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LARGE-SCALE IMPLEMENTATION OF THE NATIONAL KANTA SERVICES IN FINLAND 2010–2018 WITH SPECIAL FOCUS ON ELECTRONIC PRESCRIPTION

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DOCTORAL DISSERTATION

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ABSTRACT

The demand for healthcare system and service reforms is compelling, and there seems little choice but to introduce complex information and communication technology on a large, often nationwide scale. Major restructuring of health services is rarely possible without pervasive information infrastructure. Implementing and adopting a new nationwide health information system (HIS) is a risky mega-project: a large-scale, complex and costly endeavour, taking many years to develop and build, involving multiple public and private stakeholders and impacting millions of people.

This research aimed to assess the implementation and adoption of the *Act on Electronic Prescription* (61/2007) and the *Act on Processing Customer Data in Health and Social Care* (159/2007) from 2010 to 2018 in Finland. To achieve this, the study used the Clinical Adoption Framework (CAF) to provide an overarching conceptual model for electronic HIS adoption and the Clinical Adoption Meta-Model (CAMM) to assess post-deployment of the national Kanta Services.

This research revealed and documented the central building blocks of a large-scale nationwide development process established to implement electronic services based on national legislation in Finland and then described their implementation and adoption using specific indicators during follow-up. In addition, this research was the first both to measure prescription volumes in Finland and to investigate the nationwide use of My Kanta Pages in public primary healthcare centres (PHCs), hospital districts and university hospital special catchment areas. Use of the Prescription Centre, the Patient Data Repository and My Kanta Pages increased continuously in an exponential fashion during the follow-up. This research assessed, in a representative population sample, direct associations between demographics, self-rated health, socioeconomic position and social participation and the perceived benefits of online healthcare and social welfare services.

The results of this research suggest that it is possible to create and adopt two large-scale nationwide HIS in 5.5 years covering public PHCs and pharmacies, hospitals and private healthcare providers in a country with 5.5 million inhabitants. The Prescription Centre services were implemented and adopted first, and thereafter the Patient Data Repository services. Public healthcare service providers implemented and adopted the Kanta Services first, and thereafter private healthcare service providers.

The middle-out implementation approach employed in Finland proved an apt strategy for the nationwide adoption of the Kanta Services. It combines local consultation, locally driven investment and system choice, thus promoting a bottom-up approach, with central government support, leadership and resources and nationally agreed interoperability standards and goals, which represent elements of a top-down approach.

Large-scale nationwide implementation of the two Kanta Services (the Prescription Centre and the Patient Data Repository) were supported through a national operative coordination unit established at the Finnish Institute for Health and Welfare (THL) with an appropriate legal mandate in permanent legislation. The implementation processes and adoption efforts of the Kanta Services were supported by relatively stable national HIS architecture, recruitment of multitalented, expert professionals with long-term experience, and minimum changes in personnel during the implementation period. A dynamic and rolling platform was organized by THL for implementation and adoption knowledge transfer from actor to actor. In this dynamic system, new organizations entered a platform that already included their experienced peers, who had previously adopted and used the Kanta Services.

The initial regional hospital district implementation and adoption strategy for Prescription Centre services was changed to a certified Kanta Services compatible HIS strategy

for Patient Data Repository services. The change was based on cumulative experiences from the implementation and adoption of Prescription Centre services, especially simultaneous local and regional implementation and adoption by pharmacies and public healthcare service providers.

In this research, implementation processes and adoption efforts were followed up by rigorously utilizing log-based register data that were of utmost value in almost real-time situation and progress reporting. However, log-based register data reporting should be accompanied by completely independent, parallelly run, and long-term research and monitoring approaches that enrich the results on implementation processes, adoption efforts and effects on patients or clients.

A citizens' own electronic prescriptions and other health data have been nationally accessible via the web-based My Kanta Pages since May 2010, and users have adopted the service well: a total of two out of three adults in Finland had signed into My Kanta Pages in 2010–2018. After nationwide implementation and adoption of the Prescription Centre services by all pharmacies and all public and most private healthcare service providers, a 'big-bang' strategy was applied to introduce mandatory electronic prescription, which prescribers and pharmacies quickly adopted.

In conclusion, the follow-up data of this research from May 2010 to December 2018 provide observations on the increasing availability of the nationwide Kanta Services, which led to increasing and ongoing use among citizens and professional users, in turn resulting in observable changes in clinical and health behaviours that may have resulted in improvements in measured outcomes. Based on the results of this Kanta Services infrastructure research (log register data, registered implementation start dates, and a large population survey), long-term follow-up observations point towards the 'Adoption with Benefits' archetype of the CAMM.

TIIVISTELMÄ

Terveydenhuollon järjestelmien ja terveyspalvelujen uudistuksia kysytään jatkuvasti, ja uudistukset edellyttävät usein monimutkaisten tieto- ja viestintäteknologioiden laajaa, usein maanlaajuista, käyttöön ottamista. Terveyspalvelujen uudelleen järjestäminen on harvoin mahdollinen ilman läpitunkevaa tiedonhallinnan infrastruktuuria. Uuden maanlaajuisen terveydenhuollon tietojärjestelmän käyttöönoton suurprojekti sisältää paljon riskejä: se on laaja-alainen, monimutkainen ja kallis, sen kehittämiseen ja rakentamiseen kuluu vuosia, sidosryhmiin kuuluu useita julkisen ja yksityisen sektorin toimijoita ja muutosprojektilla on vaikutuksia miljooniin ihmisiin.

Tämän tutkimuksen tavoitteena oli tutkia ja selvittää, kuinka Eduskunnan hyväksymät lait *Laki sähköisestä lääkemääräyksestä (61/2007)* sekä *Laki sosiaali- ja terveydenhuollon asiakastietojen sähköisestä käsittelystä (159/2007)* toimeenpantiin ja valtakunnalliset tietojärjestelmät otettiin käyttöön Suomessa vuosina 2010–2018 soveltamalla teoreettista viitekehystä Clinical Adoption Framework (CAF) käyttööottoihin sekä viitekehystä Clinical Adoption Meta-Model (CAMM) valtakunnallisten tietojärjestelmien käyttöönoton jälkeiseen seurantaan.

Tutkimuksessa selvitettiin ja dokumentoitiin Suomessa lakisääteisten terveydenhuollon sähköisten palvelujen kansallisen kehittämisprosessin toimeenpanon keskeisiä piirteitä sekä kahden Kanta-palvelun käyttöönottoa, niiden etenemistä ja seurantaa tietojärjestelmien lokitiedoista tuotetuilla indikaattoreilla ja aikasarjoilla. Lisäksi tässä tutkimuksessa mitattiin ensimmäisen kerran lääkemääräysten volyymi Suomessa. Tutkimuksessa selvitettiin myös ensimmäisen kerran valtakunnallisen potilaan terveystietojen portaalin (Omakanta) käyttöä Suomessa alueellisesti terveyskeskuksittain, sairaanhoitopiireittäin ja yliopistosairaaloiden erityisvastuualueittain. Reseptikeskuksen, Omakannan ja Potilastiedon arkiston käyttö kasvoivat jatkuvasti ja eksponentiaalisesti seurannan aikana. Tässä tutkimuksessa selvitettiin myös väestötietojen, itse arvioidun terveyden, sosioekonomisen aseman ja sosiaalisen osallistumisen yhteyksiä sähköisten terveys- ja sosiaalipalvelujen koettuihin hyötyihin valtakunnallisesti edustavassa väestöotoksessa.

Tulosten perusteella on mahdollista ottaa 5,5 vuoden aikana käyttöön kaksi terveydenhuollon valtakunnallista tietojärjestelmää Suomen terveyskeskuksissa, apteekeissa, sairaaloissa sekä yksityisessä terveydenhuollossa (5,5 miljoonaa asukasta). Kanta-palveluissa Reseptikeskus otettiin käyttöön ensin ja sen jälkeen Potilastiedon arkisto. Julkisen terveydenhuollon toimijat ottivat valtakunnalliset tietojärjestelmät käyttöön ensin ja sen jälkeen yksityisen terveydenhuollon toimijat.

Kanta-palvelujen toimeenpanon ja käyttöönoton strategiaksi valittu välimuoto (middle-out) toimi hyvin valtakunnallisissa käyttöönotoissa. Välimuoto yhdistää näkökulman alhaalta ylös (bottom-up) painottamia paikallisia tarpeita ja investointeja sekä tietojärjestelmien valintoja yhteen näkökulmassa ylhäältä alas (top-down) painottuvien keskushallinnon tuen, johtamisen, resurssien ja kansallisiin sopimuksiin perustuviin yhteen toimivuuden standardien ja tavoitteiden kanssa.

Kahden Kanta-palvelun (Reseptikeskus ja Potilastiedon arkisto) käyttöönottoa tuettiin kansallisesta operatiivisen ohjauksen yksiköstä, joka oli perustettu Terveyden ja hyvinvoinnin laitokseen (THL) ja jolla oli lakeihin perustuvaa normiohjauksen toimivaltaa asiassa. Toimeenpanon prosesseja ja käyttöönottoja tukivat lisäksi suhteellisen vakaa terveydenhuollon tietojärjestelmien arkkitehtuuri, mahdollisuudet rekrytoida monitaitoista, kokenutta ja erityisosaamisen henkilöstöä sekä pienet muutokset henkilöstössä toimeenpanon ja käyttöönottojen aikana. Operatiivinen toiminta kehitti toimeenpanon tueksi dynaamisen ja rullaavasti etenevän järjestelmän (alustan), jonka tarkoituksena oli siirtää

toimeenpanon ja käyttöönottojen kokemuksia, oppeja, hyviksi ja huonoiksi osoittautuneita toimintatapoja kentän toimijalta toiselle. Dynaamisessa järjestelmässä uudet valtakunnallisia tietojärjestelmäpalveluja käyttöön ottavat organisaatiot liittyivät mukaan ryhmään, jossa oli jo mukana kokeneita toimijoita, jotka olivat ottaneet Kanta-palveluja käyttöön ja käyttivät niitä.

Reseptikeskuksen valtakunnallisten palvelujen toimeenpanossa ja käyttöönotoissa sovellettiin alueellista (sairaanhoitopiirit) strategiaa, mikä vaihdettiin Kanta-palveluihin sertifioitujen sovellusten strategiaan Potilastiedon arkiston palvelujen toimeenpanossa ja käyttöönotoissa. Muutokseen vaikuttivat keskeisesti Reseptikeskuksen valtakunnallisten palvelujen toimeenpanon ja käyttöönottojen kokemukset, erityisesti paikalliset ja alueelliset sidokset käyttöönotoissa. Valtakunnallisia palvelujan ottivat samaan aikaan käyttöön sairaanhoitopiirissä apteekit, terveyskeskukset ja sairaalat. Tätä kytkentää ei ollut enää Potilastiedon arkiston palvelujen käyttöönottojen aikana.

Toimeenpanon prosesseja ja käyttöönottojen etenemistä seurattiin järjestelmällisesti käyttämällä hyödyksi Kanta-palvelujen lokitiedostojen rekisteritietoja, jotka osoittautuivat arvokkaiksi lähes reaaliaikaisina ja soveltuvina edistymisen raportointiin. Lokitiedot eivät kuitenkaan yksinomaan riitä toimeenpanon ja käyttöönottojen seurannan tietoina; lokitietoja tulisi täydentää riippumattomilla, samanaikaisesti tehdyillä pitkän ajan tutkimuksilla ja monitoroinneilla, jotka rikastuttavat ilmiön kokonaisuutta tuomalla mukanaan potilaiden tai asiakkiden näkökulmien tuloksia.

Omatietokanta-verkkopalvelussa lääkityksen ja muut terveystiedot tulivat käyttäjälle saavutettaviksi (käyttöön) ensimmäisen kerran toukokuussa 2010. Käyttäjät ottivat palvelun käyttöön hyvin ja nopeasti: vuosina 2010–2018 kaiksi kolmesta aikuisesta Suomessa oli kirjautunut Omakantaan ainakin kerran. Reseptikeskuksen valtakunnalliset palvelut otettiin käyttöön laajasti: kaikki apteekit, kaikki julkisen terveydenhuollon toimijat sekä valtaosa yksityisen terveydenhuollon toimijoista käyttää palveluja. Laajan käytön ansiosta oli mahdollista ottaa lakisääteisesti sähköinen lääkemääräys käyttöön yön yli samanaikaisesti kaikkialla Suomessa 1.1.2017 (big bang). Lääkkeen määrääjät (lääkärit ja hammaslääkärit) sekä puhelin- ja paperiset lääkemääräykset Reseptikeskukseen elektronisiksi tallentavat apteekit ottivat sähköisen lääkemääräyksen käyttöön nopeasti.

Tämän tutkimuksen tulokset toukokuusta 2010 seurattuina joulukuun loppuun 2018 viittaavat siihen, että Kanta-palveluiden saatavuus oli edistynyt ja niiden käyttö oli kasvanut kansalaisten ja ammattilaisten keskuudessa, mikä puolestaan näyttäisi johtaneen kliinisiin ja käyttäytymisen muutoksiin, mitkä puolestaan ovat saattaneet parantaa mitattavissa olleita lopputuloksia. Kanta-palvelujen infrastruktuurin tutkimustiedot (lokitiedot, rekisteröidyt käyttöönottojen aloitusten päivämäärät sekä väestökyselyn tulokset) pitkäaikaisessa seurannassa viittaavat CAMM-viitekehyksen arkkityyppiin 'Adoption with Benefits' (käyttöönotto hyötyjen kera).

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LIST OF ORIGINAL PUBLICATIONS

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III Jormanainen V, Relander T, Jormanainen V, Lindgren M. Decreasing number of prescriptions after they became mandatory and their valid period was extended: a big bang policy change in Finland in 2017. *Stud Health Technol Inform* 2020;270:833–837.

IV Jormanainen V, Parhiala K, Niemi A, Erhola M, Keskimäki I, Kaila M. Half of the Finnish population accessed their own data: comprehensive access to personal health information online is a corner-stone of digital revolution in Finnish health and social care. *Finnish J eHealth eWelfare* 2019;11:298–310.

V Heponiemi T, Jormanainen V, Leeman L, Manderbacka K, Aalto A-M, Hyppönen H. Digital divide in perceived benefits of online health care and social services: national cross-sectional survey study. *J Med Internet Res* 2020;22:e17616.

The publications are referred to in the text by their roman numerals.

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ABBREVIATIONS

CAF	Clinical Adoption Framework
CAMM	Clinical Adoption Meta-Model
CI	Confidence interval
DESI	European Commission’s Digital Economy and Society Index
DVV	Digital and Population Data Services Authority of Finland
EHR	Electronic health record (system)
E-Tervis	Estonian eHealth Foundation
EUR	Euro
HIE	Health information exchange
HIS	Health information system
I-DESI	European Commission’s International Digital Economy and Society Index
Kanta	National data systems for healthcare and social welfare in Finland
KP	Kaiser Permanente
MSAH	Ministry of Social Affairs and Health
OECD	Organisation for Economic Co-operation and Development
OM	Ministry of Justice
PHC	Primary healthcare centre
SII	Social Insurance Institution of Finland
STM	Ministry of Social Affairs and Health
THL	Finnish Institute for Health and Welfare
Valvira	National Supervisory Authority for Welfare and Health of Finland
VN	Finnish Government
VNK	Valtioneuvoston kanslia (Prime Minister’s Office)
VTV	National Audit Office of Finland
WHO	World Health Organization
X-Road	An open-source software and ecosystem solution (data exchange layer)

1 INTRODUCTION

This research aims to assess the implementation and adoption of the *Act on Electronic Prescription* (61/2007) and the *Act on Processing Customer Data in Health and Social Care* (159/2007) from 2010 to 2018 in Finland. These two laws were introduced to Parliament as a result of preparations based on a strategy published by the Ministry of Social Affairs and Health in 1995 (*Strategy for utilizing information technology in the field of social welfare and healthcare in Finland*) (STM 1996), a 2002 long-term Government Resolution (VN 2002) and the Information Society Program (VNK 2005). Permanent legislation was accompanied by the electronic health roadmap for Finland (MSAH 2007), which provided solutions for supporting electronic services for citizens and other users of electronic (online) health information services. In addition, this research aims to develop a follow-up of the large-scale, nationwide implementation and adoption of HIS by utilizing various long-term follow-up indicators.

The Clinical Adoption Framework (CAF) was applied to provide an overarching conceptual model (Lau et al. 2007; Lau 2009; Lau et al. 2011; Lau and Price 2016). In addition, the Clinical Adoption Meta-Model (CAMM) was used, as it was developed to support the implementation, study and assessment of HIS and to help consider and describe post-deployment adoption across four dimensions over time (Price and Lau 2014; Price 2016).

In contrast to implementation research, terminology in healthcare and social welfare information technology services suffers from a lack of clarity and an absence of agreement about concept definitions (Rabin and Brownson 2012; Adler-Milstein et al. 2014; Sligo et al. 2017). Healthcare is both complex and hierarchical, characterized by interrelated subsystems, and social, characterized by formal structures and elementary units (Aarts and Peel 1999; Gloubeman and Minzberg 2001; Coiera 2009; Justinia 2009; Bowden and Coiera 2013). Most healthcare reforms are not properly followed up, and their outcomes are rarely evaluated (Couffinhal et al. 2016). As early as 1964, a research office was established at the Social Insurance Institution of Finland (SII) to assist in the development of social security issues and decision-making (Hellsten 2014). However, other assessments of healthcare policy implementations remained rare before 2000 (Teittinen 1985; Rimpelä 1992; Sihto 1997; Hämäläinen 1999) but have become more common thereafter (Ohtonen 2002; Viisainen et al. 2002; Korhonen 2005; Haahtela et al. 2006; Hämäläinen and Hyppönen 2006; Haahtela et al. 2008; Rautakorpi et al. 2010; Tuomisto et al. 2010; Kinnula et al. 2011; VTV 2011,; Keso 2012; Kuronen 2015; Virtanen et al. 2017).

To understand implementation, it is necessary to define the phenomenon (e.g., policy) to be implemented (Sinkkonen and Kinnunen 1994; Pawson and Tilley 1997; Hämäläinen 1999; Kinnunen and Nykänen 1999; Currie and Guah 2007; Vuorela 2009; Greenhalgh and Stones 2010; Bullock et al. 2021). An exact definition of evaluation and evaluation research in the public sector may be difficult to formulate (Sinkkonen and Kinnunen 1994). No one commonly accepted methodology exists to undertake such evaluations, and thus, each should be performed while considering the facts of the specific situation (Pawson and Tilley 1997; Kinnunen and Nykänen 1999). Policy, in turn, is typically a product of a public political process that has identified societal challenges and is characterized by the desire to change the political agenda (Hänninen and Junnila 2012). In Finland, policy cycles have been found to include 3–10 phases (Ahonen 1985; Sinkkonen and Kinnunen 1994; OM 2007; VTV 2011; Hänninen and Junnila 2012).

Realist evaluation is a form of theory-driven evaluation that addresses the question of what works, for whom, under what circumstances, and how (Pawson and Tilley 1997, Greenhalgh et al. 2009; Wong et al. 2016; Smeets et al. 2022). Experimental designs assume a simple linear model of causality, thus focusing on what works in relation to the achieved outcomes. However, they are of limited value for interventions of a complex nature (Smeets et al. 2022). An appropriate evaluation of complex interventions should not only focus on what works but also, as mentioned above, provide answers to why, for whom, and under what conditions the intervention is effective (Pawson and Tilley 1997). Realist evaluation supports the collection of context-linked insights to enhance programme implementation (Greenhalgh et al. 2009, Wong et al. 2016). Until now, most realist studies have focused on evaluating interventions or projects related to healthcare and health services (Marchal et al. 2012, Dossou et al. 2021). Nonetheless, the realist approach has recently been applied to national health policy implementation as well (Dossou et al. 2021).

The opportunity to introduce major societal changes or transformations usually requires political will and political capacity (Tuohy 1999). However, creating such an opportunity does not necessary lead to major changes. Small or large-scale policy change will enter a terrain populated by existing interests, institutions, preferences and understandings. Large-scale reforms are rare (Tuohy Hughes 2018).

The demand for healthcare system and service reforms is compelling, and often there is little choice but to implement complex information and communication technology on a large, often nationwide scale (Ludwig and Doucette 2009; Coiera et al. 2012). Major health service restructuring is rarely possible without pervasive information infrastructure (Coiera 2009). Reforming information systems requires consistency, experimentation, insight and a comprehensive understanding of the potential uses of customer- and patient-specific information (Virtanen et al. 2017).

This dissertation employs a macro-level approach to the CAF, with governance, standards, funding and trends dimensions, as well as meso-level implementation dimension to provide an overarching conceptual model for electronic HIS adoption (Lau et al. 2007; Lau 2009; Lau et al. 2011; Lau and Price 2016). In addition, the CAMM is utilized, as it was developed to support implementation and to describe post-deployment adoption of a HIS across four dimensions (availability, use, behaviour, clinical outcomes) over time (Price and Lau 2014; Price 2016).

This thesis is structured as follows: in the literature review, the theoretical framework is introduced, including some of the most important definitions. In addition, the theoretical constructs of the CAF and CAMM are introduced. Next, implementation of a HIS is discussed, as is the implementation and adoption of large-scale electronic HISs from the perspective of international experiences. The literature review also includes sections on preparing national health records for Finland before 2010 and the ‘proof-of-concept’ application of the CAF in the Finnish context. After the study aims and methods have been introduced, the research results are presented by utilizing the CAF and the CAMM in the assessment of the national Kanta Services in 2010–2018. In the discussion, the main findings are presented together with their interpretation, methodological considerations, and the implications for policy and future studies.

Large-scale implementation of nationwide HIS services is a rather novel research theme, the concepts and definitions of which are still to be established. Consequently, some of the most important definitions are introduced first.

1.1 DEFINITIONS

The World Health Organization (WHO) has recently introduced the term ‘digital health’, which is the use of digital technologies to improve health (Fahy et al. 2021; WHO 2021). Developments initially focused on electronic health technologies for improving existing communication processes. However, powerful mobile devices led to new mobile health applications. Subsequently, a substantial increase in the volume, pace and variety of available health data and data-driven tools led to analyses of big data. Digital health should be developed according to the principles of transparency, accessibility, scalability, replicability, interoperability, privacy, security and confidentiality (Fahy et al. 2021; WHO 2021). The WHO has also defined electronic health as the use of information and communication technology to support health and health-related fields, including healthcare services, health surveillance, health literature and health education, knowledge and research (WHO 2016), and also to improve the efficiency and quality of care and empower patients (Oh et al. 2005; Eysenbach 2011).

Health information exchange (HIE) has been defined as the electronic transfer of patient data and health information between healthcare providers or institutions regionally, nationally and internationally between different information systems (Finn 2011; Bowden and Coiera 2013; Adler-Milstein et al. 2014; Esmaeilzadeh and Sambasivan 2016; Sadoughi et al. 2018). HIE systems assist healthcare organizations in collecting, processing and disseminating electronic information internally and in their environment (Yusof et al. 2008). HIE adoption occurs in phases: initiation (awareness and attitude formation), the adoption decision, implementation (set-up and execution of implementation plan) and integration into the healthcare organization's routine (institutionalization) (Esmaeilzadeh and Sambasivan 2016; Lau and Price 2016).

An electronic health record system (EHR) has been defined as an electronic collection of health-related data concerning one subject of care – the patient (Winter et al. 2011). It provides clinical data (Coiera et al. 2018; Ammenwerth et al. 2021) and a longitudinal record of information in computer-processible form across practices and specialists in real time (Fennelly et al. 2020). The purchase and implementation of EHRs is a massive expense and a huge commitment of time and resources (Hertzum and Ellingsen 2019; Villumsen et al. 2020). Thus, assessment might not be desired (Rigby 2001) even though assessment frameworks exist (Lau et al. 2011; Cresswell et al. 2020). An EHR can include an organized web-based patient portal allowing patients independent access to their own data (Moen et al. 2013). However, only a small number of nationwide implementations of shared patient-accessible EHRs have been launched in OECD countries, including that of Finland (Bowden and Coiera 2013; Oderkirk 2017; Essén et al. 2018; Ammenwerth et al. 2019; Ammenwerth et al. 2020). Moreover, shared EHRs are complex innovations (Greenhalgh et al. 2008).

Health information systems (HIS) integrate the data collection, processing, reporting, and use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of health services (Lippeveld et al. 2000). HISs encompass a wide array of applications and information systems that are linked or interfaced and support the provision of care to patients and the business aspects of the healthcare organization by communicating information (Hassett 2002). The implementation and adoption of HISs is a lengthy process (Sligo et al. 2017), the challenges and costs of which often accrue long before any real value is seen (Hillestad et al. 2005; Deutsch et al. 2010; Houghton 2011). Comprehensive HIS implementation is risky (Berg 2001; House of Commons 2007; Deutsch et al. 2010; Houghom 2011; Flyvbjerg 2014; Ellingsen et al. 2022). Furthermore, the more comprehensive the technology or wider the implementation span, the more difficult it appears to achieve success (Berg 2001). Implementing a new nationwide HIS is a megaproject: large-scale, complex and costly, taking many years to develop and build, involving multiple public and private stakeholders and impacting millions of people (Flyvbjerg 2014; Lehtonen 2014; Price et al. 2018).

