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CAF and CAMM analyses on the first 10 years of national Kanta services in Finland

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Abstract

We report the large-scale deployment, implementation and adoption of the nationwide centralized integrated and shared Kanta health information services by using the Clinical Adoption Framework (CAF). The meso and macro level dimensions of the CAF were incorporated early into our e-health evaluation framework to assess Health Information System (HIS) implementation at the national level. We found strong support for the CAF macro level model concepts in Finland. Typically, development programs were followed by government policy commitments, appropriate legislation and state budget funding before the CAF meso level implementation activities. Our quantitative data point to the fact that implementing large-scale health information technology (HIT) systems in practice is a rather long process. For HIT systems success in particular citizens' and professionals' acceptance are essential. When implementation of the national health information systems was evaluated against Clinical Adoption Meta-Model (CAMM), the results show that Finland has already passed many milestones in CAMM archetypes. According to our study results, Finland seems to be a good laboratory entity to study practical execution of HIT systems, CAF and CAMM theoretical constructs can be used for national level HIS implementation evaluation.

Keywords: health information systems, health information exchange, clinical pharmacy information systems, electronic health records, technology assessment

Introduction

Public policy has tremendous impacts on population health. While policy development has been extensively studied, policy implementation research is newer and relies largely on qualitative methods [1]. Easy-to-use, reliable, and valid quantitative measurements of policy implementation can further our understanding of policy implementation processes, determinants, and outcomes. Implementation outcomes include acceptability, adoption, appropriateness, compliance/fidelity, feasibility, penetration, sustainability, and costs [2,3]. Implementation research aims to close the research-to-practice gap, support scale-up of

evidence-based interventions and reduce research waste [4]. Implementation research aims to facilitate the timely and routine implementation and sustainment of evidence-based interventions and services [5].

Implementation and information systems (IS) success evaluation is usually based on a theoretical framework. It has been claimed that the measurement of IS success at its core is simple because there are consistent key elements in the measurement of success, e.g. information quality, system quality, service quality, use, user satisfaction, net impacts and outcomes [6]. Still, relevance, timeliness, and accuracy of information are keys to information systems success [6]. However, many IS success and implementation frameworks are general in the sense that they can and have been applied to many situations, and they are, thus not healthcare specific.

We report the large-scale deployment, implementation and adoption of the national Kanta services by using the Clinical Adoption Framework (CAF) [7,8]. The CAF meso and macro level dimensions were incorporated early into our e-health evaluation framework to assess Health Information System (HIS) implementation at the national level [9]. The CAF model is referenced in the Nordic eHealth Benchmarking development work [10,11], it has been tested and used in British Columbia (Canada) [8] and Malaysia [12], in systematic reviews and evidence synthesis [13].

The CAF has three conceptual views of e-health adoption by clinicians in different settings, e.g. the micro, meso and macro levels [7]. Here clinicians actually refer to all professionals who do perform patient level work in healthcare or customer level work in social welfare services. In this study, our focus is in the CAF's macro-level and implementation at the meso level.

To support implementation, studying and evaluating health information systems (HIS) at national level, the Clinical Adoption Meta-Model (CAMM) was developed [14]. The four CAMM dimensions (availability, use, behavior and outcomes) are not independent but depend on each other.

The Finnish national Kanta services consist of digital data system services for pharmacies, healthcare and social welfare service providers, e.g. My Kanta Pages for citizens (patient accessible online electronic health records), Prescription Centre, Pharmaceutical Database, Patient Data Repository and Patient Data Management Service, Kelain (web-based ePresciption tool), Client Data Archive for Social Welfare Services and Kanta Personal Health Record [15]. The Kanta services is centralized (e.g., data services are produced centrally and primary data archives are kept by the Sickness Insurance Institution of Finland), integrated (e.g., electronic prescription, health and welfare data have standardized common data structures and use common codes and classifications) and shared (e.g., data systems can share data between each other). These national level data systems were built on top of regional and local data systems of primary health centres and hospital that were in place already in the beginning of 2000s [16].

The Kanta compatible data systems (class A) must pass a certification process of their conformity to the key requirements [17], whereas in case of noncompatible data systems (class B), the data system suppliers and the organizations themselves are responsible for ensuring that the systems are used in compliance with the regulations [18,19].

