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Method

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Early assessment of innovation in a healthcare setting

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Abstract

Objectives. Early assessment can assist in allocating resources for innovation effectively and produce the most beneficial technology for an institution. The aim of the present study was to identify methods and discuss the analytical approaches applied for the early assessment of innovation in a healthcare setting.

Methods. Knowledge synthesis based on a structured search (using the MEDLINE, Embase, and Cochrane databases) and thematic analysis was 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 decided among the authors. Identified methods and analysis were discussed according to the innovation stage.

Results. A total of 1,064 articles matched the search strategy. Overall, thirty-nine articles matched the inclusion criteria. The use of methods has a tendency to change according to the stage of innovation. Stakeholder analysis was a prominent method in the innovation stages and particularly in the developmental stage, as the introduction and early diffusion stage has more availability of data and may apply more complex methods. Barriers to the identified methods were also discussed as all of the innovation stages suffered from lack of data and substantial uncertainty.

Conclusions. Although this review has identified applicable approaches for early assessment in different innovation stages, research is required regarding the value of the available data and methods and tools to enhance interactions between different parties at different stages of innovation.

As the importance of innovative technology expands in the healthcare sector, new practices and organizations are constantly evolving. New technology enables the refinement and personalization of existing healthcare practices, which have the potential to prevent grave diseases and save more lives. Although the technological revolution within health care shows great potential, not all innovations serve their purposes (1). Documenting the effects of healthcare innovation is, therefore, essential in prioritizing adequate technology implementation. Unlike the product cycle of pharmaceuticals, where the timeframe from development to implementation can take several years, technology-enabled and organizational innovation in the healthcare sector move at a much faster pace (2). The methods for value assessment and priority settings, therefore, need to be adapted to a faster product cycle with a greater diversity of products.

Over the past few decades, validated methodology such as health technology assessment (HTA) has contributed to sound decision making worldwide. HTA is defined as an interdisciplinary process for synthesizing information regarding medical, social, economic, and ethical issues related to the introduction of new health technology (3). Although HTA methods and approaches have been subject to significant improvements over time, there are several challenges in the field of health technology assessment (4). HTA is deemed a robust method for technology in 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. Hospital-based HTA (HB-HTA) is an approach adapted to inform decision makers at different levels in a hospital setting and ensure acceptability at a local level. This includes processes and methods used to produce HTA reports in and for hospitals (5). Although this assessment and management tool successfully addresses decision making at an institutional level, more research is necessary to identify sustainable innovative ideas and products in the healthcare system (6). In promoting innovation in the healthcare sector, research should be dedicated to methods and approaches for early assessment to allocate public support effectively and produce the most beneficial technology for society.

Table 1. Inclusion and Exclusion Criteria

	Inclusion	Exclusion
Study type	All articles with ISBN and ISSN numbers: Descriptive design (survey, qualitative), Experimental (RCT, quasi RCT, crossover), Review design (systematic review, narrative review, meta-analysis), Observational analytic (cohort study, cross sectional, case-control study), Explorative, etc.	• Articles and papers without ISBN and ISSN numbers • Language not in English, Norwegian, or Danish
Technology (population)	• Non-invasive technology and organizational innovation	• Pharmaceuticals, invasive technology, surgical procedures
Intervention	• Methods for assessment of early stage / early assessment • Assessment related to the health sector	• Not involving early assessment • Only relevant for manufactures/ industry
Outcome	Methods (theoretical or empirical) for early assessment of health innovation: strategic analysis, economic analysis, clinical analysis	

The international network EuroScan, a collaborative network for information exchange on important emerging new drugs, devices, procedures, programs, and settings in health care, is currently evaluating the consequences of early technology assessments on the diffusion of new technologies in the healthcare sector. An article from the network states that early awareness is increasingly becoming an important component in decision making, implementation, and the spread of new health technology (7).

Although limited, an increasing number of reports on the methods of early assessment can be found in the literature. Many of these studies take an industry perspective, emphasizing market entry and reimbursement (8). Both individual studies and review papers broach the subject of early assessment of medical technology (9;10). Fasterholdt et al. (10) 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 service innovation in a healthcare setting is less embodied in the literature. A service innovation can consist of both a technology-enabled reorganization of the health supply or simply an organizational 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, reorganizing the health supply such that a healthcare worker measures blood sugar levels at the patients' homes would also be a service innovation in terms of an organizational innovation.

The aim of the present study was to identify methods and discuss the analytical approaches applied to the early assessment of innovation in a healthcare setting, with a particular focus on technology-enabled and organizational innovations. The characteristics of the analytical approaches applied will be discussed according to the stage of innovation.

Methods

A knowledge synthesis based on a structured search and thematic analysis was conducted to identify early assessment methods used to evaluate innovation in the healthcare sector. This review attempts to summarize existing studies on a specific topic to improve understanding and identify research gaps to define future research. The knowledge synthesis also seeks to address broader topics, where a diversity of study methodologies and designs exist and synthesize the findings narratively.

Search Structure

The review was structured according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (11). The review of the articles was accomplished in two consecutive screenings. (i) Articles reporting on the early assessment of innovation in the health sector (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 (ii) articles reporting on methods or practices for the early assessment of health innovations (articles were excluded if they did not report on the early assessment of technology-enabled or organizational innovation). Detailed inclusion and exclusion criteria are shown in Table 1.

