Domain analysis on an Electronic Health Records System

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ABSTRACT

Electronic Health Records (EHR) have been proposed as a means for managing the technical and organisational complexity that arises in modern healthcare. Different EHR systems are being developed around the world, and within individual countries, different services, such as electronic prescriptions, are being deployed that exploit EHR. We report on a domain analysis of England's developing EHR, as is being implemented in the NHS's National Programme for IT. The analysis, supported by the Feature-Oriented Domain Analysis (FODA) process, ultimately aims to identify commonality and variability across services that use EHR. We summarise the analysis, and describe challenges that we encountered when using FODA to support the analysis.

Categories and Subject Descriptors

H.2 [**Database Management**]: Systems; D.2.1 [**Software Engineering**]: Requirements/Specification—*Methodologies*

General Terms

Design, Experimentation

Keywords

Feature Oriented Domain Analysis, Healthcare Domain, Electronic Health Record

1. INTRODUCTION

The demand for high-quality healthcare continues to rise. The care provided today is much more complex, both technically and organisationally, than ever before. One area in which technical complexity has increased is in recording and storing patient *health records*. Paper-based health records have been in existence for centuries; their gradual replacement by electronic records has been proceeding for the last twenty years, in many different countries [8, 12]. Governments in Australia, Canada, Denmark, Finland, France, New Zealand, England and the United States have announced and are implementing plans to build integrated computer-based national healthcare infrastructures, based around the deployment of interoperable electronic health record (EHR) systems. Compared with paper-based systems, EHR-based systems are supposed to improve the safety and quality of patients' healthcare. However it has been demonstrated that implementing such large-scale healthcare IT programmes can be extremely difficult and costly [1, 5, 13, 14].

England's National Programme for IT (NPfIT) was initiated in 2003 to deliver a number of major initiatives that will enable an EHR system. The system is to be based on new network infrastructure, as well as national (standardised) services that will be based on the EHR (e.g., for supporting electronic transfer of prescriptions, and electronic booking of appointments). NPfIT is the largest outsourced public-sector IT project [10], and its size and complexity has led to substantial concerns being raised over progress towards deployment [1].

The national implementation of EHR in England is continuing, and the requirements for EHR and *applications* of EHR are continually changing. In parallel, we are investigating the challenges of implementing parts of the NPfIT programme from a software engineering point of view. In particular, there are other substantial EHR programmes throughout the world, and understanding similarities and differences between these programmes may provide benefits to England's programme, through improved understanding of technical challenges and solutions. Additionally, as mentioned above, there are a number of services that are making use of, or are intending to make use of, EHR, and the requirements for these services is changing. There is likely to be substantial commonality, as well as points of variation, amongst the functionality provided by these services, and in how the services make use of EHR.

The overall aim of our recent research has been to attempt to understand these *commonalities* and *variations* across services and EHR programmes, and to use this to help improve existing EHR infrastructure.

Our basis for this work has been the application of feature-based software engineering, particularly techniques developed for software product lines and software architecture. In this, we effectively treat EHR-based software systems as software product lines. The key idea that we take from these areas is the development of products from reusable core assets [3, 7, 9]. To develop core assets, understanding the commonality and variability (C&V) between the prod-

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ucts in the domain is essential [11, 15, 16]; feature-based approaches have been used extensively to support this [7, 15, 16].

The first stage of our ongoing research is to use feature-based approaches to analyse the commonality and variability of the domain of EHR systems in England, focusing on existing NHS NPfIT services (including the EHR system in England, electronic appointment booking, and electronic prescriptions). Our view is that an analysis of C&V may help in promoting understanding of shared requirements, simplifications to software architecture and database architecture, and may help to accelerate implementation and deployment. Ultimately, we are aiming to compare existing architectures of EHR systems with those that can be designed using feature-based approaches, in order to help to identify improvements that may be made to these existing EHR systems.

This paper presents a domain analysis of NPfIT's EHR, based on an application of Feature-Oriented Domain Analysis (FODA) [17], and as a result makes two contributions. Firstly, we summarise the results of a FODA analysis that takes into account a number of sources of domain information, including relevant standards for EHR, service specifications, and NPfIT policy documents. This is the first step towards a more detailed FODA-based C&V analysis of designs and implementations of EHR systems around the world, which will ultimately help to derive improvements to existing EHR architectures. Secondly, we will describe open problems and challenges that we identified during the application of FODA to this domain, with the intent of proposing changes to the analysis approach.

