KEYWORDS: ACTION RESEARCH, FOCUS GROUPS, TISSUE SPECIMEN, OPERATING ROOMS, PERIOPERATIVE NURSING

SPECIMEN LABELLING ERRORS JUST DON'T CUT IT IN THE OPERATING ROOM

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Understanding the depth of the problem required exploration of how and why the specimen labelling errors reported had occurred (Nakhleh, 2008).

ABSTRACT:

Action research and focus groups are used to address an identified issue with specimen collection in the operating room environment in a New Zealand District Health Board.

INTRODUCTION:

Specimen labelling problems are a patient safety issue which are preventable and could potentially result in serious patient harm from delayed or incorrect therapy or unrecognised malignancy. Research suggests this may be addressed by standardisation of the specimen collection process (Hicks, 2014; Kim, Dotson, Thomas & Nelson, 2013; Layfield & Anderson, 2010; Makary et at, 2007; Slavin, Best, & Aron 2001; Zarbo & D'Angelo, 2007).

The extent to which patient harm has occurred from this issue is not entirely certain with sparse evidence in the literature (Makary etai, 2007). Regular monitoring of our own incident reports through our reporting system identified a rise in specimen labelling related issues within the organisation and though most errors were corrected through the laboratory checking system, there was potential risk to patients. This prompted a proposal to explore and improve the specimen collection process in the Operating Room (OR) and establish a means of regular monitoring of the process as a quality improvement initiative.

Methods of Data Collection: Focus Group and Action Research

A focus group was formed from a convenient sample of 15-20 nurses during their in-service education time from one operating room department. This department was selected due to the high volumes of biopsies obtained from oncology patients in one procedure, with this identified in literature as posing an increased risk of specimen handling errors (Kim et at, 2013; Sehgal, Booth, & Cameron, 2012). The nurses were introduced to the issue by sharing the incidents reported in their department and the effect on patient care as a result; moving on to explore the primary factors they believed led to specimen labelling errors in the operating room and exploration of possible solutions. All ideas were written on a large white board in order to verify understanding and contribute to reflection. A process diagram was

created from the main points, placed in chronological order with international guidelines incorporated, and presented at the second meeting for review.

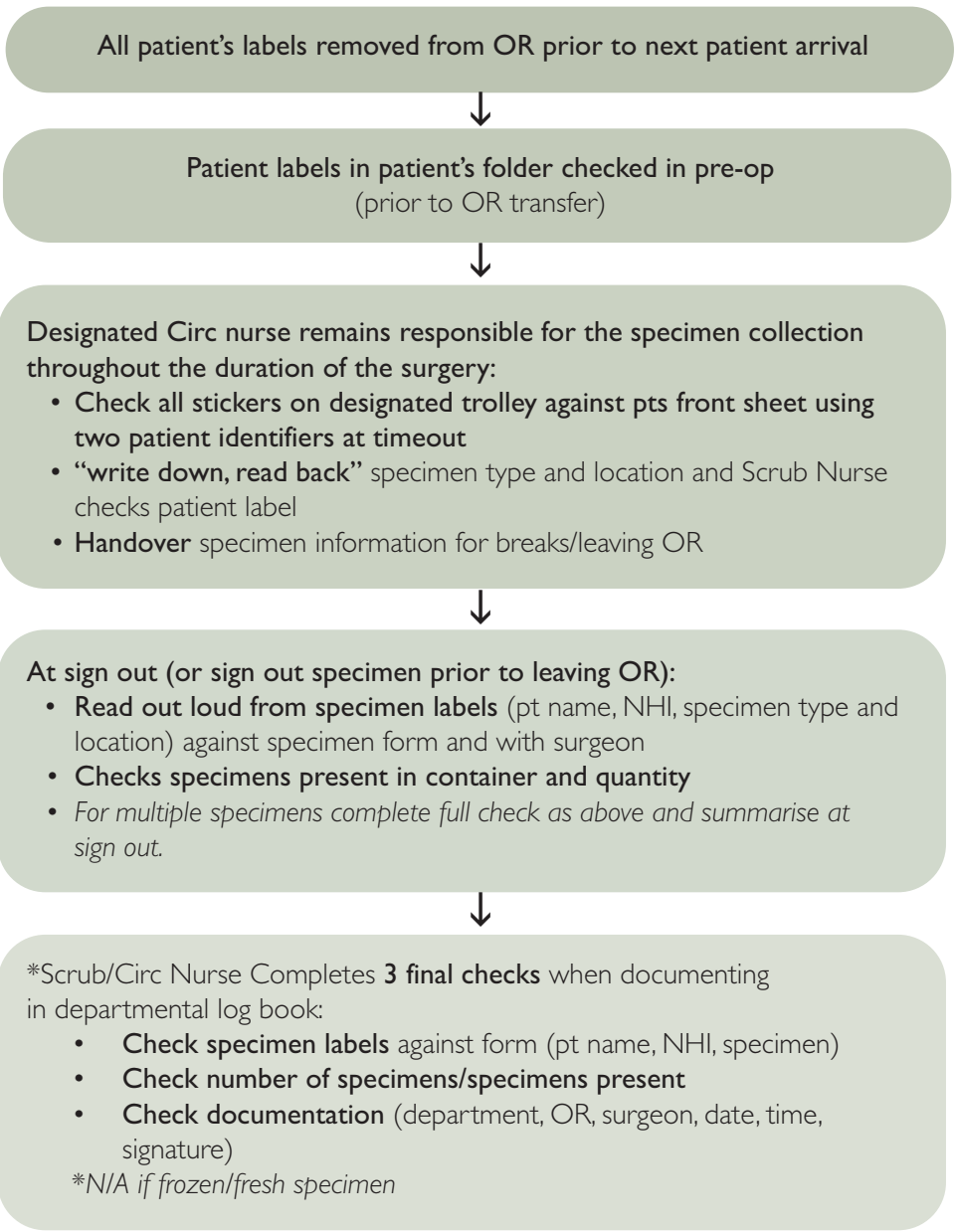
Utilising action research principles meant multiple focus group sessions were required allowing the nurses to review process, put it into practice and feedback on how the process functioned in practice. Potential issues from practice were explored such as time pressures, multi-tasking, individual responsibility and difficulties with checking multiple specimens.