Identifying the Research Issues

Based on the health technology assessment (HTA) definition of the International Network of Agencies for Health Technology Assessment, "early assessment of medical devices" can be defined as the early examination of the medical, economic, social, and ethical implications of the medical device to determine the potential of incremental value in health care (12). The research aim was to identify methods for the assessment of early assessment of technology-enabled and organizational innovation in a healthcare setting and discuss the analytical approaches applied according to the stage of innovation (development, introduction, and early diffusion).

Identifying Relevant Studies and Study Selection

A literature search was conducted in January and February 2017 of the major medical reference databases (MEDLINE Ovid and Embase Ovid). Due to the limited amount of literature on this topic, we did not set a limit on the publication date. The protocol, search strategy, and literature search were elaborated and undertaken in collaboration with a librarian with vast experience in knowledge-based synthesis.

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The search was accomplished using a combination of controlled vocabulary (medical subject headings and Emtree terms) and text words. The search strategy for MEDLINE was built using the MeSH term "Technology Assessment, Biomedical" and synonyms and near-synonyms thereof combined with the text words "early," "pilot," "novel," or "first-stage" or "first-phase" or "horizon." This search component was then combined with search terms covering various methods and theories using MeSH terms such as "Decision Support Techniques" OR "Cost Benefit Analysis" OR "Risk Assessment" and text word equivalents. The MEDLINE search strategy was translated and adjusted and then conducted in Embase.

A similar search was conducted in Cochrane Library using the keywords "Technology Assessment, Biomedical" combined with the text words "early, pilot, novel,".. Due to the novelty of the topic and that Cochrane Library is a database for systematic reviews, the search resulted in significantly fewer outcomes. The complete search is visible in the Supplementary Material.

Although the search identified literature from the EuroScan network, much of this literature was excluded as it mainly concerned horizon scanning and early alert systems which is not subject of this review.

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 LNS 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.).

Charting the Data and Collating, Summarizing, and Reporting the Results

The data were 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. 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 analyzed using templates developed iteratively with feedback from the other authors (K.K. and T.M.).

Data Collection: Framework and Themes

The following categories of data were extracted.

Stage of Innovation

Based on how Ijzerman and Steuten (13) distinguished early HTA in different stages, this review divided the innovation process into the following three stages: the developmental stage, the introduction stage, and the early diffusion stage. The developmental stage is when an innovation is in a concept phase and is not yet piloted. The introduction stage is when the innovation is undergoing the first pilot. A pilot study is normally a small test with a few patients in which the innovation is tested. Finally, the early diffusion stage is when the pilot is transferred or extended to other populations or locations.

Type of Innovation (Technology-enabled or Organizational Innovation)

Type of Study (Theoretical or Empirical)

Study Design

Type of analysis

The identified articles 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.

Methods (Qualitative or Quantitative)

Main Target Audience

An attempt was made to identify whether the assessment targeted the following audience groups: decision makers on implementation, patients/users, healthcare personnel, or innovators.

Results

Literature Retrieval

Figure 1 is a flow chart of the literature selection process. In total, the literature search yielded 1,064 papers and 373 duplicates that were excluded. Upon reviewing the 691 abstracts, 638 papers were excluded on the basis of the following criteria: not used in the healthcare sector, not an early assessment of technology-enabled or organizational innovation, and language not in English, Norwegian, or Danish. After the first exclusion of abstracts, fifty-three articles were included in full text. Based on relevance, an additional twenty-one papers were excluded. A total of thirty-two articles met the inclusion criteria, while a further seven articles were included based on screening of their reference lists.

Table 2 describes the data extracted from the included studies and summarizes the analyses of the early assessment models. Twelve studies presented the early assessment of technology that was still in the developmental stage. Fourteen studies assessed technology in the introduction stage. Thirteen papers were included in the early diffusion stage. Twenty studies presented early assessments of medical devices, while only seven studies dealt with organizational innovation alone. Twelve studies evaluated both medical devices and the consequential organizational innovation. Table 2 shows that the included articles consisted of twenty empirical studies and nineteen theoretical studies.

The main target audience of the evaluation was based on the authors' interpretation of who was likely to benefit the most from the assessment. A majority of the articles addressed decision makers on implementation as the main target audience of the assessment, equaling 36 percent of the included studies (14/39). Eleven studies targeted innovators as the main target audience, resulting in 28 percent of the included studies (11/39). A total of 26 percent of the studies targeted healthcare providers as the main audience (10/39). Only 10 percent of the studies targeted patient/users as the main audience (4/39).