In the next two sections, we will briefly introduce EHR and EHR systems, and will then describe the architecture of existing EHR systems within the NPfIT. Then, we will briefly describe the FODA process we applied, and the outcomes of the analysis, as applied to the NPfIT EHR systems. Finally, we will summarise open questions and problems that were identified as a result of the analysis.

2. EHR AND EHR SYSTEMS

The phrase 'electronic health record' is generally used to describe any digital representation of health information, with little or no concern about how this information is to be stored or retrieved. Terms used approximately synonymously include electronic medical record (EMR), electronic patient record (EPR), electronic health record (EHR), and computer-based patient record (CPR). In general, these terms can be used interchangeably, but some specific differences can be identified. For example, an Electronic Health Record typically refers to a longitudinal record of a patient's care carried out across *different* institutions and sectors, whereas an Electronic Patient Record has been defined as encapsulating a record of care provided at a *single* site (e.g., by a single health trust). In England, the NHS uses the term EHR to describe the concept of a longitudinal record of patient's health and health care, from cradle to grave. It combines both information about patient contacts with primary health care (such as a doctor or a hospital), as well as subsets of information associated with the outcomes of periodic care, which are also held in EPRs.

Different organisations define and structure EHRs in different ways, illustrating different intended applications of use. For example, the definitions from HINA (Australia) and OHIH (Canada) emphasise the characteristics (or properties) obeyed by EHR; the definitions from ASTM (USA) and CPRI (USA) highlight the contents of EHR, and IOM's (USA) definition focused on the objectives of EHR. There is no agreement or standard definition for EHR, nor is there a suitable definition of what constitutes a necessary or sufficient EHR. For the purposes of our research, it is useful to de-emphasise the focus on what systems are required in a given care context (e.g., primary care, community care, or mental health). Instead, it is helpful to look generically at the information that arises during management of patient health, regardless of the systems that generate or contain it, and to generically view the systems that create, manage and store EHRs in the context of *jurisdictional information sharing* [4].

For these reasons, we have adopted the ISO definition of EHR. In [2], EHR is defined thusly: *"The basic generic definition for the EHR is a repository of information regarding the health status of a subject of care, in computer processable form."* The IS definition further acknowledges that the sharing of EHR information can take place at three levels:

Level 1 - between different clinical disciplines or other users, all of whom may be using the same application, requiring different or ad-hoc organisation of EHRs,

Level 2 - between different applications at a single EHR node - i.e., at a particular location where the EHR is stored and maintained, and

Level 3 - across different EHR nodes - i.e., across different EHR locations and/or different EHR systems. And when level 3 is achieved and the object of the EHR is to support the integrated care of patients across and between health enterprises, it is called an Integrated Care EHR (ICEHR).

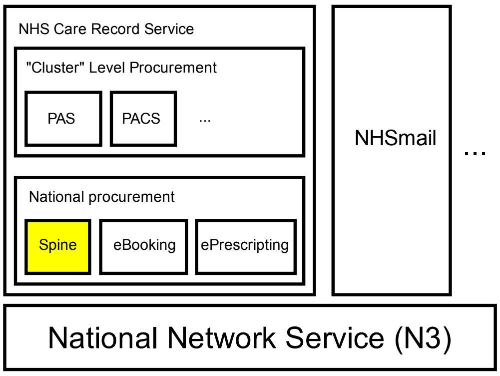
More generically, Level 1 involves sharing within one organisation and application, but by different users; Level 2 involves sharing within one organisation, but across different applications and users; finally, Level 3 involves sharing across different organisations, applications and users.

In addition, the ISO definition of EHR distinguishes between clinical information and the systems that support its provision. What we are interested in is the analysis, design and implementation of a national EHR and the applications that surround it. Thus, the term 'EHR system' in this paper refers to the information systems that stores and processes the data of EHRs; in its simplest form, this could be a database application.

