. Early health technology assessment can be defined as the early examination of the medical, economic, social, and ethical implications of a health intervention to determine the potential of its incremental value in health care [13].

In the present study, stakeholder insight and scenario drafting were used to assess potential benefit of health innovation [14-18]. Previous studies concerning early assessment of health innovation have successfully applied such approaches to align stakeholders and show potential value at an early stage. Evident in the literature are frameworks for technology still in development, methods for applying stakeholder views in prioritisation of outcome measures and the use of qualitative scenarios based on expert opinion for data collection in cost-effectiveness modelling [17,19,20].

DigiHelse may represent a significant boost for the development of digital services within the municipal health and care sector, with the potential reach to all citizens in Norway. Although the project was in a concept stage at the time of analysis, assessment of potential value in terms of quality, safety and efficiency, may provide information to reduce uncertainties surrounding decisions on further development [21,22]. Information on costs and benefits may provide key decision support in ensuring that the final solution meets the need of the population and solves the actually problem [23]. Economic evaluations are necessary in informing rational decisions about investments in quality improvement as they apprise whether the differential investment is justiciable in face of the differential benefit it produces [24]. As a consequence of the documented health and socioeconomic value the present health assessment provided, DigiHelse received funding for further development and implementation. In the next phase, the project will be piloted in four districts in Oslo, starting in March 2018. At that time, the outcome measures will be reassessed and evaluated, by the stakeholders. The long-term value of the investment in technology is however not included in the present study; the effect of establishing a digital platform was not included in the net value calculation. However, all effect measures support key objectives referred to as main goals of the municipal care and care services [1,3,4,25]. Stakeholder insight and scenario drafting were applied to supplement the poor availability of data. As such, the estimated socioeconomic value of the project is based on many assumptions. All of the model inputs are subject to sources of uncertainty, including errors of measurement, absence of information. To show the risk related to the realization of project and the estimated effects, a risk assessment was carried out for decision support.

Conclusion

This study shows how early health assessment may be applied in the conceptual phase to address quality outcomes that can be used for benchmarking purposes in the further development and implementation. Recipients of home based services and their relatives were the main target group of the intervention. The present early assessment identified potential benefits both for the patients, the home care service as well as socioeconomic benefits. We suggest that early assessment by means of stakeholder analysis and quantification of potential health gains is of value as early as in the concept stage of an improvement project. A re-assessment of identified outcome measures may provide useful to ensure that the final solution has the ability to provide the intended improvement. It also may ensure that the project development of proceeds according to plan.

Authors' Contributions

LNS, MF and AN conceived, designed, and performed the experiments. LNS, MF, and AN analyzed the data. LNS and KJK authored the manuscript. MF and AN critically reviewed the manuscript.

Disclosure

No competing interests are declared.

Patient Consent

Not applicable.

Ethics Approval

The Regional Committee for Medical Research Ethics, Region Eastern Norway provided information that consent was unnecessary.

Consent for Publication

Not applicable.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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Data Sharing Statement

All available data can be obtained by contacting the corresponding author.

Contribution Statement

All Authors meet with the ICMJE criteria for authorship.

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III

Original Paper

A Web-Based Communication Platform to Improve Home Care Services in Norway (DigiHelse): Pilot Study

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Abstract

Background: Home care service in Norway is struggling to meet the increasing demand for health care under restricted budget constraints, although one-fourth of municipal budgets are dedicated to health services. The integration of Web-based technology in at-home care is expected to enhance communication and patient involvement, increase efficiency and reduce cost. DigiHelse is a Web-based platform designed to reinforce home care service in Norway and is currently undergoing a development process to meet the predefined needs of the country's municipalities. Some of the main features of the platform are digital messages between residents and the home care service, highlighting information on planned and completed visits, the opportunity to cancel visits, and notifications for completed visits.

Objective: This study aimed to test the usability and economic feasibility of adopting DigiHelse in four districts in Oslo by applying registry and behavioral data collected throughout a one-year pilot study. Early health technology assessment was used to estimate the potential future value of DigiHelse, including the predictive value of behavior data.