Recent promising results show that electronic prescribing in Finland was observed to reduce a third of the probability of co-prescribing harmful medication combinations in early years of the national Prescription Centre [20].

Our objective was to use CAF and CAMM to gain insight from the large-scale implementation of the national Kanta services after 10 years of experience.

Material and methods

We identified the principal theory relevant changes in Finnish legislation, published strategies, other governmental and institutional norms since 1995. For the CAF meso level implementation, we present stage, project and HIS practice fit aspects. For the CAF macro level, we present governance (legislative acts, regulations and policies, governance bodies), standards (HIS standards), and funding (remunerations). We focused on some main characteristics of the CAF and CAMM based on strong evidence, and thus, we were not able to address every detail of the model elements. In this study, we introduce some examples of CAMM dimensions by using Kanta register data.

In the Finnish social welfare and healthcare system, macro level policy elements usually follow the pattern of changes in legislation, a decision on long-term funding and expressed steering guidance including normative mandates in documents. These types documentary analyses have also been utilized on Nordic level benchmarking and analyses on electronic healthcare data systems between the countries [10,11].

However, we did not perform formal content or text analyses in documents but instead we used common and trusted convenience sampled documents to identify theory based themes in Finnish guidance on development in legislation and other governance documents. One author has been deeply involved in construction and steering of the national Kanta data systems, and the other in evaluation and team working in national committees. Thus, our work is close and has elements of action research [21]. In addition, we obtained numerical data from the Social Insurance Institution of Finland (SII). The SII operates and maintains the national Kanta services. We utilize these qualitative data for CAF reporting.

The Prescription Centre, Patient Data Repository, Data Management Service, and My Kanta Pages of the Kanta services are our focus areas (Figure 1).

We describe the accumulation of data in the national Kanta services from May 2010 to the end of December 2019. The data elements presented are the numbers of persons, visitors, visits, sign-ins, electronic prescriptions and dispensations, documents, service events, organ donation documents and living wills. We utilize these quantitative data for CAMM reporting.

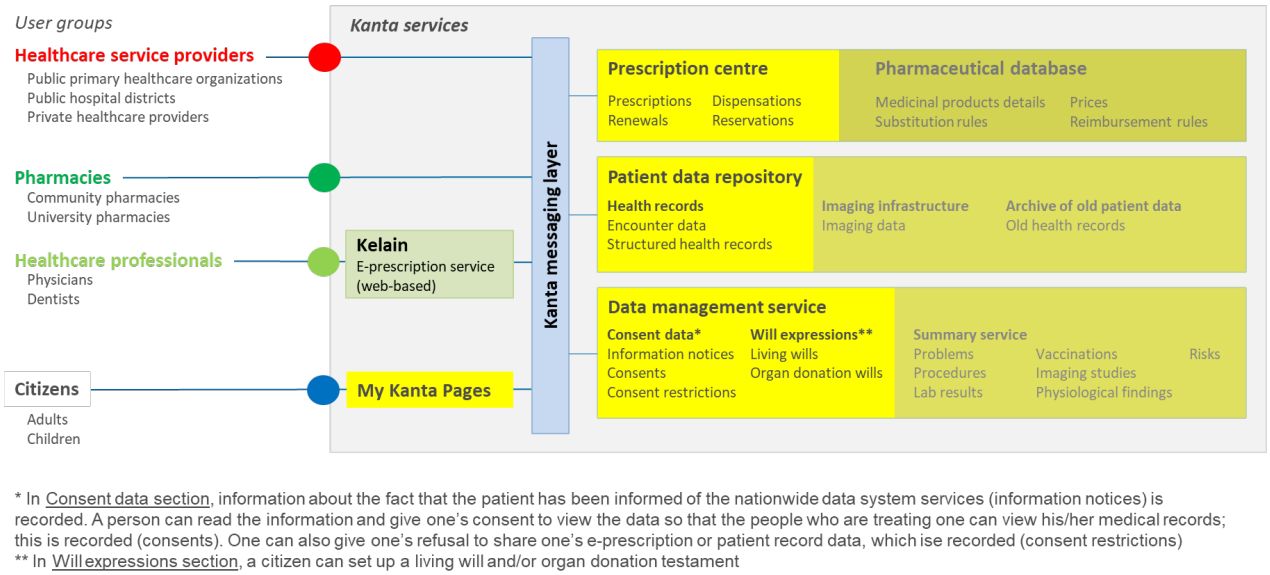

Figure 1. A simplified architecture picture of user groups and national Kanta services that are addressed in this article.

