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Part 1. Abstract

Project title: Development of a Safety Checklist for use in the Cardiac Catheterisation Laboratory (CCL).

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Partner organisation:

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Abstract

Background

Since 2000, the number of interventional cardiology procedures performed in the UK has more than tripled to over 100,000 per annum; simultaneously the complexity of many procedures has also increased. However, by comparison to surgical operating theatres, implementation of formal safety procedures has not kept pace, raising the potential for patient safety incidents (PSIs).

The WHO safe surgery checklist has been shown to reduce morbidity and mortality from elective surgery. Whether a team brief and WHO-derived checklist could improve safety, efficiency, and teamwork in the cardiac catheterisation laboratory (CCL) has not previously been investigated, and formed the hypothesis for this project.

Introduction

In April 2013, an adapted WHO Safe Procedure Checklist was introduced to the five CCLs at the Royal Brompton Hospital (RBH), a tertiary centre for the treatment of heart and lung disease, with two closely linked aims: to reduce errors in the CCL which could lead to patient harm and to improve CCL efficiency. Simultaneously, we introduced a 'team brief' at the beginning of each procedure list, at which each patient scheduled that day is briefly discussed and problems anticipated. A three-stage checklist is now used for every patient:

- 'Sign In' pre-procedural checks.
- '**Time Out**' a briefing given by the principal operator immediately prior to procedure start, covering crucial details.
- 'Sign Out' (debrief): post procedure checks, patient management, and confirmation of handover information with the receiving ward

The benefits of the checklist arise from two main mechanisms:

- 1. A structured framework to ensure that all essential procedural steps are carried out.
- 2. To empower all team members, regardless of role or seniority, to initiate the Time Out briefing and speak up if they notice anything untoward.

Methods

From March to July, weekly PDSA cycles (Plan-Do-Study-Act) were used to optimise the design of the checklist through testing and staff feedback from all CCL staff The project was introduced to CCL staff at multi–disciplinary team meetings; consultants and registrars were briefed in clinical care groups, and nurses, radiographers and cardiac physiologists

were briefed as professional groups. The project manager went to the CCL daily to educate staff on checklist use and gathering feedback.

Thereafter, the focus moved to full implementation and, initially, measuring checklist use. Eight months after roll out, a full checklist was completed in 336/356 (95%) of all procedures. Analysis showed that the 'Sign In' was completed in 99.4% of cases (354 procedures), while the 'Time Out' portion was least commonly completed (95.5%).

Challenges

- Accurate data collection initially, nurses returned completed checklist forms to a box but many were missing (frequently discovered in administration folders weeks later). Also, staff would photocopy previous versions of the checklist and use thus missing updated versions. These problems were overcome when the checklist was included in patient integrated pathway documents.
- **Layout** The Biomedical Research Unit, (BRU) an isolated CCL located on a different floor to the other facilities, lagged behind the other labs for checklist usage. The project manager focussed extra attention on this CCL, leading to 100% compliance by February 2014.
- **Non-adopters** several members of staff initially saw the checklist as unnecessary bureaucracy and refused to use it. Regular direct feedback to these individuals overcame this by highlighting the impact of the checklist and addressing specific concerns.
- Moving from arbitrary to effective use initially the checklist was seen by some as a 'tick box' exercise. The directly observed quality of the Time Out and Team Briefings has improved significantly following redesign of the checklist to be more interactive and by delivering focussed individual feedback.

Measurement

The project metrics fell into two categories: compliance (extent of checklist use) and impact (improvements in efficiency, staff & patient experience and patient outcomes). High levels of 'effective' compliance are a prerequisite to attributing any improvements to the checklist and showed continual improvement throughout the project (see graph below). Many factors affect CCL efficiency and those measured are tabled below.



• Compliance

*In August & September, insufficient completed checklists were returned.

Checklist Effectiveness Measures

Measure	How Assessed	Comments
Checklist Compliance and 'Effective' Compliance	The checklist is signed & the word 'done' circled to indicate each task is complete. The CCL daily audit sheet is completed to show which sections have been done.	Provides easily auditable data but audit sheets may be lost or incomplete The charge nurse now checks each case with staff to ensure completion and the project manager observes several briefs daily to assess effectiveness
Impact		
CCL Efficiency	Procedure duration, patient preparation time, turnaround time	Data is taken from the cath lab audit sheet and from local databases.
Patient Outcomes	Radiation exposure/screening time, blood usage, mortality & complications	Data is recorded either automatically by radiology equipment or manually post procedure
Staff Attitudes	Safety climate survey at beginning, middle, and end of project.	Final survey planned for 25 April 2014
Patient Experience	Patients are asked to complete a questionnaire the day following their procedure. Questions ask if they felt safe, their awareness of the checklist process, and how reassured they felt.	Data collected on the ward via questionnaire