Implementation science bridges the gap between developing and assessing effective interventions and implementing them in routine practice (Eccles and Mittman 2006; Tabak et al. 2012; Peters et al. 2013; Foy et al. 2015; Nilsen 2015; Pinnock et al. 2017a-b). Implementation is the process of employing or integrating an intervention within a given setting. Implementation strategies refer to systematic processes, activities and resources that are used to integrate these interventions into usual settings (Fixen et al. 2005). Experiences from early implementation or adoption sites in five English hospital trusts indicated that delivering improved healthcare through nationwide EHRs is a long, complex and iterative process requiring flexibility and local adaptability both with respect to the systems and the implementation strategy (Robinson et al. 2010). National-Health-System-wide information technology programmes in the United Kingdom have generally failed to meet expectations, and assessments have usually overlooked long-term progress (Price et al. 2019).

In research, adoption has been defined as the intention, initial decision or action to test or employ an innovation or evidence-based practice (Proctor et al. 2011). In practice, adoption refers to changes introduced to programmes or interventions to align them with a particular context (Stirman Wiltsey et al. 2013). Adoption concerns the decision of a specific organization (Hoelscher et al. 2001; Rogers 2003; Sussman et al. 2006; Zanaboni et al. 2014; Esmaeilzadeh and Sambasivan 2016; Ellingsen et al. 2022). The term adoption typically refers to the degree of uptake of technologies in terms of the number of users and extent of technology use (Kushniruk et al. 2013). However, HIS implementation processes and their adoption efforts are different (Esmaeilzadeh and Sambasivan 2016). For voluntary data systems, adoption is reflected in the usage of the system, whereas, for mandatory data systems, adoption is reflected in overall user acceptance (Ammenwerth et al. 2006). Assessment of adoption rates is essential for understanding the effect of an HIS on decision-making, care processes and health outcomes (Coiera 2015, Fraccaro et al. 2019).

The effective digitization of services is not, primarily, a technology-related issue; rather, it mostly concerns people (Berg 1999; Ludwick and Douchette 2009; Deutsch et al. 2010; Gagnon et al. 2012; Cresswell and Sheikh 2013; Priestman et al. 2016; Wachter 2016; O'Donnell et al. 2018). Implementation entails large-scale sociotechnical change or transformation (Berg 2001; Currie and Guah 2007; Coiera 2009; Greenhalgh and Stones 2010; Houghom 2011; Takian et al. 2012; de Lusignan et al. 2013; de Lusignan et al. 2014; Greenhalgh et al. 2017). Sociotechnical perspectives emphasize the interrelatedness of organizational and human factors and data-system factors and the way they shape each other over time (Robertson et al. 2010; Cresswell et al. 2012; Bowden and Coiera 2013; Valta 2013). Ultimately, HIS adoption is determined by the attitudes and behaviours of clinicians (Lau et al. 2007; Lau 2009).

The WHO has defined interoperability as the ability of multiple information and communication technology systems and software applications to communicate with one another, exchange data and use the information that has been exchanged (WHO 2019). In Finland, interoperability has been defined as ability of actors, processes and information systems that are connected to an activity to act and communicate together in such a way or scope that they can routinely use and understand each other's data (Finto 2022). Recently interoperability has been defined as how people, systems and processes talk and work together across organisational structures and professions, supported through technology (Mistry et al. 2022). Interoperability is not a single project or change process; it is an ongoing process and improves as more projects enable teams and organisations to work together with digital tools. However, technical and economic obstacles may prevent the realization of interoperability (Blumenthal 2022).

1.2 CENTRAL GOVERNMENT ACTORS IN NATIONAL HEALTH INFORMATION SYSTEM AND HEALTH INFORMATION EXCHANGE IN FINLAND

Finland is a sparsely populated (5.5 million inhabitants in a 338,145 km^2 area), high-income country with a high standard of social welfare and living conditions (MSAH 2013; Keskimäki et al. 2019). Finland's healthcare system is characterized by a highly decentralized administrative structure, multiple financing sources and three channels for statutory services in first-contact care (the municipal, national health insurance and occupational healthcare systems).

The responsibility for general strategic guidance and funding of social welfare and healthcare in Finland rests with the Ministry of Social Affairs and Health (MSAH), which prepares legislation, guides implementation, and directs and oversees the development of social security, social welfare and healthcare services and the operation of the sector. The MSAH manages client and stakeholder cooperation at the strategic level and prepares legislation concerning the national HIS (MSAH 2013; Keskimäki et al. 2019).

The Finnish Institute for Health and Welfare (THL) functions as the authority responsible for information management in the social welfare and healthcare sectors. THL also provides support and training for social welfare and healthcare professionals. THL is the official compiler of statistics in its sector and manages the collection and leveraging of data within its domain (MSAH 2013; Keskimäki et al. 2019).

The Social Insurance Institution of Finland (SII), in turn, provides basic social security for all residents in Finland as defined in the legislation and operates under the supervision of Parliament. The SII runs the statutory national health insurance scheme that covers all residents in Finland (MSAH 2013; Keskimäki et al. 2019).

In addition, the National Supervisory Authority for Welfare and Health of Finland (Valvira) oversees the provision of social welfare and healthcare services nationally and supervises the activities of public and private social welfare and healthcare organizations as well as healthcare personnel. In addition, Valvira is responsible for the accreditation of healthcare professionals and grants national licences for private healthcare service provision (MSAH 2013; Keskimäki et al. 2019).

The Digital and Population Data Services Authority of Finland (DVV) is responsible for electronic identity and certificate services. DVV authenticates healthcare professionals and other healthcare service provider employees and manages the electronic signing of documents by these workers.

The regional level of administration is part of the state administration. Six Regional State Administrative Agencies oversee the services provided in their respective districts, coordinate and supervise both municipal and private social welfare and healthcare service providers and ensure that their service quality complies with the law (MSAH 2013; Keskimäki et al. 2019).

2 REVIEW OF THE LITERATURE

2.1 IMPLEMENTATION DESIGNS OF THE HEALTH INFORMATION SYSTEMS

The decision to acquire a generic information system in public healthcare is usually founded on regional and national health policy goals. These policy goals are often translated into various forms of standardization. As a result, national and regional health-policy interests may conflict with local-level interests (Ellingsen et al. 2022).

Countries and their regions have chosen various designs for the implementation and adoption of EHRs, HIEs and HISs (Fixen et al. 2005; Ludwick and Doucette 2009; Curran et al. 2012; Proctor et al. 2013; Sholler 2020; Ellingsen et al. 2022). Implementation strategies are complex social interventions. In healthcare, they result in an information infrastructure consisting of a range of data systems, health professionals, institutions and established practices with no centralized governance structure (Aanestad and Jensen 2011; Ellingsen et al. 2022).

A top-down implementation approach is directed by the government, with the centralized procurement of a standardized HIS with central repositories and shared EHR to replace existing diverse systems (Coiera 2009; Robertson et al. 2010; Morrison et al. 2011). The fundamental flaw in top-down models is that they begin from the perspective of (central) decision-makers and tend to neglect other actors (Coiera 2009). Moreover, a top-down approach is difficult to apply in situations where there is no dominant policy or agency (Coiera 2009).

By contrast, a bottom-up implementation approach relies on local healthcare organizations taking responsibility for ensuring that their existing or newly acquired HIS is compliant with interoperability standards (Bowden and Coiera 2013). This approach preserves existing locally adjusted data systems and is more resilient to large-scale changes, since new technologies or system designs can be adopted locally (Coiera 2009). The price for preservation of local data systems is a weaker national HIS. In addition, a bottom-up approach views the development and compliance (e.g., interoperability) of standards as a voluntary affair. In contrast to a top-down approach, the overall focus of a bottom-up approach is strategic interaction among multiple actors locally or regionally (Sabatier 1986).

There is always likely to be a mismatch between centrally established targets and local requirements (Coiera 2009). Systems developed centrally and then imposed locally are far less likely to succeed than those developed at the coalface (Bowden and Coiera 2013). Therefore, the flexibility offered by the middle-out implementation approach may make it the best national strategy (Coiera 2009; Morrison et al. 2011). The middle-out approach contains elements of both the top-down and the bottom-up strategies, as it combines local consultation, locally driven investment and system choice with central government support, leadership, resources and nationally agreed interoperability standards and goals (Greenhalgh and Bowden 2011; Eason et al. 2012; Bowden and Coiera 2013; Tsai and Koch 2019).

2.2 IMPLEMENTATION AND ADOPTION OF LARGE-SCALE ELECTRONIC HEALTH RECORD SYSTEMS: SELECTED INTERNATIONAL EXPERIENCES

In Sweden, a new HIS was implemented in 40 clinics with 7,000 users at the Karolinska University Hospital, Solna, Stockholm, Sweden. The implementation was part of a merger of two 700-bed teaching hospitals, which began in 2003 and gave rise to the Karolinska University Hospital. The intervention aimed to change five legacy data systems into one new HIS. The decision on the implementation of the HIS was reached in 2004, and implementation was completed in 2005 (Ovretveit et al. 2007).

At the Saudi Arabian Ministry of National Guard Health Affairs, a decision on a new HIS was reached in 1999. Phase one of the implementation rollout occurred between September 2004 and 2005, and phase two began in 2006. The implementation time for this comprehensive new HIS was six years from the decision to upgrade the legacy system to the launch of phase-two rollout in 2006 (Justinia 2009).

Estonia began planning a national HIS in 2000, and the first X-Road services were launched in 2002 (Aaltonen et al. 2010; Saluse et al. 2010; Tiik 2012; National Audit Office of Estonia 2014; Direktoratet for e-helse 2015; Parv et al. 2016; Ross 2016; Novek 2017; Habicht et al. 2018; Metsallik et al. 2018; Taal 2018; Thiel et al. 2018; Yeh and Saltman 2019). Preparations for this nationwide Estonian HIS project occurred in 2003–2005 for four national HIS development projects (EHR, digital images, electronic prescription and digital booking). In 2005, Estonia established a national coordination unit (Estonian eHealth Foundation E-Tervis). The four national HIS projects were executed from 2006 to 2008, and the Estonian national HIS has been operational since the end of 2008. Since January 2009, it has been mandated in law that all healthcare service providers send standardized medical documents to the national EHR. The electronic prescription service was launched in January 2010. All prescriptions have been electronic since 2018. The implementation time in Estonia was eight years, and it took another year to launch the national electronic prescription service in early 2010 and another eight years before all prescriptions became electronic (2018). In 2018, a private government-owned company began operating the Estonian national HIS. The system contains the health records of all Estonian residents, and more than 10,000 healthcare professionals use the system on a daily basis (Metsallik et al. 2018). In September 2017, the actual number of medical documents in the system was more than 30 million for a population of 1.54 million people. Overall, 14 different medical document types are in use, covering more than 17 million outpatient case summaries, around 2 million stationary case summaries, and more than 8 million different medical diagnostic examination reports (Metsallik et al. 2018).

Australia's planning of HealthConnect began in 2000 (Healy et al. 2006; Pearce and Bainbridge 2014; Nohr et al. 2017; Thiel et al. 2018). The Australian Government decided to fund the national HIS implementation in early-2004, established a national coordination organization (National E-health Transition Authority) in 2005 and launched the Australian EHR in mid-2012, renaming it My Health Record in 2015. My Health Record is an online electronic summary of a person's health information. The Australian Government invested $1.15 billion in the development of the system and other digital health infrastructure between 2012 and 2016 (Auditor-General 2019). In the 2017–2018 Budget, the government allocated a further $374.2 million to continue operating the system and expand its use by making it an optout model. Nine out of ten Australians now have a My Health Record. In July 2016, the Australian Digital Health Agency was assigned the role of system operator for My Health Record (Auditor-General 2019). At the Australian federal level, implementation of the distributed national HIS took 12 years from planning the HealthConnect concept in 2000 to the national launch My Health Record in 2012.

In December 1999 in Hawaii, USA, Kaiser Permanente (KP) began preparations to implement a new tailored HIS with the planned starting date of October 2000 (Scott et al. 2005; Ovretveit et al. 2007). The first KP Hawaii site began using the HIS in October 2001. However, in early-2003, only a third of KP Hawaii sites had implemented the system fully. All KP regions halted the implementation and began to prepare a new plan to replace the HIS with another comprehensive and integrated HIS (Epic; KP HealthConnect). The KP Hawaii region was the first to fully implement KP HealthConnect in an outpatient setting (Chen et al. 2009). The implementation time for KP HealthConnect in the Hawaii region was approximately 1.5 years (Silvestre et al. 2009; Pearl 2014; Palen et al. 2016). KP HealthConnect Online (later MyHealthManager) was first implemented as a pilot project for adults (Palen et al. 2016). The implementation time from the start of use of KP HealthConnect to the start of use of MyHealthManager was two years in the KP Northwest region. In addition, the implementation time from pilot-project implementation to the launch of MyHealthManager was 2.8 years. The KP regional implementation took 1.5–2.5 years for the comprehensive EHR (KP HealthConnect) in the KP Hawaii. In addition, it took another two years to implement an add-on online module, MyHealthManager, in KP Northwest (Palen et al. 2016).

At Intermountain Healthcare in Utah and Idaho, the results of a previous systematic review (Jones et al. 2014) were utilized to identify outcome measures and data availability in constructing a 22-measure methodology to monitor performance changes in the replacement of a legacy HIS and to implement a comprehensive new EHR (Millenium) (Coliccio et al. 2016; Coliccio et al. 2017; Colicchio et al. 2018). They used an interrupted time-series design and monthly data from February 2013 to January 2017. Control sites were used from two regions where the new EHR was implemented only at the end of the study (Colicchio et al. 2017). Each of the five intervention regions included a 2-year baseline period before the EHR go-live, followed by a 10–24-month intervention period when the control sites went live in July 2017. Each intervention region included one hospital and 5–10 PHCs. Altogether, 41 outcomes were monitored. After the electronic health record went live, 41% of the 22 measures had an immediate effect, while the effect of 61% became apparent over time. Significant changes in the intervention sites were observed in 12/41 (29%) measures in three or more regions, 78% in two or more regions and 98% in at least one region. The interrupted time-series model identified seasonal effects and outcome variability that would not have been detected by studies using simple measurements or pre-post comparisons. However, no single measure consistently detected identical changes in magnitude or pattern (Colicchio et al. 2017).

2.2.1 SUCCESS AND FAILURE FACTORS IDENTIFIED IN THE LITERATURE ON IMPLEMENTATION AND ADOPTION OF HEALTH INFORMATION SYSTEMS

To understand success in HIS and national HIS implementation, it is necessary to define the characteristics of failure and success (Heeks 2006; Jackson and McLean 2012; Adami 2016). A total failure occurs when an initiative is never implemented or when a new system is implemented but immediately abandoned. In turn, a partial failure occurs when the major goals of an initiative are unattained or when significant undesirable outcomes arise. By contrast, success is characterized by most stakeholder groups' attainment of their main goals and the absence of significant undesirable outcomes. However, no consensus exists over how project failure and success should be defined, and thus it is defined subjectively or by assumptions and interpretations (Heeks 2006; Jackson and McLean 2012; Adami 2016).

In a rapid umbrella review (Fennelly et al. 2020), six organizational factors were found to be important for success in implementation. Moreover, HIS implementation governance, leaders and organizational culture were identified as paramount in ensuring success in the implementation. Furthermore, end-user involvement was important during each phase. Basic computer skills and EHR specific training were identified as key factors, and HIS training was also recommended on an ongoing basis for new staff. Expert peer support also helped end-users optimize their use. The availability of finance, a skilled workforce and time were also important. Commonly, the inability of the HIS to match workflows negatively impacted success (Fennelly et al. 2020).

Three overarching human factors were also identified. Information technology skills and personal characteristics influenced successful implementation. Moreover, end-users' perception of a positive impact on patient care and workload also facilitated success in HIS implementation. By contrast, differing end-user concerns about changes to data privacy and security, patient-clinician relationships, roles and responsibilities were related to negative impacts on implementation success (Fennelly et al. 2020).

Furthermore, six technological factors were identified as critical to successful HIS implementation. Usability impacted end-user efficiency, patient-face time, care quality, patient-clinician relationships and safety. Interoperability was identified as critical for enabling HIE within and across healthcare organizations by introducing technical standards and communication between organizations. HIS implementation success was ensured by procurement or the enhancement of infrastructure, which accounted for a large proportion of the financial resourcing. National and international standards, regulations and policies were critical for interoperability and addressing data privacy and security. Where interoperability standards were in place, the need to adapt HIS software was reduced. Finally, rigorous, resource-intensive, multi-step testing of each HIS function needed to be conducted within live environments with actual end-users (Fennelly et al. 2020).

Successful implementation may involve a lengthy process beginning with planning, designing and piloting, moving to use, modification, and acceptance and ending when the new system is considered routine (Yusof et al. 2008; Murray et al. 2011; Doherty et al. 2012; Morrow et al. 2012; May 2013; Adler-Milstein et al. 2014; Esmaeilzadeh and Sambasivan 2016; Sligo et al. 2017). A number of factors seem to facilitate successful data system implementations: the existence of appropriate organizational and technological structures, ongoing evaluation throughout the implementation process, communication across the organization, strong leadership, adequate resourcing and support for training, user involvement in all implementation phases, end users' perception of the HIS benefits, and the HIS being fit for purpose and championing technology (Justinia 2009; Ludwick and Doucette 2009; Sligo et al. 2017). In any implementation, physician leaders strive for implementation success (Ludwick and Doucette 2009; Best et al. 2012).

In a recent systematic review on the implementation of large-scale information systems, efficiency and safety of healthcare delivery, integration of information among health organizations, cost reduction and economic issues were the most expected benefits from government programmes. From the articles analysed in the review, 34 main difficulties emerged. These difficulties were related to the broader context in which the system is inserted, to the management of the programme, to technology itself and to individuals. In most countries, major concerns were a lack of standardization/interoperability, acceptance of providers and users and project financing. Such difficulties were seen to emphasize the complexity of implementing national HIS technology. In some cases, countries underestimated the challenges involved and ended up compromising the success of government initiatives and the pursuit of expected benefits. A basic requirement for effective management of the programme was a focus on integration and a shared vision between diverse participants (Luz et al. 2021).

In general, a new EHR implementation can improve documentation and screening and reduce prescription errors, but data on the effects on clinical patient outcomes remain insufficient (Priestman et al. 2018). During a two-year prospective study among physicians on the transition from a homegrown EHR to a comprehensive commercial vendor EHR, only the reminders and alerts measure first fell and then returned to the baseline (U-curve), whereas most measures fell and remained below the baseline (L-curve) (Hanauer et al. 2017).

Thus far, no comprehensive review of the empirical research literature has been performed for strategies for electronic health implementation (Varsi et al. 2019). However, in the first realist review of implementation strategies, outcomes and success among 11 studies, implementation strategy management support and engagement, internal and external facilitation, training and audit and feedback were directly related to implementation success. However, no relationship was found between the number of implementation strategies used and implementation success. In rural areas, electronic health implementation has been found to lead to sustainable adoption when the implementation carefully considers and aligns electronic health content with pre-existing structures (Hage et al. 2013).

2.2.2 MULTINATIONAL COUNTRY COMPARISONS OF DIGITAL HEALTH AND NATIONAL HEALTH INFORMATION SYSTEMS

Until recently, the existing academic literature contained no comparisons of implementation approaches or cross-country analyses of the problems associated with nationwide HER, HIE or HIS implementations (Ludwick and Doucette 2009; Deutsch et al. 2010). However, today, multinational comparisons are a common instrument to measure the readiness of national HISs (Ludwick and Doucette 2009; Adler-Milstein et al. 2014; OECD 2015; Rigby et al. 2015; Hüsers et al. 2017; Hyppönen et al. 2017; Oderkirk 2017; Essén et al. 2018; Fragidis and Chatzoglou 2018; Haux et al. 2018; Ammenwerth et al. 2020). Finland's national Kanta Services were compared to other countries in 2007–2019, and Finland has repeatedly been classified as a digital health pioneer in country comparisons (Dobrev et al. 2008; Currie and Seddon 2014; De Rosis and Seghieri 2015; Direktoratet for e-helse 2015; Oderkirk 2017; Seddon and Currie 2017; Zelmer et al. 2017; Essén et al. 2018; Haux et al. 2018; Dubois 2019; Ammenwerth et al. 2020; Oderkirk 2021; DESI 2022).

A small number of nationwide implementations of shared patient-accessible EHRs have been launched among OECD countries (Bowden and Coiera 2013; Oderkirk 2017), the healthcare systems of which have different characteristics (Jounard et al. 2010; Reibling et al. 2019). Attempts to implement EHR in healthcare settings frequently encounter difficulties (House of Commons 2010; Morrison et al. 2011). However, countries are increasingly providing patients with access to their own EHR (Moen et al. 2013; Irizarry et al. 2015; Oderkirk 2017; Essén et al. 2018; Ammenwerth et al. 2019; Ammenwerth et al. 2020) via a web-based patient portal allowing independent access to their data. Results from systematic literature reviews on the benefits and disadvantages of such patient portals have nevertheless proved inconclusive (Goel et al. 2001; Sarkar et al. 2011; Ammenwerth et al. 2012; Nagykaldi et al. 2012; Goldzweig et al. 2014; Otte-Trojel et al. 2014; Irizarry et al. 2015; Mold et al. 2015; Fraccaro et al. 2017; Kelly et al. 2018; Mold et al. 2018; Ammenwerth et al. 2019; Grossman et al. 2019; Han et al. 2019; Antonio et al. 2020).

In August 2019, healthcare professionals were partly or fully able to add patient data to a patient EHR in 14 countries (Ammenwerth et al. 2020). Among these, Finland, Hong Kong, Japan and Sweden provided healthcare professionals from various outpatient and inpatient organizations with the best access to patients' cross-institutional EHR data. Moreover, Finland and South Korea allowed patients and their caregivers the best access to their EHR data. Six countries (including Finland) allowed patients and their caregivers to add data to the patient EHR. Furthermore, Finland showed the highest uptake in 2019 (Ammenwerth et al. 2020).

In the Coiera information value chain, it is necessary for an HIS user to adopt the system and interact effectively with it in order to receive information, which might then influence their decision-making and thus lead to improved care processes and – under beneficial conditions – to better health outcomes (Coiera 2015, 2019).

Evaluating adoption rates is essential for understanding the effect of patient portals or HIS in general on decision-making, care processes and health outcomes. An overall mean adoption rate of 52% (95% confidence interval: 42–62%) has been achieved. However, adoption rates differ considerably by study type: 71% (95% CI: 65–79%) in controlled experiments and 23% (95% CI: 13–33%) in real-world experiments (Fraccaro et al. 2017).

In a 2016 OECD survey, eight countries (including Finland) reported that all or most national HISs contained structured data for key data elements (patient medication, laboratory test results, medical imaging results and surgical procedures) (Oderkirk 2017). Thirteen countries reported national laws or regulations requiring healthcare providers to adopt EHR (including Finland). Furthermore, in seven countries, laws or regulations required adherence to national standards for clinical terminology (including Finland). In addition, 14 countries certified HER vendors (including Finland). Moreover, 13 countries used financial incentives or penalties to encourage healthcare providers to adopt and maintain high quality EHRs (including Finland) (Oderkirk 2017).

The European Foundation for the Improvement of Living and Working Conditions examined the use, access to and perceptions of quality in relation to health services (primary care and hospital services), long-term care and childcare across 28 European Union Member States in 2016 (Dubois 2019). In over half of the Member States, 10% or fewer reported using medical consultation online or by telephone. By contrast, the highest use was reported in Finland: 48% for electronic prescriptions, 46% for electronic consultations and 64% for either of the two or both (Dubois 2019).

The European Commission's Digital Economy and Society Index (DESI) is a composite index that, since 2015, has summarized multiple relevant indicators on Europe's digital performance and tracked the evolution of European Union Member States in digital competitiveness. Finland, Sweden, the Netherlands and Denmark scored the highest in the 2019–2022 Digital Economy and Society Index ratings (DESI 2022).

In the 2020 International Digital Economy and Society Index (I-DESI), 24 international data sets were used to compare 27 European Union Member States and 18 non-European Union countries. Finland was the leading country in the combined international index (Foley et al. 2021).

2.3 PREPARING NATIONAL ELECTRONIC HEALTH RECORDS FOR FINLAND

2.3.1 EARLY EXPERIENCES ON TRANSFORMING PAPER-BASED PATIENT RECORDS INTO ELECTRONIC PATIENT RECORDS IN FINLAND

The development of automatic data processing in Finnish healthcare was uncoordinated in the early-1970s (Hosia 1987). When public PHCs were launched in 1972, two out of three physicians wrote their patients' medical remarks in paper-based files (Rimpelä et al. 1972). However, by the late 1970s, there was already increasing willingness to create electronic medical processes in PHCs (Hosia 1987; Saarelma 1992). Consequently, PHCs began to invest and acquire EHRs. However, added value was achieved through the compilation of administrative statistics and the enhancement of routine appointment procedures instead of through the reduced movement of piles of paper-based notes around the organization or a decrease in the multiple recording of the same information in multiple HIS sites (Hosia 1987; Sohlman 1987).