Results

CAF macro level issues in the set-up of the national Kanta services in Finland

Governance

For governance, Finland published the first national e-health strategy in 1995 [22] and the second strategy in 2015 [23]. The 1995 strategy placed specific emphasis on adoption of digital patient and client records at all levels of care, combined with nationwide interoperability between distributed legacy data systems, and supported by a high level security and privacy protection [22]. According to the Government Resolution in April 2002 [24], an integrated national electronic health record (EHR) system was to be introduced by end-2007. In 2003, a national EHR system development project (from 2003 to 2007) was set up as part of the National Health Program. A national social welfare IT development project was launched from 2005 to 2011. The national level services were defined in the national architecture in 2006. [25]

Finland phased in e-prescriptions with an Act on Electronic Prescription (61/2007) issued in 2006, which became into effect April 1, 2007 [26]. Together with the Act on Handling Customer Data in Health and Social Care (159/2007) which became effective July 1, 2007 [27], legislation on the national Kanta services were in place. These laws were further made concrete by releasing the eHealth Roadmap – Finland [28], according to which the approved policies were actually implemented and adopted. Since 2007, the Ministry of Social Affairs and Health (MSAH) is in a strategic role to steer the national centralized integrated and shared Kanta services, and carried out the first phase of the national implementation activities since the permanent legislation came into effect. The SII was set responsible for the technical infrastructure and to maintain the national healthcare information services, and after the 2015 updated legislation, also national information services for social welfare organizations. [25,28]

The 2007 legislation led to development of the national KanTa development program. The MSAH steered and guided the KanTa development program, a compilation of many projects and divided responsibilities of national authorities and other stakeholders. The MSAH had responsibility on strategic guidelines, legislation, national architecture, cooperation with other ministries, overall planning, steering, supervision, and specifications and configurations. The Finnish National Institute for Health and Welfare (THL) had responsibility on developing the National Code Server and service. The National Supervisory Authority for Welfare and Health of Finland (Valvira) developed the certificates for organizations and cards for healthcare professionals. The SII was responsible to construct and maintenance of the national centralized integrated and shared HIS services. Implementation support for the "field" was on the responsibility of the KunTo Office at the Association of Regional and Local Governments of Finland, which also coordinated regional so-called cluster projects and development of the national EHR structure and content. [28]

Standards

In order to implement the 2007 legislation in due time in 2011, a coherent national plan on needed classifications, codes, terminologies, structures and standards (including their delivery) was particularly needed. [28]

The need for unified coding of data in patient records was originally introduced in 2002, and it started the development of the National Code Server that was built from 2003 to 2004 at the THL, and has provided the main codes since 2004 free-of-charge for those who need and use them [29]. The development of certificate service administration for healthcare professionals and organizations started in 2004 [28]. Single sign-on desktop integration was implemented at local and regional levels [30]. Finland continued to utilize the early-1960s unique personal identity numbers for each citizen and inhabitant. In e-transactions, a citizen or inhabitant can be identified and verified using a FINEID card and public key infrastructure. The national information system architecture required all healthcare operating units to be designated with a unique identifier (ISO/OID code). Units will be certified by a national certification authority (THL) for e-transactions. The healthcare and social welfare unit register are maintained on the National Code Server as required for the national architecture. Furthermore, patient documents are signed electronically before deposited or recorded into the national Kanta repositories. Electronic signatures are created on a decentralized basis in the units that generate the records to be signed. The national HIS architecture specified a secure message handling service to link local and regional EHRs and the national Kanta services. [28]