Methods: Outcome measures identified by stakeholder insights and scenario drafting in the project's concept phase were used to assess potential socioeconomic benefits. Aggregated data were collected to assess changes in health consumption at baseline, and then 15 and 52 weeks after DigiHelse was implemented. The present value calculation was updated with data from four intervention groups and one control group. A quasi-experimental difference-in-difference design was applied to estimate the causal effect. Descriptive behavioral data from the digital platform was applied to assess the usability of the platform.

Results: Over the total study period (52 weeks), rates increased for all outcome estimates: the number of visits (rate ratio=1.04; *P*=.10), unnecessary trips (rate ratio=1.37; *P*=.26), and phone calls (rate ratio=1.24; *P*=.08). A significant gap was found between the estimated value of DigiHelse in the concept phase and after the one-year pilot. In the present pilot assessment, costs are expected to exceed potential savings by €67 million (US $75 million) over ten years, as compared to the corresponding concept estimates of a potential gain of €172.6 million (US $193.6 million). Interestingly, behavioral data from the digital platform revealed that only 3.55% (121/3405) of recipients actively used the platform after one year.

Conclusions: Behavioral data provides a valuable source for assessing usability. In this pilot study, the low adoption rate may, at least in part, explain the inability of DigiHelse to perform as expected. This study points to an early assessment of behavioral data as an opportunity to identify inefficiencies and direct digital development. For DigiHelse, insight into why the recipients in Oslo have not made greater use of the Web-based platform seems to be the next step in ensuring the right improvement measures for the home care service.

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KEYWORDS

early health technology assessment; eHealth; primary care; innovation; behavioral data

Introduction

The era of digital health and the demand for health information technology (HIT) brings enormous opportunities for both patients and professional users [1]. While HIT is the technology used in electronic health (eHealth) services, eHealth itself is defined as the interaction between medical informatics, public health, and businesses, referring to health services and information delivered or enhanced through the internet and related technologies [2]. One promise of eHealth solutions is that, through enhanced communication and patient involvement, and increased efficiency, reduced costs for the health care service may be achieved. It is also assumed that eHealth may enhance the quality of care by increasing transparency and availability between different health suppliers. There is, however, a discrepancy between the expected value of such interventions and the empirically demonstrated benefits [3,4]. There is a lack of case studies demonstrating the assumed cost-effectiveness and efficacy of eHealth solutions, and research to promote value-based health care in this field has been requested [3,5].

Web-based communication platforms are intended to enhance health in both somatic and mental health care [6-8]. Such platforms have shown success in reaching individuals who are hard to contact, in lifestyle behavior change, and the delivery of individualized online care [7,9,10]. For chronic illnesses, enabling people to administer their treatment and care may increase compliance to treatment regimens and improve quality of life. The translation of the Diabetes Prevention Program to online treatment is one such example [11]. The failure of adoption by end-users, however, is a challenge faced by these Web-based interventions. Accordingly, end-user engagement in the development of these interventions has been recognized as essential to increase adoption rates when they are introduced [12,13].

A health service characterized by efficiency and high quality can only be achieved if patient outcomes and costs of delivery are addressed [14]. When facing the complex health care system, not only do technical and legal issues appear, but so do organizational, economic, and social aspects [1]. User-centric design can be employed from the earliest exploratory stages to help understand and design for the needs, goals, limitations, capabilities, and preferences of all stakeholders [15]. Recommendations from an international workshop in the United Kingdom on how to create, evaluate, and implement effective eHealth interventions highlights new evaluative challenges in the field. Due to the swiftly changing technological landscape, these UK authors emphasized challenges such as continuous technological adaption and problems identifying valid outcome measures for assessment of costs and patient benefits [16]. Thus, to adjust to the rapidly changing context, standard methods for development and assessment will benefit from including the whole development cycle. Access to data and valid information from a conceptual stage of development may, however, be demanding, which could explain the lack of empirical evidence concerning the effect of eHealth interventions [3,17].

