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Reducing wrong intraocular lens implants in cataract surgery

3 years of experience with the SEIPS framework in Singapore

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Abstract

Purpose – Wrong lens implants have been associated with the highest frequency of medical errors in cataract surgery. The purpose of this paper is to explore the use of the Systems Engineering Initiative for Patient Safety (SEIPS) framework to sustainably reduce wrong intraocular lens (IOL) implants in cataract surgery.

Design/methodology/approach – In this mixed-methods study, the SEIPS framework was used to analyse a series of (near) misses of IOL implants in a national tertiary specialty hospital in Singapore. A series of interventions was developed and applied in the case hospital. Risk assessment audits were done before the interventions (2012; $n = 6{,}111$ surgeries), during its implementation ($n = 7{,}475$) and in the two years post-interventions (2013-2015; $n = 39{,}390$) to compare the wrong IOL-rates.

Findings – Although the absolute number of incidents was low, the incident rate decreased from 4.91 before to 2.54 per 10,000 cases after. Near miss IOL error decreased from 5.89 before to 3.55 per 1,000 cases after. The number of days between two IOL incidents increased from 35 to an initial peak of 385 before stabilizing on 56. The large variety of available IOL types and vendors was found as the main root cause of wrong implants that required reoperation.

Practical implications – The SEIPS framework seems to be helpful to assess components involved and develop sustainable quality and safety interventions that intervene at different levels of the system.

Originality/value – The SEIPS model is supportive to address differences between person and system root causes comprehensively and thereby foster quality and patient safety culture.

Keywords Error analysis, Patient safety, System thinking, Incident reporting, Clinical risk management, Root cause analysis

Paper type Case study

1. Background

Operating rooms (ORs) have constantly been reported to be high-risk areas for preventable patient harm (Haynes *et al.*, 2009; Langelaan *et al.*, 2010; Leape *et al.*, 2009). Surgical complications are estimated to be 3-17 per cent in industrialized countries (Treadwell *et al.*, 2014). A large part of these complications include surgery on the wrong side, the wrong procedure or the wrong patient. In a systematic review of surgical never events, Hempel *et al.* (2015) found 27 different incidence rates of wrong site surgery and estimated the overall rate on one event per 100,000 procedures. Identified root causes are communication problems, including miscommunications among staff, missing information that should be or have been available to the OR staff, surgical team members not speaking up when they noticed that a procedure targeted the wrong site, and a surgeon questioning ignorant surgical team members who questioned laterality.

Not much of these findings have been extended to eye surgery. Cataract surgery with intraocular lens (IOL) implantation, however, is the most frequently performed surgery in the world, and carries a greater risk of inserting a wrong implant than any other specialty (Hempel *et al.*, 2015; Schein *et al.*, 2012; Brick, 1999; Carayon *et al.*, 2004; Simon *et al.*, 2007; Paull *et al.*, 2015). Jin *et al.* (2007) show that the incident of wrong-site cataract is 1.125 per 10,000, about ten times higher than the average overall specialties. Simon *et al.* (2007) studied New York State reports on surgical confusions (wrong patient, wrong eye, wrong

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eye block, wrong implant, wrong transplant) before and after the introduction of the Universal Protocol, and reported 7.4 and 5.0 incidents per 100,000, respectively. Wrong implant-related errors accounted for 63 per cent of the total number of malpractice claims in New York State and the data from the Veterans Health Administration show that approximately half of the surgical errors were attributed to wrong implant.

Pikkel *et al.* (2014) evaluated the frequency of mistakes that can occur in the absence of verification among ten cataract surgeons. Before entering the OR, the surgeon was given the patient' name and asked to identify which eye needed surgery. They were asked again when they stood at a distance of 2 metres from the patient's faces (so they could not see which pupil was dilated). The surgeons only identified the correct eye in 73 per cent by the patients' names, and in 83 per cent by looking at the patients' face (Pikkel *et al.*, 2014). This shows the importance of side marking and other preventive measures.

Errors that result in a wrong implant, however, are usually not limited to the OR. A retrospective review on the UK's 2003-2010 error data showed that the majority of mistakes occurred during IOL selection and were especially related to transcription errors or errors during preoperative preparation (Kelly and Jalil, 2011; Bray *et al.*, 2009; Zamir *et al.*, 2012). This was confirmed by Paull *et al.* (2015) who studied wrong surgery events and found that all their ophthalmic surgery events were "upstream": the first error occurs before the beginning of the Universal Protocol.

The Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™, which became effective in 2004 for accredited hospitals, ambulatory care, and office-based surgical facilities, entails preoperative verification, site marking, and a "time out" just before the first incision has been made (Joint Commission, 2014, 2015). However, these precautionary measures would not affect the "upstream" errors, which seem to occur undetected before the actual day of surgery. It has been estimated that up to one-third of incorrect procedures would not be prevented by a time out (Seiden and Barach, 2006; Mulloy and Hughes, 2008; Carayon *et al.*, 2004). Again, Paull *et al.* (2015) confirmed this for ophthalmic surgery. For example, if biometry, a routine test to determine the eye length for calculation of IOL power, had been miscalculated and recorded in the patient chart, a time out before surgery would not have detected the error. The actual occurrence of an unintended outcome is related to many factors, starting even before the patients' first clinic visit. Moreover, the trend towards day surgery and advances in technology have also increased the risk for errors from high volumes and turnaround between cases (Simon *et al.*, 2007; Mathew *et al.*, 2013). A hospital OR therefore cannot be seen apart from its larger context and can be characterized as a complex adaptive system, where many mutual influencing factors play a role (McDaniel and Driebe, 2001).