Funding

Procurement of the basic HIS was set on the responsibility of the service providers. From 2000 to 2009, approximately 180 M€ in national and European Union funds were to finance social welfare and healthcare HIS projects, not including the costs of developing national EHR services (KanTa development project) or the national IT project for social services [29]. Financing was provided by the MSAH, the Finnish Funding Agency for Technology and Innovation, regional councils, and indirectly by the Slot Machine Association. Altogether 250 M€ was tied to development projects carried out from 2000 to 2010, not including the self-funded portion of aid or loans granted to enterprises or other financing granted for social welfare and healthcare IT projects. State was to contribute financially to the

construction and introduction of national centralized services from 2007 to 2010. Thereafter, services were to be funded through service user fees. [28,31]

CAF meso level implementation issues in the set-up of the national Kanta services in Finland

National operative coordination function

Since 2011, a national operative coordination function, with an appropriate legal mandate, was established by law to the THL. The THL operative coordination function is not only responsible for planning and execution of the actual implementation of the large-scale centralized integrated and shared data systems for healthcare, community pharmacies and social welfare services, but it also issues regulations and guidelines on the standardization of information management (e.g., interoperability). The intervention of the THL operative coordination function was 1) to change a set of legacy healthcare data systems to Kanta compatible data systems, certified for functionality, interoperability and security, which transfer highly structured documents to and from the national centralized repositories encrypted between identified parties; 2) to actively coordinate and support implementation and adoption activities according to a common plan complied together with stakeholders at national, regional and local levels; 3) to set up a national operative coordination function; and 4) to use prospectively and continuously collected indicator dataset to monitor execution of the implementation and adoption, and situation analyses. [15]

The operative coordination function provided implementation and adoption support (as part of the intervention) including help desks, educative and guiding videos, written guidelines and presentations, newsletters, websites, national conferences twice a year, other seminars and meetings for focus subject matters, granted State remunerations (subsidies) for pivotal development projects and especially, dedicated regional THL personnel assigned in university hospital districts for regional support. National coordination and operative steering took place, for example, in a platform among the actors that was organized in a dynamic and rolling way, in which experiences and knowledge transfer took place from one actor to another as well as solutions for problems raised during the adoption were produced in cooperation almost in real time. [15]

The operative coordination function since 2011 has close working relationships and cooperation with several national actors as well as healthcare and social welfare service providers, community pharmacies and data system vendors. In addition, it works closely with the Kela in various platforms and arenas. The operative coordination function has a legal mandate to decide and grant state subsidies to provide partial funding for breakthrough pilot programs and projects. From 2010 to 2018, altogether 28 projects (8.38 M€) in healthcare and 18 social welfare IT projects (6.05 M€) were granted a partial State subsidy by the THL. State of Finland budget allocation 2010–2018 was 118.22 M€, of which 85.37 M€ to the THL operative coordination function. [15]

Implementation and adoption strategies

From 2007 to 2009 preparations were performed for the actual implementation of the national Kanta services in Finland (since 2010). The first three national Kanta services (Prescription Centre, Pharmaceutical Database and My Kanta Pages) were launched May 20, 2010. According to the Prescription Centre services implementation plan, compiled together by the THL and the KunTo project management office at the Association of Regional and Local

Governments of Finland, the implementation was to be carried out in public healthcare in three phases on national, regional (hospital districts) and local (municipality healthcare units) levels. Applied large-scale implementation strategy was based on regional hospitals districts for the Prescription Centre. Local production pilot projects in Turku and Kotka towns were followed by regional production pilot projects in Eastern Savonia Hospital District and Länsi-Pohja Hospital District before carrying out large-scale nationwide implementation (and adoption) regionally by hospital districts for the rest of Finland. The Association of Pharmacies in Finland carried out implementation of the Prescription Centre services at the community pharmacies. In order to be introduced and to start the production in the Kanta services, data systems have to fulfill requirements for being Kanta compatible (e.g., certification) by law. [15]

The Pharmaceutical Database serves especially healthcare professionals. All healthcare units and community pharmacies that have subscribed Prescription Centre services use data based on the Pharmaceutical Database. Kelain is a service that enables issuing of electronic prescriptions for healthcare professionals. The strategic Kelain concept and online service was developed, tested and launched September 26, 2016 in order to ease efforts to make real a large-scale big bang policy change January 1, 2017. The Kelain is particularly suited for private use, i.e. in a professional capacity, by physicians and dentists. Currently Kelain can be used for issuing and renewing repeat e-prescriptions. [15]

Quantitative register data on CAF and CAMM from the national Kanta services in Finland

Availability and system use of the national Prescription Centre services

The national Prescription Centre services were launched in May 20, 2010. The launching order was the following: community pharmacies, public healthcare (healthcare centres and hospitals), and finally, private healthcare. Availability of the Prescription Centre services grew month after month during 2010–2018 (Figure 2).