Analysis of Early Assessment Models Identified: Variation in Methods Depending on Stage of Innovation

This section describes the type of analyses identified based on the innovation stage, the analytical framework used to guide the study. The methods for early data collection and assessment were categorized as qualitative ($n = 15$), quantitative ($n = 12$), and mixed method ($n = 12$). The studies 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

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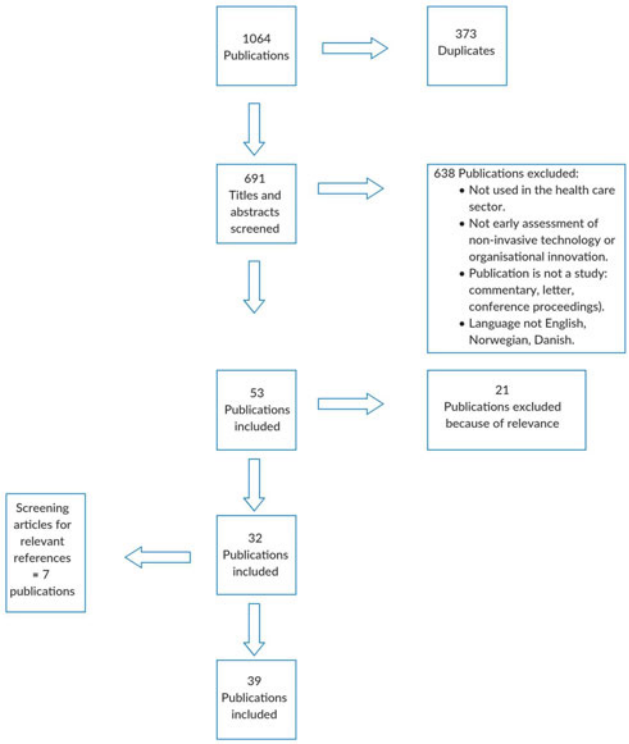

Figure 1. Overview of the inclusion process.

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.

Developmental Stage

A majority of the articles presented a combination of strategic, economic, and clinical analyses ($n = 6$). Two studies were categorized as economic analyses, one as strategic and one as clinical. One study combined strategic and clinical analyses and one combined economic and clinical analyses. The empirical articles used analytical approaches that reflected the amount of data available and the intention of the assessment in each stage. The methods applied in the developmental stage stressed the need to generate more data. Quantitative simulations based on scenario drafting applied qualitative data from stakeholder insights, expert opinions, and focus groups to provide insights into the reality of an innovation (14–17). The theoretical studies in the developmental stage recommended more complex quantitative models such as Markov modeling, Bayesian modeling, and clinical simulations, as well as strategic models such as political, economic, socio-cultural, and technological (PEST) and strengths, weaknesses, opportunities, and threats (SWOT) analyses (13;18–20). Although these analytical approaches are applicable with scarce data, they are more resource intensive than the methods applied by the empirical articles.

Introduction Stage

In this stage, the greater part of the studies focused on strategic analysis ($n = 4$). Two studies consisted of economic analyses, three consisted of clinical analyses, and three consisted of the combination of all three analyses. Two studies had a combination of clinical and strategic analysis. In the empirical studies, this stage was characterized by a mixture of preliminary data collection and estimates. Quantitative and qualitative methods for assessment and data collection such as closed questionnaires, focus groups, and semi-structured interviews were frequently used to both capture the impact for the users and facilitate the innovation process (17;21–24). Literature reviews also provided insight when a small amount of data was available (25;26). The theoretical studies highlighted case studies with subsequent economic modeling as an applicable approach to collect and analyze data (27;28).

Early Diffusion Stage

This stage showed a prevalence of studies including all three analyses ($n = 6$). One study had an economic analysis, three had strategic analyses, one combined strategic and economic analyses, and one combined strategic and clinical analyses. The empirical studies placed greater emphasis on quantitative cost-effectiveness models, implementation and diffusion scenarios, and the logistics associated with the intervention (29;30). However, among the theoretical studies, the importance of qualitative approaches to data collection such as expert opinion and stakeholder analysis were highlighted (31;32). Table 3 is a descriptive table on the identified analytical approaches.

Stakeholder Involvement for Data Generation in Early Health Technology Assessment

In the developmental stage, simulations based on stakeholder analysis and expert interviews were used to understand the effect of innovation on the target population, organization, and society. In the introduction stage, stakeholder analysis provided additional data to scenarios for simulations on the adaption and development of innovation. In the early diffusion stage, the analytical approaches placed greater emphasis on implementation and dissemination scenarios.

An early innovation stage is characterized by a small amount of data and high uncertainty. Stakeholder insight was, however, highlighted to assess the potential benefit of health innovation (19;27;31;33). Harris-Roxas and Harris (27) found that stakeholders' views regarding potential benefits are central for assisting the assessment of an innovation and also for the prioritization of effects. Such data can potentially ease adoption and diffusion through steering the intervention to achieve value-based innovation (34). This suggests that the innovation should be assessed in the context where it will be used to disclose how it is adopted and used in the real world.

Stakeholders can provide data on the underlying logic of an innovation to help understand changes in outcomes in the target population at an organizational level. Such data can provide valuable information on the potential suitability of the innovation (29). Stakeholder data can be applied in scenario analysis to provide necessary outcome overviews and direct and accelerate the procurement process (35). Through integrating qualitative scenarios from the perspective of stakeholders and experts into a cost-effective model, the potential value of the innovation can be estimated in an early phase (22). Retel et al. (22) 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.