Finnish patient records nonetheless became electronic during the 1970s (Reponen et al. 1995; Harno et al. 2000). However, even in the 1980s, the Association of Local and Regional Authorities designed a set of standardized (colours, forms) paper-based health records that were widely used in PHCs and specialized hospitals (Reponen et al. 2019). The transformation from paper-based and handwritten notes to EHRs and HISs thus occurred in phases. In PHCs, the prevalence of electronic patient records was 50% in 1998, and 50% in municipal primary healthcare hospitals in 2002; by contrast, the figure was 100% by 2007 (Winblad et al. 2008). Moreover, there did not exist a single functional electronic HIS in any of the five university hospitals in 1998; the first did not arrive until 2001. However, by 2007, all central and university hospitals had electronic patient records, electronic image repositories and laboratory systems in place (Alanko et al. 1998; Tolppanen 2000; Reponen 2001; Ahokas 2010).

2.3.1.1 Lessons learned from regional implementation of the Satakunta Macro Pilot program (1998–2001)

Finland’s first large-scale health information development programme in healthcare and social welfare services was the Satakunta Macro Pilot regional programme, which ran in Western Finland in 1998–2001 (Liikanen 2002; Nissilä 2002; Nykänen and Kairimaa 2002; Ohtonen 2002). The programme’s core objective was to create a regional distributed HIS with secure email and a regional portal to support healthcare and social welfare services. The original programme, with a total budget of EUR 10 million, was planned to include six thematic development areas with 18 projects. This ambitious and complex programme was the first state-funded development programme run locally by municipalities in a bottom-up fashion (Arnkil et al. 2002; Nissilä 2002).

Many lessons learned in the Satakunta Macro Pilot programme were highlighted for future programmes in a comprehensive assessment (Ohtonen 2002). For instance, the assessment highlighted the excessive number of simultaneous projects and the lack of consensus on core focus matters. The programme was also unsuccesful in terms of project management, including steering, reporting and project-execution monitoring and follow-up. As there were no common governance principles in place, issues were decided and plans implemented on an ad hoc basis in parallel with the development work. Moreover, funding models were not in place at the beginning of the programme. In addition, the programme changed dramatically and eventually adopted a top-down approach (Arnkil et al. 2002; Ohtonen 2002). Furthermore, the needs of healthcare service providers and other organizations were not assessed (Nylander et al. 2002). Other problems included the programme’s tendency to overreport figures, i.e., to exaggerate the numbers involved (Koivisto 2002). In addition, the original programme objectives and their consequent expected changes were so ambitious that it would only have been possible to observe them after 5–10 years rather than during the short-term timeframe of the original programme (Ohtonen 2002).

Along with the Satakunta Macro Pilot programme, more than 380 smaller projects were run in 1995–1999 (Hänninen et al. 2001). The assessment results of these projects, together with earlier experiences, suggest that a small-steps approach (incremental) and personnel involvement at all phases lead to faster implementation than that offered by a radical-change approach (Hänninen et al. 2001).

2.3.1.2 Early experiences in implementing electronic prescriptions in Finland

Half the community pharmacies in Finland already used automatic data processing systems in the early-1980s, and all community pharmacies had adopted such systems by 1998 (Ihanus and Salonen 2008). In an experiment (1989–1993) in Turku and Tampere, smartcard-based technology was tested in prescription data transfer from physicians to community pharmacies (Forström and Niinimäki 1998). Electronic prescriptions were developed further in software pilots (1994–1998) in Oulu, Helsinki and four rural municipalities in the Koillismaa area (Kivisaari et al. 1999). Electronic prescriptions were also included in the Satakunta Macro Pilot programme (1998–2001), but without any progress (Ohtonen 2002).

In June 15, the MSAH proposed that the SII together with the Finnish Medicines Agency begin assessing the requirements for developing electronic prescriptions in Finland (Koponen-Piironen and Kiiski 2001). A temporary act on the experimental piloting of electronic prescriptions was passed, and national pilots in four areas were initiated in 2002 (Sariola 2003; Hyppönen 2005). Finland ran the first national electronic prescription pilot in 2002–2006, during which 1,075 electronic prescriptions were issued in two years. This pilot was terminated because the first data system was not technologically ready for further implementation and up scaling (Hyppönen et al. 2006).

The legislation on electronic prescriptions was introduced to improve patient and medication safety and prescription efficiency with reference to some systems already implemented in other countries (Hyppönen et al. 2006). During the planning and preparation time for national HIS implementation, the results from a systematic review revealed that home-grown data systems achieved a relatively high risk reduction of medication errors and adverse drug events (Ammenwerth et al. 2008).

In 2009, nationwide use of electronic prescriptions in the 27 European Union Member States was barely more common than it was in 2003 (Mäkinen et al. 2011). In 2003, only Denmark and Sweden used electronic prescriptions on a daily basis, whereas Belgium (local hospital pharmacies), Denmark (national), the Netherlands (regional), Spain and Sweden all used them in 2009. By contrast, by 2018, 19 European Union Member States, including Finland, used electronic prescriptions on a daily basis (Bruthans 2020).

2.3.1.3 Large-scale quantitative studies on digital health in Finland 2003–2010

Finland has a long tradition of monitoring digital health issues at a national level (Hyppönen et al. 2011; Hämäläinen and Reponen 2019). Nationwide web surveys of organizations in public and private healthcare were conducted in 2003, 2005 and 2007 (Kiviaho et al. 2004; Winblad et al. 2006; Winblad et al. 2008). Moreover, THL incorporated the CAF meso- and micro-level dimensions into the institution's electronic health evaluation framework to assess national HIS implementation (Doupi et al. 2009; Hyppönen et al. 2011; Lau and Price 2016).

An electronic web-based survey of physicians conducted in 2010 – before large-scale implementation of the national Kanta Services' activities – offered, for the first time, a nationwide snapshot of the success of health information tools for patient care at public PHCs and hospital outpatient clinics in Finland (Hyppönen et al. 2011). The survey questions were initially constructed according to the Canadian Benefits Evaluation framework (Lau et al. 2007). However, the 24 questions used in the Canadian framework, in which clinical work processes were taken as the starting point for the questionnaire, were regarded as insufficient for reflecting the different impact mechanisms of elements of the Finnish national HIS when surveying physicians. The views of physicians were critical, as the HIS was regarded as too slow, partly unreliable, unable to offer the type of information (e.g., data summaries) required and the cause of some potential patient safety problems (Vänskä et al. 2010; Hyppönen et al. 2011).

In addition, data was also gathered by other large-scale, independent, parallel national health information technology surveys conducted before the national legislation on the Kanta Services became effective in 2007 and prior to implementation of the national HIS services (Hyppönen et al. 2009; Hämäläinen and Reponen 2019). As previously mentioned, nationwide web surveys of public and private healthcare organizations were conducted in

2003, 2005 and 2007 (Kiviaho et al. 2004; Winblad et al. 2006; Winblad et al. 2008). This series of national surveys also gathered data in 2011, 2014, 2017 and 2021 during the large-scale implementation of the national Kanta Services from 2010 to 2018 (Winblad et al. 2012; Reponen et al. 2015; Reponen et al. 2018; Saukkonen et al. 2022).

HIS use among Finnish healthcare organizations reached saturation point in 2007: electronic patient records were comprehensively used in public PHCs and specialized hospitals (Hämäläinen et al. 2009). Electronic patient records were used as the main or only source of patient narratives in 99% of public PHCs and in 20 hospital districts. Electronic information exchange had also progressed rapidly: electronic referrals and discharge letters were in everyday use in 77% (23% in 2003) of PHCs and 19/20 (10/20 in 2003) hospital districts. In addition, a multilateral regional electronic patient data repository was in use in 17/20 (9/20 in 2005) hospital districts and among 64% (20% in 2005) of PHCs. Moreover, fully interoperable regional patient data exchanges were in place in 2007 in Finnish public healthcare (Hämäläinen et al. 2009).

These nationwide surveys, studies and reports provided the national HIS implementation and adoption organizations and personnel with valuable background information, study results and observations required for the planning, monitoring, follow-up, execution and implementation of the Kanta Services.

2.3.2 THE CLINICAL ADOPTION FRAMEWORK APPLIED TO THE FINNISH CONTEXT AND EXPERIENCES OF EARLY INFORMATION SYSTEMS

The theoretical construct of the CAF provides a potential common framework within which the adoption of electronic health records by clinicians can be described, measured and compared over time (Lau et al. 2011; Lau and Price 2016). The CAF is described in more detail in Section 4.2. As mentioned earlier, THL incorporated the CAF's meso- and macro-level dimensions into the institute's electronic health evaluation framework to assess national HIS implementation (Hyppönen et al. 2011; Lau and Price 2016). However, the CAF was not included in a Finnish literature review of theories to enhance EHR implementation (Ekholm and Kinnunen 2016).

2.3.2.1 Governance for the national health information systems

Governance is defined at the macro level of the CAF. In 1995, the MSAH published a strategy for utilizing information technology in the field of social welfare and healthcare in Finland, followed by a second strategy in 2015 (STM 1996; MSAH 2015). The 1995 strategy placed specific emphasis on adoption of digital patient and client records at all levels of cure and care, combined with nationwide interoperability between distributed legacy HISs, supported by high-level security and privacy protection. The 1995 strategy was evaluated in 2006 (Hämäläinen and Hyppönen 2006).

In the early 2000s, it was suggested that Finland could not manage its forecasted increase in demand for healthcare and social welfare services without efficient utilization of new information and communication technology (Mattila and Kasvio 2006).

According to a Government Resolution in April 2002 (VN 2002), an integrated national electronic patient record system was to be introduced by the end of 2007. In 2003, a national electronic patient record system development project (2003–2007) was established as part of the National Health Programme (Hämäläinen and Reponen 2019). A national electronic patient implementation strategy (STM 2003) and principal EHR requirements were also published (STM 2004; Häyrinen et al. 2004; Hartikainen et al. 2009).

The EHR development project demonstrated the need for centralized national services and the standardization of basic information and regional systems supporting their integration (STM 2005). Such national-level services were defined in the 2006 national architecture (STM 2006). The creation of a centralized electronic archive for the healthcare sector emerged as an important project within the Information Society Programme, in which a ministerial committee outlined the basic precepts of the national HIS architecture in 2006 (VNK 2005, Hämäläinen and Reponen 2019).

Finland phased in electronic prescription with the *Act on Electronic Prescription*, which became effective on April 1, 2007. Together with the *Act on Electronic Processing of Health Care and Social Welfare Client Data*, which became effective on July 1, 2007, legislation on the national Kanta Services was thus in place. These laws were further made concrete by releasing the eHealth Roadmap – Finland (MSAH 2007).

In Finland, the national Prescription Centre services were developed on the basis of solutions already implemented in Denmark, Germany, England and Sweden. In turn, the national Patient Data Repository services were developed in reference to solutions introduced in Austria, Belgium, Denmark, England, the Netherlands, Sweden and the United States of America (Hyppönen et al. 2017).

Permanent legislation obliged all public healthcare providers to integrate their operations into a shared national, centralized and integrated electronic archiving system – a stipulation that also applied to private healthcare units that did not use paper-based archives. The SII was tasked with maintaining the main parts of the national HIS services. National Code Server tasks were divided between the SII (maintaining the technical code server application) and THL (providing codes, classifications and other code server contents) (MSAH 2007).

The eHealth Roadmap – Finland aimed to provide solutions to support electronic services for citizens built on top of the national architecture. Here the MSAH made two strategic choices. First, to ensure the availability of information for patients undergoing treatment, regardless of time or place, in public and private healthcare, it decided to include comprehensive digitization of customer data, development of the semantic and technical compatibility of EHR data systems for the entire contents of patient records, development of the national healthcare infrastructure and information network solutions, identification and authentication solutions, electronic signatures, and the maintenance of online information to support decision-making. Second, to enable the participation of citizens and patients and ensure that citizens' access to more and higher-quality health information, it decided to include the development of a citizen's health information portal, citizens' access to their own patient records, health information and log data, and development of electronic services (booking of appointments, electronic discussions, electronic document transfer, online consultation) (MSAH 2007).

By 2010, it was agreed that the main functional responsibility areas were to be shared between the national actors supervised by the MSAH. The SII was assigned responsibility for the technical infrastructure of electronic archiving, the national electronic prescription database and the national medication database. DVV provided smartcards for the identification of professionals, supported by information from Valvira. THL governed, and the SII hosted, nationally standardized codes and classifications, which were delivered via the National Code Server (Mäkelä-Bengs and Vuokko 2013; Hämäläinen and Reponen 2019).

2.3.2.2 Standards for use in the national health information systems

Standards are defined at the macro level of the CAF. In the 1995 strategy, the integration method chosen was message processing, a concept dovetailed with the use of standards in the Health Level 7 standard family (MSAH 2007; Hosseini and Dixon 2016), which were already in widespread use in Finland. Health Level 7 provides a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, establishing the language, structure and data types required for seamless integration between systems (Hosseini and Dixon 2016).

In order to implement the 2007 legislation in due time in 2011, it was essential to formulate a coherent national plan on classifications, codes, terminologies, structures and standards (MSAH 2007). The need for unified data coding in patient records was introduced in 2002, which triggered the development of the National Code Server (Huttunen 2002; STM 2004). It was built in 2003–2004 at THL and has provided the main codes online free-of-charge for all since 2004. The development of the certificate service administration for healthcare professionals and organizations began at Valvira in 2004 (MSAH 2007).

Since the early-1960s, Finland has used a unique personal identity code for each citizen and inhabitant, and since 2007 each citizen has also possessed an electronic identity. In electronic transactions, a citizen can be identified and verified using a Finnish electronic identity card and key public infrastructure. Moreover, commercial banks provide authentication based on one-time codes (MSAH 2007).

The national HIS architecture requires that all healthcare operating units be identified with a unique identifier. Units are certified by a national certification authority for electronic transactions. THL maintains the healthcare unit register and instructs operating units on the issue of Object Identifier codes. Private healthcare service providers acquire their codes from the licensing authority. The healthcare unit register is maintained on the National Code Server, as required by the national HIS architecture (MSAH 2007).

The national architecture also requires that patient documents be electronically signed before they are deposited/recorded in the archive and repositories. Electronic signatures are created on a decentralized basis in the units that generate the records to be electronically signed. The national HIS architecture specifies a secure message handling service to link local and regional electronic health records and the national Kanta Services (MSAH 2007).

2.3.2.3 Funding of the development of national health information systems

Funding is defined at the macro level of the CAF. Responsibility for the procurement of the basic HIS was assigned to the service providers. The MSAH provided EUR 11 million in financing for so-called cluster development projects organized around data system vendors; project clusters were coordinated at the national level in 2006–2009 (50% state-funding contribution) (Doupi et al. 2010). The MSAH had financed, and continued to finance, work on national specifications through separate state-budget funding: EUR 33 million was allocated to the construction of the national KanTa development programme services in 2006–2010. Thereafter, the services were to be funded through service user fees (MSAH 2007).

According to VTV's audit on the KanTa development programme in 2000–2009, approximately EUR 180 million in national and European Union funds went to finance social welfare and healthcare information projects, not including the costs of developing national HIE and HIS services (KanTa development project) or the National Project for Social Services Information Technology. Altogether, EUR 250 million was tied to development projects run in 2000–2010, not including the self-funded portion of aid or loans granted to enterprises or other financing granted for social welfare and healthcare information projects (VTV 2011).

2.3.2.4 Trends and assessments of national health information system development

Trends are defined at the macro level of the CAF. Finland ran its first national electronic prescription pilot programme in 2002–2006. The patients involved considered electronic prescriptions to be safe and the carrying of paper documents unnecessary. However, the pilot patients believed that the most common risks associated with electronic prescriptions were inadequate data protection and misuse of personal information (Hyppönen et al. 2006).

In 2007, THL and the University of Oulu conducted survey-based research on behalf of the MSAH to ascertain how prepared different actors were to implement, adopt and use the national, centralized, shared and integrated KanTa services under preparation (Winblad et al. 2008). In mainland Finland, 15/20 hospital districts estimated that they would be ready to begin using the electronic prescription service in 2009–2011 (five in 2009, six in 2010 and five in 2011) and the electronic archiving service in 2010 at the earliest (five in 2010 and 10 in 2011). Approximately 40 percent of PHCs could not estimate the year, and the remainder predicted that they would be ready to begin using the services in 2010–2011. At the time of this research, KanTa development project configurations were not fixed, and the survey was sent to data system users who were unlikely to have been able to influence the timetables for the HIS vendors' solutions and products (VTV 2011).

A six-month project, KaTRI, assessed the national HIS architecture that was launched in November 2008. The project evaluated five phases of the HIS: planning, development, implementation, installation and operation (Brender 2006). The project defined both the core services (electronic prescription, electronic archiving and electronic viewing) and the enabling services (certificate services, the National Code Server and changes in the legacy systems). An assessment was to be performed before (estimated from 2009 to 2011), during (2011–2016) and after implementation of the national HIS services (since 2016 onwards) (Hyppönen et al. 2009).

2.3.2.5 Early activities to develop a large-scale nationwide implementation plan

Implementation is defined at the meso level of the CAF. Following the strategic choices introduced in the eHealth Roadmap – Finland in 2007, the MSAH steered and guided the national KanTa development programme. The MSAH held responsibility for strategic guidelines, legislation, national HIS architecture, cooperation with other ministries, overall planning, steering, supervision, specifications and configurations. THL held responsibility for developing the National Code Server. Valvira developed the certificates for organizations and smartcards for healthcare professionals. The SII was responsible for the construction and maintenance of the centralized, integrated and shared national HIS services. Implementation support for the field was the responsibility of the KunTo office at the Association of Regional and Local Governments of Finland, which also coordinated so-called regional cluster projects and the development of the electronic patient record structure and content under the MSAH supervision (MSAH 2007).

The MSAH and SII signed an agreement in December 2007 in which the latter was assigned the task of constructing and maintaining the KanTa development programme's national centralized services. The SII's tasks were internally organized into the KanTo project, consisting of the following subprojects: electronic archiving, electronic prescription and electronic viewing. The electronic archiving of health data and electronic prescriptions was assigned to an external sub-contractor, whereas electronic viewing was developed by the SII itself. The SII issued regular quarterly reports on the execution of the KanTo project to the Ministerial Advisory Board and monthly reports to the Board's Coordination Division (VTV 2011; Hämäläinen and Reponen 2019).

A KunTo project management office was established at the Association of Regional and Local Governments of Finland in late-2008 and began to function in March 2009. The funding came from the MSAH (partially, 50%) and hospital districts (partially, 50%). Its main responsibility was to help regions subscribe to, implement and adopt the national HIE services. The KunTo office issued annual reports on the performance of its activities to the Ministerial Advisory Board (VTV 2011).

According to the implementation plan, compiled jointly with THL and the KunTo project management office, Prescription Centre implementation was to occur in three phases at the national, regional (hospital districts) and local (municipality healthcare units) levels (Ahlblad 2008; Järvinen-Hiekkanen 2009). Local production pilot projects in Turku and Kotka were established and run to observe working methods in the implementation (and adoption) of the HIS (product) installations and to produce common guidance by analysing the experiences gained (Figure 1).

Regional production pilot projects in the Eastern Savonia and Länsi-Pohja Hospital Districts were established and run. The Prescription Centre services pilot projects were realized on a small, local scale in two towns and regionally in two small hospital districts before scaling up. The Patient Data Repository production pilots were realized in a similar way in Kuopio and the Eastern Savonia Hospital District (Figure 2) (Jormanainen 2015).

According to a Government Resolution in April 2002, an integrated national electronic patient record system was to be introduced by the end of 2007, and the services were to go online in 2007–2010. According to the original legislation in 2007, all national HISs were to be fully functional by April 1, 2011. The implementation design in the legislation followed a big-bang approach (VN 2002).

In November 2007, the MSAH announced that the objectives for electronic prescription subscription and use readiness were to be achieved by August 30, 2008 and by December 31, 2008 for the electronic archiving service. Certifications were to be completed by December 31, 2009 (VTV 2011).

VTV conducted a comprehensive, in-depth audit of the national KanTa development programme in 2000–2009. The audit found that aid granted to HIS projects had been used to achieve implementations that were only introduced locally. The application of funds for these projects had not been coordinated nationally. Thus, the results remained local, and some activities ended after the termination of project funding. Managing small and fragmented projects and grants also placed increasing demands on administrative resources (VTV 2011).

Overall, the results achieved in the KanTa development programme were estimated to be modest. The programme execution lacked leadership; projects were technology driven, delayed and late; projects were uncoordinated run simultaneously, and the programme enjoyed only partial cost control. Moreover, there was a lack of professional information, communication technology management and leadership. Furthermore, the architecture of the national Kanta Services was modified during the ongoing development projects. Original plans changed and became more detailed during programme execution. The KanTa development programme was conducted on the basis of consensus, and unanimous decisions on configurations changed several times. Furthermore, large-scale programmes were initiated without guiding resources before previous pilots, programmes or actions had been completed. In addition, many personnel changes occurred during programme execution. De facto implementation and decision-making nonetheless occurred in the permanent ministerial organization, not within the programme structures (VTV 2011).

Moreover, the programme was based on unrealistic timetables and the economically unsound procurement and outsourcing of strategically important expertise. Programme management also lacked systematic, continuous and documented monitoring and follow-up. Different actors expressed different opinions on the timetable, programme execution or specification readiness, and various types of information were accessible from different sources (VTV 2011).

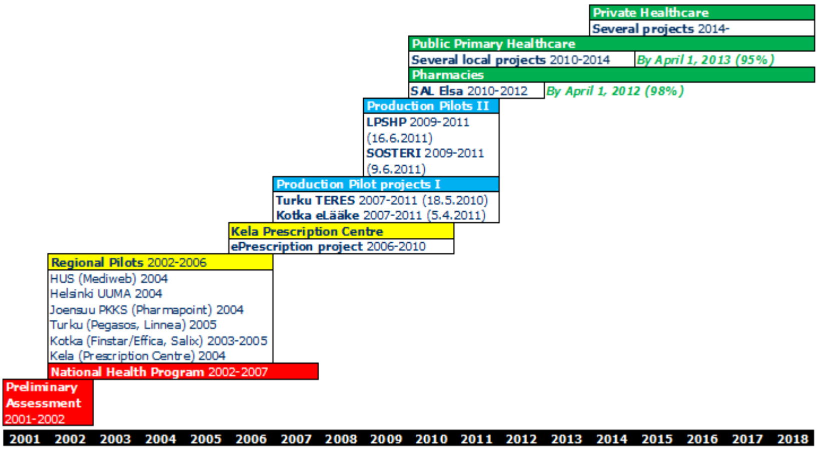


Figure 1 Scheme of the implementation of electronic prescription from the preliminary assessment in 2001–2002 (red; a part of the National Health Programme, 2002–2007) to national implementation of the Prescription Centre services in community pharmacies, and public primary and private healthcare in 2010–2018 (green).

In addition, preliminary regional pilots and the Social Insurance Institution of Finland's ePrescription projects (yellow) and local and hospital-district-wide production pilots (light blue) are described. The names, years and dates in the white boxes refer to organizations and projects.

Public primary healthcare includes specialist hospitals. Kela refers to the Social Insurance Institution of Finland. Kotka is a town in southeast Finland; Finstar/Effica are electronic health record solutions, and Salix is a pharmacy solution. Turku is a town in southwest Finland; Pegasos is an electronic health-record solution, and Linnea is a pharmacy solution. Joensuu is a town in east Finland; PKKS refers to North Karelia Central Hospital, and Pharmapoint is a solution for electronic prescription. Helsinki is the capital city, and UUMA refers to an electronic prescription project. HUS is the Helsinki and Uusimaa Hospital District, and Mediweb is an electronic prescription solution. eLääke refers to an electronic prescription production pilot project in the city of Kotka. TERES refers to an electronic prescription production pilot in the city of Turku. SOSTERI refers to an electronic prescription production pilot project in the East Savolax Hospital District. LPSHP refers to an electronic prescription production pilot project in the Länsi-Pohja Hospital District. SAL refers to the Association of Finnish Pharmacies and Elsa to the implementation of nationwide electronic medication dispensing services across pharmacies in Finland.

Source: Finnish Institute for Health and Welfare.

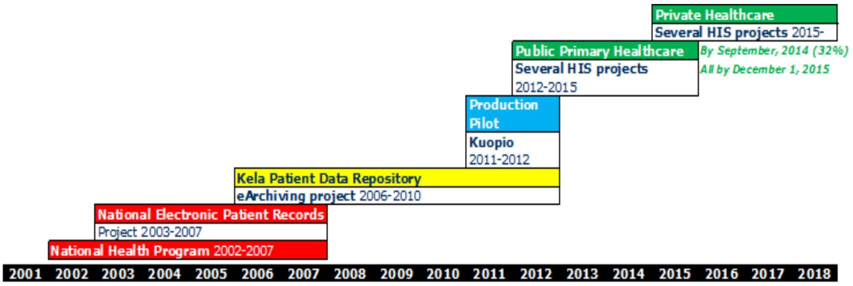


Figure 2 Scheme of the implementation of electronic patient record archiving from the national electronic patient records project 2003–2007 (red; a part of the National Health Program 2002–2007) to national implementation of the Patient Data Repository services in public primary and private healthcare in 2018 (green).