Health technology assessment (HTA) is traditionally used to provide decision support in the implementation phase of new or current health technology. HTA is defined as an interdisciplinary process for synthesizing information about medical, social, economic, and ethical issues related to the introduction of a new health technology [18]. To improve the pace and efficiency of the development and assessment of health innovation, new methods for early HTA are emerging in the literature [19]. Early HTA is a form of HTA that evaluates technologies still in development and can be defined as the initial examination of the medical, economic, social, and ethical implications of a health intervention to determine the potential of its incremental value in health care [20,21]. A standard model for early HTA is yet to be established, so research is needed to validate the proposed approaches to early HTA emerging in the literature [22].

DigiHelse is an intervention designed to reinforce the home care service in Norway and is currently undergoing a procurement process in the county's municipalities. This is the second of a series of two studies reporting on the effects of implementing the Web-based communication platform, and the first study reported on the early assessment of potential socioeconomic value in the concept stage of the project. DigiHelse was designed and developed to integrate a national Web-based communication platform for recipients of home care services. The main features of the platform were digital messages between residents and the home care service, visualizing agreed upon and completed visits with their associated information, the option to cancel visits, and final notifications of completed visits. In the concept stage of development, data was collected from stakeholders and experts to build scenarios to show the potential value of the intervention. Based on the findings, the project was granted additional funding and proceeded to its pilot phase in four districts in Oslo. Throughout this pilot study, the project needed to collect evidence on its potential benefits to ease the procurement process in other municipalities in the country.

DigiHelse is an example of an eHealth intervention still in development; thus, there is an opportunity to perform assessments on the different stages of the development cycle. A stepwise decision process with several evaluation points and iterative adoptions of the solution has been incorporated in the implementation plan to ensure that the final solution meets the needs of the end-users. This study aimed to test the usability and economic feasibility of adopting DigiHelse in four districts in Oslo by applying registry and behavioral data collected throughout a one-year pilot. Early HTA was used to estimate the potential future value of DigiHelse, including the predictive value of behavior data.

Methods

Population

The target population for the intervention is composed of all the recipients of the home care service in Norway, their next of kin, and the service providers of the home care service. The home care service in Norway is a part of the country's primary health care service. Norway has 426 municipalities that are responsible for the provision of services in primary care. Operations directed under primary care are typically health services provided outside an institution (with a preferred emphasis on health promotion and preventive work), general medical care (general practitioner), and nursing services outside the hospital. Nurses and doctors in preventive and long-term care services are usually employed in municipal health care [23]. Although the municipalities in Norway dedicate a significant part of their budgets to health services (about one quarter), the home care service struggles to meet an increasing demand for health care under the constraints of a restricted budget [24]. During 2016, there were 355,635 unique recipients of nursing and care services nationally, which equates to 6.7% of the Norwegian population. Of the unique recipients of nursing and care services, 85% received home-based services, and about 2.7 million visits ware performed every week [25].

The Intervention

This study was set in Oslo in 2018. The purpose of DigiHelse was to digitalize the dialogue between recipients and professionals in home care services in Norway through the development and implementation of a national Web-based platform. All recipients of home care services in four districts in Oslo were offered DigiHelse, in addition to regular services, in a one-year pilot project from autumn 2017 to the next year. The utilization of DigiHelse was completely voluntary. The project is based on the existing "Helsenorge.no" platform from the Norwegian Directorate of e-Health, which provides national digital health services. The realization of digital services in this project supports the overall objective of the development of information and communication technology in the health care sector to provide citizens with access to simple and secure digital services [26].

The intervention intends to cover the following objectives and needs:

- Support relatives who are involved in care tasks and strengthen the interaction between service providers and relatives through the possibility of secure digital dialogue and an overview of visits.
- Support service recipients in enhanced coping, safety, and involvement in their daily lives by providing an overview of visits and facilitating dialogue with the home care service, so that they can express their experiences and needs.
- Ensure that the home service can organize tasks more rationally and cooperate better with service recipients and relatives.
- Ensure that messages from relatives and recipients are captured and followed up with appropriately, such that phone inquiries are reduced, tasks can be registered at a more favorable time, and unnecessary trips to the recipient can be reduced.