What we have achieved:

- Development and implementation of the first bespoke safe procedure checklist designed for the cardiac catheterisation laboratory.
- Continuous improvement in checklist uptake and use across specialties (interventional cardiology, electrophysiology, paediatrics) - our 95% target was surpassed within the year.
- Reduction in procedure time for the majority of the cases for which a checklist was employed (appendix 4).
- Improvement in key measures of staff satisfaction: Staff feel the CCL is safer and they are more empowered to highlight potential safety issues.
- High levels of patient satisfaction and reassurance. (Appendix 6).
- Successful submission of initial results to four conferences in the UK, Europe, and North America.
- Establishment of the first UK meeting on patient safety in acute cardiac care as a direct result of our work.

Part 2. Quality impact: outcomes

At the start of the project, several key metrics were determined. These fell into three main categories as follows:

- 1. Determining whether the checklist was being used.
- 2. Monitoring whether the checklist was being used effectively.
- 3. Assessing the impact of the checklist on safety, performance, and efficiency.

The majority of the measures studied involved data that was already being collected for local and national databases and so was easy to access. However, as the data had never been used for internal research or audit recently, it first had to be cross-checked and reorganised into a usable format. Also, most data is currently recorded on paper and uploaded manually, allowing for lost sheets and transcription errors, both of which appear to occur periodically (156 out of 951 cases in 2014). Nonetheless, we were able to obtain a robust baseline dataset from 2012 and the first half of 2013, which allowed us to prospectively chart new trends and link them to the team brief and checklist implementation process.

It has also been noted that completion of our BCIS database often lags several weeks behind (e.g. cases done in April may not be entered until May), leading to a delay in correlating checklist use with clinical outcomes.

From the outset it was decided to identify a broad range of process and outcome measures, which have remained unchanged throughout the course of the project. The original choice was made based on what the checklist was most likely to impact and what could be measured or was already recorded. Over the year, as checklist use has continued to rise, two main of the main efficiency measures recorded have shown improvement: if the checklist is fully used, average procedure duration is shorter and screening time (radiation exposure) is reduced. In addition, outcome measures from patient and staff questionnaires have shown improvement (see below).

Staff satisfaction surveys (taken 2 & 7 months after initial checklist implementation) show a marked improvement in perceptions of team work and collaboration – which is supported by anecdotal examples of teams being more proactive in supporting each other (appendix 6). The same survey will be circulated in April 2014.

Patients have also been surveyed throughout the project, with promising results (see appendix 7). In summary, patients are reassured that we use a checklist and particularly that the consultant operator gives a Time Out briefing. This is evidenced by a slight majority (57%) of patients (under local anaesthetic) who gave an average 9.1/10 score on the Likert Scale for being reassured by seeing the briefing, even if they didn't understand what they heard. Importantly, in the better structured Time Outs observed, the consultant introduced the patient to the team and explained to the patient that s/he is about to give a short briefing.

Part 3. Cost impact

Our key cost measures have been indirect, and are derived from our assessment of the impact of the checklist on day-to-day CCL activity. As a result, the savings from the project can be described as 'light green' in the immediate term – it is hard to attribute clear bottom line savings to them. Nonetheless, the checklist appears to have improved average procedure times in the CCL, which it can be imagined will lead to further cost savings (see below); the challenge is therefore to quantify this definitively, and this may only come to fruition as our scheduling practices adapt to allow more cases to be performed each day. Shorter procedure, avoiding an unnecessary night in the hospital, freeing up beds for more patients and increasing the number of patients who can be treated annually. Therefore our understanding of the financial impact of the project has moved away from a focus on 'can the checklist save money in individual cases?' to 'can the checklist improve overall efficiency and lead to greater overall cost savings?

The cost of existing services/pathways/packages of care can be estimated from CCL databases that allow us to analyse the number of cases being performed each day, the length of each procedure, the turnaround time between the procedures, and other clinical metrics such as screening time (radiation exposure), the need to use blood products, vascular complications, etc. (see full list of metrics above). As these come from existing in-hospital databases, there are generally few problems in analysing this data. However, as noted above, data is sometimes uploaded some months after the procedure. Nevertheless we were then able to identify any reductions and make a reasonably accurate estimate of possible savings (appendix 3).

 The cost of the project has been fully met by the Health Foundation grant. It was used for the project manager's salary and the small costs associated with the project have been met from existing hospital budgets. The checklist itself is a piece of A4 paper and the various iterations/printing/stationery costs have been absorbed by the Quality & Safety Department.