Evidence Gaps and Uncertainty in Early Economic Modeling

Economic modeling of the trade-off between further technological development and the value of investing more research appears

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Table 2. Description of the Data and Data Analysis

Author (year)	Stage of innovation	Type of technology	Type of article	Study design	Analysis	Method
Bridges (2006)	Development	Both	Theoretical	Exploratory design	Strategic analysis	Qualitative
Markiewicz et al. (2014)	Development	Non-invasive	Theoretical	Review design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative/ Quantitative
Postmus et al. (2011)	Development	Non-invasive	Empirical	Cost-effectiveness analysis	Economic analysis	Quantitative
Ijzerman et al. (2011)	Development	Non-invasive	Theoretical	Review design	Strategic analysis/ Economic analysis/ Clinical analysis	Quantitative
Steuten (2016)	Development	Non-invasive	Theoretical	Descriptive design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative
Niederlander et al. (2013)	Development	Non-invasive	Empirical	Descriptive design	Clinical analysis	Quantitative
Retèl et al. (2014)	Development	Organizational	Theoretical	Descriptive design	Economic analysis	Qualitative/ Quantitative
Banta et al. (1987)	Development	Non-invasive	Theoretical	Exploratory design	Strategic analysis/ Clinical analysis	Qualitative/ Quantitative
Bartelmes et al. (2009)	Development	Non-invasive	Theoretical	Review design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative/ Quantitative
Gantner-Bar et al. (2014)	Development	Organizational	Empirical	Case study design	Strategic analysis/ Economic analysis/ Clinical analysis	Quantitative
Cosh et al. (2007)	Development	Non-invasive	Theoretical	Review design	Strategic analysis/ Economic analysis/ Clinical analysis	Quantitative
Girling et al (2010)	Development	Non-invasive	Theoretical	Case study design	Economic analysis/ Clinical analysis	Qualitative/ Quantitative
Harris-Roxas et al. (2007)	Introduction	Both	Theoretical	Exploratory Design	Strategic analysis	Qualitative
Craig et al. (2015)	Introduction	Non-invasive	Theoretical	Review design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative/ Quantitative
Porzsolt et al. (2009)	Introduction	Both	Theoretical	Exploratory design	Strategic analysis	Qualitative
Retèl et al. (2012)	Introduction	Non-invasive	Empirical	Cost-effectiveness analysis	Strategic analysis/ Economic analysis	Qualitative
Gaultney et al. (2011)	Introduction	Non-invasive	Empirical	Cost-effectiveness analysis	Strategic analysis/ Economic analysis/ Clinical analysis	Quantitative
Di Capua et al. (2016)	Introduction	Both	Empirical	Survey design	Clinical analysis	Qualitative
Chang and McLean (2006)	Introduction	Non-invasive	Empirical	Case study design	Clinical analysis	Quantitative

(*Continued*)

Table 2. (*Continued.*)

Author (year)	Stage of innovation	Type of technology	Type of article	Study design	Analysis	Method
Brear (2006)	Introduction	Both	Empirical	Descriptive and comparative design	Strategic analysis/ Clinical analysis	Qualitative/ Quantitative
Sayres et al. (2012)	Introduction	Organizational	Empirical	Survey design	Strategic analysis	Qualitative
Jastremski et al. (1995)	Introduction	Non-invasive	Empirical	Case study design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative
Beuscart-Zephir et al. (2002)	Introduction	Organizational	Theoretical	Case study design	Strategic analysis	Qualitative
Kip et al. (2016)	Introduction	Non-invasive	Empirical	Case study design	Economic analysis	Qualitative/ Quantitative
Hartz (2009)	Introduction	Non-invasive	Theoretical	Review design	Economic analysis	Quantitative
Gollamudi et al. (2016)	Introduction	Non-invasive	Empirical	Randomized controlled trial	Clinical analysis	Quantitative
Abrishami et al (2015)	Early diffusion	Both	Theoretical	Exploratory design	Strategic analysis	Qualitative
Esposito et al.(2009)	Early diffusion	Organizational	Empirical	Mixed method design	Strategic analysis/ Economic analysis	Qualitative/ Quantitative
Henshall et al. (2013)	Early diffusion	Both	Theoretical	Descriptive design	Strategic analysis	Qualitative
Retèl et al. (2013)	Early diffusion	Non-invasive	Empirical	Cost-effectiveness analysis	Strategic analysis/ Economic analysis/ Clinical analysis	Quantitative
Van de Wetering et al. (2013)	Early diffusion	Both	Theoretical	Cost-effectiveness analysis	Economic analysis	Quantitative
Kummer et al. (2012)	Early diffusion	Both	Empirical	Experimental design	Strategic analysis	Qualitative
Retèl et al. (2008)	Early diffusion	Both	Empirical	Case study design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative/ Quantitative
Manetti et al. (2015)	Early diffusion	Non-invasive	Empirical	Randomized controlled trial	Strategic analysis/ Economic analysis/ Clinical analysis	Quantitative
Gagnon et al. (2014)	Early diffusion	Organizational	Theoretical	Survey design	Strategic analysis	Qualitative
Retèl et al. (2009)	Early diffusion	Both	Theoretical	Review design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative
Joosten et al. (2016)	Early diffusion	Organizational	Empirical	Case study design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative/ Quantitative
Douma et al. (2007)	Early diffusion	Both	Empirical	Case study design	Strategic analysis/ Economic analysis/ Clinical analysis	Qualitative/ Quantitative
Retèl et al. (2009)	Early diffusion	Both	Empirical	Survey design	Strategic analysis/ Clinical analysis	Qualitative