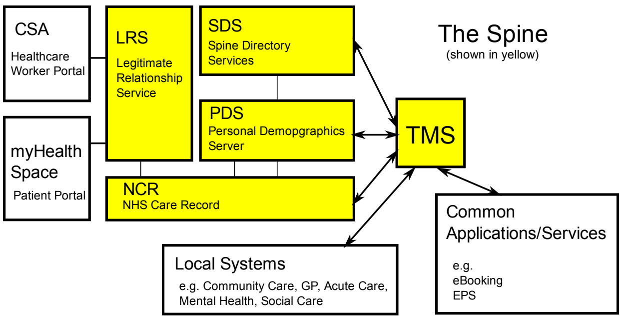
3. ARCHITECTURE OF NHS EHR

In this section, we give an overview of the current architecture of the NPfIT's EHR systems for England. This architecture has evolved over a number of years, as described in [1].

There is some compatibility between the ISO definition of EHR [2] and the architecture used in England, e.g., the separation of EHR systems into *local* EHR systems (used by one care provider) and *shared* systems. In England, the EHR system was created at two levels: a Summary Care Record (SCR) accessible across England; and a Detailed Care Record (DCR) accessible within a locally determined health community which could encompass primary and secondary care providers within a specified geographical area, e.g., London. In both cases, access to the EHRs will be subject to stringent confidentiality and security controls. The SCR primarily supports 'out-of-hours' and accident and emergency care and will eventually provide a 'cradle to grave' record of significant health information. The DCR supports more routine health interventions and will (eventually) replace organisationally based record systems such as those of hospitals and GP practices.



(a) The Spine in the Architecture of NPfIT



(b) Architecture of the Spine

Figure 1: The Scope and Structure of EHR in England

Figure 1(a) shows the national care record service in the architecture of entire NPfIT programme. The key features of this programme are new national data and IT standards, procured and paid for nationally. Implementation in acute trusts will be through one of five geographic partnerships with industry, called "clusters". The foundational infrastructure is a New National Networking service (N3). Based on this N3 service, there are several national services, e.g., electronic booking (called "choose and book"); electronic transfer of prescriptions; and a nationally accessible, life-long summary patient record called "the spine". The provision of electronic functions at local level form part of the NHS care record service, a collective term for all aspects of clinical IT support applications, from clinical decision making tools to digital X rays. The output of those applications is intended to be a health record that can be shared. Figure 1(b) is the architecture of the Spine. The spine consists of the following major components:

- TMS: transaction and messaging spine; the master "router" of all messages between systems. All messaging via the TMS is based on the HL7 version 3[1] Clinical Data Architecture (CDA).
- SDS: Spine Directory Services; provides various Directory Services (e.g., organisational details of GP practices). SDS excludes patient related demographics.
- PDS: Personal Demographics Services; provides a national service holding all personal, demographic and related information for each patient.
- NCR: National Care Record; holding a summary of clinical and associated information.
- LRS: Legitimate Relationship Service; controls what access a healthcare professional has to a person's clinical data.

4. A DOMAIN ANALYSIS OF AN EHR SYSTEM

In the previous section we described the existing EHR systems for England's NPfIT. In this section we summarise a domain analysis for an *idealised* EHR System in the context of the NPfIT, based on a feature model. We ultimately intend to use the results of the domain analysis to help develop an architecture for an idealised EHR system, which can thereafter be compared with the *existing* EHR systems presented in the previous section. However, the purpose of this paper is to describe some of the challenges we encountered in applying FODA to this domain.

To set about this, we must first more carefully scope what is in context, and what is not. Conceptually, an EHR system can be treated as a database application which stores and manages the data of patient health records. More concretely, an EHR system, according to key reports such as [6], provides eight core functions: storing health information and data; managing results; managing orders (e.g., for prescriptions); supporting decision making; improving connectivity; raising patient involvement; managing administrative processes; and reporting.

Additionally, other information constraints, requirements and functions can be identified from key literature related to NPfIT. In particular, the report on the NHS logical health record architecture (LHRA) [18] indicates that the LHRA programme is intended to provide a basis for clinical and informatics communities to achieve widespread sharing and use of clinical information via EHRs. This document captures overall requirements for a NHS LHRA in terms of current and future needs; however, these requirements may not be the same as those for NHS EHRs. Nevertheless, the future requirements for the LHRA help us to identify additional features that may be of use in the EHR programme.