In addition, the Social Insurance Institution of Finland's eArchiving project (yellow) and a local production pilot (light blue) are described. The names and years in white boxes refer to organizations and projects. Public primary healthcare includes specialized hospitals. Kela refers to the Social Insurance Institution of Finland (SII). eArchiving is the project name for the electronic archiving project(s) at the SII. Kuopio is a town in East Finland. HIS refers to Health Information System.

Source: Finnish Institute for Health and Welfare.

2.4 CONCLUSIONS FROM THE LITERATURE REVIEW

The academic literature prior to 2010 lacks comparisons of implementation approaches or cross-country analyses of the problems associated with nationwide EHR implementation (Ludwick and Doucette 2009; Deutsch et al. 2010). The current literature is dominated by reports of single organizations and the punctuality of their HIS implementation (often EHR) (Robinson et al. 2010; Ross et al. 2016; Sligo et al. 2017; Klecun et al. 2019; Luz et al. 2021). Moreover, most information-system and healthcare reforms are not properly followed up, and their outcomes are rarely evaluated (Rigby 2001; Coiera 2009; Couffinhal et al. 2016).

Healthcare system and service reforms rarely appear without the requirement of introducing complex information and communication technology on a large scale (Coiera 2009; Coiera et al. 2012). Furthermore, comprehensive HIS implementation is risky (Berg 2001; House of Commons 2007; Deutsch et al. 2010; Houghom 2011; Greenhalgh et al. 2013; Flyvbjerg 2014; Ellingsen et al. 2022). Implementing a new nationwide HIS is a megaproject: a large-scale, complex and costly endeavour requiring many years to develop and build, involving multiple public and private stakeholders, and impacting millions of people (Flyvbjerg 2014; Ross et al. 2016). Lessons from organizational studies and the management of mega-projects may provide understanding of some of the ongoing healthcare challenges (Price et al. 2019). The implementation process and adoption efforts of EHRs are critical to their success and must be carefully planned and considered across the complex and constantly changing healthcare landscape (Esmaeilzadeh and Sambasivan 2016; Fennelly et al. 2020).

The Kanta Services is the name of Finland's nationwide centralized, shared, and integrated electronic data system services. The main national Kanta Services were introduced in phases between 2010 and 2018. The Kanta Services form a unique service concept and entity comprising My Kanta Pages, Prescription Services, a Pharmaceutical Database, a Patient Data

Repository, the archiving of old patient data, a client-data archive for social welfare services, the sharing of medical certificates, the Kelain online prescription service and the Kanta client test service (Kanta Services 2022).

Before implementation of the Kanta Services began in 2010, the literature contained only a small number of studies on international experiences of large-scale national or regional HIE or HIS implementations. Moreover, in these studies, the information content varied significantly in terms of the level of detail, and hardly any research utilized a reporting framework. Sociotechnical perspectives were presented, but the attitudes and behaviours of clinicians were only rarely reported. Many studies focused on replacing one legacy HIS with a new, more tailored system in one organization or a region alone (Healy et al. 2006; Ovretveit et al. 2008; Justinia 2009; Ludwick and Douchette 2009; Aaltonen et al. 2010; Deutsch et al. 2010; Greenhalgh et al. 2010; Saluse et al. 2010; Tiik 2012; Greenhalgh et al. 2013).

The Finnish national legislation on Kanta Services came into effect in 2007. Studies published in Finland were descriptive reports of local or regional implementation and adoption efforts: South Ostrobothnia Hospital District (1999–2003) (Ristimäki et al. 2011), Helsinki city primary healthcare (2001–2002) and the Helsinki and Uusimaa Hospital District (2003–2007) (Ripatti and Laapotti 2004), the Satakunta Hospital Disctrict (2004–2008) (Mäenpää et al. 2011, Mäenpää et al. 2012) and Varkaus town (2005–2006) (Valta 2013).

The CAF (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016), which was developed before 2010, includes healthcare and clinicians' perspectives. Its meso- and macro-level dimensions were incorporated into the Finnish national electronic framework in 2009 (Doupi et al. 2009).

3 AIMS OF THE STUDY

This research aimed to assess the implementation and adoption of Parliament-approved Finnish legislation – the *Act on Electronic Prescription* (61/2007) and the *Act on Processing Customer Data in Health and Social Care* (159/2007) – from 2010 to 2018. To achieve this, the study employed the Clinical Adoption Framework to provide an overarching conceptual model for electronic health information system adoption and the Clinical Adoption Meta-Model to assess post-deployment of the national Kanta Services.

The specific aims of this research were as follows:

1. To document the central building blocks of a large-scale nationwide development process established to implement electronic services based on national legislation in Finland, and to describe the implementation and adoption of the national Kanta services in 2010–2017 in Finland using indicators during follow-up (Study I);
2. To assess the implementation and adoption in 2010–2016 of the national Kanta Services (the Prescription Centre services and the Patient Data Repository services) across community pharmacies and public primary healthcare centres in municipalities, hospital districts, university hospital special catchment areas and throughout the nation as a whole (Study II);
3. To measure prescription volumes in Finland and how healthcare professionals (physicians and dentists) learn to use new ways to issue electronic prescriptions in their care and cure processes (Study III);
4. To investigate, for the first time, the nationwide use of My Kanta Pages in public primary healthcare centres, hospital districts and university-hospital-specific catchment areas in 2010–2018 (Study IV); and
5. To examine direct associations between demographics, self-rated health, socioeconomic position and social participation and the perceived benefits of online healthcare and social welfare services in a representative random sample of the adult population living in Finland in 2017 (Study V).

4 METHODS

4.1 ROLES OF CENTRAL ADMINISTRATION ACTORS IN NATIONAL HEALTH INFORMATION SYSTEM AND HEALTH INFORMATION EXCHANGE IN FINLAND

Responsibility for the general strategic guidance and funding of social welfare and healthcare in Finland rests with the MSAH, which prepares legislation concerning the national HIS, establishes the target state and roadmap for information management in social welfare and healthcare services and the national Kanta Services, and monitors the results.

THL functions as the authority responsible for information management in the social welfare and healthcare sectors. It is responsible for the functional planning of the national HIS and participates in deployment activities in an expert capacity regarding HIS content and operating models. THL also provides support and training for social welfare and healthcare professionals.

SII is responsible for the planning and implementation of deployment projects for the national Kanta Services as well as for communication and client and stakeholder cooperation. The SII organizes events and training related to the deployment and is responsible for the maintenance and technical development of the national Kanta Services, back-up and support services related to the information systems, the technical building of the National Code Service and the coordination of joint testing.

Valvira authorizes healthcare professionals and grants national licences for private healthcare service provision. Valvira is responsible for the role- and attribute-information services required in the national Kanta Services as well as for the so-called Valvira codes.

DVV is responsible for electronic identity and certificate services. Persons using patient data systems, archiving services and the electronic prescription service must be identified and authenticated in a reliable way. It must also be possible to sign patient records and prescriptions electronically. The authentication of healthcare professionals and other employees of healthcare service providers, as well as the electronic signing of documents by such personnel are enabled via DVV’s certification services and the management of operating units’ access rights.

4.2 THEORETICAL FRAMEWORK

4.2.1 THE CLINICAL ADOPTION FRAMEWORK

This research uses the CAF to provide an overarching conceptual model for electronic health information system adoption in the assessment of the adoption and implementation of Parliament-approved legislation – the *Act on Electronic Prescription* and the *Act on Processing Customer Data in Health and Social Care* – in 2010–2018. In addition, the CAF’s macro-level dimensions, governance, standards, funding and trends, as well as meso-level implementation factors were used to analyse the time period before 2010 as a ‘proof-of-concept’ (Lau et al. 2007; Lau 2009; Lau et al. 2011).

The CAF was originally developed to promote successful clinical HIS adoption in the micro-level Benefits Evaluation framework of Canada Health Infoway (Lau et al. 2007) and was later extended by incorporating sets of meso- and macro-level factors (Lau 2009; Lau et al. 2011). Canada Health Infoway is an independent, not-for-profit organization funded by the federal government that is committed to improving the health of Canadians by accelerating the development, adoption and effective use of innovative digital health solutions to help create a health system that provides better, more connected experiences, with the patient as the focus (Canada Health Infoway).

A framework usually denotes a structure, overview, outline, system or plan consisting of various descriptive categories (e.g., concepts, constructs or variables) and the relations between them that are presumed to account for a phenomenon. However, frameworks only describe empirical phenomena by presenting a set of categories; they do not provide explanations (Sabatier 1999).

The CAF was initially based on a stable business information system environment, and thus did not include organizational and social contexts (Lau et al. 2011). The CAF has been developed especially for the healthcare context, and its efficacy has been validated by several studies (Craven et al. 2016; Lau and Price 2016). Moreover, it is currently referred to in Nordic eHealth Benchmarking development work (Hyppönen et al. 2013; Hyppönen et al. 2017; Nohr et al. 2020), and it has been used in systematic reviews (Lau et al. 2010; Lau et al. 2012; O´Donnell et al. 2018, van Mens et al. 2020) as well as in other settings (e.g. Hyppönen et al. 2011; Bassi et al. 2012; Lau et al. 2013; Kuhn and Lau 2014).

The CAF is built on theories and models of a number of disciplines outside healthcare (Lau and Price 2016), including the Information Technology Interaction Model (Silver et al. 1995; Ben-Zion et al. 2014), the Technology Acceptance Model (Davis 1989; Holden and Karsh 2010), the Unified Theory of Acceptance and Use of Technology Model (Venkatesh et al. 2003; Whitten et al. 2010), the Information System success model (DeLone and McLean 1992; DeLone and McLean 2003), the Diffusion of Innovation (Rogers and Shoemaker 1971; Greenhalgh et al. 2004), implementation research (Cooper and Zmud 1990; Kukafka et al. 2003), task-technology fit (Goodhue and Thompson 1995; Ammenwerth et al. 2006), managing change and risks (Kotter and Schelsinger 1979; Paré et al. 2008) and the people and socio-organizational aspects of electronic health (Stead and Lorenzi 1999; Kaplan and Shaw 2004).

Currently, the CAF consists of three dimensions (the micro, meso and macro levels), which are organized into several categories (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016). The micro-level dimensions and categories were defined in the Benefit Evaluation framework of Canada Health Infoway (Lau et al. 2007). At the meso-level, the people dimension is drawn from the constructs of the Unified Theory of Acceptance and Use of Technology Model, while the organization and implementation dimensions are derived from the Information Technology Interaction Model, implementation research and change management models. The macro-level factors are based on sociotechnical approaches that transcend organizations to include overall societal trends. The macro-level factors directly influence the meso-level factors, and the meso-level factors directly affect the micro-level factors (Lau and Price 2016). There is a feedback loop at each level, where adoption efforts and results may reshape higher-level views (Figure 1) (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016).

At the micro-level, it is proposed that successful HIS clinical adoption depends on HIS quality, usage quality and net benefits (Lau and Price 2016). The better the HIS quality, the more satisfied are clinicians, leading to greater tangible net benefits over time. HIS quality refers to the accuracy, completeness and availability of the clinical information content of the HIS, the features, performance and security of the system, and the responsiveness of the support services. Usage quality refers to HIS usage intentions or patterns, and user satisfaction concerns usefulness, ease of use and competency. Net benefits, in turn, concern changes in care quality, access and productivity resulting from HIS adoption by clinicians. Care quality covers patient safety, appropriateness or effectiveness and health outcomes. Access refers to provider or patient participation and availability or access to services, while productivity covers care coordination, efficiency and net cost (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016).

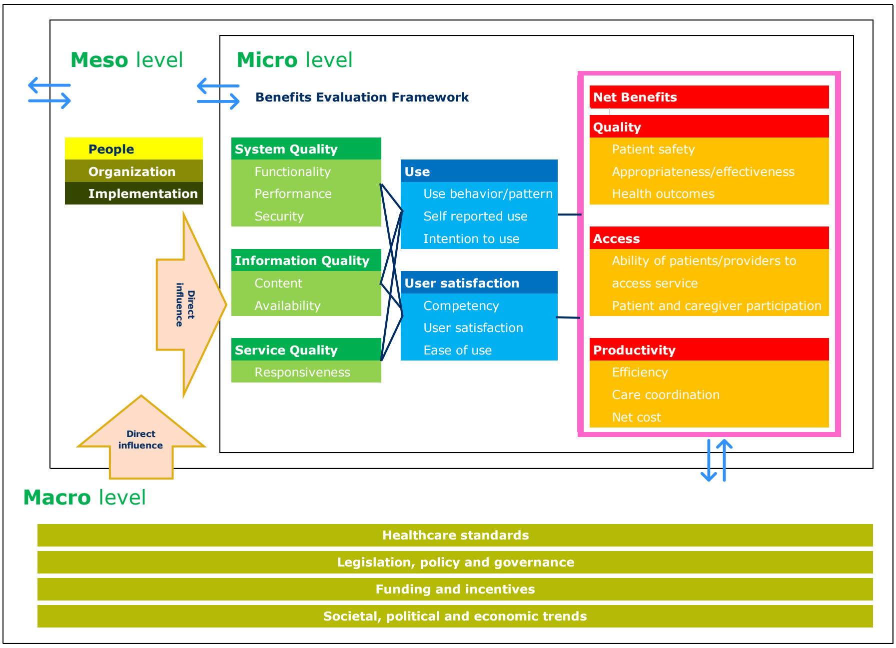


Figure 3 Micro, meso and macro level dimensions of the Clinical Adoption Framework (CAF). The micro-level Benefits Evaluation Framework is modified from Lau et al. (2007). The meso- and macro-levels are modified from Lau et al. (2011) and Lau and Price (2016).

At the meso-level, successful HIS clinical adoption depends on people, organization and implementation (Lau and Price 2016). The HIS will add value if it is designed to support organizational performance goals and the day-to-day work practices of clinicians. 'People' refers to all individuals or groups in the healthcare system who are connected in some way to electronic health, their personal characteristics and expectations, as well as their roles and responsibilities within the HIS. 'Organization' refers to the HIS fit with the organization's strategy, culture, structure and processes, information infrastructure and return on value (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016).

'Implementation' concerns the HIS adoption stages, project management approaches and the extent of electronic health practice fit planned in the future and operating at present. HIS adoption usually occurs in phases (initiation, build/buy, and introduction to adaptation). The project management approach includes planning, activities and resources for HIS adoption, (scope, objectives, constraints, governance, methodology, commitment, communication, training, risks, monitoring, reporting and expectations). 'HIS practice fit' includes the degree of fit between the HIS and organizational work practice, and the extent of change due to health information system adoption (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016).

At the macro-level, it is proposed that successful clinical adoption of the HIS depends on governance, standards, funding and trends in specific environmental contexts (Lau and Price 2016). 'Governance' refers to the influence of governing bodies, legislative acts and regulations or policies. ‘Standards’ concerns the HIS standards (types of data, messaging, terminology and technology standards), organizational performance standards (e.g. accreditation) and professional practice standards (professional competency, knowledge, skills and performance in the workplace, including HIS adoption) in place. ‘Funding’ alludes to the payment and remuneration, added values (general expectations on the return-on-value from the HIS adoption) and incentive programmes in place. ‘Trends’ concerns the general expectations of the public and the general political and overall socio-political and economic attitudes toward technologies, electronic health and healthcare (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016).

4.2.2 THE CLINICAL ADOPTION META-MODEL

In this research, the CAMM was utilized to assess post-deployment of the national Kanta services in Finland. In the CAMM, ‘availability’ defines the end-user’s ability to interact with the HIS and its content when and where required. ‘Use’ is dependent on availability and can be measured through many metrics. ‘Behaviour’ describes meaningful adaptation of clinical or health workflows to leverage the HIS features. ‘Clinical or health outcomes’ are defined as impacts that are attributable to the HIS adoption. ‘Time refers’ to the transition periods across the four dimensions (Price and Lau 2014; Price 2016).

The CAMM was developed to support the implementation, study and evaluation of a HIS and to help consider and describe post-deployment adoption of a HIS across four dimensions over time (Price and Lau 2014; Price 2016). It is time dependent and focused on the healthcare context (Figure 2). The CAMM has also been applied to evidence assessment in reviews (Antonio et al. 2020).

The CAMM suggests a logical chain beginning with availability, proceeding to HIS use and then clinical behaviour changes, and concluding with changes in outcomes (Figure 3) (Price and Lau 2014; Price 2016).

‘Availability’ defines the end-user’s ability to interact with the HIS and its content when and where required. ‘User access’ is the ability of end-users to access the system. ‘System availability’ describes how available the HIS is to its intended end-users. ‘Content availability’ concerns the information that is accessible in or through the HIS (Price and Lau 2014; Price 2016).

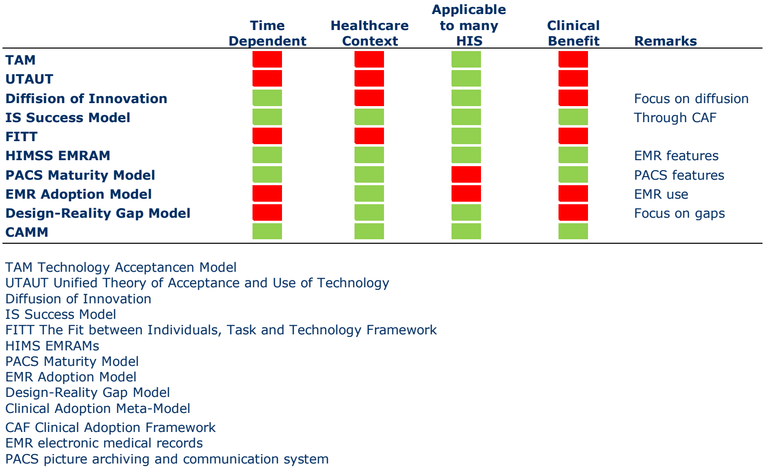
‘Use’ is dependent on availability and can be measured through many metrics (e.g. number of sign-ins). ‘User experience’ describes the subjective experience of end-users when using the system (Price and Lau 2014; Price 2016).

‘Behaviour’ describes meaningful adaptation of clinical or health workflows to leverage the HIS features. In the behaviour dimension, ‘general capacity’ is a global change or transformation in the healthcare organization, and specific behaviours can be assessed that are linked to HIS features, as can the specific workflows impacted by its implementation (Price and Lau 2014; Price 2016).

‘Clinical or health outcomes’ are defined as impacts that are attributable to HIS adoption. ‘Patient outcomes’ include aspects directly related to individual patient health, while ‘provider outcomes’ include provider-centred measures. In turn, ‘organizational outcomes’ consist of factors measured at an organizational level, whereas ‘population outcomes’ are measured across organizations. ‘Cost outcomes’ describe relative or absolute costs to the healthcare system (Price and Lau 2014; Price 2016). ‘Time’ refers to the transition periods across the four dimensions (Price and Lau 2014; Price 2016).

The CAMM is likely to produce one of seven archetypes. These seven archetypes highlight the importance of measuring multiple aspects of adoption over time to allow comparison of varying levels of successful adoption (Price and Lau 2014; Price 2016).

In the ‘No Deployment’ archetype, the HIS fails to reach end-users, since end-user deployment is stopped prior to a planned go-live event. In the ‘Low Adoption’ archetype, the HIS is deployed and available, but availability is followed by minimal or rapidly declining use. In the ‘Adoption without Benefit’ archetype, a HIS is deployed, available and used by end-users, but it fails to achieve the intended behaviour changes or the expected outcomes. In turn, the ‘Behaviour Change without Outcome Benefit’ archetype occurs when an adopted HIS produces the expected behaviour change but fails to produce the expected outcomes (Price and Lau 2014; Price 2016).



	Time Dependent	Healthcare Context	Applicable to many HIS	Clinical Benefit	Remarks
TAM	🟥	🟥	🟩	🟥	
UTAUT	🟥	🟥	🟩	🟥	
Diffision of Innovation	🟩	🟥	🟩	🟥	Focus on diffusion
IS Success Model	🟩	🟩	🟩	🟩	Through CAF
FITT	🟥	🟥	🟩	🟥	
HIMSS EMRAM	🟩	🟩	🟩	🟩	EMR features
PACS Maturity Model	🟩	🟩	🟥	🟩	PACS features
EMR Adoption Model	🟥	🟩	🟥	🟥	EMR use
Design-Reality Gap Model	🟥	🟩	🟩	🟥	Focus on gaps
CAMM	🟩	🟩	🟩	🟩	

TAM Technology Acceptancen Model
UTAUT Unified Theory of Acceptance and Use of Technology
Diffusion of Innovation
IS Success Model
FITT The Fit between Individuals, Task and Technology Framework
HIMS EMRAMs
PACS Maturity Model
EMR Adoption Model
Design-Reality Gap Model
Clinical Adoption Meta-Model
CAF Clinical Adoption Framework
EMR electronic medical records
PACS picture archiving and communication system

Figure 4 The Clinical Adoption Meta-Model (CAMM) and other adoption models compared. The CAMM is most focused on linking early adoption, e.g. availability and use, to later adoption benefits in the healthcare context. The red squares mean no and the green squares yes. HIS refers to health information system. Modified from Price and Lau (2014).

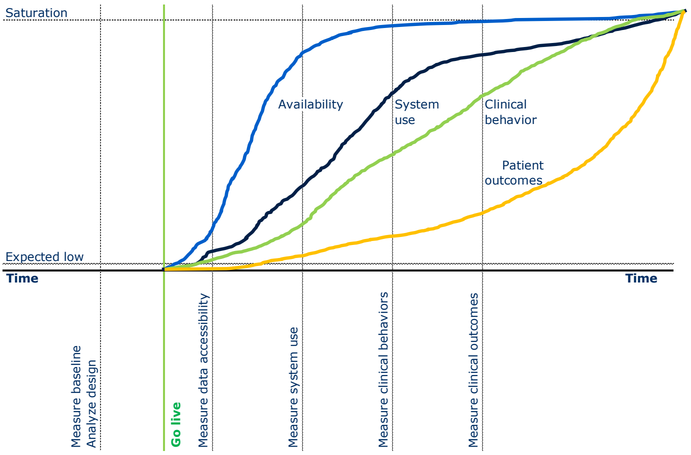


Figure 5 The Clinical Adoption Meta-Model maturity stages for describing archetype characteristics. Modified from Price and Lau (2014) and Price (2016).

The ‘Adoption with Benefits’ archetype is characterized by a clear progression of HIS availability that leads to ongoing HIS use, which then causes observable changes in clinical and health behaviour that, in turn, result in improvements in measured outcomes (Price and Lau 2014; Price 2016).

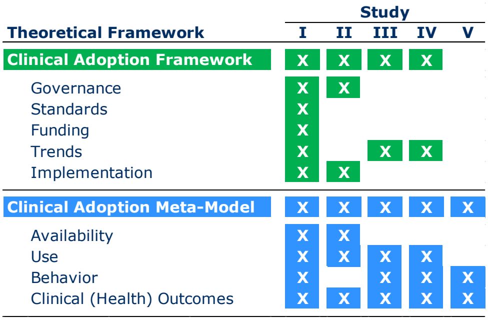
In the ‘Benefit without Use’ archetype, the expected behaviour changes and/or outcomes occur without HIS use. HIS adoption may also lead to unintended consequences and harm, which can occur from flawed design or erroneous use or from changes in other workflows resulting from the HIS implementation (‘Adoption with Harm archetype’) (Price and Lau 2014; Price 2016).

4.2.3 THEORETICAL FRAMEWORK: A SUMMARY

The DeLoan and McLean information systems success model is a well known and commonly used model that does not consider contextual and business process aspects (e.g. healthcare). Contextual elements of the meso- (people, organization and implementation) and macro-levels (standards, legislation, policy and governance, funding, and societal, political and economic trends) were added to the CAM. The THL national electronic health framework was constructed in 2009 to provide national-level information to support implementation of the national Kanta Services and to monitor its progress (Doupi et al. 2009; Hyppönen et al. 2011; Lau and Price 2016).

4.3 DESIGN AND DATA FROM STUDIES I–V

This research uses the CAF and the CAMM to assess the implementation and adoption of Parliament-approved legislation – the *Act on Electronic Prescription* (61/2007) and the *Act on Processing Customer Data in Health and Social Care* (159/2007) – in Finland between 2010 and 2018. The CAF and CAMM dimensions and categories covered by Studies I–V of this research are presented in Figure 6.



	Study				
Theoretical Framework	**I**	**II**	**III**	**IV**	**V**
Clinical Adoption Framework	X	X	X	X	
Governance	X	X			
Standards	X				
Funding	X				
Trends	X		X	X	
Implementation	X	X			
Clinical Adoption Meta-Model	X	X	X	X	X
Availability	X	X			
Use	X	X	X	X	
Behavior	X		X	X	X
Clinical (Health) Outcomes	X	X	X	X	X

Figure 6 CAF macro-level elements (governance, standards, funding, trends) and meso-level category implementation, and CAMM dimensions (availability, use, behaviour, clinical / health outcomes) covered by Studies I–V of this research.

In Study I, the SII provided statistical study indicator material covering the Kanta Services from January 2010 to December 2017 (Figure 7). The indicator data were collected in the SII from various national Kanta Services and sent to THL, usually within one working week of the end of a month. The indicator data were checked, compiled into charts and tables, and reported, mainly internally, to those who required the information. A set of statistical indicators for various monthly follow-up, communication and reporting purposes were presented. The statistical material consisted of all records in the appropriate national Kanta Services.

