

# Establishment of Requirements and Methodology for the Development and Implementation of GreyMatters, a Memory Clinic Information System

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**Abstract. Introduction:** The aim of the paper is to establish the requirements and methodology for the development process of GreyMatters, a memory clinic system, outlining the conceptual, practical, technical and ethical challenges, and the experiences of capturing clinical and research oriented data along with the implementation of the system. **Methods:** The methodology for development of the information system involved phases of requirements gathering, modeling and prototype creation, and 'bench testing' the prototype with experts. The standard Institute of Electrical and Electronics Engineers (IEEE) recommended approach for the specifications of software requirements was adopted. An electronic health record (EHR) standard, EN13606 was used, and clinical modelling was done through archetypes and the project complied with data protection and privacy legislation. **Results:** The requirements for GreyMatters were established. Though the initial development was complex, the requirements, methodology and standards adopted made the construction, deployment, adoption and population of a memory clinic and research database feasible. The electronic patient data including the assessment scales provides a rich source of objective data for audits and research and to establish study feasibility and identify potential participants for the clinical trials. **Conclusion:** The establishment of requirements and methodology, addressing issues of data security and confidentiality, future data compatibility and interoperability and medico-legal aspects such as access controls and audit trails, led to a robust and useful system. The evaluation supports that the system is an acceptable tool for clinical, administrative, and research use and forms a useful part of the wider information architecture.

**Keywords.** memory clinic system, requirements, methodology, EHR standards

## 1. Introduction

Good memory clinics are multidisciplinary and holistic, integrating health and social care as well as the voluntary sector ([www.nao.org.uk](http://www.nao.org.uk)) to meet the needs of patients and

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their relatives and carers [1]. Standards for memory clinics are specified in the United Kingdom by the Memory Services National Accreditation Programme [2]. At its conception, much time was spent in capturing clinical information, prescribing dementia drugs and monitoring the treatment. It was also recognized that valuable clinical data could be used for service development, research recruitment and primary research purposes. The importance of research has been a key component of the G8 Dementia Summit pledge to find a cure or disease modifying treatment by 2025 (<http://dementiachallenge.dh.gov.uk>). Thus, there was a need for a system to be developed for the memory clinics of Berkshire Healthcare NHS Foundation Trust (BHFT) to aid the clinical and administrative processes of assessing, diagnosing, managing and treating patients with cognitive disorders and mental health problems and to facilitate recruitment of patients in clinical trials. This memory clinic system was named ‘Greymatters’.

## 2. Methods

### *2.1 Development of Requirements Standards for EHRs and Systems and Clinical Knowledge Modelling through Archetypes*

Requirements were gathered from meetings with clinicians, pharmacists, and administrative staff from BHFT. Google forms builder was used for specifying requirements and a web-based Wiki named JIRA was developed to be able to post any issues, concerns or suggestions so they could be shared between BHFT and University College London (UCL). The software requirements specifications followed the IEEE Standard (<http://www.ieee.org>), and an EHR standard ISO EN13606 [3] was used. The international standards for EHRs like EN13606 and HL7 (accredited by the American National Standards Institute) are extensive and it was not within the scope of the memory clinic system specification to replicate the entire requirements for such systems. Instead they have been used where possible as a background reference and to validate certain of the specific requirements as they arose, against a wider context. Clinical archetypes (<http://www.openehr.org>) help to fix the hierarchy and representation of the clinical data reducing the variations in the data representation of a particular clinical domain. The clinical, prescribing and research workflow of BHFT was well studied by our clinical team and then modelled to give the design and framework for the Memory Clinic Information system to be built. The clinical data along with their specifications was formally represented by building relevant Clinical Archetypes [4] using the Archetype editor tool, ‘Object Dictionary Client’ (ODC) [5] developed by UCL.

### *2.2 Ethical Approval and Clinical Application Development*

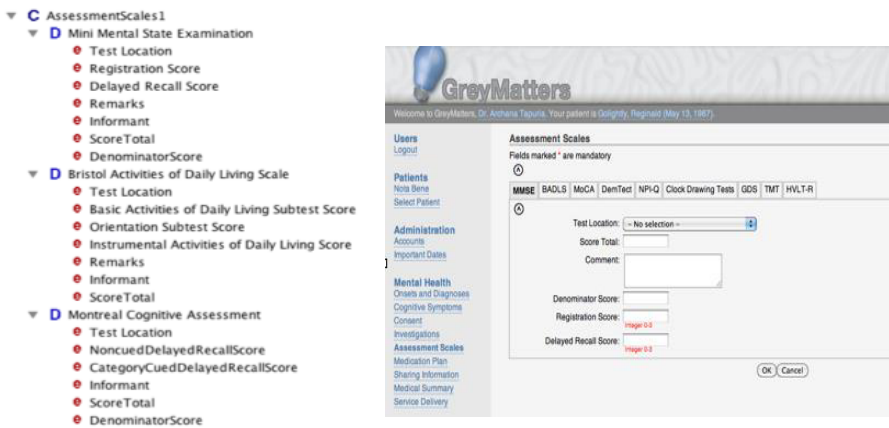
Ethical approval was not sought as the proposed development work did not directly involve patients and the implementation was a means to supporting existing care. Furthermore, the exposure to patient identifiable information was no more than the clinical team was required to access as part of their daily work as a clinician.