Healthcare providers (e.g., physicians and dentists) started to issue electronic prescription in a continuously increasing trend, and the electronic prescription market share grew steadily. Variation in the number of new electronic prescriptions recorded in the national Prescription Centre did not change after introducing mandatory electronic prescribing by law in Finland on January 1, 2017.

Also recipients of the electronic prescriptions (patients) used their electronic prescriptions to make medicine purchases in the community pharmacies of their own choice. Recorded medicine purchases in the national Prescription Centre vary by month and year (Figure 3).

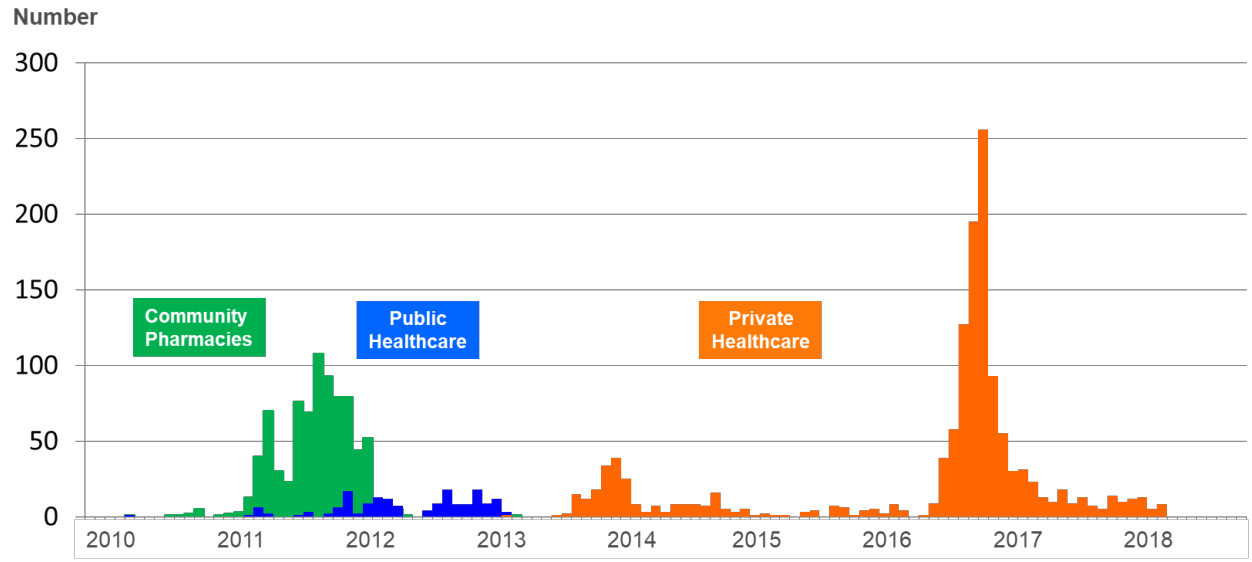

Figure 2. Number of subscribers of the national Prescription Centre services by 4-week time periods from 2010 to May 31, 2018 in Finland.