In a systems approach to health care, scientific insights are applied to determine the elements that influence health outcomes; the relationships between those elements are modelled; and care design, processes, or policies are modified on the basis of the resultant knowledge to produce better health at lower costs (McDaniel and Driebe, 2001; Ozkaynak *et al.*, 2015). Carayon *et al.* (2014) provide a system approach with their Systems Engineering Initiative for Patient Safety (SEIPS) model, which draws on Donabedian's structure-process-outcome model (Donabedian, 1966) and targets patient safety. It addresses implementation of systems design, quality management, job design, and technology that can affect safety-related patient and organizational and/or staff outcomes (Kaplan *et al.*, 2013; Carayon *et al.*, 2006; Xie and Carayon, 2015; Clarke and Eales-Reynolds, 2015). The work system (external environment, technology and tools, person, organization, tasks, physical environment) influences the process (care processes and others), which subsequently influences outcomes (quality of care, patient safety and employee and organizational outcomes). Both outcomes and processes feed back into the work system (Carayon *et al.*, 2014).

The SEIPS model can be considered as a socio-technical framework, and has been used to analyse and categorize the impact of health information technology (IT) on patient safety (Salahuddin and Ismail, 2015; Holden, 2011), bar-code medication administration in pediatric hospitals (Holden *et al.*, 2011) and to identify and categorize patient safety hazards in cardiovascular ORs (Gurses *et al.*, 2012) and in situ simulated cardiac arrests (Barbeito *et al.*, 2015). Acher *et al.* (2015) used the SEIPS model to evaluate contributors to readmissions after complex abdominal surgery, and found that poor patient and caregiver understanding, and insufficient educational process and materials, negatively affected by electronic health record design played a role in readmissions. Earlier, Sarkar *et al.* (2014) showed how the SEIPS model helped in indicating that improving the diagnostic process requires attention to the organization of the health system in addition to the cognitive aspects of diagnosis. The SEIPS model seems to be a useful framework for identifying the causes of errors, contributing factors (system issues) related to errors, and identifying interventions to reduce errors (Frith, 2013). So far, the model has however not been applied to reduce wrong implants in cataract surgery.

Singapore performs about 38,000 cataract surgeries annually; 45 per cent of these cases are performed within the case study hospital, a national specialty centre (Ministry of Health Singapore, 2015). Such a high volume and rapid turn-over of cases daily carries with it a high risk of committing errors at any point compared to other types of implant surgeries. In 2014, the hospitals' risk management team analysed a series of recent (near) incidents, or near misses (Chang *et al.*, 2005), and explored these from an SEIPS system's perspective in order to recognize areas of limitation in its current system and practice and explore how additional safety management could enhance the effectiveness of safety protocols.

2. Methodology

The setting of our study was the Singapore National Eye Centre, a tertiary academic eye centre in Singapore. We used a mixed-methods approach, and have used the Standards for Quality Reporting Excellence (SQUIRE) 2.0 guidelines to report (Ogrinc *et al.*, 2015).

First, in October 2013, we conducted an in-depth retrospective case series review of all wrong IOL cases that were formally reported by OR staff during a one-year observation period (March 2012-June 2013). The respective heads of the OR, Nursing (LHP) and Risk Management (RM) departments reviewed the incident reports raised, in accordance with the organization's Clinical Governance Policy. From August 2012 onwards, the head of the Cataract Subspecialty Service (CSP) had provided additional comments or recommendations for improvement.

Second, from September 2012 onwards, we gathered structured qualitative descriptions of (near) incidents and IOL (reservation) errors during the study period. All operating theatre nurses ($n = 41$) were briefed and reminded weekly to document various types of (near) misses or accounts related to IOL implants in a pre-structured document including date of surgery, patient and staff details. The reports were written in a paper format available at the OR and gathered on a daily basis. A fresh data collection sheet was printed at the start of the week and placed into every OR room. A senior operating theatre nurse (LHP), who was part of the risk and quality improvement committee, collected, evaluated and reviewed the entries of these reports. Clarifications on the events were sought directly from the person who made the entries. Accounts that fitted the criteria of near miss were reviewed by the Institutional Risk Manager (RM) based on potential severity, impact, and proximity of event. For example, potential effects on the patient as well as logistics effects of cancellation or delay were included if the event was found to be close to the surgical date. A validation was done by the whole team to review all case types.

Third, based on the results of the first two steps the different components of the SEIPS model were used as a reference framework and the incidents were classified to tools, technology, tasks, physical environment, organization, person, processes, and outcomes (see Table I).

Component	Characteristics	Findings in case hospital
Work system		
Person	Can be a single individual (e.g. physician, nurse, patient) or a group of individuals (e.g. team, organizational unit)	Diagnosing surgeons Operating surgeons Surgical assistants Nursing staff in various departments
Tasks	Variety, content, physical and psychological demands	IOL reservation Biometry parameter check Biometry stamping Biometry form copying Time out performance
Tools and technologies	Health information technologies, medical devices, other tools and technologies	Reservation chit system IOL types and power differences IOL holder at OT Pictorial IOL reference
Physical environment	Physical layout, workstation design, noise, lighting, temperature, and humidity, air quality	Physical distance between the clinics and the OT Storage design Temperature at OT
Organization	Formal and informal organization, organizational culture and climate, rules and procedures, organizational structure and management	Cultural differences between operating room and clinic room Role and hierarchy differences Standardization and training practices Academic subspecialty focus
External environment	Geographic and cultural factors	Asian cultural factors Public hospital setting Hospital part of larger health care cluster Pharmaceutical vendors
Process		
Care processes	Inpatient, outpatient, ambulatory and surgical processes	Clinic visit and follow-up checks Day surgery flow
Other processes	Patient support, logistics, supply chain, food services, administrative processes	IOL reservation Surgical material and device ordering IOL stock management Urgent (< 24 h) order management
Outcomes		
Patient outcomes	Medical outcomes; patient satisfaction and experiences	Visual acuity Surgical complications Patient reported visual outcomes
Employee and organizational outcomes	Staff satisfaction and retention; organizational results	(Sub)specialty public hospital with strong research and education focus