Based on the description of LHRA and the report in [6], we produced a feature model that captures these additional features. A more detailed description of the features is in the appendix.

In the list, the top level features are *F1 store the clinical data*, *F2 process the data*, *F3 decision support*, *F4 administrative management* and *F5 patient support*. These are the key features listed in [6] and they are implemented in almost every EHS system around the world. Considering England, the requirements which are not supported by current system

[1] http://www.hl7.org/

and desired by future needs are documented in [18]. In the feature model (Figure **??**), the existing features are omitted. In the diagram, they are new features under the key features. The description of these new features can be found in Appendix.

We used the results of applying FODA to produce a prototypical architecture for an EHR, shown in Figure 2, which we aimed to use as a basis for comparison with existing EHR systems. The FODA results led us to choose between a service-oriented architecture and model-view-controller architecture. More specifically, we determined that there would need the following components:

- Interface to the public, which is a portal to the public. Its function will be to provide educational meterials to the public so that it will increase the awareness of national health.
- Interface to patients, which is a portal to the patients. It achieves the feature of *patient support* — feature *F5* and its sub-features in Appendix.
- Authentication and access control, which are basic security mechanisms of the system. Its function is to provide an authentication service and control access from outside of system.
- Medical data processing service, which is the *"model"* of a MVC architecture. It processes the patient's medical data, which corresponds to feature *F2*.
- Patient summary and historical data services, which are data storing services. The patient summary data service stores the summary and the data regarding the patient's current health status, while the patient historical data service stores a summary of the patient's health history. These two services are the kernel of entire system, which support most of the features listed in the appendix.
- NHS service directory, which provides a directory service. Because the NHS EHR system is a distributed system with a service-oriented architecture, this service provides information which links to other NHS services or local systems when they are needed by the service of data processing or local healthcare system.
- Interface to other NHS services and local healthcare system, which will provide an interface to other systems. Together with data storing services, they support the features of data sharing and processing, e.g., *F21, F31* and *F53a*.

The intention of this exercise was to be able to compare the results of FODA and a prototypical architecture with an *existing* architecture. In the next section we outline some key open questions that result from comparing it with our results.

5. OPEN QUESTIONS

We followed the process of FODA, as described in [17] - content analysis, domain modelling, and architecture modelling - to analyse the domain of EHR systems in the NPfIT. During the process, we identified several challenges and open questions related to FODA. We briefly describe these here.

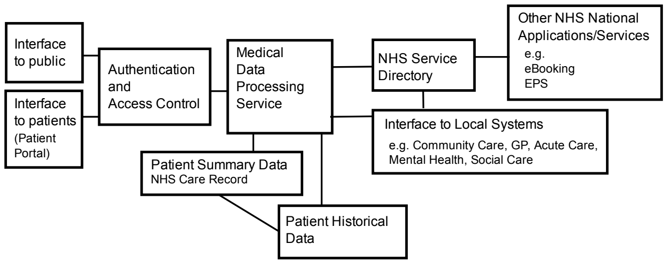


Figure 2: Prototypical Architecture of NHS EHR in England

5.1 Architectural Concerns when Analysing Content of System

Most applications of domain analysis techniques, including FODA, focus on non-distributed systems; our domain of interest is large-scale distributed systems. There are many difficulties and challenges related to applying FODA (and similar techniques) to such systems. One such challenge is that it can be complicated to precisely identify the boundary of such a system, particularly large-scale distributed systems based on a loosely coupled service-oriented architecture. There are other challenges as well, particularly related to the extent to which system *architecture* should be considered with the FODA process, as we now explain.