The material for Study II consisted of dates provided by community pharmacies and public PHCs during the implementation and adoption phases to the SII's national Kanta Services unit and THL's operative management unit in 2010–2016 (Figure 7). Implementation dates for municipalities and local primary healthcare joint municipality authorities were recorded. Usually, each municipality contained at least one community pharmacy.

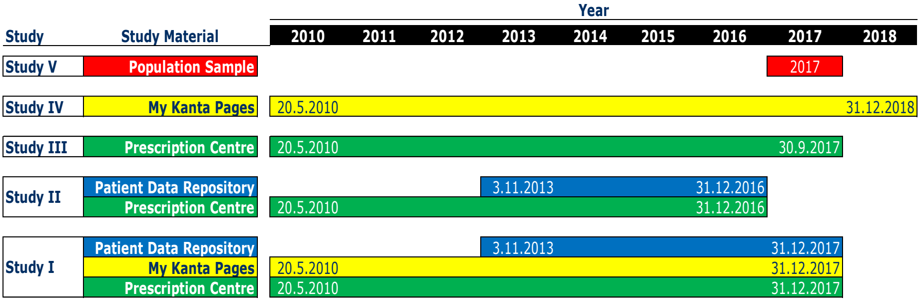


Figure 7 Overview of the study material from the national health information system data registries in 2010–2018 and a random population sample survey in 2017.

Green refers to the national Prescription Centre (Study I–III), yellow to the national My Kanta Pages (Study I and IV) and dark blue to the national Patient Data Repository (Study I–II), all of which are part of the national Kanta Services. Red refers to a random population sample survey conducted in 2017 (Study V).

The material for Study III consisted of national monthly Prescription Centre indicator data in aggregate form from May 2010 to September 2019 (Figure 7). The data consisted of the number of electronic, paper-based and telephone prescriptions, and their medication dispensations recorded at the Prescription Centre.

The material for Study IV comprised the total number of Finnish national My Kanta Pages users by municipality in 2018, including each unique personal identification code (Figure 7). The monthly use numbers were calculated as sums of the total number of sign-ins. Monthly use numbers were also calculated for repeated electronic prescription renewal requests, information management notifications (information notices, consents and consent restrictions) and declarations of intent (organ donation testaments and living wills). The SII (record holder of the national My Kanta Pages) provided the statistical research material. Municipal population data were collected from Statistics Finland's StatFin public online services. The adult population (18 years or older) on December 31, 2017, was used as a common denominator in the analyses. Data on 39,226 children, i.e. younger than 18 years of age, who had accessed the national My Kanta Pages by using their own authentication codes were excluded; they accounted for 1.4% of users in 2018.

The material for Study V consisted of a large random sample of 10,000 people representative of the adult population (at least 20 years of age) living in Finland. For 75-year-olds or older, double picking probability was used to guarantee a sufficient group size. The questionnaire was sent by post to all persons sampled in 2017 (Figure 7). Reminders were sent three times to those who had not responded. Ultimately, 4,497 (47%) participants responded. Dependent variables (benefits of online health and social care services) were measured with three scales evaluating perceived health, economic and collaboration benefits. Independent variables included demographics (age, gender, degree of urbanization of the residential municipality), health status, indicators of socio-economic position, indicators of social participation, and information and communication technology related variables (access to online services, skills to use online services, and the extent of use of online services in health and social care).

4.4 STATISTICAL METHODS

Since the implementation of the two nationwide Kanta Services was based on permanent legislation, both voluntary and mandatory data systems are present. Consequently, the terms ‘usage of the system’ and ‘overall user acceptance’ are used interchangeably (Ammenwerth et al. 2006).

In Study I, statistical indicator data in monthly and annual time series were calculated. In Study II, the duration of implementation and adoption by community pharmacies and primary healthcare centres, municipalities, public PHCs, hospital districts, university hospital specific catchment areas, and the nation as a whole of the national Kanta Services was observed separately for the Prescription Centre and the Patient Data Repository. Prescription Centre service implementation durations were investigated separately for community pharmacies and PHCs; moreover, Patient Data Repository implementation occurred only in public PHCs. The implementation duration in days was calculated systematically by using the formula [duration] = [end-date] – [start-date] + 1; i.e. implementation on a day was assigned a value of 1 (day). Duration in years was calculated by dividing the duration in days by 365. Mean implementation durations of the Prescription Centre and the Patient Data Repository were analysed by electronic patient record solutions (commercial trademarks), public PHCs and hospital districts.

In the material for Study III, variation in the monthly number of electronic prescriptions and their dispensing events was smoothed using a 3-month moving average. In the annual calculations, each patient’s unique personal identification code was included only once.

The results of Study IV are presented in a table and four figures, one of which is a map. The number of persons who had signed into the service was defined as the sum of person identification codes during a month, while the number of sign-ins was defined as the sum of portal sign-ins during the month. The annual sum of signed-in persons includes just one unique personal identification code per person.

In Study V, the sum of services used by a respondent was calculated, resulting in a range of 0–16 functionalities. In addition, associations between the independent variable and outcome variables related to perceived benefits were examined using analyses of covariance (in separate analyses) conducted in three steps. First, the analyses included demographics and health status. Then, variables related to socio-economic position and social participation were added to the model. Finally, information-and-communication-technology-related variables concerning access, skills and the extent of use were also added. Since the skills and access correlated, they were examined in separate analyses to avoid multicollinearity. Methods suitable for weighted data were used (e.g., a complex samples general linear model for analyses of variance and complex samples descriptives/frequencies for descriptive statistics). The data collection and questionnaire formulation (Hyppönen and Aalto 2019) as well as statistical analyses (Härkänen et al. 2014) have been reported in more detail elsewhere.

4.5 ETHICAL CONSIDERATIONS

The study material in Studies I–IV consisted of aggregated indicator data compiled during the deployment, implementation, adoption and use of the national Kanta Services in 2010–2018 in Finland. These indicator data cannot be linked to any persons, and the study material is purely statistical. These indicator data characterize organizations (e.g., community pharmacies, publicly funded PHCs or public specialized hospitals) at a local (municipalities), regional (hospital districts, university hospital specific catchment areas) or national level. Thus, neither ethical governance procedures nor informed consent is required for this research.

Ethical approval for the Study V was received from the Research Ethics Committee of THL. The data were collected with no direct identification information concerning the respondents, and therefore no individuals can be identified from the data.

5 RESULTS

The study results are presented by utilizing the CAF to provide an overarching conceptual model for electronic health information system adoption and the CAMM to support implementation of the national Kanta Services and help describe post-adoption deployment of the Kanta Services over time.

5.1 CLINICAL ADOPTION FRAMEWORK ASSESSMENT OF THE KANTA SERVICES IN 2010–2018

5.1.1 GOVERNANCE

This research focuses on the CAF macro-level dimensions governance, standards, funding and trends as well as meso-level implementation.

Governance can be seen as ensuring that strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system design and accountability. Study I presented the initial architecture plan of the national Kanta Services. Some notable changes have been introduced thereafter (Figure 8). For example, a new group of receivers of medical certificates (e.g., insurance companies, police administration) was added to the User Groups. Moreover, DVV was added to 'Other national services'. In the Kanta Services section, new names and a new grouping of services were added to clarify the architecture. A new service, a data lake for healthcare and social welfare, was also introduced.

Monthly and annual time series data of follow-up and performance indicators in 2010–2017 were used to present the national My Kanta Pages, Prescription Centre, Pharmaceutical Database, Patient Data Repository, Kelain web service, My Kanta Personal Health Record and Client Data Archive for Social Welfare Services (Study I). The 2018 data show a further increase in performance indicators.

In general, a middle-out implementation strategy was adopted (Study I). Advice was sought and needs were identified, for example, from citizens, healthcare and social welfare service providers (public and private), pharmacies, the information technology industry (vendors) and government. A common set of technical goals and underpinning standards was also created.

For the implementation and adoption of the national HIS services, a new national operative coordination unit with an appropriate legal mandate was established at THL by permanent legislation in January 2011. The coordination unit has since maintained close working relationships and cooperation with several national actors and healthcare and social welfare service providers, pharmacies and data system vendors. In addition, the coordination unit has worked closely with the SII in various platforms and arenas. THL's coordination unit received a legal mandate to decide upon and grant state aid to provide partial funding for breakthrough pilot programmes and projects.

It was necessary for national, regional and local implementation designs and planning to (at least) take into consideration variations in population sizes, number of municipalities, public PHCs and hospitals, main community pharmacies and their sub-premises and different comprehensive solutions or other systems at different organizational levels.

The implementation strategy for the national Prescription Centre services was based on a regional (e.g., hospital district) approach. The approach was changed to a certified Kanta-compatible data-system strategy for the national Patient Data Repository services. THL granted partial state funding to pilot production projects.

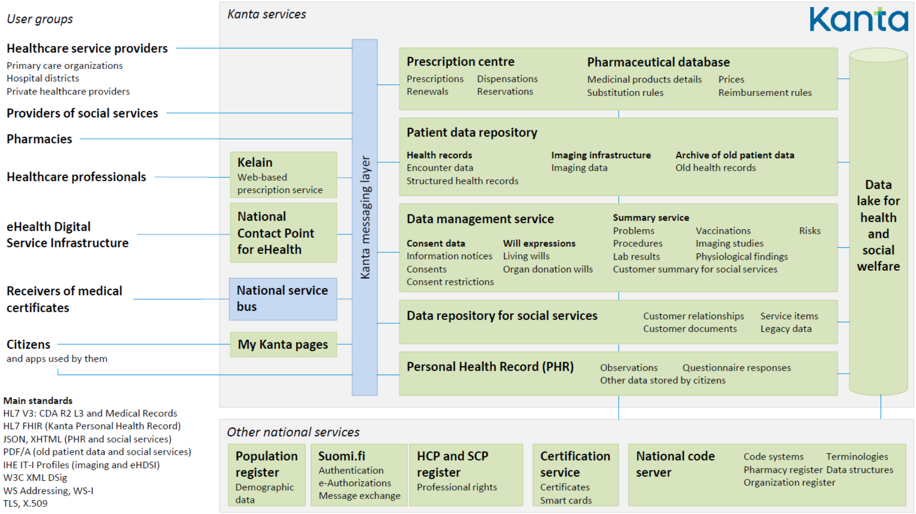


Figure 8 Current architecture plan of the national Kanta services in Finland.

National Service Bus is also a message transfer service. HCP refers to Health Care Personnel and SCP to the Social Care Personnel Register at the National Supervisory Authority for Welfare and Health of Finland. For main standards, see Section 5.1.2. Source: Social Insurance Institution of Finland.

5.1.2 STANDARDS FOR THE NATIONAL HEALTH INFORMATION SYSTEM

International technical standards were utilized in the development of the national HIS infrastructure. The main technical standards are shown in Figure 8 (Section 5.1.1). These include Health Level Seven for medical records (HL7 V3: CDA R2) and the Kanta Personal Health Record (HL7 FHIR), JavaScript Object Notation and eXtensible Hypertext Markup Language for Personal Health Record and social welfare Client Data Archive services.

Other technical standards include Portable Document File A for legacy patient data records and social welfare client data records, Integrating the Healthcare Enterprise profiles for imaging and eHealth Digital Service Infrastructure operations, digital signatures, Web Services Addressing for interoperability between web services, Transport Layer Security for communications security, and the X.509 cryptographic standard for defining the format of Public Key Certificates.

5.1.3 FUNDING OF THE NATIONAL HEALTH INFORMATION SYSTEM

In addition to the funding findings presented in Study I, THL provided grants to 46 partially state-funded projects (EUR 14.43 million) in 2010–2018: altogether 28 projects (EUR 8.38

million) in healthcare and 18 projects (EUR 6.05 million) in social welfare. Earlier state-funded projects were healthcare related, whereas later projects focused on social welfare services. THL also granted partial state funding for the implementation of the pilot production projects.

Finland's implementation and current sustainable use of the national Kanta Services may have been impossible without the provision of adequate funding (Study I). The MSAH financed development of the national Kanta Services through annually granted state budget funds that before 2011 had been allocated in several state budget provisions. In 2011, the MSAH began to use a new state budget provision simultaneous to the entering into force of changes in the permanent national legislation on the national Kanta Services. By introducing a single State budget provision (33.01.25; funds transferable within 3 years) under MSAH control, funding-use cases and allocation to organizations (the MSAH, THL, and the SII) became more straightforward.

Table 1. *State of Finland annual budget allocation (million euros) to the Ministry of Social Affairs and Health (provision 33.01.25; transferable within 3 years), Ministry of Social Affairs and Health allocated funds (million euros) to the THL's coordination unit and the coordination unit's costs (million euros) by category and calendar year from 2011 to 2018.*

	State budget (MEUR)								
	2011	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	All
MSAH moment 33.01.25	16,400	16,700	11,800	16,330	17,330	15,330	13,330	11,000	118,220
MSAH allocation to THL	8,110	10,070	10,070	11,400	10,730	15,230	12,700	4,000	82,310
THL costs	2,227	3,908	6,145	9,101	18,846	13,394	16,829	14,918	85,368
Materials	0,020	0,026	0,039	0,039	0,012	0,011	0,016	0,010	0,174
Rents	0,002	0,196	0,105	0,064	0,046	0,019	0,007	0,004	0,444
Personnel	0,649	1,413	1,536	1,768	2,043	1,784	1,551	1,758	12,502
Services (including Kela)	1,152	2,286	3,584	5,880	12,528	10,066	13,369	11,623	60,488
Traveling	0,072	0,110	0,124	0,108	0,119	0,106	0,114	0,122	0,875
Other costs	0,001	0,001	0,012	0,028	0,066	0,440	0,341	0,155	1,043
State remunerations	0,331	0,044	0,740	1,214	4,032	0,972	1,431	1,185	9,949

MEUR refers to million euros.
MSAH refers to the Ministry of Social Affairs and Health.
THL refers to the Finnish Institute for Health and Welfare.
Kela (SII) refers to the Social Insurance Institution of Finland.
Source: Finnish Institute for Health and Welfare.

In addition to the findings presented in Study I, provision 33.01.25 of the State budget permitted further central funding allocations to THL's coordination unit as well as additional coordination units costs (official accounting) in 2011–2018 (Table 1). A total of EUR 82.31 million was allocated to THL and, via this institute, other organizations for implementation and parallel Kanta Services development tasks. The largest cost categories for THL's coordination unit were service procurement (71% of all costs), personnel costs (15%) and state remunerations (partial funding; 12%). A major part of service procurement comprised development costs of the Kanta Services at the SII according to agreements between the partners. However, THL was the sole decision-maker in all these cases. The development costs of the centralized, shared and integrated national Kanta Services were funded by the State.

5.1.4 TRENDS IN USE OF THE NATIONAL HEALTH INFORMATION SYSTEM

The number of adult (18 years or older) users of the national Kanta Services has increased considerably since May 2010 (Study I). The number of different electronic identities was cumulatively 2.797 million by the end of 2018 for My Kanta Pages. Moreover, the cumulative number of different unique identity codes reached 5.965 million by the end-2018 for the Patient Data Repository. A similar exponential increase in performance indicator trends was observed for the number of sign-ins to the My Kanta Pages, electronic prescriptions and dispensations recorded at the Prescription Centre, and documents and service events recorded in the Patient Data Repository. The cumulative number of Prescription Centre service subscribers (pharmacies and public or private healthcare service providers) increased to 2,311 by the end of 2018. In turn, the cumulative number of Patient Data Repository subscribers was 1,330 at the end of 2018. As the number of national HIS service subscribers rose, performance indicator data increased exponentially, and the use and number of users of the national My Kanta Pages also increased dramatically.

However, one exception to this exponential growth was observed (Study III). The number of electronic prescriptions recorded at the Prescription Centre was 28.30 million in 2018, whereas it was 31.91 in 2017 (an 11% decrease) (Figure 9). Mandatory electronic prescription entered into effect on January 1, 2017 (big bang approach) simultaneous to the extension of the prescription validity period from one to two years. The number of dispensations at community pharmacies was nonetheless 5% higher in 2018 (64.42 million) than it was in 2017 (61.39 million).

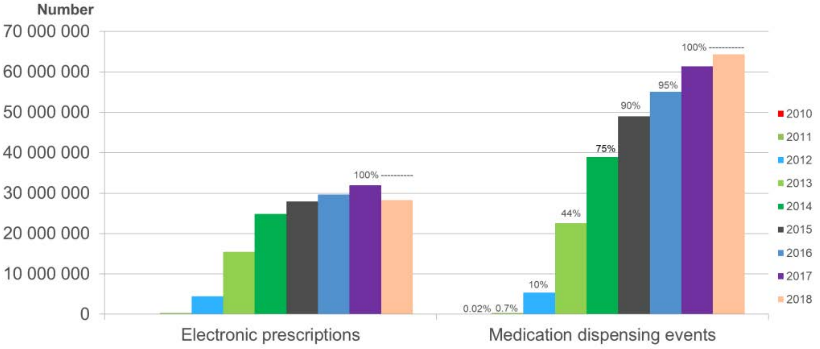


Figure 9 Annual number of electronic prescriptions recorded at the national Prescription Centre and their dispensing events at community pharmacies in Finland from May 2010 to December 2018. Electronic prescriptions became mandatory in January 2017.

In 2010–2018, the proportions (%) of medication dispensing events were calculated by dividing the annual number of medication dispensing events from electronic prescriptions by all medication dispensing events (including paper-based, fax and telephone prescriptions). Source: Social Insurance Institution of Finland and Finnish Institute for Health and Welfare.

Community pharmacies began to record paper-based and telephone prescriptions with the Prescription Centre on January 1, 2017. The number of paper-based and telephone prescriptions recorded at community pharmacies was 0.404 million in 2017 (1.26% of all prescriptions) and 0.384 million in 2018 (1.23%). The number was highest (on average 37,000 per month) in the first quarter of 2017, after which it decreased towards the end-2018 to an average of 31,000 per month. These prescriptions are treated as exceptional in the legislation: if one issues a paper-based or a telephone prescription, the reason for this action must be recorded. Legal reasons for non-electronic prescriptions include a technical data system failure (on average 80% of the recorded reasons) and the emergency need for medication (12.5%). The proportion of 'other' reasons decreased from 10% in 2017 to 5% in 2018.

At a practical level, mandatory electronic prescriptions were introduced via the Kelain web service, which was developed, tested and launched in September 2016. Using Kelain, the number of electronic prescriptions issued (and recorded at the Prescription Centre) was 0.020 million in 2016, 0.322 million in 2017 and 0.301 million in 2018. Monthly numbers rose rapidly to 25,000–30,000 but have since decreased to the current level of 20,000–25,000 prescriptions. The number of registered Kelain web-service users (physicians and dentists) rose rapidly to 18,600 in September 2019, comprising approximately 50% of physicians and dentists in Finland.

My Kanta Pages, launched in May 2010, is an online service where users can browse their own health information recorded at the Prescription Centre and in the Patient Data Repository. A total of 2.8 million persons had accessed My Kanta Pages 23.2 million times (49.2 million sign-ins) by the end-2018 (Figure 10) (Study IV). Thus, in total, 51% of the Finnish population and 63% of all adults (18 years or older) had signed-in to My Kanta Pages from May 2010 to December 2018.

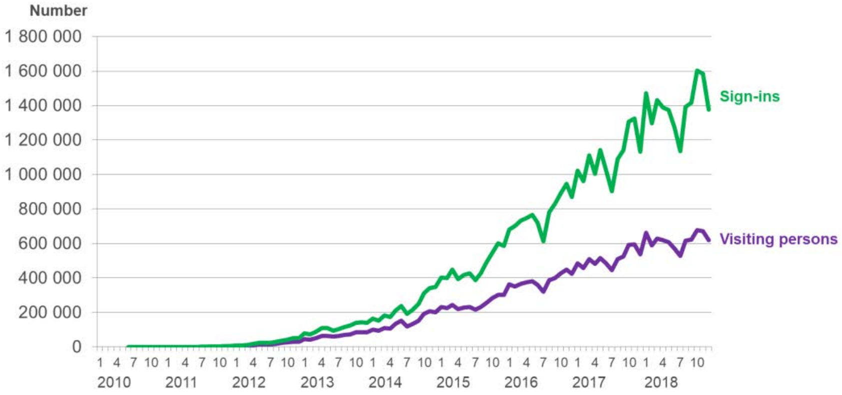


Figure 10 Numbers of signed-in persons and sign-ins to the Finnish national My Kanta Pages web service by month from May 2010 to December 2018. Source: Social Insurance Institution of Finland and Finnish Institute for Health and Welfare.

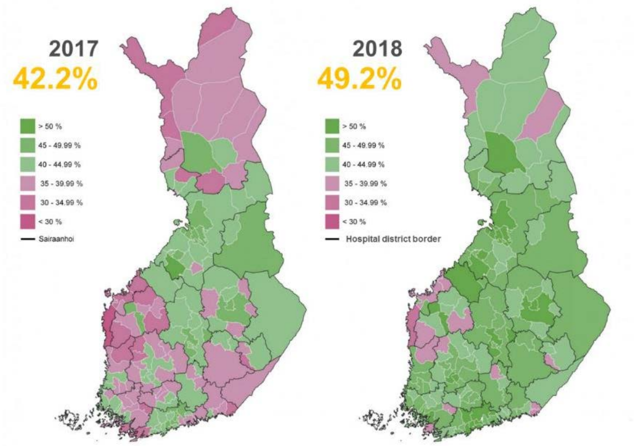


Figure 11 Proportion of adults (18 years or older) who used My Kanta Pages in 2017 (42.2%) and 2018 (49.9%) by primary healthcare centres by hospital districts. Data from the Åland Islands are not shown (14.5% and 20.9%, respectively). Source: Social Insurance Institution of Finland and Finnish Institute for Health and Welfare.

In addition, 6.0 million electronic prescription renewal requests have been sent to healthcare organizations since November 2015. Furthermore, by the end-2018, there were 6.3 million information notices, 3.3 million consents and 93,732 consent restrictions in the national Patient Data Management Service (part of the Patient Data Repository). Moreover, 467,055 organ donation testaments and 93,484 living wills have been recorded in the service.

In 2018, at a total of 2.19 million persons (49% of adults) signed-in 16.8 million times to My Kanta Pages, constituting an average of 18,610 times daily visits (Study IV). The proportion of My Kanta Pages users in 2018 varied between age groups: it was used by 1.9% of persons younger than 18 years of age, 50% of working age adults (18–65-year-olds) and 36.7% of persons older than 65 years of age. These users submitted a total of 2.1 million electronic prescription renewal requests to healthcare services.

In addition to the results presented in Study IV, the proportion of adult My Kanta Pages users in 2017 and 2018 is presented in Figure 11 by PHC and hospital district. At the national level, the adult user proportion was 42.2% (1.88 million persons) in 2017, and it rose further to 49.9% (2.19 million persons) in 2018, including the Åland Islands. Use of My Kanta Pages among adults varied between the 142 PHCs (21–62%), 20 hospital districts (21–53%) and five university-hospital-specific catchment areas (45–51%) (Study IV). The three highest adult user proportions among PHCs were recorded in Kempele (61.7%), Liminka (57.7%) and Muhos (56.6%), all in the Northern Ostrobothnia Hospital District. The highest adult user proportions among hospital districts were found in Northern Ostrobothnia (53%), Helsinki-Uusimaa (53%), Northern Savonia (51%) and Central Ostrobothnia (51%), whereas the Åland Islands accounted for the lowest proportion (21%).

5.1.5 IMPLEMENTATION AND ADOPTION OF THE NATIONAL HEALTH INFORMATION SYSTEM KANTA SERVICES

When it comes to the implementation design of the Kanta Services, a middle-out approach was selected (Study I). Implementation of the Prescription Centre services at community pharmacies was planned and executed at a national level by the Association of Pharmacies in Finland, with partial State funding granted by the MSAH (Study II).

According to the implementation plan formulated together with THL and the KunTo project management office, Prescription Centre implementation was to be carried out in three phases at national, regional (hospital districts) and local (municipality healthcare units) levels (Study II). First, local production pilot projects in Turku and Kotka were established and executed to observe working methods for the implementation (and adoption) of HIS installations and to produce common guidance by analysing the experiences gained. Second, regional production pilot projects in the Eastern Savonia and Länsi-Pohja Hospital Districts were established and executed. These regional pilot production projects further developed implementation models and processes for more common scaling-up 'copy-and-paste' purposes. The production pilot projects were partially funded by state grants issued by THL (Study I). Third, large-scale nationwide implementation was carried out for the rest of Finland by region.

In addition to findings presented in Study I and Study II, Figure 1 (Section 2.4.2, page 32) presents the scheme for electronic prescription that led to the large-scale, national-level implementation of the Prescription Centre services in 2010–2018. In addition, Figure 2 (page 33) presents the scheme for patient data archiving that led to the large-scale, national-level implementation of the Patient Data Repository services in 2013–2018.