Notes: IOL, intraocular lens; OT, operating theatre
Source: Based on Carayon *et al.* (2014)

Table I.
SEIPS model components and related findings in the case hospital

For example, if an ophthalmologist made an illegible entry or did not use the approved description to order the implant, the classification "person" was used. An intraocular implant entered into the surgery order system but reflected different from the final order written inside the patient notes would be classified as "technological". For all incidents, the relationship among the different components was discussed, and suggestions were made how improvement could be initiated. Risks in a particular area or process were discussed among the respective stakeholder groups (surgical, nursing, operations, pharmacy, human resource, engineering, vendors) and solutions were deployed if necessary. In order to allow easy reference for physicians and nurses, and to ensure that a correct description of the IOL

implant was entered, the departments of IT, nursing, and vendors would work together to display the information in the hospitals information systems and intranet. Nursing and administrative staff inside and outside the operating theatre were briefed where to access this information and how to apply the information during a patient consultation.

Incrementally, over 2012 to early 2013, a multiple layer set of interventions was developed to reduce the chance of wrong intraocular implants. A multidisciplinary group with ophthalmologists, OR nursing staff, and quality improvement experts was involved.

We used a before-after design to assess the effects of a series of improvements based on the SEIPS framework. The (near) incidents that were reported in the six months before the introduction of the improvement (in 2012) were compared to the (near) incidents reported during the six months implementation period (2012-2013) and the reported (near) incidents in the two years after the introduction (2013-2015).

3. Findings

3.1 Three system interventions

From September 2012 onwards, three Plan-Do-Study-Act (PDSA) cycles were piloted at the hospital's private clinics with purpose of understanding the types of near misses from transcription process, inaccurate description of implant and missed or double reservation (see Table II).

The private clinics were chosen, as reservation errors were commonly found in the "premium" IOLs that are less common in the subsidized clinics.

3.1.1 Transcription process redesign. The first PDSA aimed to reduce the chance of transcription process error by clinic nurses. Existing workflow placed great responsibility on the clinic nurse to transcribe the implant information written in the case note over to an IOL order slip and dispatched this to the operating theatre. The operating theatre manager then acknowledged the slip and placed the order accordingly. Analysis showed the following issues during the transcription process: illegible hand writing, extensive time required for transcribing, lack of knowledge on what was written by doctors, and time spent

Plan	Do	Study	Act
PDSA 1: transcription process redesign			
Reduce IOL transcription errors by clinic nurses	Reduce step to copy information to separate dispatch chit Analysis of (near) incidents	Number of IOL implants Ratio of rejected order slips Transcription time per slip Number (near) incident reports	Root cause analysis to other system factors
PDSA 2: visual pictorials redesign			
Improve IOL flow design and classify system-related issues	Design a visual pictorial reference system Pilot the use of the pictorial system with 11 cataract surgeons	Ratio of rejected order slips Surgical preference and use of the pictorial references	Intranet reference for hospital wide application Implement the system hospital wide
PDSA 3: reservation system redesign			
Reduce missed or unnecessary double reservations	Capture of case notes with reservation slips Manual screening against available IOL implants	Ratio of reservation chits Ratio of missed reservations Ratio of double reservations	Continue to implement as business-as-usual Explore CPOE reservation system

Table II.
Three PDSA cycles executed in the case hospital

Notes: IOL, intraocular lens; CPOE, computerized physician order entry

to rectify an error by operating theatre staff. The intent of the newly developed workflow was to reduce unnecessary process steps and stop nurses from transcribing themselves but to use the order page written by doctors and dispatch directly to operating theatre. Instead of rejecting ordering slips with ambiguities, verifications between surgeons and operating theatre managers were done directly. Although the new flow saved 30 seconds of transcription time per slip after intervention, overall reduction in near misses was not observed initially. Multiple other factors seemed to play a role.

3.1.2 Visual pictorial reference system. To address these factors, a second PDSA was designed to capture all potential types of near misses and to classify various levels of system-related issues. There was a spike of near misses captured at a certain week due to vigilant measures taken in ensuring that all potential cases were reported. As the analysis showed there was confusion on the visual details of the IOL, a pilot study with 11 cataract surgeons was conducted to determine if a pictorial reference of lenses was useful and feasible. A standard pictorial reference was uploaded into the hospital computer system to allow doctors to refer and write accurately. In total, 10 out of 11 surgeons rated positively and indicated a frequent use.

In the next phase, the pictorial reference system was implemented for all 27 surgeons over a period of two weeks. Although, there was a reduction in the number of rejected slips, compliance rate among all surgeons was only 60 per cent. Five surgeons preferred to rely on their memory than to launch the pictorial reference from the hospital computer. Seven surgeons who used the reference during their order showed significant improvement in describing an implant correctly.