Staff time and training has been absorbed into day to day activities. For CCL staff, the majority of training has been scheduled for monthly training days, but has also been performed ad hoc during breaks between cases. Management have fitted the time into their regular working schedules – the project has not taken any time from other activities.

The estimated cost of running an operating theatre at the Brompton is £20 per minute, a figure that can reasonably be used to estimate CCL running costs. A table extrapolating the financial saving associated with shorter procedure times, when the full checklist is used, is at appendix 5. In short, it is expected that the reduced procedure time seen in cases that use a checklist will allow more cases to be done during the working day, leading to less 'down time' and increased productivity.

In addition, a new stock management system is currently being introduced, which will allow us to record the exact cost of equipment used during a procedure. It is hoped that many of the efficiency benefits seen as part of the checklist project will translate into reduced wastage (e.g. fewer items being opened in error) which our new stock management system will be able to measure. We intend to compare the monthly spend for items against the number of procedures for which they are routinely used, giving another indication of cost savings.

Part 4: Learning from your project

Without question the main objective of the project has been achieved: a Team Brief followed by a complete checklist process is used in over 95% of interventions on patients in our cardiac catheterisation laboratories, and has shown efficiency benefits as well as being is popular with staff and reassuring for patients.

There are several groups of people who have contributed to the project's success. Firstly, CCL staff (doctors, nurses, radiographers, technicians) have for the most part been highly enthusiastic about the checklist process, and have actively used the checklist and fed back on its design.

Secondly, the cath lab management team has been strongly supportive, which has permeated through to the staff, all of whom have been open to a new way of working and were tolerant while the checklist was developed and processes were improved.

Lastly, although small the project team has functioned very well with good backup from higher management in the organisation. As a result, the management team at Harefield, our sister hospital, has been very receptive to ideas initiated by the project and has invited teams from the Brompton to participate in their simulation training programme.

Staff buy in was crucial to the success of this project and therefore communicating with staff dominated the early stages. In the first instance, the project manager briefed the Multidisciplinary Team meetings on the checklist and followed this up by one on one meetings with all consultants to explain it in more detail. The investment of this time meant that misconceptions could be cleared up and the strengths of the checklist emphasised. One factor that was important was that each change to the checklist suggested by a member of staff was made immediately, thereby showing people that their input was noted. This encouraged people to engage with the process and suggest any changes they thought valid.

Non-clinician staff groups (nurses, radiographers & physiologists) were briefed in their separate groups. Thereafter, the project manager was regularly in the cath labs to advise when needed and frequently met with the charge nurse to discuss issues/ways to improve take up. Fortunately, the majority of consultants saw the benefits of a checklist early on, which helped the project gain momentum. For those that did not use the checklist, it was noted that their teams became so used to being briefed by other operators, that nurses, radiographers, and physicians felt empowered to ask relevant questions ahead of the procedure. Subsequently, even initial non-adopters began to see the benefits of the checklist in terms of team cohesion.

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The main challenges were as follows:

Getting initial buy-in

A few non-responders initially saw the checklist as purely an unnecessary piece of bureaucracy, however these individuals were soon persuaded by notable changes in team functioning and also by targeted individual feedback.

Pacing the introduction of the checklist

It was important to pace the project carefully. Had we tried to force the pace of change, rather than letting people see the benefits and work out how to adapt the

process to suit their working style, we would probably have met with more resistance. Especially in the early stages, this could have significantly hindered initial progress.

> Getting the checklist process followed productively, rather than arbitrarily

In the early stages, while people were familiarising themselves with the process, it seemed that for much of the Time Out element especially, some staff were 'going through the motions.' To a certain extent, this was inevitable although the majority of people improved quite quickly in their delivery as a result of seeing the benefits of the checklist process.

Obtaining accurate data

This was essential to measure progress and identify trends, or to know where to focus our attention. A lot of effort was therefore spent persuading staff to keep accurate records and submit them, regardless of whether or not the processes were completed.

This was problematic, as some staff were more conscientious about completing the audit sheets and others were content to tick boxes regardless of whether or not the process stages were completed. This appears to have been rectified, by repeated feedback on the noticeboards and at management meetings, and also by ad hoc support and encouragement. There will be a final summary session in April 2014.

Also, during the Summer holiday period of August and September, with large numbers of temporary staff and disruption to the schedule, the number of checklists submitted fell sharply (see graph on page 5) – to the point that we had too little data to conduct any meaningful analysis. This was improved in October when the checklist was put into the Integrated Care Pathway (ICP), making it a formal part of the procedural documentation and compliance for each stage is now annotated on the lab audit sheet

Compliance:

We have surpassed our target of 95% checklist completion for all cases.