Choice of Health Outcomes

Summary

In the concept stage of DigiHelse, a multidisciplinary team of stakeholders managed to identify both quantitative and qualitative outcome measures comparing the new solution to the current situation. Through scenario building, a present value calculation on socioeconomic impact was carried out. The outcome measures, based on each scenario elaborated on in the previous study of DigiHelse, are presented below.

Increased Predictability for Recipients

Notifications of appointments and any delays might give recipients a greater sense of predictability and greater confidence in the home care services. Digital services may also provide better information security for recipients than email and texting, thus more thoroughly safeguarding the privacy of the recipients. In the concept assessment, increased predictability gave a predicted annual value of €408.4 million (US $458.3 million) per year. This was based on the assumption that if the recipients knew the exact arrival time of their home service care, an hour waiting time per visit might be saved. This effect was not included in the present value calculation as the value of free time is debatable.

Increased Involvement From Relatives and Volunteers

Improved communication between relatives and the home service was assumed to amount to savings of €13.8 million (US $15.5 million) a year. For relatively self-sufficient recipients, relatives and volunteers may carry out one visit per month on average.

Increased Predictability of the Home Care Service

The assumption in the concept stage was that the staff in the home care service might be able to better manage their workday by using digital channels rather than the telephone. They may experience reduced time consumption for administrative tasks and have more time for preventive work. Increased predictability of the home service may also result in fewer unnecessary trips to the users, as unwanted visits may be easily canceled in the portal. With the ability of the user to digitally cancel and postpone visits, a reduction of 30% of unnecessary trips was estimated, which results in assumed savings of €3.8 million (US $4.3 million) a year.

Greater Dialogue Efficiency and Time Management

Through interviews with professionals from the home services, the stakeholders estimated potential administrative time savings in administrative time of 30 minutes per day, with an hourly rate of €46 (US $51.60) with digital communication, resulting in savings of €7.1 million (US $8 million) a year.

Reduced Phone Inquiries

The estimated impact of reduced phone inquiries may amount to €1 million (US $1.2 million) per year on a national basis. To assess whether the intervention may reduce phone inquiries that otherwise could be solved digitally, the project group conducted a phone survey in Oslo and Bergen. After the survey, a scenario where digital communication could reduce phone inquiries to the home service by 40% was built.

Provide a Technical Basis for Developing Digital Services

Providing a technological basis for developing digital services may result in a one-time saving of €18.25 million (US $20.5 million). If 50% of the municipalities in Norway each procure a platform, they will, on average, consume €100,000 (US $110,000) each, including procurement, infrastructure, licenses/rent, etc. This effect was not included in the present value calculation because the digitalization of home services is still not statutory in the country's municipalities.

In the present study, three outcomes (increased involvement from relatives and volunteers, increased predictability of the home care service, and reduced phone inquiries) were reassessed using empirical data from the one-year pilot in four districts in Oslo, and a control district. The remaining outcome measures will appear unchanged in the present value calculation, as will the unit costs of investment, training, and maintenance.

Data Sources

In this pilot assessment, descriptive behavioral data from the Web-based platform was collected to study the usability of the platform. Data points, such as the number of digital users, digital inquiries, and active users, were retrieved from the platform's server. In this study, we used behavioral data on the number of active users to study usability. All recipients in the intervention districts were offered the chance to log into the platform and create a profile. The number of active users is defined as the number of users who not only created a profile but also had interactions with the home care service in the platform. Aggregated data from the electronic patient record (EPR) system Gerica was retrieved to study changes in health consumption in the home care service in the four intervention districts and one control district in Oslo. Data collection was performed through three measurement points in time: at baseline (the week before the intervention), during the short period (15 weeks after the intervention), and over the total study period (52 weeks after the intervention). Data was collected on the number of visits of the home service to the recipient to assess if the intervention may give an incentive to increase involvement from relatives and volunteers in the care of recipients.