3.1.3 Reservation slip check. The third and final PDSA aimed to reduce missed or unnecessary double reservation during the process of dispatching the reservation slips. The most common reasons were chits ended up not dispatched, late dispatches, and delays from rectifying wrong transcriptions made by nurses. Cases with reservation documented in case notes were captured by nursing team one day before surgery and the list handed to project team members inside operating theatre. The list was screened thoroughly against available IOL implants. Any missed or double reservation was documented in the data collection slip. There was obvious improvement after four weeks of implementation.

3.2 IOL implant incidents and near misses

The number of cataract surgeries since the introduction of the reporting system in March 2012 till August 2012 was 6,111. The number of cataract surgeries during the six months implementation period of the initiative (September 2012 till March 2013) was 7,475, and the number of surgeries in the two years after the introduction (April 2013 till July 2015) were 39,390.

The number of reservation-related errors was reduced. Although the absolute number of incidents was low, as shown in Table III, the incident rate decreased from 4.91 before to 2.54 per 10,000 cases after.

Near miss IOL error decreased from 5.89 before to 3.55 per 1,000 cases after. The number of days between two IOL incidents increased from 35 to an initial peak of 385 before stabilizing on 56. There was a significant improvement in the entire reservation process – particularly in direct reservation with the vendors and ambiguous description of the implant. Missed reservations from high volume and late clinic session were common before the intervention, and have been minimized after the implementation of the SEIPS bundle. The number of reported actual IOL errors was lower during and after implementation.

During the study period, six IOL implant incidents were formally reported, and 250 near misses were reported using the descriptive format. The breakdown was as follows:

(1) 138 reports (55 per cent) indicate that the IOL reflected in the surgical list is different from the final reservation.

	Before SEIPS $n=6{,}111$ March-August 2012	During SEIPS $n=7{,}475$ September 2012-March 2013	After SEIPS $n=39{,}390$ April 2013-July 2015
Cataract surgery characteristics			
Number of intraocular lens (IOL) errors	3	1	10
IOL error rate	4.91^{-4}	1.32^{-4}	2.54^{-4}
Number of intraocular lens (IOL) near miss errors	36	9	140
IOL near miss error rate	5.89^{-3}	1.20^{-3}	3.55^{-3}
Main work system incentive for IOL error			
Person			
Surgeon forget to order	11 (31%)	6 (67%)	6 (60%)
False assumption that reservation was made from pre documentation	5 (14%)	0	0
Tasks			
Wrong order (wrong model/diopter)	9 (25%)	1 (11%)	1 (10%)
Direct arrangement with vendor	3 (8%)	0	0
Tools and technologies			
Change of IOL model	1 (3%)	2 (22%)	2 (20%)
Organization			
Late reservation after scheduled hours	5 (14%)	0	1 (10%)
Other	2 (6%)	0	0

Table III. Characteristics of intraocular lens errors in cataract surgeries at the case hospital, before, during, and after SEIPS-related interventions, 2012-2015

(2) 55 reports (22 per cent) were IOL near miss incidents which were rectified before actual day of surgery. For example, a surgeon who forgot to indicate a non-standard IOL or a surgeon who described the IOL model wrongly.

(3) 37 reports (15 per cent) were on IOLs that were reserved twice due the lack of a common interface between OR and outpatient administrative applications.

(4) two reports (1 per cent) were on multiple IOL implants for one surgery reserved on the same day.

(5) 18 reports (7 per cent) were categorized as "others" – for example, a reservation was made with vendor but not reported to the OR or an own method was used to describe an IOL model, e.g. "Alcon yellow lens" (which is a unique domain for Alcon WF series).

3.3 Case issues related to wrong IOL implant

The IOL implantation process entailed several steps – from determining the refractive aim, biometry, process of IOL selection to surgery. Each of these steps is carried out by different people and in a different sub-environment. Lapses were visible in the following three key areas. First, the adherence to the time out protocol within the intra-operative practices was lower than expected ("person", "organization", "tasks"). Analysis of the (near) incidents showed that the IOL was not visually checked, and there was lack of surgical team's participation during the time out. The IOL could also be chosen from the wrong designated column. Even when clearly indicated, a surgeon could accidentally read from the wrong page or could also happen to pick up the wrong IOL if more than one piece of IOL is placed within the OR after the time out.

Second, inadequate knowledge of the nursing staff was determined with regard to the various IOL models especially the "Advance Technology Implants" ("person", "technologies and tools", "environment"). Apart from error promoting factors like similarity in the company's packaging and descriptions of the model, the majority of the nurses were unsure

on information reflected on the IOL box. Even when the information read out from the notes during the time out protocol was correct, staff did not realize that IOL at hand could be incorrect. For example, an IOL coded SN6AD1 (a multifocal) at hand is different from one coded SN6D1T3 (a multifocal toric) written in case note.

Third, the reservation process of lenses was found as an important source of error ("processes"). Clinic nurses are required to follow the reservation workflow closely especially for IOL diopter falling outside the common power and advanced technology IOLs. Most common reservation process errors include transcribing errors – encountered when nurses transcribe the biometry order to the reservation chit. Illegible doctors' hand writing and non-standardized description of an IOL model lead to confusion and thereby incomplete orders when transcribing the order over to a reservation chit ("person"). Other errors include factors like incomplete reconciliation of the documentation during reservation and personal arrangement between clinicians and vendors leading to missed or double reservations.

3.4 Characteristics of person(s) involved in the task

The SEIPS component "person" was initially considered to be an important root cause for incidents. In one case (a transcription error), where a patient was scheduled for left cataract surgery, the surgeon requested a 19 D PCIOL (posterior chamber IOL) on an IOL order form. As the hand written numeric 9 appeared like 4 in the reservation chit, a 14 diopter IOL was reserved and announced during the time out procedure (which was confirmed by surgeon). This led to hyperopic refractive surprise (6/21), which was resolved after IOL exchange with original diopter (visual acuity of 6/12). In a separate incident, a wrong IOL was selected when the surgeon mistakenly chose an IOL model and diopter based on previous surgery's calculation for the fellow eye. Retrieving the wrong IOL could also happen when multiple pieces were available within the OR.