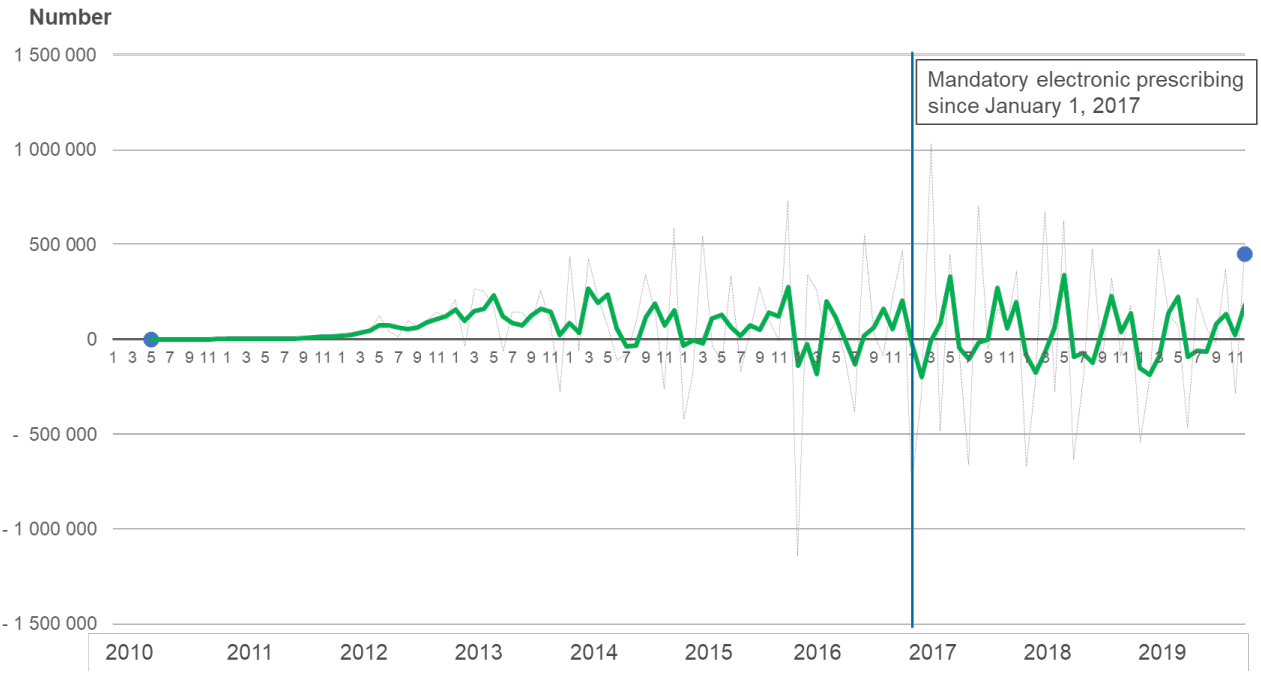

Figure 3. Monthly number of new electronic prescription recorded into the national Prescription Centre from May 20, 2010 to December 31, 2019 in Finland with a 3-month moving average.

Annual number of persons who were prescribed an e-prescription rose from 5,285 in 2010 to 4.379 million (cumulatively 5.700 million) in 2019. Annual number of e-prescriptions rose from 11,733 in 2010 to 29.307 million in 2019. Annual number of dispensations at community pharmacies in Finland rose from 9,343 in 2010 to 67.015 million in 2019. Number of e-prescription dispensations abroad was 6,834 in 2019 (in Estonia and Croatia).

Availability and system use of the national Patient Data Repository

The Patient Data Repository was launched in November 2, 2013. The launching order was the following: public healthcare and private healthcare. Availability of the Patient Data Repository grew fast. Cumulative number of persons who had health data in the Patient Data Repository rose from 2.715 million in 2014 to 6.106 million in 2019. Annual number of service events rose from 19,737 in 2011 to 194.911 million in 2019. Annual number of documents recorded into the Patient Data Repository rose from 51,407 in 2011 to a total of 410.375 million in 2019.

Data Management Service is part of the Patient Data Repository. Cumulative number of informings rose from 2.242 million in 2014 to 6.804 million in 2019. Cumulative numbers were 0.694 million in 2014 and 3.742 million in 2019 for consents, and 9,847 and 108,576 for consent restrictions, respectively. Cumulative number of organ donation testaments in the Data Management Service rose from 149,031 in 2016 to 611,218 in 2019, and those of living wills from 33,983 in 2016 to 136,344 in 2019.

Clinical/health behavior: access to Kanta web pages and My Kanta Pages

Annual number of persons who signed in to the nationally patient accessible electronic health records (patient portal; My Kanta Pages) rose from 683 in 2010 to 2.381 million (cumulatively 3.143 million) in 2019. Number of annual sign-ins rose from 996 in 2010 to a total of 20.924 million in 2019. Access to My Kanta Pages has gained popularity quarter after quarter since 2010, indicating at least change in health behavior of citizens and inhabitants, especially increased use of their own health data (Figure 4).