Further, to assess if the option to cancel unwanted trips in the portal may result in fewer unnecessary trips and increased predictability of the service, data was also collected on the number of unnecessary trips by the home care service to the recipient. An unnecessary trip is when the home service arrives at a recipient's home for a planned visit, and the recipient does not answer the door. Finally, to study if digital dialogue may reduce the number of phone calls to the home service, phone calls to the service were registered during the three measurement points. Input variables on the cost of the present value calculation are shown in Multimedia Appendix 1.

Data Analysis

A 10-year present value calculation model with a discount rate of 4% was used to estimate the potential value of the intervention. The potential value was first estimated every year, and by employing the cost of investment, training, and implementation pace, the overall value was calculated over ten years. The assumption of the 10-year life cycle is based on national recommendations from the Directorate for Financial Management [27]. The data from the intervention and control group was analyzed using the quasi-experimental difference-in-difference design to estimate the causal effect and to update the present value calculation. Such a design is typically used to estimate the effect of an intervention by comparing the changes in outcomes over time between a population exposed to the intervention (intervention group) and a population not exposed (control group) [28]. A Poisson regression analysis was used to fit the model, as the dependent variables are counts of events.

First, to test for an effect of the intervention, interaction models with dummy variables were used for the intervention and the period. To assess both the short-term and long-term effects, analyses were done separately for time points one week before the intervention versus 15 weeks after, and before intervention versus 52 weeks after. The number of those exposed to the intervention in the model corresponded to the number of home care recipients (user base) in each group because all recipients in the intervention group had, in principle, access to DigiHelse, and all analyses are based on aggregate data. The interaction coefficient between the intervention and the time period dummies indicates the effect of the intervention. Second, to assess the effect of the proportion of active users in the intervention districts, an interaction model with continuous-time and continuous rates of digital users was used in each district. Different rates of active digital users were then extrapolated to assess how this would influence the rates for visits, unnecessary trips, and phone calls, and thereby, the costs in the present value analysis. All calculations were done in kr and converted to euros based on the exchange rate from May 2018 (9.54) [29]. All analyses were performed in Stata 15.1 (StataCorp, College Station, Texas, United States) and Excel 2010 (Microsoft, Redmond, Washington, United States).

Results

Study Parameters

Table 1 and Table 2 show the demographic distribution and aggregate data from the EPR system Gerica for each of the intervention districts and the control district. District 2 has the highest percentage of active digital users. This district has a relatively high percentage of immigrants, but the lowest percentage of people under retirement age. The user base is the number of recipients of home care services in each district, and the digital users are the recipients who have logged in to the digital platform. The active digital users are the recipients who use the portal to actively administer their services and contact with the home care service. Finally, the demographic data shows the composition of people over retirement age and immigrants of the total population in each district.

Table 3 shows the rates for the number of visits, the number of unnecessary trips, and the number of phone calls extracted from the EPR system for every ten users. The rates in the intervention and control groups at baseline, after 15 weeks (short period), and after 52 weeks (total study period), with their associated percentage changes compared to baseline, are presented. Also presented are *P* values for whether the difference over time is significantly different between intervention and control, which corresponds to whether the intervention has an effect.

The intervention group had a 12% (8.32/69.33) higher rate for the number of visits at baseline (77.65) compared to the control group (69.33). After 15 weeks (short period), the rate for the number of visits in the control group increased by 7% (4.97/74.30). In the same period, the rate for the number of visits also increased in the intervention group by 6% (4.26/81.91; rate ratio=1.06; *P*=.59). In the total study period (after 52 weeks), the rate for the number of visits increased in the control group by 7% (5.05/74.38), but by 11% (8.77/86.42) in the intervention group (rate ratio=1.04; *P*=.10). Both unnecessary trips and phone calls had a lower rate at baseline in the intervention group (19%) compared to the control group (28%) at baseline. However, over time the rates were further reduced in the control group compared to the intervention group for both unnecessary trips and phone calls.