Table 3. Description of Analytical Approaches

Analytical approach	Method	Enablers	Barriers
Stakeholder analysis	Qualitative	The process of the assessing a decision's impact on relevant parties and the parties impact on the decision, by weighing and balancing all of the competing demands.	The utility of this analysis is in assisting a decision process is subjective and time-limited and should be complemented by other analysis approaches.
Scenario analysis	Qualitative/ quantitative	The process of analyzing possible future events by considering alternative possible outcomes, combining optimistic, pessimistic, and more and less probable developments.	Scenario analysis struggle with loss of information and the risk to not cover all outcomes in a real world system
Cost-effectiveness analysis	Quantitative	A form of economic analysis that compares the relative costs and outcomes (effects) of different courses of action.	Early assessment 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	Qualitative	The synthesis of opinions of authorities of a subject where there is uncertainty due to insufficient data.	There is no universal method for expert elicitation and different approaches may lead to different results.
Sensitivity analysis	Quantitative	The study of how the uncertainty in the output of a model can be apportioned to different sources of uncertainty in its inputs.	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	Qualitative/ quantitative	Technology assessment which takes into account the social problems surrounding technology by including a large diversity of actors in technological design and implementation processes, with emphasis on social actors.	This framework has been criticised for its lack of structure in including sufficient public participation, as patients or users, in the decision process.
Bayesian modeling	Quantitative	Statistic modelling which include evidence about the true state of the world expressed in terms of degrees of belief known as Bayesian probabilities.	These models require data, competence and can be difficult to implement in practice. It can be challenging to define a prior.
Markov modeling	Quantitative	Stochastic model used to model randomly changing systems where it is assumed that future states depends only on the current state.	Markov models are 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	Quantitative	Is the amount a decision maker would be willing to pay for information prior to making a decision.	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	Quantitative	A situation in which an investor is able to choose between two different investments where both choices involve tangible assets, typically a trade-off of investing in development of more research.	The alternative practice must be well defined and understood, data issues arise when estimating key model inputs, since the value or price of the underlying cannot be directly observed.
PEST analysis	Qualitative	Political, economic, socio-cultural, and technological analysis, describes a framework of macro-environmental factors used in strategic management.	This analysis requires a great amount up-to-date data on external factors to be collected and the viability of the analysis is time-limited.
SWOT analysis	Qualitative	A study undertaken by an organization to identify its internal strengths and weaknesses, as well as its external opportunities and threats.	This analysis does not prioritise the issues identified in the four areas and crucial data may be overlooked

largely in the developmental and introduction stage. The studies which contained economic analyses in the early diffusion stage were used to steer the implementation and facilitate proper investments.

It is believed that early economic analysis of an innovation's likely cost-effectiveness can help steer the implementation and restrain resource-inefficient technologies (36). Numerous attempts to fill evidence gaps in early economic models were detected in the literature. Expert elicitations using scenario drafting can provide qualitative and quantitative data to fill the evidence gaps in early health technology assessment (15;23). Potential economic consequences can be estimated to forecast the effects of healthcare innovations already at the early research and concept phase to prevent ineffective investments (14;24;35).

Scenario drafting can also be useful for identifying critical factors that may affect the speed of adoption (37). To account for the dynamic characteristics of an early innovation, future technological development, organizational change, and learning curves should be incorporated into the models (38;39). Studies pointed to the use of sensitivity analysis to deal with uncertainty in the interpretation of results and to test the impact of different implementation strategies when the technology is still dynamic (14;18;24;26;38;40).

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Constructive technology assessment that takes into account the learning curve seems to be appropriate in the early assessment of technologies that are still dynamic (19;22;41–43). Modeling based on sophisticated mathematic techniques such as Bayesian modeling or Markov modeling can also play an important part in early decision support and provide incentive for data collection before implementation. Use of such models in early economic modeling can help determine which efficacy and clinical performance has to be attained for different cost outcomes (19;36;39;44).

Uncertainty is an issue in all decisions; information is valuable because it reduces the expected cost of uncertainty surrounding decisions. Value of information (VOI) analysis recognizes the option to postpone the adoption or development of the technology and investing in more research to reduce uncertainty. Waiting may, however, result in health benefits forgone, and developing before conducting research may also reduce uncertainty (13;36;44). Real option analysis (ROA) can be useful for establishing the trade-off between development and research (13;19;20;44).

Clinical Efficacy in Trials with a Small Amount of Data

Articles containing clinical analyses were primarily found in the developmental stage. Assessing clinical efficacy in early stages can be challenging. Randomized clinical trials (RCTs) have long been considered the gold standard in assessing clinical outcomes. However, RCTs can have limitations, especially for evaluations of early stage interventions (45). RCTs require a large amount of data and, therefore, consume time and resources. The difficulty of blinding was also evident in the literature on the assessment of technology-enabled and organizational innovation. The literature, however, pointed out some applicable methods. Clinical trial simulations based on prior clinical outcomes can supply information otherwise unavailable in early stages (13;36;46;47). Input data for clinical simulations can also consist of expert opinions or a structured literature search on clinical outcomes (14;35;38;48). Clinical trials performed in a controlled laboratory setting, such as bench studies, were also highlighted in the literature to reduce uncertainty regarding the efficacy of clinical outcomes (18).

