Institution: University College London

Unit of Assessment: 11 – Computer Science and Informatics

Title of case study: A clinical management service for stroke prevention

1. Summary of the impact

Helicon Health is a UCL spin-out company providing a stroke prevention clinical management service (Helicon Heart) developed through UCL health informatics research. In partnership with Whittington Health, a large north London hospital, Helicon Heart provides stroke prevention management to 5 NHS Clinical Commissioning Groups (CCG) across north London and Hertfordshire, covering 2 Hospital Trusts, 30 General Practice delivery sites and 3 Community Pharmacies. The system underpins clinical care for 3,000 at-risk patients, and Helicon Health has secured additional contracts to extend this to 4,500 patients in 2014. Every prevented stroke saves the NHS £16,000 per annum; the estimated saving to each CCG is approximately £500,000 per annum, to which the Helicon Heart service makes a significant contribution.

2. Underpinning research

Clinical information is recognised to be highly complex, knowledge intensive and contextual. Tens of billions of pounds in eHealth programme investments across the world over the past decade have still not delivered in any country a scalable means of capturing and communicating a unified Electronic Health Record (EHR) for each patient. The representation of EHRs comprehensively, interoperably and in a medico-legally robust way is one of the fundamental challenges of health informatics.

Since 1996 UCL has led European research to develop an EHR information architecture (information models, knowledge models, persistence architecture and services) to represent "cradle to grave" EHR information. This research has directly led to international requirements specifications and interoperability standards for a federated architecture to consolidate EHR data from multiple heterogeneous clinical systems in a semantically coherent way, including the representation of healthcare context and provenance to ensure medico-legally acceptable interpretation. Dipak Kalra (Professor of Health Informatics, at UCL since 1995) has led much of this research, which has spanned 14 EC, EPSRC and MRC funded projects, totalling £44 million to date, with partners from many European countries from academia, industry, healthcare organisations, health insurers and health ministries. The UCL component of this funding was £5.6 million and resulted in publications from UCL on:

- formally specified requirements for EHR representation and interoperability [1];
- information models (in Unified Modeling Language, UML) for the representation of clinical meaning, provenance and context within EHRs [2];
- access control and privacy protection frameworks to support differential access policies within an EHR federation;
- the challenges and best approaches to enable semantic interoperability;
- comprehensive Service Oriented Architecture (SOA) to enable componentised implementation and deployment [3,4];
- interfacing the EHR to decision support algorithms and components;
- optimising repository (persistence) design to enable high-performance query and retrieval;
- the integration of clinical advisory components within EHRs to support evidence-based and safe clinical practice;
- the re-use of federated EHR repositories as a research platform.

On the basis of this research, in 2002 Professor Kalra was appointed to lead standards development Project Teams in CEN (the European Committee for Standardization) and ISO (the International Organization for Standardization) on the electronic health record, which have published 12 requirements and interoperability standards in this area since 2008, such as ISO 13606 Part 1 [5].

In order to ensure that these standards are in practice technically implementable, that the ISO 13606 EHR specifications do meet clinical care requirements and that fully functioning clinical systems can be built on top of these EHRs, Professor Kalra established a software engineering

research team led by Dr Tony Austin (Principal Research Associate, at UCL since 1997). This team has implemented the full set of international EHR interoperability standards, together with a rapid application development platform to enable specific clinical applications (for any speciality or care setting) to be designed and developed [6]. This has enabled the EHR repository and services to, in effect, be profiled and deployed in particular usage scenarios and yet always to maintain a complete EHR for each patient across all of the deployment settings. The largest deployment (now branded as Helicon Heart) supports shared care for anticoagulation and stroke prevention between hospitals and GPs across north London and East Hertfordshire. The system includes a decision support middleware component that improves anticoagulation control and reduces the risk of complications. The middleware is implemented in Java, backed by a PostgresQL database and web service infrastructure, deployed on servers hosted inside the NHS firewall (therefore meeting stringent NHS standards) and is collaboratively supported by the UCL research team and NHS IT staff. There are additional deployments of the (same) EHR system for managing dementia.

The evaluation feedback from these clinical settings has informed the standardisation processes and also led to an iterative maturing of the UCL EHR products.