Solutions were tested in practice and discussed at subsequent focus group meetings. On average the group met every two to three weeks for four months. Refining the process continued until the point when the group was satisfied there was nothing left to modify. Action research methods provided the opportunity to empower the group and allowed it to play a participatory role in the research so it could be a part of the solution with focused reflection on action (Curtis & Redmond, 2007). Ideally this provided a more in-depth understanding of how theory influenced practice. The final specimen collection process was then trialled in multiple OR departments with observational audits on practice completed after each trial to refine and develop the process further until a definitive solution was established, documented, laminated and made available in all clinical areas.

Continuing audits monitoring incidents through checking labelling at laboratory entry will not only prompt immediate follow-up, but will involve establishing whether there needs to be further improvements to the process (Kim et al., 2013).

Figure 1: Finalised Specimen Collection Process

(Editor's Note: NHI refers to the New Zealand equivalent of the patient's unique identifying number)



Analysis

Understanding the depth of the problem required exploration of how and why the specimen labelling errors reported had occurred (Nakhleh, 2008). For this purpose, retrospective data was collected from the Auckland District Health Board's (2014) 'Risk Monitor Pro' system for incident reporting and used for qualitative refection.

The laboratory had a system for specimen labelling error correction which included a checking system by staff prior to laboratory entry and lodging incidents for all errors found. A

Table 1: Specimens collected in the OR destined for histology laboratory per year with numbers of labelling errors attributed to the pre-analytical phase (ADFIB, 2014).

Year	Total specimens collected	Number of mislabeling errors	% of errors per specimens collected
2012	8869	1	0.01
2013	9440	15	0.15
2014 (Jan-June)	3508	15	0.42
TOTALS	**21,817**	**31**	**0.14**

report was run of all errors between January 2012 and June 2014 which were classified as a 'diagnostic test' with the associated specific incident type including:

- Identification label/specimen mismatch;
- unlabelled specimen;
- incorrect label; and
- lost specimen.

Each incident description was read and incidents discarded if it was possible the error could not be attributed directly to OR management of the specimen. All remaining incidents were compared against the total numbers of specimens documented on the intra-operative Patient Information Management System and destined for the histology department, in order to establish the denominator and true significance of the issue (Table 1).