Other cases show lack of product knowledge, which also can be attributed to the "person" component. A patient with cataract and astigmatism underwent uncomplicated surgery with the intention of inserting a multifocal toric IOL. Time out was done using the information written on the patient's notes and confirmed by assisting surgeon. However, the IOL was not visually checked by main surgeon. The nurse performing the time out did not realize that the IOL at hand was a normal multifocal IOL. The error was discovered upon implantation when the surgeon could not locate the mark to adjust the toricity and the patient was informed – she did well post operatively and was pleased with the post-operative visual outcomes.

3.5 Characteristics of the tasks

The SEIPS component "tasks" was also often recognized during the analysis of the IOL incidents. The errors occurred despite the fact that a "time out protocol" to prevent wrong site was in place since 2003. In one case, IOL power of 2D was mistaken for 20 and in another, +20 was mistaken for 12.0 by three operating theatre staff. Many of the patients in the case hospital underwent IOL exchange either on the day of surgery or had to be rescheduled to correct the refractive error. The remaining patients did not require any intervention as the refractive outcome was deemed acceptable after the IOL has settled into the capsular bag to reach its final position, usually after a few weeks (Simon *et al.*, 2007; Seiden and Barach, 2006). The measures undertaken to reduce such errors in the case hospital include the spelling out of diopter instead of D, elimination of "+" to signify positive diopter and using the word "minus" to indicate negative diopter. From our near miss reports, there were at least 14 ambiguous or unclear orders that were returned back for clarifications. For example, the IOL "Zeiss MF 14D" does not have a clear description of the correct description of the model. The accurate description should include the company name followed by the model and diopter: "Zeiss (company) AT Lisa 809M (Model) 14D (Diopter), a Multifocal IOL".

3.6 Facilitation and hindrance of processes

Despite having a clinical process in place for IOL checking and reservations, 36 cases did not have their special or required IOLs available prior to surgery. IOLs had to be delivered as "urgent" on day of surgery in 12 cases resulting in delays. For instance, when a reservation is required for special premium or uncommon diopters, the surgeon selects his order into the case notes and a nurse transcribes the order over to a reservation chit which will be dispatched to the operating theatre for arrangements. Although the root causes were not analysed, several potential error points were identified: a chit was not dispatched, late dispatches, and delays from rectifying wrong transcriptions. Reservations that were missed but resolved in time contributed to about 66 per cent of overall reported near miss incidences during the data collection period before implementation. If the discoveries were not rectified on time, surgical schedule was delayed or readjusted. Urgent delivery cost is either borne by the company or the hospital itself.

Root causes related to processes also became clear through cases with incomplete documentation for the reservation of IOLs. A patient was listed to have his right cataract removed. However, the biometry and toricity was calculated based on left eye's parameters. The incongruity was noted only on day of surgery. Upon checking and recalculating, an entirely different model of IOL was required (monofocal toric) and the reserved IOL was not suitable (multifocal toric). Patient was informed and surgery had to be delayed. IOL arrived in two hours and surgery proceeded without complications. Special reservations must be accompanied by complete documentation reference including the web-based calculated print out. The discrepancy could have been discovered a day earlier if both print outs (biometry order and calculation print out) were presented to the operating theatre for reservation.

Implementation of the systems improvements seems to show a change in the work system incentives. Initially, 33 per cent of the errors were related to "tasks" (wrong order, direct arrangement with vendor). This was reduced to 10 per cent after introduction of the bundle. The increasing availability of different lens types has resulted in an increase of "tools and technologies" related errors from 3 per cent before implementation to 20 per cent after the implementation of the bundle. The work system element "environment" was not indicated as incentive for IOL errors. The human factor category ("person", e.g. surgeon forget to order) was, however, still the main category of errors (45 per cent before and 60 per cent after implementation). This was the main reason for the introduction of a digital IOL ordering system, including automated order check before surgery that is currently being fully implemented.

4. Practical implications

Our study showed how taking a system's perspective using the SEIPS framework has sustainably improved safety of cataract surgery. Taking an organization system's perspective, the lack of standardization of IOLs has shown to be a main cause of error during the diagnosis, reservation as well the actual implantation phase. With a wide variety of IOL models available, each with different design and diopter options, errors involving the selection of an IOL remain one of the critical areas that leads to undesirable consequences and outcomes. Health care organizations can be characterized as professional organizations characterized by high level of individual autonomy (Freidson, 1970; Buchanan, 2008). The nature of hospital work, with its complexity and specific knowledge requirements, can only partly be standardized (Freidson, 2001; Plochg *et al.*, 2009). There are examples of hospital systems that go far in restricting IOL variety to one or two types (e.g. Aravind Eye Care System in India, see Mehta and Shenoy, 2013). In our case hospital, the role as national academic centre brings a focus on research and development, as well as setting recommendation for new IOL's for Singapore's public health care and industry. A closed loop system linking all stakeholders would be preferable and will require novel views on

cost sharing and information security involved. Any IOL error however undermines the patient's confidence in the organization's reputation and creates unnecessary distress for both the patient and surgeon in addition to being a potential source of litigation. While the actual number of wrong IOL errors is low, our rate of 4.2 per 10,000 surgeries seems to be larger than the earlier reported rate of 1.06 per 10,000 in the US Veterans Health Administration (Schein *et al.*, 2012).