Impact:

Project aims, as detailed in application:

- Reduced morbidity and mortality following CCL procedures
 - Mortality and morbidity (see appendix 12) are both extremely low. Data will therefore be analysed over a longer time period.
- Improved patient experience and staff satisfaction
 - See appendices 6 & 7. By the end of April 2014, we will have conducted the final staff attitude survey and the target is to have surveyed 100 patients.
- Improved CCL productivity and work flows
 - The best indication of the checklist's impact on efficiency is that when the full checklist is used, 64.9% of procedures are shorter than the average (appendix 4).

As in many areas of the NHS, the CCL can often appear to have a culture whereby working practice is dominated by consultants. We overcame this by approaching all staff members, highlighting that the checklist was to be used by everyone, and accepting feedback from all care groups.

No staff left the project; we had complete continuity, which played an important role in the success of the project.

Working towards routine 95% compliance over 12 months allowed people to adopt, get comfortable with and amend the checklist to suit their style, without being unduly pressured. This bodes well for longer term sustainability, as people are using the checklist voluntarily, because they have seen the benefits, rather than because they have been told to.

Part 5. Plans for sustainability and spread

We believe that the benefits of our project are likely to be sustainable in the long-term. The team brief and checklist process is now carried out as a matter of course in all CCLs, with few exceptions. This is with no external prompting and staff now expect the two briefings (Team Brief & Time Out), and so often remind the operator should s/he forget. Furthermore, the lead nurse signs to confirm that s/he has completed the Sign In and the process can be audited for every procedure. Similarly, the post procedure checks (Sign Out) are mandatory and giving a clear, accurate handover to the ward has proven beneficial.

Now that we are starting to see efficiency benefits, interest in the checklist has heightened, as efficiency during a procedure (having the right equipment on hand when required) is very important and mistakes which delay the procedure can adversely affect the outcome. It is also in everybody's interests to treat patients on the scheduled day and not to have to cancel them into the next day.

<u>Abstracts & Posters</u>. We have presented our interim findings at a patient safety forum at the Royal Society of Medicine (RSM, Nov 2013), where our abstract was chosen as one of the top five of over 200 submitted. We have also submitted abstracts for the following conferences:

- International Forum (Paris, April 2014) accepted
- EuroPCR (Paris, May 2014) accepted
- The Patient Safety Congress (Liverpool, May 2014) accepted
- QCOR (US Patient Safety Congress, Baltimore, June 2014) presentation; accepted.
- HSJ Awards (London July 2014) (pending)

<u>Symposium</u>. We are hosting a symposium on 24 April 2014 to convey our learning from the checklist project; we have a range of expert speakers who have extensive expertise in related patient safety fields.

The focus will be split between checklist use (what to do) and human factors (how to do it – simulation/handovers/leadership & communication skills). We are advertising nationally but are also arranging for as many staff from both trust hospitals as possible to attend.

<u>Three Hospital Study</u>. We have taken the first steps towards organising a three hospital study, to further test our checklist and implementation methodology on a larger scale. If this is successful, the next step would be to work towards national rollout.

External contacts – already engaged with.

- Dr Rod Stables, Cath lab director at Liverpool Heart & Chest hospital has just completed a six centre study to test a checklist process and has been instrumental in developing the cardiology service at LHCH, improving efficiency and cath lab management.
- Professor Colin Bicknell, Imperial College NHS Trust Clinical Senior Lecturer, agrees in principle to work on a three hospital study to further research into the checklist
- Owen Bennett, patient safety lead at Nottingham University Hospitals NHS Trust, who is also interested in pursuing the three hospital study.
- Project Check Atul Gawande's team at Brigham & Women's hospital (Boston), who are dedicated to developing checklists and spreading their use internationally
- Phil Higton former airline pilot & owner of Terema (human factors training consultancy)
- Suren Arul paediatric surgeon who adapted the checklist for use by British Army trauma teams in Afghanistan and successfully implemented the same procedures at Birmingham Children's Hospital
- Asklepios Klinik (Hamburg) Contacts established following visit to explore opportunities to improve efficiency

Appendix 2: Resources from the project

- RBH Safe Procedure Checklist
- Efficiency Data
 - Procedure duration
 - o Checklist impact on procedure length
 - Efficiency cost savings
- Patient survey results
- Staff attitude survey
- Patient Outcomes
 - Radiation/Screening time including checklist impact
- Blood required
- Complications, mortality and incidents
- Stills from checklist instructional video