3. References to the research

1. Patterson, D., Ingram, D., Kalra, D. (1999). ”Information for clinical governance”, in Lugon, M., Secker-Walker, J. (ed.) Clinical governance: making it happen. London: Royal Society of Medicine Press. ISBN: 1-85315-383-4. Available on request.
2. Grimson, J., Grimson, W., Berry, D., Kalra, D., Toussaint, P., Weier, O. (1998). A CORBA-based integration of distributed electronic healthcare records using the Synapses approach. IEEE Transactions on Information Technology in Biomedicine on Emerging Health Telematics Applications In Europe 2(3), 124-138. DOI http://doi.org/b6ch99
3. Kalra D, Lloyd D, Austin A. O’Connor A, Patterson D, Ingram D. (2002). ”Information architecture for a federated health record server”, in Mennerat F (ed.) Electronic Health Records and Communication for Better Health Care. Proceedings of EuroRec 2001. IOS Press, 47-71. ISBN: 978-1-58603-253-1. Available on request.
4. Kalra, D., Ingram, D., Austin, T., Griffith, V., Lloyd, D., Patterson, D., Kirstein, P., Conversin, P., Fritsche, W. (2004). Demonstrating wireless IPv6 access to a Federated Health Record Server. International Conference on Computational Science. Lecture Notes in Computer Science Volume 3039, 2004, pp 1165-1171. ISBN 978-3-540-22129-6. Available on request.
5. Kalra, D., Lloyd, D. (2008), ISO 13606 Electronic Health Record Communication Part 1: Reference Model. International Organisation for Standardization, Geneva. http://www.iso.org/iso/catalogue_detail.htm?csnumber=40784. Available on request.
6. Austin, T., Lim, Y., Nguyen, D., Kalra, D. (2011) Design of an Electronic Healthcare Record Server Based on Part 1 of ISO EN 13606. Journal of Healthcare Engineering, 2011 2 (2), 143–160. ISSN 1756-8250. DOI http://doi.org/fkd7gj

References [2], [3] and [5] best demonstrate the quality of the research.

4. Details of the impact

The research described in section 2 has led to widespread **benefits to patients and healthcare providers, along with the adoption of a new ISO standard for electronic health records.** Healthcare providers in south-east England have **adopted a new anticoagulation management technology**, which is unique in the UK [a]. This has been commercialised by the **new UCL spinout company Helicon Health**.

The success of the Helicon Heart stroke prevention service is crucially enabled by distributed teams of clinicians having access to a shared and medico-legally robust EHR for every patient, which meets all of the requirements, standards and architectural features summarised in Section 2. Helicon Heart tailors UCL’s complete ISO EN 13606 conformant EHR implementation specifically to cardiovascular shared care. It incorporates a care plan for patients at risk, especially those needing preventive anticoagulation treatment, and provides computerised decision support to ensure that care is optimally managed.

The use of Helicon's stroke prevention and anticoagulation management system is important because each patient has a narrow and unique safe dosage window, subject to variation over time, which can be influenced by lifestyle changes, other medications and certain foods; it therefore requires regular blood test monitoring (every few weeks) and careful dose adjustments. Both too high and too low a level of anticoagulation can lead to serious or fatal haemorrhages, or stroke. Anticoagulants are one of the three classes of drugs most commonly associated with fatal medication errors in the UK, and in the top five in the US and Australia. The NHS Litigation Authority has reported that medication errors involving anticoagulants fall within the top ten causes of claims against NHS trusts [b], and have amongst the highest litigation cost of any NHS treatment: in the UK, an average of fifty patients per year experience serious adverse events arising from preventable warfarin-induced complications; ten of those patients die. In financial terms, every prevented stroke saves the NHS £16,000 per annum [c]; the estimated saving to each CCG is approximately £500,000 per annum, to which the Helicon Heart service makes a significant contribution, as discussed below.

Following the successful evaluation of a pilot version in 2004 [d], the EHR repository was enhanced for greater resilience and performance, and the clinical application enriched following user feedback. It was installed in the Whittington Hospital and accessed by an early adopter community of GPs and high street pharmacists; it went into full clinical use from August 2008 [e]. Helicon Heart is now being used by 5 NHS Clinical Commissioning Groups (CCG) across north London and Hertfordshire, covering 2 Hospital Trusts, 30 General Practice delivery sites and 3 Community Pharmacies (including Boots). The system **underpins clinical care for 3,000 at-risk patients**, and Helicon Health has secured additional contracts to extend this to 4,500 patients from 2014 [f]. This shared EHR system facilitates **collaboration between community staff and hospital specialists** [g, h, i], and has enabled the Whittington Hospital to **transfer over 600 patients over the last few years from the more inconvenient and expensive hospital service** to a more local GP or Community Pharmacy service, whilst being able to continue to **remotely monitor their quality of care** [a]. This has released capacity in the hospital for the referral of new and often more complicated patients. A member of the Haringey Clinical Commissioning Group said the service, which the CCG has been using throughout the impact period, "provided a safe option for monitoring INRs[1] in primary care. It provides the commissioners, providers and patients with information that assures them of the quality of the service being provided" [h]. This service was highlighted in the NHS Customer Service Excellence award made to the Whittington Cardiovascular Department. It commended the community-based anticoagulant and stroke prevention service as a "transformational service" to the Cabinet Office [j].