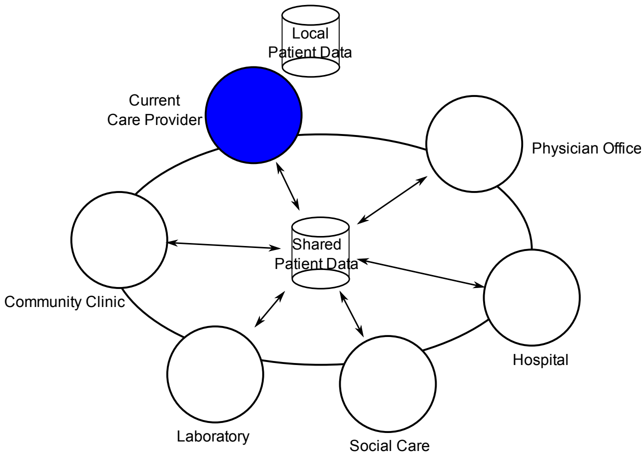


Figure 3: Deployment Architecture of NPfIT Spine

There are many architectural styles that have been used for large-scale distributed systems; [12] summarises four popular ones. For example, the EHR system in England has a centralised architecture, illustrated in Figure 3. In the case of EHR systems (and other, similar systems), the choice of architectural style directly dictates the feature set. Hence, the architectural style should be considered when the context of the EHR system is analysed. More specifically, the system architecture for EHR systems is both a result of domain analysis and (at least partly) a prerequisite of domain analysis. Consider the example of Feature 1 in List 6: *storing clinical data*. This feature needs additional features in order to synchronise the database operation, in the case where the data is stored in a distributed manner. In practice, it is likely that only a partial view of the architecture will be needed to help control the process of domain analysis.

Our perspective is that the domain analysis for distributed system should be carried out iteratively, e.g., via a loop added to the domain analysis process suggested in [17]. Our suggested process is shown in Figure 5.1.

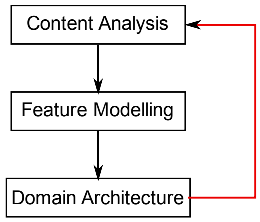


Figure 4: Iterative Domain Analysis

In practice, it is not difficult (and sometime it is necessary) to refine the understanding of the system, its scale and scope. The question is to which degree the details of the system architecture should be considered in order to maintain a cost-effective analysis process. This question seems to be open because the answers of this question may depend on the domain of the application. In the domain of EHR systems, a generic domain model may not be as useful as expected because variations between individual EHR system and the generic model may be too substantial.

5.2 Organisational Goals vs. Feature Model

Political objectives and policy are often one of driving forces behind the implementation of EHR systems. In initial proposals and requests for expressions of interest for implementing EHR systems, organisational goals may be the only requirements that are stated explicitly, as these are essential for making the political case for the systems. For example, with respect to England's NPfIT, the NHS Connecting for Health web site [2] says: *"The NHS Care Records Service will make caring for you across organisational boundaries safer and more efficient. It will also give you access to your record that covers your care across different organisations, such as the GP practice and the hospital. The purpose of NHS CRS is to allow information about you to be accessed more quickly, and gradually to phase out paper and film records which can be more difficult to access."*

Such goals and objectives are generally easily understood and accepted by the public and other stakeholders. However, there is a disconnect between these objectives and goals and what is delivered by feature modelling approaches like FODA: it is difficult to demonstrate how the features in the feature model satisfy organisational business goals. As a result, it can be difficult to demonstrate the system to be developed at early stage to major stakeholders.

There approaches in the field of requirements engineering, such as goal-driven and scenario-based requirement engineering, which may be helpful to integrate with approaches such as FODA, in order to show connections between organisational and business goals and features. This is particularly important for EHR systems, which may be controversial in the minds of certain stakeholders, where concrete arguments and evidence as to how goals are to be achieved is important to capture.

[2] `http://www.nhscarerecords.nhs.uk/what-is-the-nhs-crs`

6. CONCLUSIONS

In this paper, we briefly introduced EHR systems in England, under the auspices of the NPfIT. Healthcare information systems are amongst the most complex IT system in the world. We took a domain analysis approach to analyse the commonalities and variations of EHR systems, with the ultimate aim of identifying ways in which to improve existing implementations. In the process, we reported on challenges associated with using domain analysis, particularly FODA, for such systems. We are continuing our work in describing a prototypical architecture for EHR systems in England and are using this to propose improvements to existing architectures. At the same time, we are investigating alternative EHR systems, particularly those that take a *transformative* approach to EHR (i.e., where multiple different types of EHR are used, rather than standardising on a single type of record), and the impact that this approach has on both the FODA approach and the architecture that can be derived.

7. REFERENCES

[1] The national programme for IT in the NHS: progress since 2006. Public Accounts Committee. `http://www.publications.parliament.uk/pa/cm200809/cmselect/cmpubacc/153/153.pdf`, January 2009.