The application takes advantage of a framework built at UCL based on the EN13606 standard for EHR exchange. Clinical model designs created in the ODC are embedded in Java classes (<http://www.oracle.com/technetwork/java/index.html>) using

relevant classfile metadata. In use, the application runs in an application container JBoss (www.jboss.com) which is installed with an Object-Relational-Mapping (ORM) tool called Hibernate (www.hibernate.org). This provides a rapid means of creating standards-compatible storage for healthcare data. The server could stand alone and accept access requests from any client that can authenticate using Enterprise JavaBeans (http://www.oracle.com/technetwork/java/javaee/ejb/index.html). However, we have created a screen generation framework that behaves rather as an ORM tool does for a database, examining classfile metadata for aggregation and type information to provide screens based on a clinical model expression automatically. This additional facility provides a complete turnkey application development paradigm entirely driven by the original clinical model expression.

### 2.3 Memory Clinic Archetypes

The following is a list of the main archetypes developed: Demographics, GP details, Alerts/allergies, Consent, Diagnosis, Clinical registers, Cognitive symptoms, Assessment scales, Mental Health Liaison, Referral Data, Medical summary, Medication, Prescribing and dispensing, Research application screen.



**Figure 1.** Example of a clinical archetype model and screenshot of the application (Assessment scales)

### 2.4 System implementation

The application consists of three broad feature sets. The first, for a system administrator, permits “accounts” to be created, “roles”, “users”, and “patients”. An account is a grouping within which users are associated with patients and can see their own care lists. Roles are the named purposes for which users access the care record of a patient. The second feature set is one of care delivery. A set of screens is provided that enable data to be captured in the clinic. Finally, a major component of the system was to offer prompts for repeat prescribing, transfer of prescriptions and dispensing. This area of development proved to be more complex than anticipated and requirements changed as the Trust moved to shared care prescribing. Although built this part of the system was not deployed.

### 3. Results

The requirements, methodology, technology chosen and standards adopted made the construction, deployment, adoption and population of a memory clinic and research database feasible, along with its research application.

#### 3.1 Deployment and Evaluation of the System

The system was deployed within an NHS managed server environment as a Web application supported by the relational database, PostgreSQL.

To date over 14000 patients are registered on the system. It is currently used by 2 of the 6 locality memory clinics running within the Trust as well as the Research Department and the mental health liaison team for older people in the acute trust. It is primarily used by clinic administrators and secretaries (6 users) who have a key role in recording clinical data, 2 research staff and up to 6 clinicians. In order to integrate the system with the Trust's existing systems and to minimise the burden on administrators, an XML extract is created on a nightly basis of the demographic data of all newly registered patients on the main information system. In an automated process patients are imported into the correct GreyMatters accounts within 24 hours of referral.

An evaluation was undertaken to assess user satisfaction and system usability of GreyMatters in 2014 [6] using the IBM computer usability satisfaction questionnaires [7]. Clinicians and research staff were generally more satisfied than administrators. Overall responses demonstrated mild to moderate satisfaction with the overall system and with individual tasks. Most notably recording of new drug and recording of liaison referral data were considered unsatisfactory. The evaluation shows that the system is an acceptable tool for clinical, administrative, business and research use and forms a useful part of the wider information architecture.

#### 3.2 Research Application

Patient and carer agreement to be contacted about research is recorded in GreyMatters. A previous research database is also being migrated into the GreyMatters database.

From the clinicaltrials.gov research register, it is apparent that the breadth of data items required to identify potential participants for the trials is unlikely to be met by a single system. However, Greymatters dataset captures important data items such as age, sex, diagnosis, assessment scales (e.g. MMSE, BADLS), dementia drug use, antipsychotic use, driving status, and accommodation type, etc. The patient health record including the assessment scales and scores provides a rich source of objective data for audits and research. It helps to establish study feasibility as demographics and 'inclusion and exclusion criteria' can be used in a database search to derive numbers of potential participants. A browser based data mining tool was built on the SQL Server Reporting Platform to pull together data from GreyMatters and other Trust information systems to allow the research department to perform such searches. There are plans to extend the scope to include data from primary care and other secondary care providers.

The latest version of the ODC used to develop the formal information model underpinning GreyMatters is a Web-based application now known as Aruchi, which is recently published [8]. Specific models relating to dementia have been published and are open-source for use (at <https://aruchi-helicon.rhcloud.com/pattern/describe?id=134>). GreyMatters itself may be licensed in future.

#### 4. Discussion

The development of a system like GreyMatters needs to take into account the existing data collection methods and other information systems that will be used alongside. It was challenging to come to a shared view of the design and requirements of the system given the multidisciplinary nature of the stakeholders, which include Trust members, developers and end users. Significant gaps or errors may not be picked up until systems have been built and are ready for testing or use. The use of the Google forms builder for specifying requirements improved the efficiency and quality of interactions with end users. The benefits of the system have been further enhanced by developing data flows between the different systems. For instance, new patient registrations within the main Trust system are automatically imported into GreyMatters. The browser based recruitment tool for clinical trials added to the benefits of the system. There are plans to roll out GreyMatters further to other locality memory clinics within the Trust.

#### 5. Conclusion

The establishment of requirements and methodology, the importance of the underlying system to address issues of data security and confidentiality, future data compatibility and interoperability and medico-legal aspects such as access controls and audit trails, which led to a robust and useful system. It was beneficial to use a system modelled around standards like IEEE and EN13606 that are based on long established research. This differentiates GreyMatters from simple web based capture forms and this provides the confidence that the system can meet the medico legal challenges of an EHR. The next consideration was to have a flexible approach to capturing clinical data so that it could be reworked to adapt to changing requirements over time. In part this was met by GreyMatters but lack of resources meant that development did not allow the application to exploit certain features to their full potential, for instance the inability to show through the interface successive versions of forms. Its strength is that it provides flexibility to record clinical information. The system has been deemed acceptable by most users although there is dissatisfaction with some aspects and needs further work.

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