The total errors between 2012 and June 2014 were then stratified into specific specimen error types including:

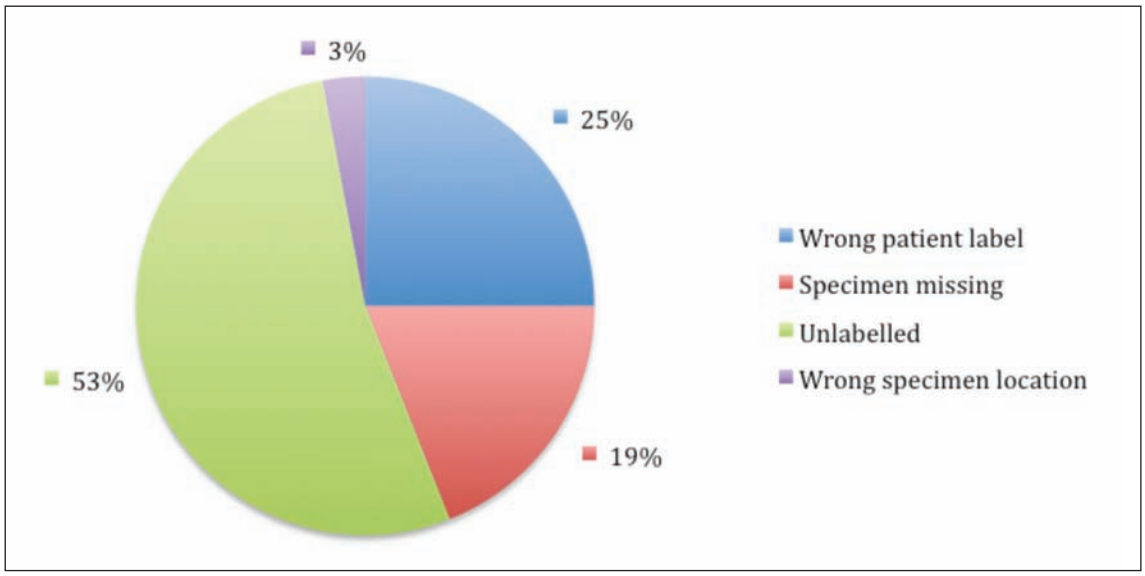
- wrong patient labels where there is a different patient's identification label on the specimen container compared with the requisition form;
- missing patient identification labels on the specimen container; and
- missing specimens where there is a labelled container and requisition form with no specimen present in the container (Figure 2).

An advantage of this method of analysis was it allowed detailed errors to be contextualised (Kohn, Corrigan, & Donaldson, 2000; Mahajan, 2010). The largest group of errors by type were the unlabelled specimens (n=17, 53 per cent of total errors reported) followed by wrong patient identification labels on specimens (n=7,25 per cent) and finally specimens missing from the specimen containers on arrival in the laboratory (n=6,19 per cent).

One specimen had the correct patient identification label but the site of tissue transcribed on the container was incorrect. The impact of the delays in correcting the wrong patient labels and the unlabelled specimens are unknown. However, where there were missing specimens, laboratory testing was unable to be conducted at all. Specimens were reported as being more likely to be lost, mislabelled, misplaced, or not collected at all rather than getting lost upon transportation to the laboratory (Pennsylvania Patient Safety Authority, 2005; Slavin etal., 2001).

On reflection the percentages appear small. However, it is

Figure 2: Percentage of Specimen errors attributed to OR mislabeling categorized according to stratifed groups (ADHB, 2014).



SPECIMEN LABELLING ERRORS (cont.)

important to acknowledge the potential for harm. Just one mis-labelled specimen could have a devastating impact on that person. One such example is outlined in a report completed by the Ministry of Health in 2012 where five sentinel events resulted in unnecessary surgical procedures or no intervention was required, due to mis-labelling and mis-identification of patients in the laboratory phase of specimen processing (National Panel to Review Breast Biopsy Errors, 2012).

Reason's Model was used for analysis and allowed comparison between active errors reported and the standardised process established by the focus group to see exactly where in the process the error can be identified and determine what intervention would be most effective at this point (Figure 3).