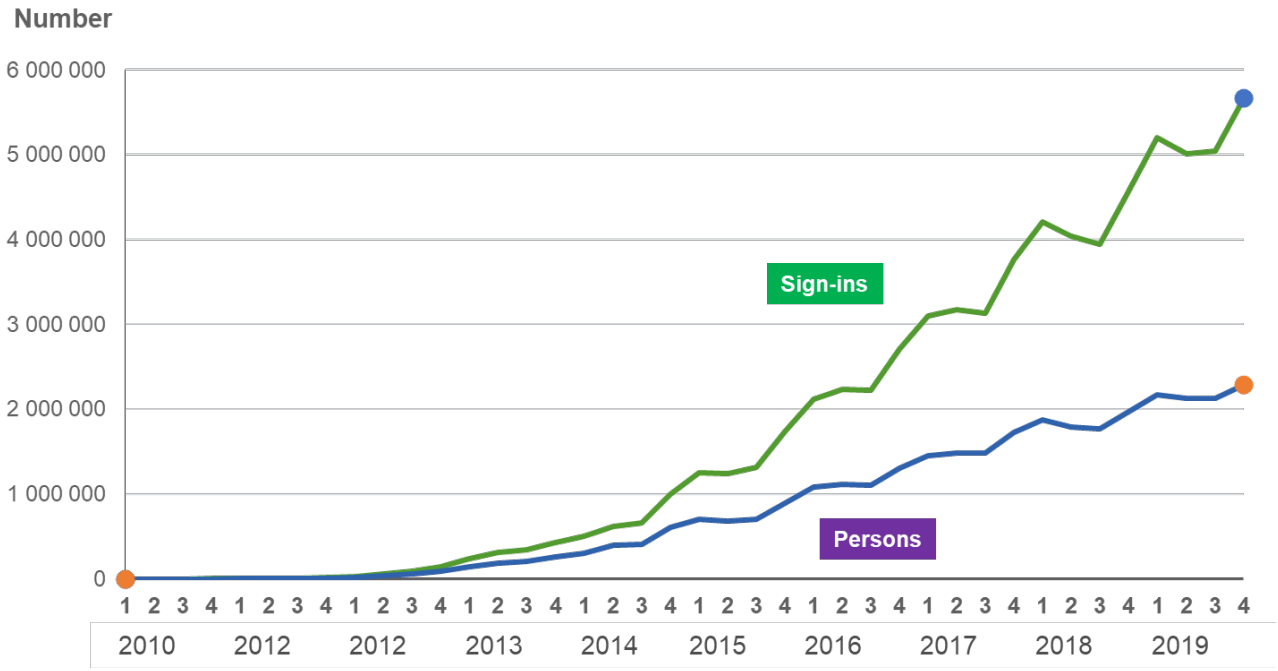

Figure 4. Quarterly number of sign-ins and persons of the national patient accessible electronic health record My Kanta Pages from 2Q2010 to 4Q2019 in Finland.

In 2018, a total of 49.2% (2.38 million persons) of the adults used My Kanta Pages at least once, whereas 42.2% in 2017. Respective proportion is 53.6% in 2019 (preliminary data). Among the working-age groups (18–65-year old) some 50–51% had used My Kanta Pages in 2018, whereas 57–58% in 2019. The proportions were 37% and 45% among the at least 65-year old seniors.

Annual number of e-prescription renewal requests rose from 101,350 in 2015 to 2.780 million in 2019. Annual number of acting on behalf of children under 10-year-olds rose from 138,972 in 2016 to 1.597 million in 2019. The new semi-interactive services at the My Kanta Pages also have been well-adopted by citizens and inhabitants.

Discussion

Based on the conceptual views of e-health adoption, there are relevant steps identified in the Finnish transformation towards an integrated national digital service system. The main acts of CAF macro level [8] are identified in the Finnish policies, starting form legislative acts and extending to issues of governance, standards and funding. We found strong support for the CAF macro level model concepts in Finland. Characteristic for Finland, development programs were followed by government long-term policy commitments, appropriate legislation and state budget funding before the CAF meso level implementation activities were put in place. Framed by national level legislation, partly state budget subsidized implementation activities were carried out service after service in national coordination, together with local and regional public and

private organizations. To the best of our knowledge, the CAF or CAMM models have not been used on national level (macro level).