THL formulated the implementation strategy for the national Patient Data Repository services. The orientation was changed from a regional implementation approach to a certified HIS-based approach. The change was based on the cumulative experiences gained from and analyses of implementation of the Prescription Centre services (Study II). Consequently, it was unnecessary to consider geographical issues such as the simultaneous implementation of data systems in community pharmacies and public healthcare. In the implementation of the Patient Data Repository, a pilot production development project was run in just one local organization for a vendor's HIS product. Only successful HIS production development projects were granted certification (Kanta compatibility), and only certified HISs were released for large-scale implementation nationwide. However, not all HIS vendors chose to utilize this scheme for their solutions. The production pilots were granted partial state funding. Once the piloted HIS solution had been certified, neither its implementation nor adoption by the organizations concerned was subsidized by the state.

5.1.5.1 Time from certification to the first and the last installation

The first certifications for healthcare and pharmacy data systems were granted in May 2010 for the Prescription Centre and October 2013 for the Patient Data Repository (Study II) (Table 2). The first installations and their data production began within a week. Nonetheless, from the first certified data system installation, it took over 1.3 years to reach 10% population coverage for Prescription Centre implementations. By contrast, similar coverage was achieved in just 0.5 years for Patient Data Repository implementations. In addition, from the first certified data system installation, 2.3 years elapsed before 50% population coverage was reached for Prescription Centre implementations, whereas only one year was required for Patient Data Repository implementations. Full coverage required 3.4 years for the Prescription Centre and 2.1 years for the Patient Data Repository service. In addition to their different strategies, the organizations concerned are likely to have learned largely from their locally conducted adoption and nationally coordinated implementation activities.

Table 2. *Dates of the first certification and installation and time in days to 10–100% coverage of the national Kanta Services from 2010 to 2015 by Prescription Centre and Patient Data Repository. Source: Finnish Institute for Health and Welfare.*

	Prescription Centre		**Patient Data Repository**	
Implementation strategy	By Hospital District		By Product	
Population proportion	Date	Time	Date	Time
To 100% coverage	28.10.2013	1 258	1.12.2015	760
To 90% coverage	5.2.2013	993	28.2.2015	484
To 75% coverage	6.11.2012	902	26.11.2014	390
To 50% coverage	24.9.2012	859	12.11.2014	376
To 25% coverage	27.2.2012	649	7.6.2014	218
To 10% coverage	9.9.2011	478	14.5.2014	194
The first installation	20.5.2010	1	2.11.2013	1
The first certification	18.5.2010		28.10.2013	

In addition to the findings of Study II, the dates of the first certification and installation, the time from certification to the beginning of the first and last installation, and the duration of installation (from certification to the beginning of the last installation) provide information on implementation execution performance. Table 3 presents these data for seven data systems in use at public healthcare organizations by Prescription Centre and Patient Data Repository and for both services combined.

The time from certification to the first installation of a Kanta-Services-compatible data system varied between data systems and Kanta Service implementation, as did the installation time from the first installation to the beginning of the last installation. Overall, for the seven data systems, the time from certification to the beginning of the last installation (duration) was longer for Prescription Centre implementation (Table 3).

Table 3. *Dates of the first certification and installation, and time in days from certification to installation start (time1), time in days from the first installation to the start of the last installation (time2) and duration in days from certification to the start of the last installation by Prescription Centre, Patient Data Repository and both national Kanta Services and by data system solution trademarks (and vendors) used by public healthcare providers in Finland from 2010 to 2015. Source: Finnish Institute for Health and Welfare.*

	Prescription Centre					
System trademark (Vendor)	Certified	Time1	Start	End	Time2	Duration
Pegasos (CGI)	18.5.2010	2	20.5.2010	28.10.2013	1 258	1 260
Effica (Tieto)	24.3.2011	11	4.4.2011	21.3.2013	718	729
Uranus (CGI)	8.4.2011	377	19.4.2012	14.12.2012	240	617
Graafinen Finstar (CGI)	22.11.2011	111	12.3.2012	4.4.2012	24	135
Mediatri (Mediconsult)	22.11.2011	22	14.12.2011	28.3.2013	471	493
Abilita (Abilita)	19.3.2012	67	25.5.2012	29.12.2012	219	286
Esko (PPSHP)	12.3.2013	-	19.5.2011	27.3.2013	679	16
All		590	20.5.2010	28.10.2013	1 258	1 260
On average		98			516	505

	Patient Data Repository					
System trademark (Vendor)	Certified	Time1	Start	End	Time2	Duration
Effica (Tieto)	28.10.2013	5	2.11.2013	2.3.2015	486	491
Pegasos (CGI)	16.5.2014	6	22.5.2014	20.5.2015	364	370
Uranus (CGI)	22.9.2014	88	19.12.2014	12.8.2015	237	325
Graafinen Finstar (CGI)	23.10.2014	13	5.11.2014	28.11.2014	24	37
Abilita (Abilita)	19.12.2014	46	3.2.2015	16.4.2015	73	119
Mediatri (Mediconsult)	20.5.2015	7	27.5.2015	10.11.2015	168	175
Esko (PPSHP)	18.6.2015	104	30.9.2015	1.12.2015	63	167
All		269	2.11.2013	1.12.2015	760	765
On average		38			202	241

	Prescription Centre and Patient Data Repository				
System trademark (Vendor)	Time1	Start	End	Time2	Duration
Pegasos (CGI)	1 460	20.5.2010	20.5.2015	1 827	1 829
Abilita (Abilita)	1 017	25.5.2012	16.4.2015	1 057	1 124
Effica (Tieto)	950	4.4.2011	2.3.2015	1 429	1 440
Esko (PPSHP)	-	19.5.2011	1.12.2015	1 658	995
Mediatri (Mediconsult)	1 276	14.12.2011	10.11.2015	1 428	1 450
Graafinen Finstar (CGI)	1 067	12.3.2012	28.11.2014	992	1 103
Uranus (CGI)	1 264	19.4.2012	12.8.2015	1 211	1 588
All	1 858	20.5.2010	1.12.2015	2 022	2 024
On average	1 172			1 372	1 361

Considerable variation occurred in certification, both in terms of time and order. The first data system for the Prescription Centre was certified in May 2010 and the last in March 2013 (almost a 3-year time span), whereas the first data system for the Patient Data Repository was certified in October 2013 and the last in June 2015 (1.5-year time span).

5.1.5.2 Adoption of Prescription Centre and the Patient Data Repository services

National adoption of both Kanta Services (i.e. the Prescription Centre and the Patient Data Repository) required 5.5 years, an average of 4.6 years in the five university-hospital-specific catchment areas and 3.6 years in the 20 hospital districts (Study II). The Prescription Centre was adopted in December 2016 in the Åland Islands, which does not use the Patient Data Repository at all. Nationally, the Prescription Centre services were subscribed to and adopted by community pharmacies in an average of 2.4 years, whereas subscription and adoption required 3.4 years for public PHCs. Nationally, the Patient Data Repository services were subscribed to and adopted in an average of two years by public PHCs.

As presented in Table 4, the greater the number of organizations involved or the larger (hospital district, university-hospital-specific catchment area, national) the area in question, the longer adoption of the Prescription Centre or/and the Patient Data Repository services took. In addition, the more complex the adoption set of Kanta Services (Prescription Centre only, Patient Data Repository only, or both), the longer it took to be implemented.

Implementation progress and execution were measured systematically, continuously and based on documentation in order to control, monitor and follow-up the situation and establish timetables and cost control for the implementation of the Kanta Services. For example, measures of population coverage (e.g., proportions of population) and the time required to reach a certain population coverage milestone were utilized. Much of this information is presented in Study II; moreover, it took 2.3 years from the first certified HIS installation to reach 50% population coverage for the Prescription Centre implementation, whereas only one year was required to achieve the same coverage rate for the Patient Data Repository. Finally, it took 3.4 years for the Prescription Centre and 2.1 years for the Patient Data Repository service to reach full national coverage (100%).

Table 4. *Mean number of years from the start of the first implementation project to the start of the last implementation project (minimum time and maximum time in brackets) by Prescription Centre, Patient Data Repository, both services combined, and by 21 hospital districts, 5 university-hospital-specific catchment areas and at a national level from 2010 to 2015. PHC refers to Primary Healthcare Centre. Source: Finnish Institute for Health and Welfare.*

Kanta services to implement	**Hospital Districts** Mean (range: min-max)	**Specific Catchment Areas** Mean (range: min-max)	**National** Mean
Prescription Centre, pharmacies	**0.6** (0.1-2.0)	**1.3** (0.9-2.0)	**2.4**
Prescription Centre, PHCs	**0.6** (<0.01-2.0)	**2.0** (0.9-3.4)	**3.4**
Prescription Centre, pharmacies + PHCs	**1.1** (0.02-2.4)	**2.3** (1.8-3.4)	**3.4**
Patient Data Repository, PHCs	**0.6** (<0.01-1.6)	**1.5** (1.1-2.0)	**2.0**
Both, PHCs	**3.0** (1.6-5.1)	**4.3** (3.6-5.1)	**5.5**
Both, pharmacies + PHCs	**3.6** (2.5-4.3)	**4.6** (4.4-5.1)	**5.5**

In addition to the findings of Study II, and as shown in Figure 12, implementation and adoption times varied by hospital district. In many cases, a considerably length of time elapsed from the end of Prescription Centre implementation to the beginning of implementation of the Patient Data Repository. In addition, implementation time for each national service varied among hospital districts. Similar observations were obtained from PHCs within hospital districts.

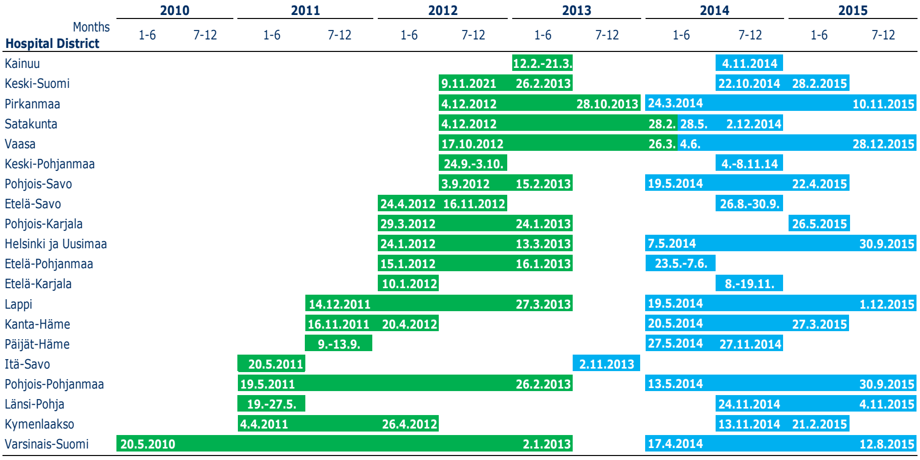


Figure 12 Implementation of Prescription Centre services (green) and Patient Data Repository services (blue) by the 20 mainland Finnish hospital districts from May 2010 to December 2015 in six-month time periods. Source: Social Insurance Institution of Finland and Finnish Institute for Health and Welfare.

5.2 CLINICAL ADOPTION META-MODEL ASSESSMENT OF KANTA SERVICES IN 2010–2018

5.2.1 AVAILABILITY OF NATIONWIDE KANTA SERVICES

For the infrastructure, the first certification for healthcare and pharmacy data systems was granted on May 18, 2010, while the first installation occurred on May 20, 2010, for the Prescription Centre and on October 28, 2013, and November 2, 2013, for the Patient Data Repository (Study II). Full (100%) coverage – i.e. national availability of the services – took 3.4 years (from May 20, 2010, to October 28, 2013) for the Prescription Centre and 2.1 years (from November 2, 2013, to December 1, 2015) for the Patient Data Repository service.

National adoption of both Kanta Services took 5.5 years: an average of 4.6 years in the five university hospital specific catchment areas and 3.6 years in the 20 hospital districts. The Prescription Centre and the Patient Data Repository were adopted from May 19, 2010, to November 10, 2015, in 147 PHCs and 597 community pharmacies.

As described in section 5.1.5, full availability of the Prescription Centre and the Patient Data Repository services to healthcare professionals and patients varied considerably nationally, by university-hospital-specific catchment area and hospital district area (and within areas), by HIS solution (trademarks) and by implementation strategy (Study I, Study II).

5.2.2 USE OF NATIONWIDE KANTA SERVICES

The performance and follow-up indicators utilized in this research showed constantly increasing trends for Kanta Services (Study I, Study II, Study III and Study IV). This was also observed in the principal indicators for My Kanta Pages and the Prescription Centre as well as the Patient Data Repository (Study I).

All prescriptions in Finland have been electronic since 2017. By September 2019, only 1.2% of prescriptions recorded with the Prescription Centre by community pharmacies were paper or telephone based (Study III). Nonetheless, the number of recorded electronic prescriptions began to decrease after the dual intervention big bang on January 1, 2017, whereas community pharmacies' medication dispensing indicator continued to show further increases.

During the period from late May 2010 to the end of December 2018 (7.5 years), all (100%) public and 1,330 private healthcare providers and all (100%) community pharmacies had subscribed to and used the Prescription Centre services (Study IV). Moreover, a total of 2.8 million (63% of adults at least 18 years of age) persons had signed in a total of 49.2 million times to My Kanta Pages, and they sent 6.0 million electronic prescription renewal requests via My Kanta Pages to healthcare service providers. Furthermore, parents and guardians viewed the medical records of their under-10-year-old children a total of 1.1 million times from October 2016 to the end of December 2017 (Study I). However, the use of My Kanta Pages varied by university-hospital-specific catchment area, hospital district and PHC.

5.2.3 BEHAVIOUR OF CLINICIANS, HEALTH PROFESSIONALS AND CITIZEN USERS

Performance indicators showed a constant increase in the use of Kanta Services since their launch (Study I, III and IV). Prescribers (physicians, dentists and nurses) quickly learned to issue and use electronic prescriptions after January 1, 2017, when electronic prescription became mandatory in Finland. In addition, pharmaceutical professionals in community pharmacies quickly learned to record paper-based and telephone prescriptions with the Prescription Centre (Study III). Healthcare professional and citizen users had thus learned to use and utilize the services and their content (Study I).

The free-of-charge Kelain web service was launched in September 2016 to support the start of mandatory electronic prescription in January 2017 (Study III). The number of registered Kelain users rose rapidly to 18,000 and the number of electronic prescriptions issued via Kelain rose to 0.301 million in 2018. Thus, prescribing professionals (physicians and dentists) were willing to register to and use the Kelain web service to issue electronic prescriptions.

A population survey in 2017 found that access to online services, a person's own information and communication technology skills and extent of use were consistent factors associated with all benefits examined (health, economic and collaboration benefits) (Study V). The respondent's own information and communication technology skills were observed to be the most important factor, and self-rated poor health was consistently associated with lower levels of perceptions of the benefits examined as well as with dimensions of social participation. HIS availability, use, and changes in clinical and health behaviours may benefit many, but they can potentially harm those without the essential skills and equipment to access and use the HIS.

5.2.4 CLINICAL (HEALTH) OUTCOMES

Since the Kanta Services achieved full (100%) national coverage (Study II), performance and follow-up indicators reflecting national HIS and HIE use and behaviour changes by healthcare professionals and other users have shown constant (exponentially) improvement (Study I, III and IV). Prescribers learned to issue electronic prescriptions and switched quickly – almost overnight – to mandatory electronic prescription in January 2017, supported by the Kelain web service, which was launched in September 2016 (Study I and III). Pharmaceutical professionals in community pharmacies began to record data from paper-based and telephone prescriptions with the Prescription Centre in January 2017 (Study III). These changes have led to a considerable fall in the number of paper-based and telephone prescriptions (Study III). By the end of December 2018, all (100%) public healthcare providers, a major proportion of private healthcare providers and all (100%) community pharmacies were using the Kanta Services (Study IV).

Moreover, 63% of adults in Finland had signed-in to My Kanta Pages during 2010–2018, and they had sent 6.0 million electronic prescription renewal requests to healthcare organizations in 2015–2018 (Study IV). Furthermore, in 2018, the Patient Data Management service contained 6.3 million information notices, 3.3 million consents and less than 0.1 million consent restrictions filed by users.

The population survey mentioned above found that access to online services, a person's own information and communication technology skills and the extent of use were consistent factors associated with all benefits examined (health, economic and collaboration benefits) (Study V).

5.2.5 CLINICAL ADOPTION META-MODEL ARCHETYPES AND THE NATIONWIDE KANTA SERVICES

The Kanta Services already reached end users in a clinical setting in May 2010 (escaping the No Deployment archetype).

The implementation then matured and escaped the 'Low Adoption' archetype, in which the Kanta Services would have been deployed and available, but availability would have been followed by minimal or rapidly declining use. Data from the current study show that use of the Kanta Services increased exponentially from May 2010 to December 2018. Similarly, the Kanta Services achieved the intended behavioural changes (e.g. professionals recorded data in Kanta Services repositories and patients signed into My Kanta Pages to view their electronic prescription and health data) and thus escaped the 'Adoption without Benefit' archetype. As mentioned above, Kanta Services use exhibited the desired behavioural changes and clinical health outcomes, for instance, users signed into My Kanta Pages and used services for e-prescription renewal requests, information management notifications (e.g. information notices, consents and consent restrictions) and declarations of intent (e.g. organ donation testaments and living wills). Thus, the 'Behaviour Change without Outcome Benefit' archetype was also avoided, as was the 'Benefit without Use' archetype, since the benefits of Kanta Services accrued through use.

These research data provide observations on the progression of Kanta Services availability that led to increasing and ongoing use and thus to observable changes in clinical and health behaviours, which, in turn may have resulted in improvements in outcomes measured in this study. Based on the research results for Kanta Services infrastructure, the most apt CAMM architype is 'Adoption with Benefits'.

6 DISCUSSION

6.1 MAIN FINDINGS

This research utilized the CAF (Lau et al. 2007; Lau 2009; Lau et al. 2011; Lau and Price 2016) and the CAMM (Price and Lau 2014; Price 2016), both theoretical constructs, to assess the implementation and adoption of Parliament-approved legislation – the *Act on Electronic Prescription* and the *Act on Processing Customer Data in Health and Social Care* – between 2010 and 2018. The research also applied the CAF to the Finnish context for the period prior to 2010 as a 'proof-of-concept'.

Study I contributed to the literature on the nationwide implementation of a HIS. It assessed and documented the central building blocks of a large-scale nationwide development process that was established to introduce electronic services based on national legislation in Finland. It also described the implementation and adoption of the two national Kanta Services in 2010–2017 by introducing and using indicators during the implementation follow-up based on log register data. Study I presented the initial architecture plan for the Kanta Services. The national services' performance was assessed using monthly and annual time series data from the follow-up and various performance indicators. The MSAH chose a middle-out implementation strategy and established by permanent legislation a national coordination unit at THL with an appropriate legal mandate. Partial state funding was granted to production pilot projects. The MSAH introduced a new State budget provision in 2011 for the development and construction of national healthcare and social welfare information technology and centralized data systems. Use of these centralized HIS services increased exponentially during the follow-up.

Study II assessed in detail the implementation and adoption of the Prescription Centre services and the Patient Data Repository services across community pharmacies and public PHCs by municipality, hospital district, university-hospital-specific catchment area and at a national level between 2010 and 2016. According to the implementation plan, the implementation strategy for the Prescription Centre services was based on a regional hospital district approach, which was subsequently changed based on cumulative experiences to a certified Kanta-compatible HIS strategy for the Patient Data Repository services. To study implementation and adoption in detail, registered dates provided by community pharmacies and public PHCs were used to calculate mean implementation durations of the two Kanta services by electronic patient record solutions, public PHCs and hospital districts. Full (100%) implementation and adoption of the Prescription Centre services took 3.4 years, whereas just 2.1 years were required for the Patient Data Repository. Adoption of the two Kanta services took 5.5 years. Dates of the first certification and installation, the time from certification to the beginning of the first installation and the start of the last installation, and the duration of installation provide valuable information on implementation execution performance – details that have rarely been reported in the literature.

Study III contributed to the literature on the implementation of mandatory nationwide electronic prescription via a big-bang approach. Prescription Centre log register data (number of electronic, paper-based and telephone prescriptions, and their medication dispensations) in aggregate form were utilized to assess monthly indicator data from May 2010 to September 2019. A 3-month moving average was calculated for the monthly time series. With the exception of the Prescription Centre time series, exponential growth was generally observed. By September 2019, only 1.2% of prescriptions recorded by community pharmacies with the Prescription Centre were issued on paper or via the telephone. Nonetheless, the number of recorded electronic prescriptions began to decrease following the dual intervention big bang on January 1, 2017, whereas the community pharmacies' medication dispensing indicator continued to improve. Prescribers quickly learned to use electronic prescriptions after January 1, 2017. In addition, pharmaceutical professionals at community pharmacies quickly learned to record paper-based and telephone prescription information with the Prescription Centre. The free-of-charge Kelain web service was launched in September 2016 to support the start of mandatory electronic prescriptions. The number of registered and qualified Kelain users rose rapidly to 18,000 by the end of December 2018, and the number of electronic prescriptions issued via Kelain rose to 0.3 million in that same year. The fact that prescribers registered to use the Kelain and issued electronic prescriptions serves as a clear example of behavioural change.

Study IV, which used monthly time-series data from 2010–2018, was the first investigation of the nationwide use of patient-accessible EHR records (My Kanta Pages). In 2018, a total of 2.19 million persons (49% of the adults) signed into My Kanta Pages. User proportions varied by PHC, hospital district and university-hospital-specific catchment area. User proportions also varied by age group: less than two percent of persons younger than 18 years of age used My Kanta Pages, whereas the service was used by half of working age adults (18–65-year-olds) and over a third of persons older than 65 years of age. From late-May 2010 to end-December 2018, all (100%) public healthcare providers, 1,330 private healthcare providers, and all (100%) community pharmacies had subscribed to and used the Prescription Centre services. A total of 63% of adults in Finland had signed into My Kanta Pages in 2010–2018, and they had sent 6.0 million electronic prescription renewal requests to healthcare provider organizations. In addition, the Patient Data Management service contained 6.3 million information notices, 3.3 million consents and less than 0.1 million consent restrictions filed by users in 2018.

Study V contributed to the literature on the direct associations between demographics, self-rated health, socioeconomic position and social participation and the perceived benefits of online healthcare and social welfare services in a large representative random sample of the adult population (at least 20 years of age) living in Finland in 2017. Access to online services, the information and communication technology skills of the respondents (4,497; 47% response rate) and the extent of use were consistent factors associated with all examined health, economic and collaboration benefits.

These research data provide observations on the progression of the availability of Kanta Services, which led to increasing use among citizen and professional users and, in turn, to observable changes in clinical and health behaviour, thereby resulting in potential improvements in measured outcomes. Based on the Kanta Services infrastructure research results (log-based register data, registered implementation start dates, and a large population survey), long-term follow-up observations point towards the 'Adoption with Benefits' archetype of the CAMM.

6.2 INTERPRETATION OF THE RESULTS

Digitalization refers to the use of digital technologies in the context of the production and delivery of a product or service; it is an organizational and cultural process (EXPH 2019). The introduction, implementation, use and funding of digital health technologies should be carefully evaluated and monitored. As the Wachter advisory group (2016) suggests, digitalization should be performed for the correct reasons; moreover, creating an effective, fit-for-purpose system should take precedence over speed of rollout. Healthcare in general has entered an era where improved understanding of the use of EHRs is more critical than ever (Lanham Jordan et al. 2012), and the use of EHRs in primary healthcare practice has already superseded the traditional use of medical records (Terry et al. 2019). However, EHR data differ from other research data in their methods of collection, storage and structure (Hersh et al. 2013; Thiru et al. 2013; Weiskopf Gray et al. 2013).

Haux (2006) identified seven general tasks for a HIS over time: to move from paper-based processing and storage to computer-based; to move from local to national and global HIS; to include patients as HIS users; to use HIS data for healthcare planning, clinical and epidemiological research (aside from patient care and administration); to change focus from technical aspects of the HIS to management change and strategic information management; to place more emphasis on image and molecular data; and to acknowledge the steady increase of new types of technologies. In general, the Finnish experiences and observations presented in this research provide evidence of the transformation of HIS tasks over time. During the implementation phase, much paper-based processing and storage was replaced by computer-based electronic records and data processing with centralized national data repositories. In addition, EHRs have commonly been used in local healthcare since 2007, after which they were later introduced regionally and nationally through the introduction of the national, centralized, and integrated Kanta Services. Electronic prescription became mandatory in 2017, and in early 2019 Finland and Estonia were the first European Union Member States to introduce cross-border data exchange of electronic prescriptions. Patients in Finland are frequent users of the national Kanta Services via the web-based My Kanta Pages patient portal.

In the planning, implementation and adoption phases alike, the Kanta Services offer an apt example of a complex system with many interconnected human and non-human components, interacting unpredictably on some occasions (Hyppönen et al. 2011). The services exhibit a structure, defined by its parts and their composition and behaviour, which involves inputs, processing and outputs of material, energy and information (or data). It is also characterized by interconnectivity: the various parts of the system exhibit functional as well as structural interrelationships. In Finland, certified legacy HISs with interfaces are connected to and transmit nationwide standardized and encrypted messages to each other via the Kanta Services. The enhancement and maximization of interoperability was established as a national and later international goal (EXPH 2019).