Latent errors refer to the errors caused by higher decision-making or are decisions made at a higher level which impact on the practical working conditions such as policies, staffing pressures, time pressures and competing priorities. Active errors are the slips and lapses which have a direct impact on the patient or process (Reason, 2000). The defences are where we can block the errors from occurring. Reason's model takes on two approaches which appealed: the person and the system (Reason, 2000).

One step in particular which was highlighted as a critical checking point was the "sign-out" section of the Surgical Safety Checklist, because it invites the attention of the whole team to focus on the patient safety aspect of the specimen collection. At this point it was important to refine the technique for specimen checking to encourage reading directly from the label on the specimen pot while checking against:

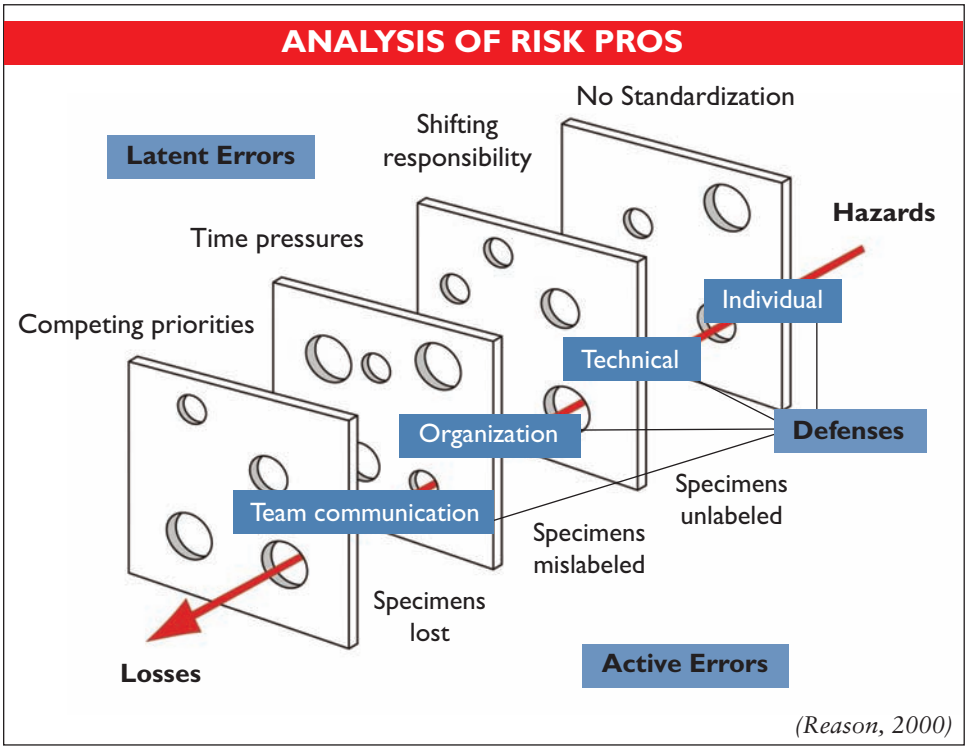
- the laboratory form;
- two patient identifiers;
- the specimen name and site; and
- that the specimen is present.

This particular step in the process has meant sharing expected practice with the multi-disciplinary team while simultaneously introducing changes in the Surgical Safety Checklist process. This critical checking point was also presented at a high level Surgical Board Meeting and supported by all Clinical Directors across the surgical services.

Results

Prior to the quality initiative, specimen labelling errors had been under reported by the histology laboratory and it was therefore difficult to determine accurate error reduction following the introduction of the standardised specimen collection process. There has been a significant reduction in reported errors monitored through the incident reporting process despite an increase in reporting by the laboratory staff. However, more time is required to determine significance in the results due to the infrequency of the error rate.

Figure 3: Reason's cheese model utilised to analyse latent and active risk of specimen labelling errors.



(Reason, 2000)

However, the histology department has self-reported a reduction in specimen labelling errors since the quality project was initiated and on-going monitoring of incidents reported by the lab will ultimately determine the success of the intervention. Education for histology staff about how to accurately report specimen labelling errors from the ORs and reassurance that all specimen labelling errors would be followed up, has led to an increase in incident reporting. Improved communication between the laboratory as a support service and ORs working as a team in the patient continuum, has created a culture of shared patient safety aimed at continuous monitoring and quality improvement.