Advanced technologies and super-specialization has resulted in a wide variety of available IOLs that can fit to many different needs and preferences. Having more options available can benefit sight of individual patients, however, the downside of this option should not be underestimated. Having more choices increases the chance of making the wrong one. Cost-effective methods like the applied pictorial communication guide made available within the organization's web page provided a quick reference in standardizing the IOLs' descriptions and, hence, reduced varying degree of interpretation by receiving party. The pictorial summary is easily accessible by nurses who could verify various types of IOL order. These process redesigns are easily implemented and inexpensive. It allowed staff to act on immediately when a mistake or discrepancy is discovered. Good practices from surgeons who routinely indicate their choice of IOL unto the surgical list is also worth exploring.

Within the Asian context (as part of the "environment" part of the SEIPS model), open reporting, and discussion about (near) incidents is a bigger challenge as compared to our Western counterparts. It is therefore not a surprise that patient safety research reports from this part of the world are currently scarce. While the concept and importance of a "no blame culture" formally has been acknowledged, disclosure of (anonymized) non-optimal performance data is not common. This is clearly evident from a study that concluded medical students from Singapore and Hong Kong show relatively low scores on "error reporting confidence". They viewed the importance of patient involvement and team functioning as low and consider medical errors being inevitable and mainly caused by professional incompetence (Senders and Senders, 1999).

Although Singapore has a strong regulatory environment and long tradition of quality (such as a mandatory quality assurance committee for all hospitals (1980), a national clinical audit programme (1999) and specialty specific clinical indicators (2003), participating in the WHO's global patient safety challenge (2006) and a national hospital performance indicator framework (2012)) the effects and outcomes of these programmes have not been systematically evaluated. A culture of rigorous programme evaluation, greater public involvement, and greater patient empowerment is still lacking (Leung *et al.*, 2013; Lim, 2004). This possibly reflects on the Singapore patient safety culture as it has been indicated that "locally we have an intense blame culture to grapple with and this constitutes our greatest hurdle in developing our hospitals into high reliability organizations" (Mack, 2002). Addressing this "environment" element from the SEIPS framework and its relation with the various other elements was not investigated in this study but need to be taken into account.

4.1 Limitations

The underreporting of the (near) events has been the main limitation in this study. Reports would need to be delivered to a nursing staff that also had a hierarchical leadership position at the operating theatre according to institutional policy. While this has been regarded as common practice in Asia and beyond, literature has showed the importance to distinguish and explore various methods of the reporting pathway apart from the formal one. Expanding the boundary of reporting facilitates a rich source of input that should enable better reflection of practice and successful implementation of guidelines or changes (Mack, 2002). There might also have been a Hawthorne effect, as these were hospital quality improvement projects with surgical nursing involved. While we have tried to limit this by

only involving one surgical nursing staff in the actual evaluation, it might have been possible that others were aware.

This study has a few other limitations. While a systems approach is realistic and useful, it is however difficult to relate the specific part of the intervention bundle to the results. The bundle only provided an overview frame combining multiples aspects within a system. There was a small reduction in overall error rate in the two time frames, before and during and during and post, bundle implementation which were not statistically significant. Even though, the overall near misses between similar time frames of before and during showed signs of sustainability and was statistically after the project, studies have shown that immediate improvement in the short term with no strong evidence of sustained impact in the long term is common – especially if it involved multilevel interventions, changing of culture, and organization system (Edmondson, 2003). Strategies for integrating improvement techniques into the system through use of technology were deemed more effective than changing human-dependent behaviour.

As a result of using the SEIPS framework, the case hospital is currently exploring the feasibility of using an electronic order system in order to minimize more human-related ("person") error. A digital system would help to facilitate information exchange and improve network transparency between outpatient, scheduling, day ward, and theatre. This could possibly reduce system-related errors and inefficient double booking, inappropriate descriptions or inconsistency in surgical list. However, the high upfront developmental, upgrading and maintenance cost of such magnitude may create a barrier for implementation. Potential disadvantages associated with technology can arise from disruption to workflow as a result of learning a new system and also other type of challenges, yet unseen.

5. Conclusion

The SEIPS framework is helpful to assess all components relevant for sustainable improvement of surgical safety. Our three year experience in cataract surgery shows that safety improvement cannot be reduced to standardized checks at the operating theatre, but is much related to system's factors all over patient pathways. Reducing wrong surgical implants requires a system's perspective and cannot be limited to the operating theatre. While final verification on the day of surgery remains paramount, there is no doubt that upstream reduction of the large variety of available implant types, controlling the external environment, and computerized physician order entry of implants in the clinic provide a more solid basis for a safer future.

References

Acher, A.W., LeCaire, T.J., Hundt, A.S., Greenberg, C.C., Carayon, P., Kind, A.J. and Weber, S.M. (2015), "Using human factors and systems engineering to evaluate readmission after complex surgery", *Journal of the American College of Surgery*, Vol. 221 No. 4, pp. 810-820.

Barbeito, A., Bonifacio, A., Holtschneider, M., Segall, N., Schroeder, R., Mark, J. and Durham Veterans Affairs Medical Center Patient Safety Center of Inquiry (2015), "In situ simulated cardiac arrest exercises to detect system vulnerabilities", *Simulation in Healthcare*, Vol. 10 No. 3, pp. 154-162.

Bray, P., Cummings, D.M., Wolf, M., Massing, M.W. and Reaves, J. (2009), "After the collaborative is over: what sustains quality improvement initiatives in primary care practices?", *Joint Commission Journal on Quality and Patient Safety*, Vol. 35 No. 10, pp. 502-508.