Over the 52 total weeks of the study period, unnecessary trips decreased in the control group by 33% (–0.21/0.42), and the rate for unnecessary trips reduced in the intervention group by 10% (–0.05/0.46). This is still less than in the control group, with a rate ratio of 1.37 *(P*=.26*)*. Phone calls were reduced in the control group by 2% (–0.05/2.66) and increased in the intervention group by 22% (0.42/2.36), by a rate ratio of 1.24 (*P*=.08*)*. In conclusion, all point estimates indicate that the intervention increases the rates for all outcomes, although none of the intervention effects were significant.

Table 1. Description of user base.

Users	District 1	District 2	District 3	District 4	Control
User base, n					
Baseline	812	667	746	1073	590
Short period	874	684	741	1064	607
Long period	863	662	802	1078	600
Digital users, n					
Baseline	0	0	0	0	0
Short period	19	46	32	33	0
Long period	442	269	382	351	0
Active digital users, n					
Baseline	0	0	0	0	0
Short period	7	15	23	21	0
Long period	21	21	36	43	0

Table 2. Demographic data of user base.

District	Population, N	Over retirement age, n (%)	Immigrants, n (%)
1	57,000	6954 (12.2)	15,960 (28)
2	36,000	1836 (5.1)	12,600 (35)
3	49,200	5806 (11.8)	17,220 (35)
4	49,800	6823 (13.7)	8964 (18)
Control	51,400	2878 (5.6)	20,046 (39)

Table 3. Outcome rates in the intervention and control groups for every ten users.

Outcome	Baseline (week 0)	Short period after intervention (after 15 weeks)	Short period change, rate (%)	*P* value	Total study period (after 52 weeks)	Long-period change, rate (%)	*P* value
Rate of visits							
Intervention	77.65	81.91	4.26 (6)	—	86.42	8.77 (11)	—
Control	69.33	74.30	4.97 (7)	.59	74.38	5.05 (7)	.10
Rate of unnecessary trips							
Intervention	0.51	0.41	–0.1 (–20)	—	0.46	–0.05 (–10)	—
Control	0.63	0.48	–0.15 (–24)	.83	0.42	–0.21 (–33)	.26
Rate of phone calls							
Intervention	1.94	1.81	–0.13 (–7)	—	2.36	0.42 (22)	—
Control	2.71	2.64	–0.07 (–3)	.75	2.66	–0.05 (–2)	.08

Incremental Costs and Outcomes

In the prior concept stage assessment of the project, a 90% adoption rate of the digital portal DigiHelse was assumed. Applying behavioral data made available from the platform's server revealed that the adoption rate after the one-year pilot was not as expected. Only 3.55% (121/3405) of active users were registered in the data, which makes it a challenge to both predict whether the precision and the fit of the concept model were good and compare the present value calculation with and without empirical pilot data. As such, the present analysis may only show that the control district improved over time compared to the intervention districts and that the adoption rate of the intervention was considerably lower than expected. From the difference-in-difference analysis, a 37% (0.46/0.34) increase in the rate of unnecessary trips in the intervention group was found, but this was given the observed adoption rates of around 3.55% (121/3405). Using continuous-time and adoption rates in the model and extrapolation to 50% active digital users, the effect of the intervention would have been a 128-fold yearly increased rate of unnecessary trips. The same trend was found for the number of visits. When extrapolating for 50% of active digital users, the effect of the intervention would be a 1.04 times higher increase in the intervention group compared to the control group. Finally, if there were 50% active users, the effect of the intervention would be a 55-fold increase in the phone call rate.

When including the outputs from the difference-in-difference model comparing the intervention and control group into the present value calculation model from the concept stage, the estimated value of the intervention changes radically (see Multimedia Appendix 2). The net present value of the intervention after adding data form the pilot is reduced by €241.8 million (US $271.3 million) over ten years from the first assessment, resulting in a loss of €62.2 million (US $69.8 million) over ten years. Based on the present pilot assessment, costs are expected to exceed potential savings by €67 million (US $ 75.2 million) over ten years, compared to potential gains of €172.6 million (US $ 193.7 million) from the prior concept assessment.