In Finland we have developed step-by-step our national data systems for healthcare, pharmacy and social welfare service providers, public or private, from initial and well advanced development programs. Reality bites – our road has not in all cases been clear or straightforward as the delivery has involved several steps aside or even backwards due to issues brought up during the execution of the development programs. However, it is also true that all these steps have been important learning points and also inevitable since a forerunner does not always have experiences or best practices available from other organizations or literature. Some actions and experiences have brought up issues that have been adopted into the legislation as corrections, e.g. reorganization of the Acts in 2010.

Our quantitative data point to the fact that implementing large-scale health IT systems in practice is a rather long process as in case of the electronic prescribing, prescriptions and national Prescription Centre services. At least in Finland, these digital IT systems have been adopted by both healthcare professionals and inhabitants alike.

For IS and health IT systems success in particular, inhabitants' and citizens' acceptance is essential. This is why indicators for use and utilization of patient accessible electronic health record (My Kanta Pages) are of paramount importance. These indicators and their maintained levels and increasing trend support the view that we have passed most of the CAMM archetypes of no deployment, low adoption, adoption without benefit, behavior change without outcome benefit, benefit without use, and adoption with harm [7]. Our data point towards the CAMM archetype adoption with benefit. We observed clear progression of HIS availability that led to ongoing use of the HIS, which led to observable changes in clinical and health behaviors that, in turn may have resulted in improvements in measured outcomes. However, in reality causation between the HIS and the outcomes usually cannot be assumed just because they are measured.

According to the current data safety policies in Finland, it must be stressed that the Kanta compatible data systems (class A) must pass a certification process of their conformity to the key requirements including functionality, interoperability and data security [17]. To the best of our knowledge, no data leaks have taken place in these class A data systems. However, a recent large data leak occurred in a data system (a private service provider, which did not have a Kanta compatible data system) that according to the public sources had its health data accessible for data hackers. In these noncompatible data systems (class B), the data system suppliers and the organizations themselves are responsible for the in-house control of data security and data protection, as well as ensuring that the systems are used in compliance with the regulations [18,19].

It has been already observed that there has been substantial variation in the quality of prescribing before the adoption of electronic prescribing in Finland. For example, the prevalence of harmful medication combinations varied across municipalities [20]. In a registry study in Finland, electronic prescribing was observed to reduce over a third of the probability of co-prescribing warfarin with non-steroid anti-inflammatory drugs in rural regions in early years of the Prescription Centre. It may thus have improved care coordination by reducing potentially harmful interacting prescriptions.

Our study has several limitations. First, for the CAF macro level study, we used data on a convenience series of documents which may have introduced selection bias in our results. However, many of these

documents were official publications, and thus, reliable by definition. Second, we provide some register data on adoption and subscriptions of the national Prescription Centre and use of the patient accessible electronic health record (My Kanta Pages) only besides a phone interview results on My Kanta Pages' market penetration 10 years after its launch. Had we performed larger analyses on several Kanta services would have provided us with more consistent results in our CAF and CAMM model application. Third, we did not focus on all the Kanta services but an essential set of four: Prescription Centre, Patient Data Repository, Data Management Service and My Kanta Pages.

To conclude, our case of national Kanta services in Finland suggests that the healthcare specific CAF and CAMM theoretical constructs can be used on the national level IS and HIS implementation evaluation. In addition, Finland seems to be a good laboratory entity to study practical execution of IS and HIS since we have already carried out extensive development programs, long-term policy commitments, organized governance and legislation accordingly, put system-wide national standards in place for interoperability, and funded centrally the essential development of IS and HIS in particular. The implementation was carried out in close cooperation between public and private stakeholders at national, regional and local levels involving several functions from legislation to more practical professionals.

Conflict of interest statement

Vesa Jormanainen has acted as director of the national operative coordination function at the THL in 2010–2017. Jarmo Reponen has acted as a researcher in STEPS1–3 research projects funded by the MSAH in 2014–2020.

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