Brick, D.C. (1999), "Risk management lesson from a review of 168 cataract cases", *Survey Ophthalmology*, Vol. 43 No. 4, pp. 356-360.

Buchanan, D.R. (2008), "Autonomy, paternalism, and justice: ethical priorities in public health", *American Journal of Public Health*, Vol. 98 No. 1, pp. 15-21.

Carayon, P., Schultz, K. and Hundt, A.S. (2004), "Righting wrong site surgery", *Joint Commission Journal of Quality and Patient Safety*, Vol. 30 No. 7, pp. 405-410.

Carayon, P., Schoofs Hundt, A., Karsh, B.T., Gurses, A.P., Alvarado, C.J., Smith, M. and Flatley Brennan, P. (2006), "Work system design for patient safety: the SEIPS model", *Quality and Safety in Health Care*, Vol. 15 No. 1S, pp. i50-i58.

Carayon, P., Wetterneck, T.B., Rivera-Rodriguez, A., Schoofs, A., Hoonakker, P., Holden, R. and Gurses, A.P. (2014), "Human factors systems approach to health care quality and patient safety", *Applied Ergonomics*, Vol. 45 No. 1, pp. 14-25.

Chang, A., Schyve, P.M., Croteau, R.J., O'Leary, D.S. and Loeb, J.M. (2005), "The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events", *International Journal for Quality in Health Care*, Vol. 17 No. 2, pp. 95-105.

Clarke, C. and Eales-Reynolds, L. (2015), "Human factor paradigm and customer perceptions", *International Journal on Health Care Quality Assurance*, Vol. 28 No. 3, pp. 288-299.

Donabedian, A. (1966), "Evaluating the quality of medical care", *Milbank Mem Fund Quarterly*, Vol. 44 No. 3, pp. 166-206.

Edmondson, A.C. (2003), "Speaking up in the operating room: how team leaders promote learning in interdisciplinary action teams", *Journal of Management Studies*, Vol. 40 No. 6, pp. 1419-1452.

Freidson, E. (1970), *Professional Dominance: the Social Structure of Medical Care*, Artherton Press, New York, NY.

Freidson, E. (2001), *Professionalism*, University of Chicago Press, Chicago, IL.

Frith, K. (2013), "Medication errors in the intensive care unit: literature review using the SEIPS model", *AACN Advanced Critical Care*, Vol. 24 No. 4, pp. 389-404.

Gurses, A.P., Kim, G., Martinez, E.A., Marsteller, J., Bauer, L., Lubomski, L.H., Pronovost, P.J. and Thompson, D. (2012), "Identifying and categorising patient safety hazards in cardiovascular operating rooms using an interdisciplinary approach: a multisite study", *BMJ Quality & Safety*, Vol. 21 No. 10, pp. 810-818.

Haynes, A.B., Weiser, T.G., Berry, W.R., Lipsitz, S.R., Breizat, A.H., Dellinger, E.P., Herbosa, T., Joseph, S., Kibatala, P.L., Lapitan, M.C., Merry, A.F., Moorthy, K., Reznick, R.K., Taylor, B. and Gawande, A.A. (2009), "A surgical checklist to reduce morbidity and mortality in a global population", *New England Journal of Medicine*, Vol. 360 No. 5, pp. 491-499.

Hempel, S., Magard-Gibbons, M., Nguyen, D.K., Dawes, A.J., Miake-Lye, I., Beroes, J.M., Booth, M.J., Miles, J.N., Shanman, R. and Shekelle, P.G. (2015), "Wrong-site surgery retained surgical items, and surgical fires: a systematic review of surgical never events", *JAMA Surgery*, Vol. 150 No. 8, pp. 796-805.

Holden, R. (2011), "What stands in the way of technology-mediated patient safety improvements? A study of facilitators and barriers to physicians' use of electronic health records", *Journal of Patient Safety*, Vol. 7 No. 4, pp. 193-203.

Holden, R.J., Brown, R.L., Alper, S.J., Scanlon, M.C., Patel, N.R. and Karsh, B.-T. (2011), "That's nice, but what does IT do? Evaluating the impact of bar coded medication administration by measuring changes in the process of care", *International Journal of Industrial Ergonomics*, Vol. 41 No. 4, pp. 370-379.

Jin, G.J., Crandall, A.S. and Jones, J.J. (2007), "Intraocular lens exchange due to incorrect lens power", *Ophthalmology*, Vol. 114 No. 3, pp. 417-424.

Joint Commission (2014), *Comprehensive Accreditation Manual for Hospitals*, Joint Commission Resources, Oak Brook, IL.

Joint Commission (2015), *National Patient Safety Goals. Hospital: 2015 National Patient Safety Goals*, Joint Commission Resources, Oak Brook, IL.

Kaplan, G., Bo-Linn, G., Carayon, P., Pronovost, P.J., Rouse, W. and Saunders, R. (2013), *Bringing a Systems Approach to Health*, Institute of Medicine and National Academy of Engineering, Washington, DC.

Kelly, S.P. and Jalil, A. (2011), "Wrong intraocular lens implant; learning from reported patient safety incidents", *Eye (London)*, Vol. 25 No. 6, pp. 730-734.

Langelaan, M., Baines, R.J., Broekens, M.A., Siemerink, K.M., van de Steeg, L., Asscheman, H., de Bruijne, M.C. and Wagner, C. (2010), "Monitor health care related injury in 2008: record study in Dutch hospitals", NIVEL, Utrecht (article in Dutch).