Now that the system is widely distributed across many sites, clinical governance is vital. A Clinical Governance Board oversees the quality and safety, for which Helicon Heart generates **real-time clinical governance quality measures**, which is possible because of the high-quality and comprehensive EHR data it contains. This information is a huge asset for the clinical governance process and provides great learning opportunities for different general practices who can compare each others' quality performance. The governance data show that most of the hospital, GP and pharmacy sites are maintaining satisfactory anticoagulation control metrics and are improving year on year. The system has helped to demonstrate that community sites deliver safe and well-regarded care [h]. This is particularly appreciated by patients, for whom a visit to their GP or local community pharmacy is usually much more convenient than being treated as a hospital outpatient. An independent patient satisfaction study was commissioned in 2009, undertaken by UCL staff who are world experts in health technology assessments but had no prior connection to this project. They showed that **patients unanimously favoured the new anticoagulation service**, which they found to be more convenient, had shorter waiting times, required a minimally invasive test (less bruising), and led to them getting the results and treatment instructions immediately [g]. They could take away a clear and well-structured paper summary of their condition, care and treatment that could also be shown to any other care provider.

Creation of spin-out company: In May 2012, UCL Business and Whittington Health formed the

[1] INR is the International Normalised Ratio, the blood test used to measure the coagulation state of blood.

spin-out company, Helicon Health, to support the roll out of anticoagulation and stroke prevention services (Helicon Heart) including the EHR system, decision support and clinical governance [k]. The company employs 10 people and generated £200,000 income in its first year. This company has joint funded with UCL the enrichment of the Helicon Heart system to cover atrial fibrillation management, another critical factor in stroke prevention, which was completed in May 2013. [f]

Wider adoption of ISO standard: ISO EN 13606 is the only internationally endorsed standard for communicating EHRs between heterogeneous systems. Countries that have publicly adopted the ISO EN 13606 EHR interoperability standard since its publication in 2008 include the UK (NHS England), Sweden, Spain and Brazil. It is, however, mandatory in all EU countries. Countries still considering its adoption include Norway, Ireland, Japan, Korea, Rwanda and Australia. Several EHR vendors have chosen to use it as the basis for their EHR systems. These standards are now being adopted by the NHS for its logical record architecture: for example, every week over 11,000 patients change their general practice in England safe in the knowledge their whole life general practice record will be available at their first consultation with their new GP using ISO EN 13606 based messages.

5. Sources to corroborate the impact

[a] Corroboration of the historic and cumulative benefits to Whittington Health can be found in a statement from the Consultant Cardiologist, Whittington Hospital. Available on request.

[b] The NHS's finding that anticoagulant medication errors are a major source of claims against trusts, see page 1 of NHS National Patient Safety Agency, Risk assessment of anticoagulant therapy. Available from: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814

[c] The savings from a prevented stroke, from which the £500,000 CCG savings were projected, can be found on page 2 of National Institute for Clinical Excellence. NICE cost impact and commissioning assessment: quality standard for stroke. Available from: http://www.nice.org.uk/nicemedia/live/13820/60152/60152.pdf

[d] An evaluation of the safety and acceptability of an anticoagulation clinic in a community pharmacy setting - a pilot study, Coleman B, Martin C, Barber N, Patterson D., Pharm J 2004;273:822-4. Available on request.

[e] The Whittington Hospital's use of the system is confirmed on pages 6-7 of Austin T, Sun S, Lea N, Iliffe S, Kalra D, Ingram D, Patterson D. (2009). Clinical Benefits of an Embedded Decision Support System in Anticoagulant Control. World Academy of Engineering, Science and Technology 53, 2009 1063-1069 ISSN: 2070-3724. Available on request.

[f] Letter from the Chairman of Helicon Health corroborates how many people it employs, the first year income and that Helicon Heart is used by the 5 CCGs in London. Available on request.

[g] The independent patient satisfaction study was undertaken by UCL staff who are world experts in health technology assessments but had no prior connection to this project. Oyelakin O, Greenhalgh T, Boynton P. (2009). An evaluation of the patient experience of a community based anticoagulation service in Barnet. Available on request.

[h] Corroboration of the benefits to a CCG can be found in the statement from the Deputy Head of Medicines Management at the Haringey Clinical Commissioning Group (CCG). Available on request.

[i] Corroboration of the benefits to a hospital consultant can be found in the statement from a Consultant Haematologist from North Middlesex University Hospital. Available on request.

[j] For the NHS Customer Service Excellence award made to the Whittington Cardiovascular Department and commendation of the community-based anticoagulant and stroke prevention service as a "transformational service" to the Cabinet Office, see http://www.whittington.nhs.uk/default.asp?c=8360

[k] Helicon Health website corroborates that the software at the core of HeliconHeart was originally developed at UCL: http://heliconhealth.co.uk/about-helicon/company-overview/