Discussion

Primary Findings

Through a case of early HTA employing empirical data from a pilot study, the present study updated effect estimates made in the concept stage of the development of DigiHelse. Based on the present pilot assessment, costs are expected to exceed potential savings by €67 million (US $75.2 million) over ten years, compared to potential gains of €172.6 million (US $193.7 million) from the first assessment. After one year, only 3.55% (121/3405) of recipients used the platform actively. The prior socioeconomic analysis, conducted in the concept stage of DigiHelse, was based on stakeholder insight and scenario drafting. Collecting empirical data from the one-year pilot of DigiHelse, the present study evaluated the potential value of the intervention and assessed the precision of early HTA using stakeholder analysis and scenario drafting. Three of the outcome measures identified in the first study constituted the basis for the difference-in-difference analysis, and related costs were analyzed using a 10-year present value calculation with a rate of 4%. We found a significant gap between the estimated value in the concept stage of DigiHelse and the estimated value using empirical data from the one-year pilot.

This may indicate that early assessment using stakeholder insight and scenario drafting applied in the concept stage was less precise than expected. Another explanation may be, at least in part, suboptimal pilot implementation, as it is known that adoption and diffusion of eHealth solutions may be time-consuming and require significant adaptation of work practices [30]. However, by assessing behavioral data on the actual use of the platform, an important issue likely to affect the outcome of the assessment was found: a very low rate of DigiHelse users among recipients of home care services. This may explain why there was no significant change in the outcome measures between the control and the intervention districts after the pilot.

A review study highlighting methodological challenges in early HTA emphasizes both the lack of proof on the efficacy of the methods and the absence of a standardized framework for early assessments [20]. Empirical and theoretical attempts have been made to fill the evidence gaps in early assessment modeling, with theoretical recommendations on the use of sophisticated mathematical techniques such as Bayesian modeling or Markov modeling [31-34]. Empirical models based on scenario drafting and expert elicitation have also been used to compensate for the lack of data and steer the innovation in the right direction [31,35-38].

Findings from the review showed how stakeholder insights and scenario drafting might be used in an early phase to collect data on patient outcomes and effects on costs [17,39,40]. However, there are some presented concerns are, such as the high uncertainty regarding the availability of adequate data sources for modeling outcomes and that the models suffer from the precision required for data input [31,41]. Although a strength of the present study was the availability of concept stage assumptions and assessment based on stakeholder insights and scenario drafting when empirical data from the present pilot were analyzed, lack of precision was found. In line with similar research on the subject, we found that early-stage analyses may suffer from loss of information, as they are unable to reflect all possible outcomes [39,42]. Further, it cannot be excluded that stakeholders may be positively biased towards the value of the technology in which they have a particular interest [43]. This may explain the identified gap between the estimated socioeconomic value and the value assessment based on empirical pilot data in the present study.

While the low acceptability rate among recipients of the home care service in Oslo was an important concern found in the present study, other studies addressing the acceptance of eHealth solutions tested in clinical settings have indicated high patient acceptability rates [44-46]. However, it is unclear how the adoption rate of eHealth solutions may be affected once the technology is moved outside the boundaries of the clinic and is implemented in users' homes. Discrepancies in access to the internet and technological literacy in different subgroups may influence the adoption rate and, thus, the estimated improvement in efficiency and cost reduction expected from the implementation of eHealth [47-49]. Identified subgroups that are especially challenged by eHealth solutions are the elderly [47,48], minorities [49], and the socioeconomically disadvantaged [48,49].

Effective adoption among users is a prerequisite for successful implementation, and the effectiveness of eHealth is compromised if the solutions are suboptimally implemented. Discomfort with the new technology and a preference for well-known, earlier provided services are reasons reported to influence the adoption of eHealth technologies [50,51]. Qualitative methods are needed to explore the experienced discomfort about or preference for existing analog health services. Such methods are increasingly being explored to accompany quantitative assessments of complex innovations to provide a deeper understanding of the adoption of eHealth [52]. While quantitative methods explore relationships between digitalization and disease outcomes, qualitative methods may provide a deeper understanding of contextual factors influencing these relationships, such as information on drivers and barriers to technological implementation [53].