User Involvement

Involvement of potential users of an innovative technology in the early stages could make assessments more relevant and acceptable (49). Although users or patients should be an important part of a stakeholder analysis, this is not always the case. Stakeholders are all the affected parties of an innovation, for example, an innovator, decision maker at the hospital or municipality, purchase unit, etc. A user is the one who directly uses the innovation. In this review, only 10 percent (4/39) of the studies targeted patients or users as the main target audience of the analysis. Early analysis and modeling of outcomes from user involvement in early assessment helps prevent failures and can accelerate implementation (16). Gollamudi at al. (50) addressed the significance of user and health data collected through mobile devices. Such data allow individuals the opportunity to make informed health decisions and provide researchers and decision makers the opportunity to assess innovative health technology in real time. Smartphone-enabled health technologies provide a novel source of data for qualitative and quantitative analysis purposes.

Discussion

The purpose of this knowledge synthesis was to identify methods for early assessment of innovation in a healthcare setting and discuss the analytical approaches applied according to the stage of innovation. As illustrated in the Results section, several 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 analyses. However, no article validated the specific methods used for early assessment against a technology assessment completed in later phases with additional data. In the earlier innovation stages, the methods focused on identifying available data sources, while in later stages various simulation and analysis methods were used in new ways to increase the impact of the scarce availability of data. However, the involvement of stakeholders was considered a prominent data source in every stage.

Challenges Concerning Early Assessment of Health Innovations

The present study has identified empirical and theoretical approaches for the early assessment of innovations in a healthcare setting. Although contributions have been made to the development of new methodology, the choice of method may lead to different outcomes as no universal method was found. Markiewicz et al. (18) argued that there is a lack of evidence on how effective the methods are and that there is a need to develop an agreed-upon method for early assessment. This coincides with the perception by Hartz and John (36) on the use of early economic data, which is scarcely used in decision making on public policy. Bridges reported the need for new health financing mechanisms to ensure the implementation of valuable innovation (33). However, it has been argued that evaluations are rarely seen as an integral part of implementation, thus resources are not usually dedicated to evaluation (17).

A further challenge stressed in the literature is the scarce evidence available in an early innovation stage (19;29;36). Small data sets 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. Efforts have been made to deal with uncertainty and lack of data through applying more complex mathematical models. However, Craig et al. (39) argued that these models suffer from the precision required for data input. Such potential sources of data could be challenging to acquire at an early stage. Furthermore, the authors highlighted that these models can be difficult to apply without in-depth knowledge of economic modeling.

Scenario analysis built on expert elicitation has been used to acquire data on potential outcomes in early assessment. However, there are concerns regarding the loss of information that may occur in scenario analysis, as a scenario does not cover all outcomes in a real-world system (22;34). The same is true for expert elicitation as different approaches were used, which may lead to varying results (24). Different studies included in the present review have also stressed the need for the integration of patient or user perspectives or preferences in early assessment (13;18;37). Bartelmes et al. (19) suggested that early assessment of health innovation cannot replace a comprehensive HTA, but rather form a preceding step in a multi-staged HTA process.

Limitations

This knowledge synthesis may not have identified all published studies on the early assessment of health innovation, in particular

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the grey literature. 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 Library), 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. Finally, although the method was systematically followed by the reviewers, each reviewer subjectively included studies based on the study criteria. The classification and interpretation of the results were also subject to reviewer bias.

Further Research

Although this knowledge synthesis has identified several different methods applied in early assessment, no single method can be highlighted as prominent relative to the robustness of the results or the frequency of use. More research is, therefore, needed to systematically validate the methods suggested in this review with the aim of finding a standardized recommendation for methodology concerning early health technology assessment. An empirical test of the precision of the early assessment method needs to be competed in practice. Research should be dedicated to enhance the precision of methods that deal with lack of data and uncertainty. Such research may suggest combining existing methods to address risks from more perspectives or/and profit from the elevated availability of data sources in an increasingly digitalized world. This was also emphasized by Ijzerman et al. in a recent study of early HTA where observational studies and big data were highlighted as data sources that would allow more detailed analysis in early HTA (51).

In conclusion, existing health technology assessment is considered a robust method to support decisions in later phases when the technology is well tested in clinical environments and a large amount of data is collected. Research on altering and adopting these methods to earlier phases of decision making is emerging in the literature. This knowledge synthesis has shown that the use of methods has a tendency to change according to the stage of innovation. Stakeholder analysis was highlighted in this review as a prominent method of collecting data in the three innovation stages. This applies particularly in the earliest stage of innovation, the developmental stage, as the introduction and early diffusion stage involves greater availability of data and the use of more complex methods and models.

Barriers to the identified methods have also been discussed as all of the innovation stages suffer from lack of data and much uncertainty. Early assessment may address clinical value and risk but due to short investigation periods, it is challenging to obtain concluding evidence. Although user or patient involvement in the early phases of innovation is recommended in the literature, there is a shortage of studies in this review that effectively involves them. More research is required to promote innovation and dynamic interaction between health institutions and industry through the use of HTA. Although this review has identified applicable approaches for early assessment in different innovation stages, research is required regarding the value of the available data and methods and tools to enhance interactions between different parties at different stages of innovation.

