

Institution: University of Leeds
Unit of Assessment: UoA4
Title of case study: Case Study 2: Influencing the introduction, design and use of safer devices for spinal injections in the UK NHS
<p>1. Summary of the impact</p> <p>Misconnection errors involve the administration of drugs via the wrong route. For example, the injection of a toxic drug into the spine which should only be injected into a vein. Following a death in 2001 and 13 others in the UK over the previous 15 years, work began to find an engineered solution to misconnection errors. R.Lawton, at the University of Leeds (UoL), evaluated the usability and acceptability and explored the implementation of these different engineered solutions. This research was the basis for the UK National Patient Safety Agency policy and was used by companies to inform the design of these new devices. Ultimately, this research has led to the production of safer devices that are now being purchased by NHS Trusts to reduce patient risk.</p>
<p>2. Underpinning research</p> <p>Luer-locks are the standard connectors used on a range of devices that deliver fluids to, or remove them from, a patient. This standardisation leads to misconnection errors, which are usually fatal when involving toxic drugs being administered into the spine. Following the death in 2001 of Wayne Jowett, a young man who had vincristine mistakenly delivered into his spine, the Department of Health (DoH) Patient Safety Research Portfolio (PSRP) issued a call for a prospective hazard analysis and pre-implementation evaluation of prototype non-Luer connectors to be used to deliver drugs or test fluid in the spine. The aim was to respond to a government pledge to “reduce to zero the number of patients dying or being paralysed by maladministration of spinal injections” (DoH, <i>Organisation with a Memory</i>, 2000, p.86). A team led by R.Lawton (Professor, Psychology of Healthcare, UoL, 1999-present) had already been working on solutions to the problem [1] [i, ii] and had filed a patent for a set of connectors (one for each route of entry to the body) differentiated by shape and texture [A] putting them in a strong position to respond to the funding call. Following a competitive bidding process, this team was selected to conduct the research, which began in 2006 and was carried out in two phases [iii, iv]:</p> <ol style="list-style-type: none"> 1. (a) A prospective hazard analysis which involved analysing existing data on adverse incidents associated with traditional Luer connection systems; performing a task analysis for oncology and anaesthetics; and using this as a basis for workshops with clinicians to analyse the potential hazards of using new devices; (b) Testing prototypes on a spinal simulator to assess the usability of the new connector devices. 2. Evaluation of new devices in four NHS trusts to see how safe, effective and practical they were. This involved use of the new devices by clinicians to administer over 350 injections into the spinal canal. The implementation of the new devices and other organisational factors (e.g. storage and pharmacy) were also investigated at this stage. <p>The project was conceived and led by R.Lawton, in close collaboration with Gardner (Senior Lecturer in Statistics and Human Factors, 1995-present, UoL). Both worked in the Institute of Psychological Sciences at the UoL throughout the period. There were two external contributions in Phase 1. Data collection and analysis for the simulator testing was contracted to Dr. Davey at the Bath Institute of Medical Engineering (the protocols for the testing were designed by the UoL team). Professor Chamberlain at Sheffield Hallam University conducted a design evaluation of two proposed design options [4]. In Phase 2, Edwards of NHS Logistics conducted a supply chain analysis. Both were reported as appendices in the PSRP reports [4, 5].</p> <p>The UoL team were the only researchers conducting research in this field. This novel research demonstrated that a prototype (Neuraxial) connector design could be used in practice to treat patients more safely [3-6]. It identified weaknesses in two other designs [1-4]. The research indicated that further refinement of the successful prototype connector design was required to optimise intuitive use and minimise the need for training [2-5] and specified aspects of the design that should be improved. The work provided guidance on appropriate testing methods to allow “design for safety” and produced a literature review of the implementation of devices and equipment in healthcare that informed the development of a healthcare technology pre-implementation questionnaire [5,6]. An important feature of the research was that by recognising</p>

human limitations and exploring the use of the devices in practice it established the system changes (e.g. to packaging, storage) that would be necessary for a safe and smooth implementation [2, 3, 5].

3. References to the research

[1] Chamberlain, P. **Gardner***, P., & **Lawton***, R. (2007). Shape of things to come. In R.M. Birkhauser (Ed.), *Design Research Now: Essays and Selected Projects* (pp. 99-119). Berlin: Birkhäuser GmbH.

This chapter describes the principles of affordance, haptic cues and usability that underpinned our early work on the design of new non-Luer devices.