Discussion

Incidents of specimen labelling issues are infrequent and relatively rare. However, they largely occur at the pre-analytic (OR) and post-analytic (pathology) phases of specimen management. Mislabelled and unlabelled specimens can occur at a rate of 0.4 to 0.1 per cent, however many may go undetected as the process relies on human factors and accurate patient and specimen identification checks (Morrison et al,, 2010). Similar to the results from this project incident report analysis, unlabelled specimen containers were also the highest reported specimen labelling error in a prospective cohort study completed by Makary etal., (2007) aimed at defining and measuring frequency of specimen mislabelling errors in the OR.

It has been recognised that a standardised process is necessary in reducing errors. However, there are no international or national standards currently available which outline the specimen collection process and it has been suggested the responsibility falls between the clinical environment and laboratory gap (Plebani, 2012). Literature suggests this may be addressed by standardisation of the specimen collection process (Hicks, 2014; Kim etal., 2013; Layfield & Anderson, 2010; Makary etal., 2007; Slavin etal., 2001; Zarbo & D'Angelo, 2007).

Standards for practice were integrated within the process to support and provide necessary evidence, making the process replicable in other organisations' OR departments (Connor etal., 2013).

Standardising tasks and processes, reducing the number of possible steps and refining the process reduce variabilities. It also improves patient safety, prevents time wasted following up on specimen errors by laboratory staff, reduces costs and can make the process easier.

Focus group action research assisted with developing a standardized specimen collection process which moved the accountability from the individuals' assumptions about the practice to a systems approach with safeguards built in, as is advised in evidence (Collins, Newhouse, Porter, & Talsma, 2014; Kohn etal., 2000; Anonymous, 2008). Furthermore, the Surgical Safety Checklist's "sign out" provides a forced function which requires the physical examination of the specimen and team discussion, while having the team focus on the patient safety aspect of the specimen collection process (World Health Organisation, 2009). A change in practice results from an intervention designed through collaboration with participants who know the phenomenon within the context of their own practice and are able to challenge existing assumptions (Holter & Schwartz-Barcott, 1993; Plebani, 2012). Action research involves thinking and critical self-reflection on practice which is shared with others and provides opportunity for learning from others (McNiff, 2013).

Reason's analysis of errors illustrates the point that incidents are more likely to be the result of a systems failure rather an individual error. It can instead allow the incident to be viewed beyond the lapse itself to the wider assumptions about human behaviour to identify the organizational context. Reason describes an error as the inability of a planned sequence to reach its intended outcome when this inability cannot be attributed

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to chance (Collins etal., 2014; Kohn etal., 2000).

Specimen collection and handling involves a series of assumed processes which rely on certain safe-guarding organisational principles of patient safety, with the Surgical Safety Checklist representing a formidable barrier to errors if performed as intended (Collins etal., 2014).

There are varied opinions about utilising computer technology such as using bar-coding with the objective of reducing specimen labelling errors (Kim etal., 2013; BhatTiwari, Chavan & Kelkar, etal, 2012). Cost would be an obvious draw back and bar coding would not necessarily be a solution for the 17 unlabelled specimens.

CONCLUSION

Though most internal organisational incidents alert us to near misses of specimen labelling errors in the OR, these have allowed a system which monitors indirect patient safety with the ability to continually improve the quality of care we provide to our patients. The specimen collection process relies on a human function which makes it vulnerable to human elements and organisational influences such as time pressures. Standardising a process such as this allows for consistency and sets a standard by which expectations of practice are set.

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ORNAC Standards pertaining to this article can be found in the Operating Room Nurses Association of Canada (ORNAC) Standards for Perioperative Registered Nursing Practice (12th edition October 2015) Section 3.2.97 to 3.2.113, pages 198 - 200.

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PRNABC celebrated its 50th anniversary at its 25th Biennial Conference, June 24 to 27, in Kelowna, BC. BC Past Presidents (L to R) Rupinder Khotar, Gloria Stephens, Marcy McKay, and Bonnie McLeod were honoured at the event.

La PRNABC a célébré son 50e anniversaire lors de son 25e Congrès biennal qui s'est tenu du 24 au 27 juin, à Kelowna, C.-B. Les anciennes présidentes de la C.-B. (de g. à d.), Rupinder Khotar, Gloria Stephens, Marcy McKay et Bonnie McLeod ont été honorées lors de l'événement.