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Supplementary Appendix 1: https://doi.org/10.1017/S0266462318003719

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References

1. **Strønen F, Hoholm T, Kværner KJ, Støme LN** (2017) Dynamic capabilities and innovation capabilities: The case of the 'innovation clinic'. *J Entrep Manag Innov* **13**, 89–116.
2. **Tarricone R, Torbica A, Drummond M** (2017) Challenges in the assessment of medical devices: The MedtecHTA Project. *Health Econ* **26** (Suppl 1), 5–12.
3. **Kristensen FB, Lampe K, Chase DL, Lee-Robin SH, Wild C, Moharra M, *et al.*** (2009) Practical tools and methods for health technology assessment in Europe: Structures, methodologies, and tools developed by the European Network for Health Technology Assessment, EUnetHTA. *Int J Technol Assess Health Care* **25**(Suppl 2):1–8.
4. **Husereau D, Henshall C, Sampietro-Colom L, Thomas S** (2016) Changing health technology assessment paradigms? *Int J Technol Assess Health Care* **32**, 191–199.
5. **Sampietro-Colom L, Lach K, Cicchetti A, Kidholm K, Pasternack I, Fure B, *et al.*** (2015) The AdHopHTA handbook: A handbook of hospital-based Health Technology Assessment (HB-HTA); Public deliverable; The AdHopHTA Project (FP7/2007-13 grant agreement nr 305018); http://www.adhophta.eu/sites/files/adhophta/media/adhophta_handbook_website.pdf (accessed January 3, 2019).
6. **Nielsen CP, Funch TM, Kristensen FB** (2011) Health technology assessment: Research trends and future priorities in Europe. *J Health Serv Res Policy* **16**(Suppl 2):6–15.
7. **Packer C, Simpson S, de Almeida RT** (2015) Euroscan International Network Member Agencies: Their structure, processes, and outputs. *Int J Technol Assess Health Care* **31**, 78–85.
8. **Hartz S, John J** (2008) Contribution of economic evaluation to decision making in early phases of product development: A methodological and empirical review. *Int J Technol Assess Health Care* **24**, 465–472.
9. **Redekop K, Mikudina B** (2013) Early medical technology assessments of medical devices and tests. *J Health Policy* **1**, 26–37.
10. **Fasterholdt I, Krahn M, Kidholm K, Tderstræde KB, Møller Pedersen KM** (2017) Review of early assessment models of innovative medical technologies. *Health Policy* **121**, 870–879.
11. **PRISMA**. 2017. http://www.prisma-statement.org/ (accessed January 3, 2019).
12. **Assessment(INAHTA) INoAfHT**. International Network of Agencies for Health Technology Assessment(INAHTA). http://www.inahta.org/HTA/ (accessed April 16, 2014).
13. **Ijzerman MJ, Steuten LM** (2011) Early assessment of medical technologies to inform product development and market access: A review of methods and applications. *Appl Health Econ Health Policy* **9**, 331–347.
14. **Steuten LM** (2016) Early stage health technology assessment for precision biomarkers in oral health and systems medicine. *OMICS* **20**, 30–35.
15. **Retel VP, Joosten SE, van Harten WH** (2014) Expert elicitation used for early technology assessment to inform on cost-effectiveness of next generation sequencing. *Value Health* **17**, A652.
16. **Beuscart-Zephir MC, Watbled L, Carpentier AM, Degroisse M, Alao O** (2002) A rapid usability assessment methodology to support the choice of clinical information systems: A case study. *Proc AMIA Symp*, 46–50.
17. **Brear M** (2006) Evaluating telemedicine: Lessons and challenges. *Health Inf Manage J* **35**, 23–31.
18. **Markiewicz K, van Til JA, Ijzerman MJ** (2014) Medical devices early assessment methods: Systematic literature review. *Int J Technol Assess Health Care* **30**, 137–146.
19. **Bartelmes M, Neumann U, Luhmann D, Schonermark MP, Hagen A** (2009) Methods for assessment of innovative medical technologies during early stages of development. *GMS Health Technol Assess* **5**, Doc15.