[2] **Lawton***, R.J., **Gardner***, P.H., Green, B.J., Davey, C., Chamberlain, P. Phillips, P., Hughes, G. (2009). An engineered solution to the maladministration of spinal injections. *Quality and Safety in Healthcare*, 18, 492-495. doi: 10.1136/qshc.2007.025767

A peer reviewed journal and the leading international publication in Quality and Safety in Healthcare. The studies reported in this paper show that one prototype was inadequate, but the second scored well in simulation tests and with some modifications could be used in clinical tests.

[3] **Lawton***, R.J. (2010). Testing new devices to help prevent 'misconnection' errors in health care. *Journal of Health Services Research & Policy*, 15(1), 79-82. doi: 10.1258/jhsrp.2009.09s114

A peer reviewed journal of the Royal Society of Medicine. This paper summarises both phases of the project, reporting on the usability of the prototypes and the factors that need to be considered in their implementation e.g. packaging and storage.

The PSRP was funded by the Policy Research Programme and the DoH and reported directly to Sir Liam Donaldson, the Chief Medical Officer. The research by **R.Lawton** et al. was submitted as part of this programme in 2008 and received very positive feedback from all three peer reviewers (available on request). Final reports at:

[4] Phase 1 report: <http://www.birmingham.ac.uk/Documents/college-mds/haps/projects/cfhcp/psrp/finalreports/PS038Lawton2008Phase1SpinalConnectors.pdf>

[5] Phase 2 report: <http://www.birmingham.ac.uk/Documents/college-mds/haps/projects/cfhcp/psrp/finalreports/PS049Non-LuerFinalReport.pdf>

[6] Briefing paper:

<http://www.birmingham.ac.uk/Documents/college-mds/haps/projects/cfhcp/psrp/BriefingPaperPS038-12-08-Lawton.pdf>

Key Funding and Grants

[i] Pilot funding from Braun. (2001-2002). *Misconnection of Medical devices in anaesthesia: Are tactile cues the answer?* **Lawton***, R.J., **Gardner***, P.H., & Bickford-Smith, P. £15,000.

[ii] Health Technology Development (HTD). (2004-2006). *Misconnection of medical devices: the shape of things to come?* Chamberlain, P., **Lawton***, R.J., **Gardner***, P.H., & Bickford-Smith, P. £120,000.

[iii] Department of Health. (2006-2007). A prospective hazard analysis and pre-implementation evaluation of the non-luer spinal connector. **Lawton***, R.J., **Gardner***, P.H., & Chamberlain, P. £79,849.

[iv] Department of Health. (2006-2008). *Evaluation of non-luer spinal connectors*. DoH. £120,445. **Lawton***, R.J., & **Gardner***, P.H.

Note: All UoA4 researchers in **bold**; *research conducted by academics at the UoL.

3. Details of the impact

This research had policy, commercial and health and welfare impact, described in turn below. The impact was realised via three pathways: a workshop event targeting the manufacturers of devices; recommendations within the project report; and publications and the National Patient Safety Agency (NPSA) guidance.

Policy impact

The research formed the main basis for NPSA alerts issued to the NHS in 2009 and 2011

(“Safer spinal (intrathecal), epidural, and regional devices”) [B] that introduced non-Luer spinal connectors to the NHS. The supporting information for both alerts [B, C] referenced the research and said the design tested by **R.Lawton** and collaborators had “successfully completed laboratory, simulation and clinical assessment stages, and was found to meet the functional specification” and “demonstrated that such a design could be developed and used in devices to treat patients.” [C] The alerts reflected the Leeds-led team’s call for further development of the successful prototype connector, saying “refinement of this connector design and other designs and their inclusion in a range of spinal (intrathecal), epidural and regional devices is required” [C]. The alerts said all spinal bolus doses and lumbar puncture samples should be performed using such non-Luer connectors by 1/4/2011 (later revised to 1/4/2012) and that all epidural, spinal and regional infusions and boluses should use such non-Luer connectors by 1/4/2013. The Association of Anaesthetists for Great Britain has used the research to argue for robust testing of devices to ensure safety before implementation [D].

Commercial impact

The research has shaped the provision of non-Luer spinal connectors in the UK. It resulted in revisions to existing non-Luer connectors and to the design of the new devices introduced in line with the NPSA alerts. Three of the five developers of non-Luer connection systems sent statements [E-H] indicating that the research by **R.Lawton** et al. [2-5] influenced design, packaging and implementation of their devices. Indeed, at the time of the NPSA alert the Leeds team were the only team to have tested prototype non-Luer designs. The Surety system is currently accepted as the non-Luer connector of choice by the majority of epidural, spinal (intrathecal) and regional anaesthesia kit manufacturers (CME Medical, 2013: [I]) and is currently being purchased by 52 of the 55 NHS Trusts that have adopted safer products. This research:

“ ... was used as the basis for the design of the Surety® system, assisting us in the definition of its essential and desirable features.” Surety system manager [G].