The engagement of end-users in collaboration with product developers may succeed in increasing acceptability in particularly vulnerable groups by incorporating favorable eHealth designs to overcome barriers, although this may not be sufficient [54]. Predictive behavioral data represents another important tool, as it provides valuable information on the usability of a digitalized service and its corresponding population, and thus may determine whether the predefined intent of the new service is met. The digitalization of services in health care provides a new, potentially valuable data source as real-time data can be extracted and analyzed at any time [55]. According to the Lean Startup framework, behavioral data from initial testing provides essential information on how the market will respond to a service or a product [56]. Measuring quantifiable behavioral data outcomes provides an opportunity to assess usability [57]. Qualitative information on the directions of the developmental improvements of services may then be assembled from the same study sample. This allows for iterative modifications and adaptations at the initial project phase to avoid the implementation of ineffective services. Through this process, the likelihood of developing a user-centric service which complies with market expectations may increase as the early assessment of behavioral data provides the ability to test whether the service meets its initial intent and contributes to value-based health care [56].

Limitations

There are several limitations of this study. Firstly, health economic analysis commonly presents results as cost per patient. The present analysis applied the net present value of the presented investment, weighting potential benefits against investment costs. In this case, the model was chosen due to the significant heterogeneity among recipients receiving home services and the early nature of the analysis.

Further, a quasi-experimental design was used. This means that many confounders may affect the results, such as changes over time independent of the intervention, aging in the population, and heterogeneity between the intervention and control groups. The homogeneity of the districts in the analysis may also be questioned due to the baseline data. To increase the representativeness of the selected control group, data could preferably have been collected from more than one control district. An increased number of measurement points before the intervention would have provided an opportunity to assess trend assumptions between the control and intervention group, which is crucial for difference-in-difference analyses.

Further, if the behavioral data had shown a higher adoption rate, both these issues would have been resolved before the difference-in-difference analysis. In addition to empirical results, the present value model could have been used to predict the socioeconomic outcomes if the adoption rate was 90%. However, given the unexpectedly low adoption rate, collecting more measurement points, and performing a sensitivity analysis of the findings was deemed futile. It should also be taken into consideration that the value of DigiHelse was calculated on a national basis, although, due to the Norwegian municipal health budget autonomy, it is uncertain whether all municipalities will implement the service. A final limitation of this study is that the analyses are based on aggregated numbers and not individual data. On the positive side, the database is larger than typical pilot studies; however, it comes with an inability to connect data sources to adjust for confounders on the individual level.

Conclusion

Measuring objective behavioral data provides an important source to assess usability. This study reported on the attempt to evaluate methods for early HTA by reassessing DigiHelse by comparing pilot intervention data to a corresponding control group. In this pilot study, the low adoption rate may, at least in part, explain the inability of the DigiHelse pilot to perform as expected. This study points to an early assessment of behavioral data as an opportunity to identify inefficiencies and direct digital development. Implementing eHealth solutions is known to be challenging and time-consuming. To ensure adoption, effective diffusion strategies are needed, including user training programs. For DigiHelse, learning strategies may be targeted to increase adoption in the next phase.

The integration of behavioral data in early planning and assessment provides an opportunity to address implementation challenges and user adherence, where early HTA modeling has a purpose. For DigiHelse, insight into why the recipients in Oslo have not made greater use of the Web-based platform seems to be the next step in ensuring the right improvement measures for the home care service. We encourage more research on early HTA and the use of behavioral data in case studies as tools to empirically demonstrate eHealth intervention benefits.

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Authors' Contributions

LNS and TM conceived, designed, and performed the experiments. LNS and TM analyzed the data. LNS authored the manuscript. KJK and KK critically reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Summary of cost units.
[DOCX File , 18 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Summary of priced effects in the concept phase and after the pilot phase.
[DOCX File , 18 KB-Multimedia Appendix 2]

Multimedia Appendix 3

CONSORT EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3533 KB-Multimedia Appendix 3]

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Abbreviations

eHealth: electronic health
EPR: electronic patient record
HIT: health information technology
HTA: health technology assessment

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