20. **Cosh E, Girling A, Lilford R, McAteer H, Young T** (2007) Investing in new medical technologies: A decision framework. *J Commer Biotechnol* **13**, 263–271.
21. **Di Capua P, Wu B, Sednew R, Ryan G, Wu S** (2016) Complexity in redesigning depression care: Comparing intention versus implementation of an automated depression screening and monitoring program. *Popul Health Manag* **19**, 349–356.
22. **Retel VP, Joore MA, Linn SC, Rutgers EJ, van Harten WH** (2012) Scenario drafting to anticipate future developments in technology assessment. *BMC Res Notes* **5**, 442.
23. **Sayres LC, Allyse M, Cho MK** (2012) Integrating stakeholder perspectives into the translation of cell-free fetal DNA testing for aneuploidy. *Genome Med* **4**, 49.
24. **Kip MM, Steuten LM, Koffijberg H, Ijzerman MJ, Kusters R** (2018) Using expert elicitation to estimate the potential impact of improved diagnostic performance of laboratory tests: A case study on rapid discharge of suspected non-ST elevation myocardial infarction patients. *J Eval Clin Pract* **24**, 31–41.
25. **Jastremski M, Jastremski C, Shepherd M, Friedman V, Porembka D, Smith R, *et al.*** (1995) A model for technology assessment as applied to closed loop infusion systems. Technology Assessment Task Force of the Society of Critical Care Medicine. *Crit Care Med* **23**, 1745–1755.
26. **Gaultney JG, Sanhueza E, Janssen JJ, Redekop WK, Uyl-de Groot CA** (2011) Application of cost-effectiveness analysis to demonstrate the potential value of companion diagnostics in chronic myeloid leukemia. *Pharmacogenomics* **12**, 411–421.
27. **Harris-Roxas BF, Harris PJ** (2007) Learning by doing: The value of case studies of health impact assessment. *N S W Public Health Bull* **18**, 161–163.
28. **Porzsolt F, Ghosh AK, Kaplan RM** (2009) Qualitative assessment of innovations in healthcare provision. *BMC Health Serv Res* **9**, 50.
29. **Esposito D, Taylor EF, Gold M** (2009) Using qualitative and quantitative methods to evaluate small-scale disease management pilot programs. *Popul Health Manag* **12**, 3–15.
30. **Retel VP, Hummel MJ, van Harten WH** (2008) Early phase technology assessment of nanotechnology in oncology. *Tumori* **94**, 284–290.
31. **Abrishami P, Boer A, Horstman K** (2015) How can we assess the value of complex medical innovations in practice? *Expert Rev Pharmacoecon Outcomes Res* **15**, 369–371.
32. **Henshall C, Schuller T** (2013) Health technology assessment, value-based decision making, and innovation. *Int J Technol Assess Health Care* **29**, 353–359.
33. **Bridges JF** (2006) Lean systems approaches to health technology assessment: A patient-focused alternative to cost-effectiveness analysis. *PharmacoEconomics* **24**(Suppl 2), 101–109.
34. **Kummer TF, Schafer K, Todorova N** (2013) Acceptance of hospital nurses toward sensor-based medication systems: A questionnaire survey. *Int J Nursing Stud* **50**, 508–517.
35. **Gantner-Bar M, Meier F, Kolominsky-Rabas P, Djanatliev A, Metzger A, Voigt W, *et al.*** (2014) Prospective Assessment of an innovative test for prostate cancer screening using the VITA process model framework. *Stud Health Technol Inform* **205**, 236–240.
36. **Hartz S, John J** (2009) Public health policy decisions on medical innovations: What role can early economic evaluation play? *Health Policy* **89**, 184–192.
37. **Joosten SE, Retel VP, Coupe VM, van den Heuvel MM, van Harten WH** (2016) Scenario drafting for early technology assessment of next generation sequencing in clinical oncology. *BMC Cancer* **16**, 66.
38. **Girling A, Young T, Brown C, Lilford R** (2010) Early-stage valuation of medical devices: The role of developmental uncertainty. *Value Health* **13**, 585–591.
39. **Craig JA, Carr L, Hutton J, Glanville J, Iglesias CP, Sims AJ** (2015) A review of the economic tools for assessing new medical devices. *Appl Health Econ Health Policy* **13**, 15–27.
40. **Postmus D, de Graaf G, Hillege HL, Steyerberg EW, Buskens E** (2012) A method for the early health technology assessment of novel biomarker measurement in primary prevention programs. *Stat Med* **31**, 2733–2744.
41. **Douma KF, Karsenberg K, Hummel MJ, Bueno-de-Mesquita JM, van Harten WH** (2007) Methodology of constructive technology assessment in health care. *Int J Technol Assess Health Care* **23**, 162–168.
42. **Retel VP, Bueno-de-Mesquita JM, Hummel MJ, van de Vijver MJ, Douma KF, Karsenberg K, *et al.*** (2009) Constructive Technology Assessment (CTA) as a tool in coverage with evidence development: The case of the 70-gene prognosis signature for breast cancer diagnostics. *Int J Technol Assess Health Care* **25**, 73–83.
43. **Retel VP, Hummel MJ, van Harten WH** (2009) Review on early technology assessments of nanotechnologies in oncology. *Mol Oncol* **3**, 394–401.
44. **Retel VP, Grutters JP, van Harten WH, Joore MA** (2013) Value of research and value of development in early assessments of new medical technologies. *Value Health* **16**, 720–728.
45. **Chang WR, McLean IP** (2006) CUSUM: A tool for early feedback about performance? *BMC Med Res Methodol* **6**:8.
46. **Niederlander C, Kriza C, Wahlster P, Djanatliev A, Kolominsky-Rabas P** (2013) Early technology foresight for the development of biomarkers for prostate cancer screening: Prospective Health Technology Assessment (ProHTA). *Eur J Cancer* **49**, S199.
47. **Banta HD, Gelijns AC, Griffioen J, Graaff PJ** (1987) An inquiry concerning future health care technology: Methods and general results. *Health Policy* **8**, 251–264.
48. **Manetti S, Cecchi F, Sgandurra G, Cioni G, Laschi C, Dario P, *et al.*** (2015) Early stage economic evaluation of caretoy system for early intervention in preterm infants at risk of neurodevelopmental disorders. *Value Health* **18**, A358.
49. **Gagnon MP, Candas B, Desmartis M, Gagnon J, La Roche D, Rhainds M, *et al.*** (2014) Involving patient in the early stages of health technology assessment (HTA): A study protocol. *BMC Health Serv Res* **14**:273.
50. **Gollamudi SS, Topol EJ, Wineinger NE** (2016) A framework for smartphone-enabled, patient-generated health data analysis. *Peerj* **4**, e2284.
51. **Ijzerman MJ, Koffijberg H, Fenwick E, Krahn M** (2017) Emerging use of early health technology assessment in medical product development: A scoping review of the literature. *PharmacoEconomics* **35**, 727–740.

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