6.2.1 USING THE CLINICAL ADOPTION FRAMEWORK AND THE CLINICAL ADOPTION META-MODEL

A basic premise of the CAF is that health information technology adoption and its effects are not deterministic. The full CAF is a complex framework consisting of 43 categories from 15 dimensions, which are further separated into three levels (micro, meso and macro). Therefore, it can be difficult to understand and apply the CAF in practice (Craven et al. 2016; van Mens et al. 2020). In addition, there is little guidance and documentation with explicit descriptions and rules regarding CAF use.

In this research, the CAF was first applied in Finland retrospectively as a 'proof-of-concept' before 2010 to the preparatory phases and implementation stages of the national HIS in order to gather data on and record experiences of earlier events and issues in the relevant macro- and meso-level implementation dimensions. Applying the CAF was an encouraging endeavour that produced in-depth understanding of past achievements, developments and practices. Secondly, the CAF was applied in conjunction with the CAMM to further assess the implementation and post-deployment adoption of the Kanta Services using the CAMM's four dimensions over time. The CAF also proved effective in a real-world national implementation context and for documentation purposes by structuring data, achievements, development and practices into a long-term assessment. Nonetheless, in part, the trends in the CAF's macro dimension represented a challenge for this research, since the national legislation had already established the contents and timetables for the national implementation and adoption of the Kanta Services. The focus of the implementation efforts was thus predetermined: the aim was to fulfil a set of societal, political and economic goals. Both theoretical constructs were tested on a smaller scale in Finland (Jormanainen and Reponen 2020).

This research utilized pre-set data system log-based indicators for the national implementation of the two Kanta Services during the follow-up and production phases. These log-based indicator data can be generally characterized as describing events and matters that occurred within the Kanta Services' infrastructure to facilitate transactions between legitimate actors in healthcare for care and cure. The infrastructure nature of log-based register data at that time, the division of labour between the actual implementation programme and the research coalition, and the restrictive permanent legislation meant that the effects of the implementation and adoption programme were most readily observable in the availability, use and behaviour dimensions of the CAMM. The research coalitions were intended to fill knowledge gaps, especially when it came to clinical or health outcomes. However, the clinical or health outcomes dimension of the CAMM was not fully accessible, since this research utilized log-based register data and lacked the opportunity to utilize the contents of health data in the national repositories.

The original THL national electronic health assessment framework was constructed in 2009 to provide national-level information to support the implementation and adoption of the Kanta Services and to monitor their success (Doupi et al. 2009; Hyppönen et al. 2011). The design of the electronic health assessment framework consisted of the actual implementation and adoption work, and assessment of progress and success of the national HIS using feedback from large-scale national surveys that were independently created and conducted in broad cooperation between research actors in a coalition funded by the MSAH.

6.2.2 THE CLINICAL ADOPTION FRAMEWORK: MESO LEVEL IMPLEMENTATION

6.2.2.1 Implementation of the Kanta Services was a large-scale, transformational megaproject

From a policy analysis perspective (Tuohy 1999), a typical starting point for policy development would be the identification of a societal challenge, such as the exchange of client or patient data between organizations or the nationwide My Kanta Pages. The opening of a window of opportunity places an issue on the agenda, and regardless of the scale and pace at which it is enacted, policy change enters terrain populated with existing interests, institutions, preferences and understandings (Tuohy Hughes 2018). The outcomes of policy reforms depend on the intersection and, especially, the interaction of scale and pace.

Many if not all such scale and pace intersections were present in these two nationwide HIS implementation processes and adoption efforts. The time before the permanent national legislation of 2007 was an era of incrementalism and mosaic systems: distributed data systems and rapid/piecemeal small-scale changes dominated the field (Tuohy Hughes 2018). The time from 2007 to 2010 witnessed the emergence of a blueprint for homogenization, since a consolidated plan was formulated on how to integrate the Kanta Services into healthcare services. Finally, a big bang policy change occurred on January 1, 2017, when mandatory electronic prescription came into effect overnight, simultaneous to the extension of the prescription validity period from 12 months to two years. This big-bang policy change was founded on the large-scale implementation of the nationwide, centralized, and integrated Prescription Centre services.

Transformational change (e.g. implementation of a nationwide HIS or infrastructure) involves significant and fundamental systemic change in an organization's working methods, requiring changes in structure, culture and management (Harrison and Kimani 2009; Perla et al. 2011; Best et al. 2012; Halfon et al. 2014; Waddell et al. 2015; Melvin et al. 2018; Sligo et al. 2019). The transformational change of organizations is usually required for successful implementation and adoption of a large-scale HIS or HIE. However, successful transformational change programmes are rarely replicated in another setting (Harrison and Kimani 2009; Fennelly et al. 2020). Moreover, large-scale transformation health system processes usually involve possible tensions between bottom-up and top-down approaches (Melvin et al. 2018). Large-scale transformation can be distinguished from incremental and reform change (Tuohy Hughes 2018).

Most of the literature on change, reforms and transformations in healthcare describes relatively small-scale initiatives typically performed by a single healthcare organization or by one service alone (Ovretveit et al. 2007; Deutsch et al. 2010; Best et al. 2012; Greenhalgh et al. 2018). Large-scale system transformations in healthcare are interventions aimed at coordinated, system-wide, transformational change affecting multiple organizations and care providers (Best et al. 2012). The sparse literature on this topic highlights the crucial influence of the political and institutional context (Tuohy 1999; Tuohy Hughes 2018). Evidence for achieving large-scale system transformation stems from richly described case studies about what tends to work, for whom, and in what circumstances (Best et al. 2012; Greenhalgh et al. 2018). The literature suggests that the success of a large-system transformation depends on local history, and, in particular, the role of the physicians appears to be crucial to healthcare transformations.

During the planning stages of the large-scale implementation of the national Kanta Services, it soon became evident that little or no common or evidence-based operative models existed to facilitate this process. The sparce extant research consisted of single case studies of single organizations or software applications; moreover, these studies were mostly retrospective and cross-sectional (Ovretveit et al. 2007; Deutsch et al. 2010). Some theoretical models for implementation assessment were available in the literature, but they were neither adapted to a healthcare context nor applicable to the planning and execution of a large-scale, long-term, nationwide implementation involving many projects. As an international pioneer, Finland lacked references and examples of similar solutions introduced elsewhere. Thus, no other choice existed than to construct a novel solution and tailor implementation and adoption to the Finnish healthcare context.

In retrospect, the 'home-made' 6-3-1 model for the implementation and adoption project was successful (Study I). The preparations in organizations implementing the Kanta Services were standardized and followed a common scheme with tasks assigned in milestones approximately six (6) months, three (3) months and one (1) month before the production trial and start of production. It was estimated that at least 900–1,000 successful projects were undertaken at the local, regional and national levels in multi-stakeholder cooperation during the large-scale nationwide implementation. This estimate does not include the number of projects (hundreds) that were run to prepare the centralized HIS or those required during maintenance and further development after the centralized HIS entered the production phase. Thus, the total number of projects could well exceed 1,000 if all such projects were included in the figure.

To offer an example from one hospital district area, a regional implementation project for 13 PHCs was run to adopt the Prescription Centre services from February 17 to June 4, 2012 (unpublished final project report). At the time, three comprehensive EHR were in use in the region's PHCs. The regional implementation project group consisted of 25 persons and, in addition, local project groups consisting of approximately 5–10 persons in implementing organizations. The 13 PHCs trained 3,560 healthcare professionals to use electronic prescriptions in their EHR. In addition, the implementing organizations trained 5,370 healthcare and 1,860 social welfare professionals in electronic education platforms on privacy and safety issues. The organizations established 17 registration centres for smartcards and educated 78 smartcard specialists. At the end of the regional implementation project, there were 4,620 official smartcards in use issued by DVV. The regional project produced a handbook on personal privacy and data safety matters, established a common cooperation model for PHCs and community pharmacies, created a common regional model on troubleshooting matters and a common regional model on change management. Total costs allocated to the regional implementation project were EUR 1.3 million, excluding the costs of community pharmacies.

6.2.2.2 National coordination unit in Finland

In January 2011, a national coordination unit with an appropriate legal mandate was established at THL by permanent legislation (Study I). The THL's coordination unit was responsible for the planning and execution of the large-scale implementation of the Kanta Services for healthcare and pharmacies. It also issued regulations and guidelines on the standardization of information management (e.g., interoperability). Implementation and adoption support (as part of the intervention) provided by the coordination unit included help desks, educational and instructional videos, written guidelines and presentations, newsletters, websites, national biannual conferences, and other seminars and meetings on a range of issues. Moreover, it granted state funding for pivotal development projects, their follow-up and control, and, especially, for dedicated regional personnel assigned to university hospital districts for regional support.

THL's national coordination unit worked as a task force striving towards a common goal together with the regional and local implementation coordination organizations. National coordination and steering occurred, for example, on a platform for the actors involved that was organized in a dynamic and iterative way to allow the exchange of experiences and knowledge. Solutions for problems raised during the adoption were jointly formulated in almost real time. In this dynamic, iterative system, new organizations entered a platform that already included other organizations that were either in the process of adopting the national HIS or had recently adopted it and had begun production of the Kanta Services.

The concept of a national operative coordination organization has been applied in many countries since 1993 (New Zealand): Denmark (1994), Norway (1996), National Health System of England (1999), Germany (2005), Canada (2002), Australia (2004), France (2004), the United States of America (2004), Estonia (2005), Switzerland (2008) and Finland (2011). In addition, similar national coordinating organizations exist in Israel and Sweden. However, not all such organizations have been successful in establishing national HIS or HIE services in their countries.

6.2.2.3 Implementation timetables for the national Kanta Services in Finland

The KaTRI project assessed the Kanta Services' architecture, defined core services (the Prescription Centre, the Patient Data Repository and My Kanta Pages) and enabling services (certificate services, the National Code Server and changes in legacy data systems) (Hyppönen et al. 2009). Before launching the large-scale nationwide implementation of the Kanta Services, it was estimated that the implementation timetable would follow a scheme divided into three periods: prior to (estimated 2009–2011), during (2011–2016) and after the implementation of the Kanta Services.

According to the permanent legislation (2007), all Kanta Services were to be fully functional by April 1, 2011. The original design for the implementation of the Kanta Services allowed only four years for all planning and preparatory activities with various stakeholders and actors. This design was retrospectively assessed to be unrealistic (VTV 2011). The original deadline was also reported to be unrealistic by the MSAH in 2010, when the government proposed changes in the *Act on the Electronic Processing of Client Data in Social and Health Care*. Consequently, the implementation design was changed to a 3-phase design approach.

Community pharmacies were to subscribe to and adopt the Prescription Centre services (to begin to dispense electronic prescriptions) by April 1, 2012. Public healthcare service providers were to be able to send electronic prescriptions to the Prescription Centre by April 1, 2013, while the deadline for private healthcare service providers was April 1, 2014. During parliamentary hearings, the deadline for private healthcare providers was further divided into two phases: providers issuing more than 5,000 prescriptions annually were due to subscribe to the Prescription Centre services by April 1, 2014, while for the remainder the deadline was January 1, 2017.

The implementation timetable for the Patient Data Repository services was also divided into two sub-phases: public healthcare service providers were allowed to begin voluntary use of the Patient Data Repository services on January 1, 2014, but they were compelled to subscribe, adopt and use the services by October 1, 2014. The dates for private healthcare service providers were January 1, 2015, and October 1, 2015, respectively.

Even these legislation-based deadlines introduced in 2010 failed to match reality. Only certified HISs were to be implemented. However, the time from certification to the first Kanta Service-compatible data system installation varied between EHR solutions and by national HIS service implementation approach. It took approximately two years to implement and adopt one national HIS service irrespective of the number of adopting organizations. The fewer solutions that were in use in the implementing public PHCs, the less time was required to adopt one Kanta Service. The more organizations there were or the larger the area was, the longer it took to adopt both Kanta Services.

In Finland, the implementation time for the national Prescription Centre was three years from when the permanent legislation came into effect in March 2007 to the launch of the services in May 2010. In turn, 6.5 years elapsed from the start, in July 2007, to the launch of the Patient Data Repository, in November 2013. Then, another 6.5 years were required before all prescriptions became electronic in January 2017. However, if we view the start as January 2011, when THL's operative coordination unit was established, it took some nine months to launch the Prescription Centre services and to reach 10 percent population coverage, and three years to launch the Patient Data Repository and 3.5 years to reach 10 percent population coverage.

6.2.2.4 Comparison of national health information system implementation and adoption times in Estonia and Finland

Estonia's large-scale nationwide HIS implementations offer point of comparison for the implementation and adoption of the Kanta Services in Finland (Aaltonen et al. 2010; Saluse et al. 2010; Tiik 2012; National Audit Office of Estonia 2014; Direktoratet for e-helse 2015; Parv et al. 2016; Ross 2016; Novek 2017; Habicht et al. 2018; Metsallik et al. 2018; Taal 2018; Thiel et al. 2018; Yeh and Saltman 2019).

Finland's first national electronic health strategy was published in 1995, while Estonia announced its strategy in 1998. In Estonia, establishment of an operative coordination organization (E-Tervis) occurred in 2005, simultaneous to the national decision to begin national HIS implementation. In Finland, it took 3.5 years to establish a national operative coordination unit at THL (in 2011) after the permanent legislation came into effect in 2007. From the government decision to implement a centralized HIS to the launch of the first national electronic prescription service, implementation took four years in Estonia and three years in Finland. All prescriptions have been electronic since 2018 in Estonia (12 years after the HIS implementation decision) and since 2017 in Finland (nine years after the decision).

Comparing the two centralized approaches, Finland reached the decision to implement the Kanta Services two years after Estonia, established an operative coordination organization five years after Estonia, launched the Prescription Centre four months after Estonia and introduced mandatory electronic prescription one year before Estonia. In the literature, the two neighbouring European Union Member States are often considered electronic-health forerunners. On January 21, 2019, Estonia and Finland became the first European Union Member States to exchange cross-border electronic prescription data.

In 2018, the Estonian patient portal was actively used by 37% (0.48 million persons) of the Estonian population, and less than 1% (<700 persons) of users had opted out of the system (Estonian Ministry of Health and Estonian Health Insurance Fund, personal communication 2019). In Finland, 49% of adults or 39% of the Finnish population had signed into My Kanta Pages in 2018, while 61% of the Finnish population had given their consent and 4% of My Kanta Pages users had restricted their consent in that year (Study IV).

6.2.2.5 Current implementation governance and structures in response to the audit findings on management and implementation

The principal lessons learned were derived from a previous large-scale regional initiative, the Satakunta Macro Pilot Programme (Arnkil et al. 2002; Koivisto 2002; Liikanen 2002; Nissilä 2002; Nykänen and Kairimaa 2002; Nylander et al. 2002; Ohtonen 2002), and a comprehensive audit of the KanTa development programme (VTV 2011).

In response to the lessons learned, the Kanta Services' development projects and production pilot projects were nationally planned and coordinated to follow the implementation plan, even though the projects were executed by regional public healthcare hospital districts or by local municipal PHCs. Most of the results were utilized and applied to development and implementation practices and scaling-up at a national level. At times, managing these large, long-term projects was demanding, since they were executed in parallel, and each project demanded more administrative tasks (of an increasingly mandatory nature) and resources for execution.

The national HIS architecture remained surprisingly stable during the implementation. At the very beginning, and before the inception of THL's national operative coordination unit, the means for rigorous cost control, monitoring and follow-up schemes were introduced. A decision was taken to recruit multitalented and expert HIS and HIS professionals educated or widely experienced in healthcare or social welfare service provision, many of whom possessed information and communication technology management and leadership capabilities. Dedicated regional and university-central-hospital support for the organizations adopting the Kanta Services was introduced by allocating experienced personnel to offer consultation and also provide broad feedback from the field to THL's operative coordination unit. Only minor changes in personnel occurred during the implementation; instead, THL permitted the recruitment of qualified persons to many supporting functions and teams. The implementation plan for the Kanta Services development projects was cautiously initiated, with the projects run simultaneously and coordinated nationally.

In close cooperation with various stakeholders, a wide array of support activities and platforms were organized for the Kanta Services' development programme and its projects in order to provide the stakeholders with clear and detailed guidance in the execution, implementation and communication of their tasks. Implementation and adoption support included help desks, educational and instructional videos, written guidelines and presentations, newsletters, websites, national biannual conferences, and other seminars and meetings on a variety of issues. However, due to the urgent need for change, some minor alterations were introduced to the national Kanta Services architecture based on accumulated experiences from pilot development and production projects.

Steering efforts in development, implementation and adoption were based on common ground and the legal mandates of stakeholders. Decision-making on operative matters was organized according to the legislation and to THL's norms and rules. THL organized clear and succinct internal and external reporting feedback for those who required data and reports. Common reports on the actions of all actors involved in the implementation were prepared to enhance systematic, continuous monitoring and follow-up. As mandated by the relevant legislation, decision-making and practical preparations occurred within the participating permanent hierarchical organizations. The participants strived to communicate different perspectives on the timetable or execution of the programme in a uniform fashion through various channels. In addition, restricted access was granted to some planning activities and free access was provided to information through common channels and websites.

The two strategic choices revealed in Finland's eHealth Roadmap were fundamental to the development programme of the Kanta Services and the implementation of the national HIS and HIE thereafter (MSAH 2007). Most of the aims of these two strategic choices were already achieved by May 2010, when the first nationwide, centralized, and integrated Kanta Services were launched. Current use of the Kanta Services for healthcare would not have been possible without the political support of the Parliament, and the long-term vision (since 1995) and support for the accepted policy from several successive government coalitions on the basis of a Government Resolution in 2002. The 1995 national strategy on the principles of citizen-centred and seamless service structures survived the first 10 years of strategy implementation, but in practice these principles were seldom adopted (Hämäläinen and Hyppönen 1996; Hämäläinen and Reponen 2019). Some local projects were launched (VTV 2011), but the first national online HIS service for citizens and patients remains My Kanta Pages, introduced in May 2010 (Winblad et al. 2008; Hyppönen et al. 2011).

The Information to Support Well-Being and Service Renewal – eHealth and eSocial Strategy 2020 (MSAH 2015) consisted of six major themes: citizens as service users (a DIY approach), professionals (smart systems for capable users), service system (effective utilization of limited resources), refinement of information and knowledge management (knowledge-based management), steering and cooperation in information management (from soloists to harmony), and infrastructure (ensuring a solid foundation). It was published in 2015 with the goal of improving information management and expanding the volume of online services in healthcare and social welfare services. Mapping of the 2015–2020 strategy objectives and measures was performed (Hyppönen et al. 2016).

An effective, secure way to share information embedded in medical records between different health structures would greatly improve the quality of healthcare (Quantin et al. 2011; Lapsia et al. 2012). One solution would be standardizing and centralizing all the information about every patient or client in a single electronic medical record, while the other solution would be coupling (Eason and Waterson 2013). In a tightly coupled HIS, all users work with an identical database of electronic medical records (centralized). In a loosely coupled system, users may use different databases and may therefore retain some local control over the information they input into the system and how they use it (distributed). It seems logical that if one desires to provide integrated health service care, all healthcare agencies should share a common HIS (Eason and Waterson 2013). However, centralization requires standardization, and standardization is demanding (Quantin et al. 2011; Lapsia et al. 2012). A distributed health-data network allows secure remote analysis of separate data sets, each derived from a different medical (or other) organization's records (Maro et al. 2009; Quantin et al. 2011; Lapsia et al. 2012). Such networks allow data holders to retain physical control over the use of their data, thereby avoiding many problems related to confidentiality, regulation and proprietary interests. A distributed model creates institutional autonomy, and improved scalability and parsimony (Maro et al. 2009; Lapsia et al. 2012). However, a simulation study found the distributed model to be inferior in terms of the volume of transactions necessary to present a complete patient record (Lapsia et al. 2012). Standards are not static, and they should respond to new technologies and healthcare needs (Coiera 2009). Regulations remain one of the most important strategic instruments to ensure that adequate standards are introduced and maintained in a given service (Schliemann et al. 2019).

6.2.3 THE CLINICAL ADOPTION FRAMEWORK MACRO LEVEL TRENDS

Implementation of the Kanta Services benefited strongly from findings and observations produced by parallel and independently conducted HIS technology research during the Kanta Services development programme (2003–2007) and the nationwide implementation of the services (2007–2017) (Vehko et al. 2019). Another research coalition has utilized community pharmacies in Finland as their sampling base and used surveys among pharmacy professionals (2014–2017) and community pharmacy customers (2015–2019) (Timonen et al. 2016; Kauppinen et al. 2017a-b; Lämsä et al. 2017; Lämsä et al. 2018; Timonen et al. 2018; Lämsä et al. 2019; Sääskilahti et al. 2020; Sääskilahti et al. 2021).

In Finland, surveys were conducted between 2007 and 2017 on the nationwide Kanta Services and the national healthcare organization (Winblad et al. 2008; Reponen et al. 2015; Hyppönen et al. 2017; Reponen et al. 2018). In addition, national general population surveys were conducted three times between 2014 and 2020 (Hyppönen et al. 2014; Hyppönen et al. 2018; Kyytsönen et al. 2021). The results of a series of cross-sectional postal surveys among adults from 1999, 2002, 2005 and 2008–2014 (Mononen et al. 2019) revealed that in Finland physicians, community pharmacists and medication package leaflets were the most common sources of medication information. Furthermore, healthcare professionals have been the focus of several surveys in 2010–2020: physicians in 2010, 2014 and 2017 (Vänskä et al. 2010; Winblad et al. 2010; Lääveri et al. 2011; Viitanen et al. 2011; Vainiomäki et al. 2014; Vänskä et al. 2014; Lääveri et al. 2015; Kaipio et al. 2017; Vainiomäki et al. 2017; Metsäneimi et al. 2018; Saastamoinen et al. 2018; Kaipio et al. 2019; Kaipio et al. 2020; Lääveri et al. 2020; FMA 2021; Saukkonen et al. 2022), dentists in 2012 (Savola et al. 2017) and nurses in 2017 and 2020 (Hyppönen et al. 2017; Hyppönen et al. 2018; Kaipio et al. 2020; Kyytsönen et al. 2020). The national surveys among healthcare professionals have focused on the CAF's micro-level benefits evaluation framework, particularly on the usability of the EHR and HIS currently utilized within organizations and between healthcare service providers.

The first assessment of experiences on electronic prescription and use of the recently introduced national Prescription Centre was performed for 269 general practitioners in two PHCs, who were the first to adopt electronic prescription in Finland (Kivekäs et al. 2014). The majority of respondent physicians found their EHR easy to use and useful for their work. Moreover, most respondents considered that electronic prescription increased patient safety. However, electronic prescription was not considered to enhance the effectiveness or productivity of work.

Heponiemi et al. (2017) examined trends in perceived stress related to HIS among Finnish physicians during a 9-year follow-up in three surveys (2006, 2010 and 2015). They found that changing, difficult and poorly functioning HISs were a prominent source of stress among Finnish physicians, and this perceived stress seemed to continue to rise. This increase was most pronounced in PHCs from 2006 to 2015, whereas, in specialized hospitals, stress levels were no longer found to have increased between 2010 and 2015.

Finland is the first country to have performed regular national monitoring of HIS usability from the end users' perspective (Hyppönen et al. 2019). A validation study among a nationally representative sample of Finnish physicians in 2014 and 2017 found that the National Usability-Focused Health Information System Scale was as a useful tool for measuring HIS usability and represented a valid measure for monitoring long-term HIS development on a large scale.

Surveys among pharmacy professionals were conducted in 2014–2017 (Timonen et al. 2016; Kauppinen et al. 2017; Timonen et al. 2018), among pharmacy customers in 2015–2019 (Lämsä et al. 2018; Sääskilahti et al. 2020; Sääskilahti et al. 2021) and primary healthcare physicians in 2015 (Kauppinen et al. 2017). Most respondents (62%) were familiar with the

My Kanta Pages web service and 46% of the respondents had signed into My Kanta Pages and viewed their electronic prescriptions at least once (Lämsä et al. 2018). Pharmacy customers who had used My Kanta Pages were extremely satisfied with its usability. Most primary care physicians considered that electronic prescriptions were convenient because of the paperless procedure and that information on patients' prescriptions was better available through the Prescription Centre (Kauppinen et al. 2017). In spring 2019, 83% of questionnaire study respondents reported they had used My Kanta Pages (Sääskilahti et al. 2020).

A 2019 questionnaire study among adult community pharmacy customers was used to investigate the functionalities respondents used in My Kanta Pages (Sääskilahti et al. 2021). The most frequently used functionalities were found to be browsing prescription information (97%) and accessing records of their own healthcare visits (96%), the results of laboratory tests and written statements of radiology examinations (90%). Most (70%) users had also requested a prescription renewal via My Kanta Pages. By contrast, the least frequently used functionalities were browsing disclosed information (56%) and printing out prescription information (43%). My Kanta Pages was perceived as being easy to sign into (95%), possessing a clear user interface (88%), working without problems (82%) and offering easy-to-find information (79%). Over 90 percent of users considered My Kanta Pages useful for monitoring their health information and felt that it provided a good overall picture of their prescribed medication. Most (86%) users found the information recorded about them easy to understand. However, 20 percent of users feared that unauthorized persons might view their information and that their information might disappear. Overall, 90 percent of users were nonetheless satisfied with the My Kanta Pages service in 2019. Most (72%) My Kanta Pages users had consented to the disclosure of their health information in the service. In addition, 20 percent of users had issued an organ donation testament and 10 percent had issued a living will in the service. Only on rare occasions had the participants reported they had limited disclosure of their health (six percent) or prescription information (three percent).