[2] I. 20514:2005. Health informatics - electronic health record - definition, scope and context. Technical report, International Organization for Standardization (ISO), 2005.

[3] J. Bosch. *Design and Use of Software Architectures: Adopting and Evolving a Product-line Approach.* Addison-Wesley, 2000.

[4] H. Chen, H. Atabakhsh, S. Kaza, B. Marshall, J. Xu, G. Wang, T. Petersen, and C. Violette. Bordersafe: cross-jurisdictional information sharing, analysis, and visualization. In *dg.o 2005: Proceedings of the 2005 national conference on Digital government research*, pages 241–242. Digital Government Society of North America, 2005.

[5] S. Clamp and J. Keen. The value of electronic health records: A literature review. Technical report, Yorkshire Centre for Health Informatics, University of Leeds, 2005.

[6] C. Clancy. Key capabilities of an electronic health record system: Letter report. Technical report, Institute of Medicine, 2003.

[7] P. Clements and L. Northrop. *Software Product Lines: Practices and Patterns.* Addison-Wesley Longman, 2001.

[8] M. Corporation. Electronic health records overview. Technical report, National Institues of Health, National Center for Research Resources, April 2006.

[9] P. Donohoe, editor. *Software Product Lines: Experience and Research Directions.* Kluwer Academic Publishers, 2000.

[10] P. Dyke. Healthy connections? *Public Finance*, September:24–26, 2003.

[11] D. Fey, R. Fajta, and A. Boros. Feature modeling: a meta-model to enhance usability and usefulness. In G. Chastek, editor, *Proceedings of the Second Software*

Product Line Conference, pages 198–216. Springer, 2002.

[12] G. E. T. Force. Electronic health records: A global perspective. Technical report, HIMSS Enterprise Systems Steering Committee, 2008.

[13] M. Herbert. Professional and organizational impact of using patient care information systems. *Medinfo*, 9:849–853, 1998.

[14] K. Herbst, P. Littlejohns, J. Rawlinson, M. Collinson, and J. Wyatt. Evaluating computerised health information systems: Hardware, software and human ware: Experiences form the northern province, south africa. *J Public Health Med*, 21:305–310, 1992.

[15] K. Kang, J. Lee, and P. Donohoe. Feature-oriented product line engineering. *IEEE Software*, 9(4):58–65, 2002.

[16] K. Kang, K. Lee, and J. Lee. *Domain Oriented Systems Development:: Practices and Perspectives*, chapter Feature Oriented Product Line Engineering: Principles and Guidelines, pages 19–36. C&C, 2002.

[17] K. C. Kang, S. G. Cohen, J. A. Hess, W. E. Novak, and A. S. Person. Feature-oriented domain analysis (FODA) feasibility study. Technical Report CMU/SEI-90-TR-21, Software Engineering Institute (SEI), Carnegie Mellon University, 1990.

[18] L. Sato. A NHS logical health record architecture: Vision, objectives and success criteria. Technical report, National Program for IT, NPFIT-FNT-TO-SCG-0019.04, 2008.

APPENDIX

The extra features (derived from [18]) for the future needs of England's EHR programme are summarised in the following list.

F1 Storing the clinical data.

1. Capturing data that fulfils medico-legal requirements for patient records.
2. Capturing data that will be re-used for high-quality clinical communications within and between organisations.
3. Storing data for clinical research or central returns where appropriate.

F2 Processing the data.

1. Supporting Aggregation, integration and/or selectively viewing of current and historical patient data from a variety of sources, in a timely, reliable, safe and meaningful way.

F3 Supporting decisions.

1. Assisting with decision support that is based on the particular requirements of an individual patient.

F4 Administrative management.

1. Auditing practices and their service or service provider with a view to provide comparisons with peers using data that is clinically meaningful, and that supports the objective of improving care outcomes.
   (a) Recording patient data that can be compared against pathway expectations.
   (b) Recording patient data that can be compared against 'markers' for desired (or undesired) clinical outcomes.

F5 Supporting Patient involvement.

1. Using applications to personalise pathways or journeys that meet the individual needs of a presenting patient.
2. Supporting automated personal pathways, which will help generate information to share with the patient.
3. Storing the history appropriately for the patient's care.
   (a) Sharing the historical data across clinicians and other carers.