Leape, L., Berwick, D., Clancy, C., Conway, J., Gluck, P., Guest, J., Lawrence, D., Morath, J., O'Leary, D., O'Neill, P., Pinakiewicz, D. and Isaac, T. (2009), "Transforming health care: a safety imperative", *Quality and Safety in Health Care*, Vol. 18 No. 6, pp. 424-428.

Leung, G., Ang, S., Lau, T., Neo, H., Patil, N. and Ti, L.K. (2013), "Patient safety culture among medical students in Singapore and Hong Kong", *Singapore Medical Journal*, Vol. 54 No. 9, pp. 501-505.

Lim, M.K. (2004), "Quest for quality care and patient safety: the case of Singapore", *Quality and Safety in Health Care*, Vol. 13 No. 1, pp. 71-75.

McDaniel, R.R. and Driebe, D.J. (2001), "Complexity science and health care management", *Advances in Health Care Management (Advances in Health Care Management, Vol. 2)*, Emerald Group Publishing Limited, pp. 11-36.

Mack, P. (2002), "Patient safety and medical errors: a Singapore perspective", *Singapore Medical Journal*, Vol. 43 No. 5, pp. 263-264.

Mathew, R., Ferguson, R. and Hingorani, M. (2013), "Clinical negligence in ophthalmology: 15 years of NHS litigation authority data", *Ophthalmology*, Vol. 120 No. 4, pp. 859-864.

Mehta, P.K. and Shenoy, S. (2012), *Infinite Vision: How Aravind Became the World's Greatest Business Case for Compassion*, Harper Collins, New York, NY.

Ministry of Health, Singapore (2015), "Costs and financing cataract surgery.available at: www.moh.gov.sg/content/moh_web/home/costs_and_financing/HospitalBillSize/cataract_surgery.html (accessed 7 November 2015).

Mulloy, D.F. and Hughes, R. (2008), "Wrong-site surgery: a preventable medical errors", in Hughes, R.G. (Ed.), *Patient Safety & Quality: An Evidence Based Handbook for Nurses*, Agency for Healthcare Research and Quality, Rockville, MD, pp. 381-395.

Ogrinc, G., Davies, L., Goodman, D., Batalden, P., Davidoff, F. and Stevens, D. (2015), "SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process", *Joint Commission Journal on Quality and Patient Safety*, Vol. 41 No. 10, pp. 471-479.

Ozkaynak, M., Johnson, S.A., Tulu, B., Donovan, J.L., Kanaan, A.O. and Rose, A. (2015), "Exploring the effects of complex patients on care delivery tasks", *International Journal on Health Care Quality Assurance*, Vol. 28 No. 5, pp. 494-509.

Paull, D.E., Mazzia, L.M., Neily, J., Mills, P.D., Turner, J.R., Gunnar, W. and Hemphill, R. (2015), "Errors upstream and downstream to the universal protocol associated with wrong surgery events in the Veterans Health Administration", *American Journal of Surgery*, Vol. 210 No. 1, pp. 6-13.

Pikkel, D., Sharabi-Nov, A. and Pikkel, J. (2014), "It is the left eye, right?", *Risk Management Healthcare Policy*, Vol. 8 No. 7, pp. 77-80.

Plochg, T., Klazinga, N.S. and Starfield, B. (2009), "Transforming medical professionalism to fit changing health needs", *BMC Medicine*, Vol. 7, p. 64, doi: 10.1186/1741-7015-7-64.

Salahuddin, L. and Ismail, Z. (2015), "Classification of antecedents towards safety use of health information technology: a systematic review", *International Journal of Medical Informatics*, Vol. 84 No. 11, pp. 877-891.

Sarkar, U., Simchowitz, B., Bonacum, D., Strull, W., Lopez, A., Rotteau, L. and Shojania, K.G. (2014), "A qualitative analysis of physician perspectives on missed and delayed outpatient diagnosis: the focus on system-related factors", *Joint Commission Journal on Quality and Patient Safety*, Vol. 40 No. 10, pp. 461-461.

Schein, O.D., Banta, J.T., Chen., T., Pritzker, S. and Schachat, A. (2012), "Lesson learned: wrong intraocular lens", *Ophthalmology*, Vol. 119 No. 10, pp. 2059-2064.

Seiden, S.C. and Barach, P. (2006), "Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events", *Archives of Surgery*, Vol. 141 No. 9, pp. 931-939.

Senders, J.W. and Senders, S.J. (1999), "Failure mode and effects analysis in medicine", in Cohen, M.R. (Ed.), *Medication Errors: Causes, Prevention, and Risk Management*, Jones and Bartlett, Sudbury, MA, pp. 31-38.

Simon, J.W., Ngo, Y., Khan, S. and Strogatz, D. (2007), "Surgical confusions in ophthalmology", *Archives of Ophthalmology*, Vol. 125 No. 11, pp. 1515-1522.

Treadwell, J.R., Lucas, S. and Tsou, A.Y. (2014), "Surgical checklists: a systematic review of impacts and implementation", *BMJ Quality & Safety*, Vol. 23 No. 4, pp. 299-318.

Xie, A. and Carayon, P. (2015), "A systematic review of human factors and ergonomics (HFE)-based healthcare system redesign for quality of care and patient safety", *Ergonomics*, Vol. 58 No. 1, pp. 33-49.

Zamir, E., Beresova-Creese, K. and Miln, L. (2012), "Intraocular lens confusions: a preventable 'never event' – the Royal Victorian Eye and Ear Hospital protocol", *Survey Ophthalmology*, Vol. 57 No. 5, pp. 430-447.

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