In a Finnish internet panel survey conducted in October 2020 among 1,650 Finnish residents aged 18–79, nine out of ten reported using the My Kanta Pages online patient portal (Jormanainen 2022). Ten percent of users had only accessed their prescription, ten percent other health data and 81% both. Eleven percent had not used My Kanta Pages, and 1.5% were unaware of its existence. Compared with non-users, My Kanta Pages users were more likely to be female city dwellers with a higher-than-average household net income and more reported independent use of online services. Moreover, use of My Kanta Pages increased by poor self-rated health status, the number of reported prescribed medicines, long-term diseases and physician visits during the six previous months.

In a cross-sectional web-based survey in June 2021, data were collected from 3,135 (0.7% response rate) patient users of the Finnish My Kanta Pages patient portal (Kujala et al. 2022). Overall, patient evaluations of My Kanta Pages were positive, and its usability was rated as good on the System Usability Scale. Patients found the portal to be most useful for managing prescriptions and viewing the results of examinations and medical notes. Viewing notes was the most frequent reason (31%) for visiting the portal, followed by viewing the results of examinations (22%) or prescriptions (17.5%), renewing a prescription (15%), and viewing their COVID-19 vaccination status (7%). By contrast, other functions were used by only a handful of respondents. The most frequently used functions were also deemed to be the most useful. The benefits listed by patients of reading medical notes included remembering and understanding the explanations, advice, and instructions provided by health professionals during an appointment, the convenience of receiving information about health and care, the ability to check the accuracy of medical notes, and the use of such information to support self-management. However, patients also highlighted challenges related to the difficulty of understanding medical terminology, incorrect or inadequate notes, missing notes, and usability issues. Nevertheless, patients actively used medical notes to help them follow professionals' instructions on the management of their own health, and thus patient access to electronic health records can clearly support self-management.

The author of this research has conducted several register studies, mainly using log-based indicator data covering the period 2010–2017 (Jormanainen 2015, Study I; Jormanainen et al. 2018). These data were first used to inform general practitioners and later wider audiences about the implementation and adoption of the national Kanta Services.

In a Master's thesis published in 2015, the factors affecting data quality (usability) were assessed through a literature review and an empirical, retrospective case-control study was carried out that utilized the national Prescription Centre data (Takala 2015). The study data consisted of 596 patients (cases) with cancellations, changes or prescription renewals in their electronic prescriptions recorded in November 2014, and a sample of 600 patients (controls) without any of the aforementioned entries in November 2014. Electronic prescription data from 2012–2014 on the cases and the controls were retrieved from the Prescription Centre for analysis. Among the 596 cases, 76,411 prescriptions had been issued, out of which, two out of three were from community pharmacies, one third from public sector service providers and one percent from private sector service providers. Among the 600 controls, the number of entries was 50 percent less than among the cases. The three most common entries were the same among cases and controls: dispensations (46% cases and 47% controls), electronic prescriptions (27% cases and 33% controls) and electronic prescription renewal requests (13% cases and 8% controls). Changes to the content of electronic prescriptions made by community pharmacies were small.

The rollout implementation schedule of the national Prescription Centre services from May 2010 to December 2014 was utilized to study the effects of the digitization of prescriptions on pharmaceutical use and health outcomes (Böckerman et al. 2019a). The population in question consisted of patients whom physicians had issued benzodiazepine prescriptions dispensed in a community pharmacy and reimbursed from the National Health Insurance scheme in 2007–2014. Utilizing difference-in-difference estimations, the study found on average no impact on benzodiazepine use, but among younger patients (less than 40-year-olds) electronic prescription increased the use of repeat prescriptions. Following the implementation in municipalities, the take-up rate of electronic prescriptions by patients increased sharply and continued to increase gradually over time until the end of December 2014. The results suggest that, without sufficient monitoring, easier access to healthcare through utilization of the Kanta electronic prescription data services might facilitate the overuse of prescription drugs, as observed in the case of benzodiazepines.

Utilizing the same register study material from 2007–2014 (Böckerman et al. 2019a), electronic prescription was observed to affect coordination between PHC service providers and the quality of prescription in terms of incompatible medication, for example simultaneously prescribing warfarin and non-steroidal anti-inflammatory substances (Böckerman et al. 2019b). The study results suggest that electronic prescription provided critical information in settings where treating physicians change, mitigating coordination failures in medication. An interoperable HIS can improve coordination in a complex healthcare service system where information is typically dispersed. In addition, the Kanta Services can reduce regional disparities in prescription quality overall and help reduce the information acquisition cost for physicians.

In a register study in Finland (2012–2016), all electronic prescriptions and their dispensations, cancellations and corrections for oral anticoagulant medication were retrieved from the Finnish Prescription Register (an electronic repository of reimbursed medication purchases at community pharmacies) and the Kanta Services (the Prescription Centre) (Aarnio et al. 2020). In 2016, the total number of electronic prescriptions identified for oral anticoagulants in the Kanta Services was 257,751 and the total number of recorded dispensations of oral anticoagulants in the Kanta Services was 786,597. The number of direct oral anticoagulant users was higher in the Kanta Services than in the Finnish Prescription Register in 2014–2016.

6.3 METHODOLOGICAL CONSIDERATIONS

6.3.1 STRENGTHS AND LIMITATIONS OF THE STUDY

HIS or HIE implementation and adoption studies can deliver observations on programme management, implementation strategies and adoption details in organizations and among personnel. In addition, they can provide insights into the funding, initial start and sustainable use of the new HIS or HIE. However, these interesting experiences and observations often remain in project and programme execution plans and results at the micro level, and thus these valuable details are rarely published or found in the literature. The present research aimed to highlight and document the central macro- and meso-level building blocks of the implementation and adoption of the two nationwide, centralized and integrated Kanta Services, which provide complex and multi-actor healthcare in Finland.

A major strength of the present study is access to comprehensive and detailed national log-based register data on the project management, implementation, adoption and sustainable use of nationwide HIS data from central and field organizations. Meso-level implementation planning and execution activities were followed prospectively and longitudinally from 2010 to 2018 at the national level by using monthly log-based register data from a series of pre-set indicators. Due to this comprehensive data access, implementation situation reporting was up to date and occurred in almost real time. The present research might be among the first of its kind to publish detailed data on the adoption of healthcare data services at national, regional and local levels stratified by two national services and by healthcare provision segments. Since May 2010, Finland has allowed adults to access their own health and prescription data online via the web-based My Kanta Pages. Some characteristics of patients' use of My Kanta Pages were assessed. Half of the entire Finnish population and two out of three adults used My Kanta Pages in 2018. Similarly high levels of use have rarely been reported in the literature.

Another key strength of this research is its application of two healthcare-specific theoretical constructs on nationwide and large-scale HIS implementation and adoption. The CAF was used to study macro-level factors – governance, standards, funding and trends – in addition to the meso-level implementation dimension. The CAF is complex, consisting of 43 categories that belong to 15 dimensions, which are further separated into three levels. Thus, the CAF seemed well-suited to the Finnish healthcare context.

The CAMM supported retrospective assessment of post-deployment of the Kanta Services, with its five dimensions (availability, use, behaviour, clinical outcomes and time). Use of the CAMM suggested that Finland's HIS conforms to the archetype Adoption with Benefits: there was a clear progression of the availability of the Kanta Services that led to ongoing HIS use and subsequent observable changes in clinical behaviour that, in turn, may have resulted in improvements in the outcomes measured in this research.

Issues related to the implementation of the two Kanta Services were also assessed using criteria established in the 2007 electronic health data system roadmap for Finland. Assessment was performed using systematically collected and analysed time series of log-based register data, in order to monitor, react to and adjust implementation and adoption performance appropriately. Performance of the HIS solutions and services was assessed from their initial implementation and start of the production. Data were also gathered from other official administrative sources, including the central administration and state funding in the state budget. A major proportion of the content and proposed services derived from the two strategic choices were already in place by May 2010, when the first Kanta Services were launched. However, national services for the booking of appointments, electronic discussions, electronic document transfer and online consultations were not included in the first development waves.

The large investments required for HISs and HIEs have driven demand for effective monitoring of the resulting adoption, use and impact (Villumsen et al. 2020). Longitudinal monitoring can provide valuable feedback on underlying policies and highlight the complex nature of monitoring and the assessment of implementation (and adoption). Based on a systematic review, adoption, as a term, has often used when applying measures of availability of HIS or HIE functionality as a proxy for actual use (Villumsen et al. 2020). Nonetheless, monitoring the actual use of a functionality, and whether it is used as intended, is the key task of functionality assessment. In order to establish an evidence base for health information policies, trends and developments may be demonstrated by utilizing transparent, published and continuous monitoring and assessments.

Implementation of the two national Kanta Services was monitored and followed up from early May 2010 until the end of December 2018. This exceptionally long and continuous follow-up was comprehensive in terms of implementation infrastructure and use but less comprehensive from a socio-technical viewpoint. This research has produced observations from the log-based register data available for follow-up purposes according to the restrictive legislation of the time.

Since the implementation of the two nationwide Kanta Services was based on permanent legislation, both voluntary and mandatory data systems are present. Consequently, the terms ‘usage of the system’ and ‘overall user acceptance’ were used interchangeably (Ammenwerth et al. 2006). In addition, the four adoption phases of the HIS or HIE (Esmaeilzadeh and Sambasivan 2016) were only partially covered in this research. It would have been preferable to collect data on adoption indicators from organizations’ own documentation and/or from interviews; however, this was considered too laborious due to the large number of projects and organizations. Consequently, the study suffers from, for example, a lack of adoption decision dates, and thus the four adoption phases could not be measured.

The unique material in Study II consisted of dates from the actual implementation projects carried out in the field in community pharmacies and public PHCs across Finland in 2010–2016. To the author’s knowledge, almost no previous studies exist on the implementation of two national HIS services conducted in a time-series fashion. In addition, these dates allowed quantification of the differences in time required for adoption of the two implementation strategies, i.e., the regional (based on hospital districts) Prescription Centre and Kanta compatible HIS-based Patient Data Repository implementation strategies.

In retrospect, analyses of these dates turned out to be challenging and complex due to the production pilots. In this research, the start the implementation was defined as the first time it was introduced in a municipality, hospital district, university hospital specific catchment area or at the national level. If the production pilots were excluded from the analyses, the mean duration of the implementation and consequent adoption times would be approximately six months shorter than in the results presented in this research.

In Study IV, even though complete numbers of adult users of the web-based My Kanta Pages were available by municipality, the majority of user characteristics were lacking. Therefore, this research could only provide results based on geography and organization levels (municipality, primary healthcare centre, central hospital and university hospital specific catchment area). Other user characteristics, such as disease or illness prevalences, would be essential in order to explain differences between populations and sub-populations.

6.3.2 STATISTICAL TESTING AND THE WHOLE STUDY POPULATION CONCEPT

In this research, neither statistical tests nor confidence intervals were calculated. The reason for not performing these statistical operations was the likelihood that all cases or observations during follow-up were included in Finland’s national electronic prescription and health register data. It is commonly agreed that statistical inference is inapplicable to complete population studies due to the absence of sampling variability (Alexander 2015).

Reporting p values and confidence intervals implicitly requires a target population that is wider than the sample under investigation (Alexander 2015). Regardless of the definition of target population (e.g. persons, visits and sign-ins), some statistical units might always be excluded. However, theoretically, the statistical units of these log-based register data populations might contain characteristics that would divide the register population into two parts: a population in which there are no missing target variables, and a wider observed sample including cases with and without missing target variables (Beresewitcz et al. 2018). Moreover, it may be reasonable to suppose that such a wider target population might be identified as other countries intending to implement a national HIS or HIE. In these cases, the results and estimates generated in Finland might offer a valuable point of comparison for a middle-out implementation approach and matters of governance, standards, funding and trends, as described in this research.

In addition to the target and whole population, there might be other sources of selectivity in the whole population that are connected to infrastructure (selectivity in coverage) and to users (organizations and individuals) (Beresewitcz et al. 2018). Selectivity in the coverage of the Kanta Services was actively reduced by performing vigorous, systematic and complete nationwide implementation and adoption of the HIS in public healthcare providers (100%) and the large majority of private healthcare providers (at least 98%). Only organizations or private practitioners without electronic patient records are excluded from using the Kanta Services. Private practitioners might, however, utilize web-based electronic prescription tools (e.g., Kelain) to issue electronic prescriptions during their free time and without any commercial use. On the other hand, these register data might exclude persons consulting private practitioners who keep paper-based notes of their patients’ records instead of using the Kanta Services. Nonetheless, such persons can provide or restrict their consent to allow other professionals to use their health data. In both cases, these persons’ health data are then recorded in the Kanta Services but processed in healthcare provider units according to the individuals’ stated consent and its restrictions. Thus, these data are also included in aggregate register data analyses.

In quantitative terms, had the data analyses been performed, for example, according to Bayesian statistical methods, the research data results would most likely have been extremely similar to the original research results.

The research literature states that prevalence estimates for long-term conditions can vary by over 20 percent depending upon the denominator (Cocoros et al. 2019). EHR systems do not include definitive lists of all patients associated with a practice at any given time. Moreover, the literature is scarce on how to best determine the size of the population at risk when estimating disease prevalence and incidence rates using EHR data. In addition, estimating population denominators using the EHR approach can be problematic for multiple reasons in dynamic populations.

This research aims to assess the implementation and adoption of two Finnish healthcare laws in 2010–2018. The unique opportunity to report in detail the results and events of a nationwide megaproject was based on data from healthcare provider organizations and pharmacies. Two theoretical constructs were applied at a macro level, and thus person-level data and comparative study designs are missing. Person-level data could possibly enrich the findings and provide a more in-depth view on implementation and adoption, for instance, how the CAF (Lau et al. 2007; Lau et al. 2011; Lau and Price 2016) would conceptualize implementation processes and adoption efforts among subpopulations, or within hospital districts or among public PHCs. Comparative study designs, for instance, a stepped-wedge pragmatic study design, could also be used, but this approach would have been challenging due to the large number of implementing organizations.

In addition, this research aims to develop further follow-up methods for the implementation and adoption of large-scale, nationwide, centralized HISs or HIEs. A small number of indicators were used in the follow-up to describe the progress of the implementation processes and adoption efforts, after which the CAMM was applied to assess and describe post-deployment adoption across four dimensions (availability, system use, clinical behaviour and patient outcomes) over time by producing pre-defined archetypes (Price and Lau 2014).

It has been claimed that an appropriate assessment of complex interventions (e.g. large-scale and nationwide implementation and adoption of HIS) should not only focus on efficacy but should also provide answers to why, for whom, and under what conditions the intervention has been successful (Pawson and Tilley 1997; Greenhalgh et al. 2009; Wong et al. 2016; Smeets et al. 2022). Answering these questions demands a largely qualitative approach and a realist evaluation in which context-linked insights are collected by using multiple data sources and methods in a pragmatic and reflexive manner to build a picture of the case and follow its fortunes over a particular period (Greehalgh et al. 2009). Such methods may include ethnographic observation, semi-structured interviews, and document analyses and other contemporaneous materials. Even when an ambitious change programme diverges from its original goals and experiences unforeseen challenges, a realist evaluation can draw useful lessons about how particular preconditions increase the likelihood of particular outcomes. However, it cannot produce predictive guidance or a simple recipe for success. In the context of implementing and adopting a nationwide HIS in Finland, each of the two megaprojects contained numerous objectives and multiple work streams operating at local, regional and national levels. One may describe them as dynamic local contexts, the progress of which is unpredictable, and the different subprojects were continually modified as each one developed and benefited from experience. In addition, realist evaluations have been performed on individual interventions or among individual organizations, and only recently at a national level (Dossou et al. 2021). The main analytic challenge in realist evaluations as applied to the healthcare context may not be to determine whether the transformation effort works but to reveal how the outcomes are shaped, enabled, and constrained by interaction between the programme context and the chosen mechanisms of change.

6.4 POLICY IMPLICATIONS

According to the literature, major restructuring of health services and systems is rarely possible without a pervasive information infrastructure (a HIS, in particular), since such restructuring exerts large effects on service provision and productivity. To understand implementation and adoption of the HIS, it is essential to define the policy or policies to be implemented or adopted. In this research, such policies were related to the 1995 national strategy, Parliament-approved laws – the *Act on Electronic Prescription* and the *Act on Processing Customer Data in Health and Social Care* in 2007 – and the 2007 eHealth roadmap for Finland. In addition, the present research assessed the implementation and adoption, through a big bang approach, of a mandatory nationwide electronic prescription policy in 2017.

Because healthcare is complex and hierarchical, comprehensive HIS or HIE implementation and adoption constitute a risky, costly and lengthy process. Therefore, it is crucial to learn from policy implementations and transformational changes in different environments, systems and contexts (Lau et al. 2010). Most healthcare reforms are not properly followed up, and their outcomes are rarely evaluated. The literature prior to 2009 contains no comparisons of implementation approaches or cross-country analyses of nationwide EHR-implementation-associated problems. Moreover, the current literature only provides superficial descriptions, short reports, and post-deployment assessments that fail to use healthcare-specific theoretical constructs. Furthermore, few studies provide detailed accounts of HIS or HIE implementation and adoption efforts and solutions.

Healthcare infrastructure and HIS technology adoption and their effects are not deterministic; rather, they depend on the dynamic interplay of many factors over time. These are well covered by the theoretical constructs of the CAF and the CAMM. Currently the CAF is referred to in Nordic eHealth Benchmarking development work and THL's electronic health evaluation framework. This research found the CAF useful both when retrospectively applied to the preparatory phases of the Kanta Services and also in the evaluation of the actual implementation and adoption of the Prescription Centre and the Patient Data Repository services. In addition, the accompanying CAMM was found extremely useful for the implementation and adoption follow-up.

For the monitoring and follow-up of implementation and adoption, this research utilized log-based register data, registered dates and results based on a national random sample questionnaire study among adults (Study I–III). Implementation and adoption were accompanied by a pre-determined national research plan and efforts, the timing of which were adjusted to the launches of the new national Kanta Services. Independent and parallel national surveys were conducted among organizations, the general population and healthcare professionals (physicians, dentists and nurses). Another research coalition conducted surveys among pharmacy professionals and customers. These research data accompany and enrich the results acquired using this research's log-based register data, registered dates and the questionnaire study. In addition, they allowed for the utilization and assessment of CAMM perspectives in the implementation and adoption follow-up. These data together form a rich and continuously enlarging knowledge base.

In the near and long-term future, Kanta Services data and data flows are likely to be increasingly important for different stakeholders, both in Finland and internationally. According to the latest architecture vision for healthcare and social welfare services in Finland (Pentikäinen et al. 2019), social welfare and healthcare services should be easily accessible, citizens' involvement and autonomy should be encouraged and supported, and services should be integrated and the number and volume of digital service channels increased. Moreover, Citizens' data should always be accessible when and where citizens are provided with social welfare and healthcare services. Furthermore, health and client data should be up-to-date, consistent, processed in secure ways, and technologically standardized. Structured client data enable intelligent summaries and other data analyses. National information system data services are common platforms for the transmission of information and data recording, which are utilized by the client and HIS in respective organizations. National information system data services also enable the secondary use of client data for healthcare and social welfare data purposes.

Conceptually, knowledge flows can be categorized into control information and national- and regional-level information steering (Laihonen 2009). The Prime Minister's Office supported development of a model intended to improve understanding of knowledge and information management and develop individual organizations' knowledge and information management practices according to their own needs and goals (Leskelä et al. 2019). However, knowledge and information management without big data (e.g. Kanta Services) can be challenging.

Nationwide HIS or HIE implementation and adoption should continue to focus on nationally planned and coordinated development, production pilots and implementation and adoption projects, even if practical implementation and adoption is performed by regional or local actors (Study I–II). Projects should be recorded and their realtime execution kept up to date in a national master plan of activities. National HIS and HIE architecture is a prerequisite for successful implementation of an HIS and HIE, and this architecture should remain relatively stable during the implementation period. It is extremely beneficial to establish a national operative coordination organization with an appropriate legal mandate to perform implementation and adoption operations, such as rigorous cost control, monitoring and follow-up schemes by multitalented and expert professionals with years of experience in healthcare service provision and capabilities in information and communication technology management and leadership (Study I). Moreover, the organization should strive to minimize changes in personnel during the implementation. A wide array of support activities and platforms should be organized according to need in order present the various stakeholders with clear guidance in the execution, implementation and communication of their activities. The most appropriate basis for steering and decision-making is current legal mandates, norms and rules that the actors already know. Furthermore, clear and succinct reporting feedback should be organized and performed for systematic and continuous monitoring of the implementation and adoption progress. These progress and situation reports should be recorded for various use cases and available to all those who require them. Moreover, it is essential to communicate the up-to-date timetable or programme execution in a uniform fashion through various channels. The successful conducting and execution of projects and programmes in a multi-actor environment require strong steering, clear decision-making and appropriate resources for programme management from an organization capable of rapidly reacting to issues and matters as they arise. Execution monitoring should be systematic, continuous and parsimonious through the utilization of log-based register data and appropriate indicators. Monitoring should be complemented by external research coalitions to perform additional tasks (e.g. surveys and other applied-research activities).

6.5 IMPLICATIONS FOR FUTURE STUDIES

Surveys are the most common data collection method for the monitoring and assessment of the national availability and use of a HIS (Villumsen et al. 2020). Other sources of data may be more objective, such as harvesting log-based data from central servers, but in only a handful of publications have they been reported. These essential and continuous monitoring and feedback matters should be considered at early stages of policy or other intervention implementation planning. In addition, it would be worth considering a mixed methods study approach as well as other methods. An essential element of monitoring is time (e.g. time-series analyses or difference-in-difference estimations).

The suggested four adoption phases (initiation, adoption decision, implementation process and institutionalization) should be the focus of more in-depth future research (Esmaeilzadeh and Sambasivan 2016). Most of the HIE literature has analysed adoption as a single phase, regardless of the interconnected processes of investment (funding), implementation and institutionalization. This perspective is closely related to the micro- and meso-level factors of the CAF (Lau et al. 2007, Lau et al. 2011, Lau and Price 2016).

Numerous legislation-based policy changes are introduced every year. It would be rational to consider their follow-up and monitoring during parliamentary hearings and after parliamentary decisions by conducting document or qualitative analyses, which can now be performed more easily due to online electronic memoranda repositories. In addition, at least in Finland, Government proposals to Parliament usually contain accurate, up-to-date, in-depth information on the subject matter in a structured format. Many monitoring possibilities are already in place for enhancing the planning and execution of future implementation processes and adoption efforts.

7 CONCLUSIONS

The following conclusions can be drawn from Studies I–V:

1. It is possible to implement and adopt two large-scale nationwide health information systems in 5.5 years covering public primary healthcare centres and pharmacies, hospitals and private healthcare providers in a country with 5.5 million inhabitants. The Prescription Centre services were implemented and adopted first and thereafter the Patient Data Repository services. Public healthcare service providers implemented and adopted the Kanta Services first and thereafter private healthcare service providers.
2. The middle-out implementation strategy worked well in case of the Kanta Services in Finland. It combines local consultation, locally driven investment and system choice, thus promoting a bottom-up approach, with central government support, leadership, resources and nationally agreed interoperability standards and goals, which provide elements of a top-down approach.
3. Large-scale nationwide implementation of the two Kanta Services was supported by a national operative coordination unit with an appropriate legal mandate in the permanent legislation. This unit was located at THL, an established public health institution.
4. Kanta Services implementation processes and adoption efforts were supported by relatively stable national HIS architecture, the recruitment of multitalented, expert professionals with long-term experience, and minimum changes in personnel during the implementation period.
5. A dynamic, rolling platform was organized by the THL national operative coordination unit for implementation and adoption knowledge transfer from actor to actor. In this dynamic system, new organizations entered a platform that already included their experienced peers: organizations that had already adopted and used the Kanta Services.
6. The regional hospital district approach to Prescription Centre services implementation and adoption was changed to a certified Kanta-Services-compatible HIS strategy for the Patient Data Repository services. The change was based on cumulative experiences from the implementation and adoption of the Prescription Centre services, in particular simultaneous local and regional implementation and adoption by pharmacies and public healthcare service providers.
7. In this research, implementation processes and adoption efforts were followed up by rigorously utilizing log-based register data that were of utmost value in almost real-time situation and progress reporting. However, due to the limitations of log-based register data, reporting should be accompanied by independent, long-term, parallel, research and monitoring approaches that enrich the findings on implementation processes, adoption efforts and the effects on patients or clients.
8. Patients' own electronic prescription and health data have been nationally accessible via the web-based My Kanta Pages since May 2010, and users have adopted the service well: a total of two out of three adults in Finland had signed-in to My Kanta Pages in 2010–2018.
9. After nationwide implementation and adoption of the Prescription Centre services by public and private healthcare service providers, a big bang strategy was applied to introduce mandatory electronic prescription, which prescribers and pharmacies adopted quickly.

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9 ORIGINAL PUBLICATIONS

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