The product manager of Flexicare Medical Ltd., which markets the Hall Lock Spinal range of devices, said the work had not only changed the company’s general approach- underlining the need for a “simple and intuitive (technology) with little operation difference to existing equipment”- but defined details of design and training:

“The study played a major part in fine tuning our device evaluation protocols ... focused our development teams on areas now known to illicit [sic] the most doubt, like for example leaking, training, packaging and impact on safety... Flexicare followed the recommendations for implementation closely where possible, immediately widening the group of clinicians involved in development and using visual aids to support simulated evaluations ... We found the training recommendations to be very useful and, based on the feedback contained in your report, immediately produced a training video which could accompany the hands-on practice we offered” [F].

The co-inventor of the Neurax system, which has been licensed to two UK manufacturers [H], said the system had been altered in light of the research by **R.Lawton** et al. with connector parts now being made from polypropylene rather than polycarbonate materials to avoid leaks. The syringe had been modified to deal with connection issues identified by the research and a longer needle had been adopted. New packaging was also being explored in response to the research.

The potential UK market for non-Luer spinal devices is estimated at £5-21 million per annum [F-H]. At the time of writing (August 2013), 55 of 161 UK hospital trusts were purchasing and using non-Luer spinal connectors and adoption was continuing across the country. The potential international market has been estimated at up to £2 billion [H] and there is significant investment in the new devices [H]. The Neurax connector design tested in the field and modified based on the research is the basis for a draft ISO standard. The competing design for the ISO designation (Surety) was also strongly influenced by the research [E]. The Head of Medication Safety at the NPSA said:

“I would like to emphasise the importance of your (Leeds team’s) work in developing/testing the Neurax design, a variation of which is likely to be the new ISO standard design used globally in a few years time” [J].

The UK is the first to make the changeover to non-Luer systems and the ISO standard will influence adoption of non-Luer designs internationally.

Health and Welfare

The significance of the research ultimately rests on the safe introduction in hospitals of new equipment that reduces the risk of clinical errors that kill and severely injure some patients. It is difficult to quantify how many deaths and serious injuries have been avoided by the new designs in the short period since the introduction of the new devices, but there have been no reports of fatal or paralyzing misconnection errors in the UK involving the safer non-Luer designs since their introduction in 2009. The research at Leeds has informed the design of safer devices which have and will continue to reduce profound risks to patients in the UK and, potentially, internationally.

5. Sources to corroborate the impact

[A] Patent details: 'Identification systems for compatible components and apparatus for use with such systems'. (WO/2004/097994). International Application No. PCT/GB2004/001745. Retrieved from <http://patentscope.wipo.int/search/en/WO2004097994>

[B] *Safer spinal (intrathecal), epidural, and regional devices*, NPSA, Part A update (NPSA/2011/PSA001, 31 January 2011) and B (NPSA/2009/PSA004B, 24 November 2009). Alerts can be retrieved from <http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/?entryid45=94529>

[C] Patient Safety Alerts NPSA/2011/PSA001 and NPSA/2009/PSA004B Safer spinal (intrathecal), epidural and regional devices – Part A and Part B Supporting information.

2011 supporting information:

<http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=94524&type=full&servicetype=Attachment>

2009 supporting information:

<http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=65258&type=full&servicetype=Attachment>

[D] The Association of Anaesthetists for Great Britain and Ireland (AAGBI) referred the PSRP report [3] in a position statement (October 2011). The AAGBI used it to support their argument that new devices introduced into the NHS for use by anaesthetists should first undergo a rigorous testing process to avoid unforeseen errors (p. 6). Retrieved from

<http://www.aagbi.org/sites/default/files/Neuraxial%20position%20statement.pdf>

[E] The managing director of Intervene, which markets the Surety system, argued for his devices as the basis for an amended ISO standard in a presentation to the International Organization for Standardization in Seattle in 2010 (ISO/TC210-IEC 62D/JWG 4/PG). His argument rested to a significant extent on showing its compliance with **R.Lawton** et al.'s PSRP research report's findings [3].

[F] Correspondence with the product manager of Hall Lock system, Flexicare Medical Ltd (11.4.13-16.4.13).

[G] Correspondence with the managing director of Intervene Ltd., which markets the Surety system (16.4.13).

[H] Correspondence with the managing director of B-Link and co-inventor of the Neurax system (29.3.12- 12.4.13).

[I] CME Medical statement. Retrieved from

<http://www.cmemedical.co.uk/newsitems/MKGSURETYFAQ12.pdf>

[J] Correspondence with the NPSA Head of Medicines Safety (23.3.11 and 30.7.13).