Pre-analytical specimen labelling and processing errors in the ICU

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ABSTRACT

Introduction: Specimen rejections have been associated with increased in-hospital stay and cost. The majority of errors occur in the pre-analytic phase. Specimen rejection can lead to high rate of recollection, delay in result availability, and high rate of test abandonment. These factors affect patient care and safety.

Methods: This study conducted a retrospective review of Patient Safety Learning System (PSLS) reports for the intensive care unit (ICU) at The Ottawa Hospital General Campus (TOH) between 2010 and 2018, and a prospective review using interviews, surveys, and process mapping.

Results: From 2098 PSLS reports, 52.6% were related to laboratory specimen collection and processing (pre-analytic phase). Specimen mislabelling with the wrong patient identifier accounted for 9.8% of pre-analytical error reports, while 16.4% of errors were due to non-sufficient quantity (NSQ) of specimen. 12.2 % of pre-analytical error reports involved cytology specimens.

Conclusions: Pre-analytical errors are not only costly and resource draining, but may also place a burden on patients. Areas where errors were found include labels and requisitions stored in bedside cabinets, inconsistencies between specimen labels and requisitions, out-dated and difficult to access laboratory manuals, and non-sufficient quantity specimen collection. In the future we hope to start new initiatives to tackle these issues to improve patient safety and hospital efficiencies. This includes the development of a website for the laboratory manual, so that it is more easily accessible and user-friendly. With a new electronic medical record (EMR) system at TOH in 2019, we will explore the affects of pre-analytical processing of specimens.

RÉSUMÉ

Introduction: Les rejets d'échantillons ont été associés à une augmentation du séjour et des coûts à l'hôpital. La majorité des erreurs se produisent dans la phase pré-analytique. Le rejet de l'échantillon peut entraîner un taux élevé de récollection, un retard dans la disponibilité des résultats et un taux élevé d'abandon du test. Ces facteurs affectent les soins et la sécurité des patients.

Méthode: Cette étude a mené un examen rétrospectif des rapports du système d'apprentissage sur la sécurité des patients (SASP) pour l'unité de soins intensifs (USI) du Campus général de l'Hôpital d'Ottawa (L'HO) entre 2010 et 2018, et un examen prospectif à l'aide d'entrevues, de sondages et de processus cartographie.

Résultats: Sur 2098 rapports SASP, 52,6 % étaient liés à la collecte et au traitement des échantillons de laboratoire (phase pré-analytique). Les erreurs d'étiquetage des échantillons avec le mauvais identifiant de patient représentaient 9,8 % des rapports d'erreurs pré-analytiques, tandis que 16,4 % des erreurs étaient dues à une quantité non suffisante (QNS) d'échantillons. 12,2 % des rapports d'erreurs pré-analytiques concernaient des échantillons cytologiques.

Conclusion: Les erreurs pré-analytiques sont non seulement coûteuses et épuisent les ressources, mais peuvent également constituer un fardeau pour les patients. Les domaines où des erreurs ont été trouvées comprennent les étiquettes et les réquisitions stockées dans les tables de chevet, les incohérences entre les étiquettes des échantillons et les réquisitions, les manuels de laboratoire obsolètes et difficiles d'accès et la collecte d'échantillons en quantité insuffisante. À l'avenir, nous espérons lancer de nouvelles initiatives pour résoudre ces problèmes afin d'améliorer la sécurité des patients et l'efficacité des hôpitaux. Cela comprend l'aide au développement d'un site Web pour le manuel de laboratoire, afin qu'il soit plus facilement accessible et convivial. Avec un nouveau système de dossier médical électronique (DME) à L'HO en 2019, nous explorerons les effets du traitement pré-analytique des échantillons.

INTRODUCTION

Clinical decisions are often directly connected to laboratory results. However, these results can be subjected to delays and rejections, and can be attributed to the wrong patient with pre-analytical errors and processing. In an emergency department study, specimen rejections have been associated with increased in-hospital stay and cost.[1] A retrospective review of incident reports in a pediatric emergency department revealed that the majority of errors occurred in the pre-analytic phase involving improper collection, labelling, or loss of specimens.[2] 17.4% of patients were harmed by these errors.[2] In another Emergency Department study, unintended hemolysis occurred in 3.3% of all routine samples, accounting for to 40-70% of all unsuitable specimens.[3]

Specimen rejection can lead to high rates of recollection, delays in result availability, and high rates of test abandonment.[4] Unfortunately, there continues to be a lack of data and review in this field. In the ICU, laboratory samples and specimens are frequently sent for processing. Getting these results in a timely manner can have significant consequences for patients, and can result in potentially costly repeat procedures to obtain specimens that put patients at risk. The focus of this project was to quantify the number of errors that occur in a tertiary ICU as well as to categorize these errors into 3 types.[5]

1. Frequent and able to fix
2. Tolerated and/or difficult to fix
3. Never events/egregious

The study also aims to help identify factors that cause these errors in hopes to improve patient safety and efficiencies.

METHODS

ETHICS

This study was reviewed by the Ottawa Health Science Network Research Ethics Board (OHSN-REB). It was determined that the project is not "human subject research", and falls within the context of quality initiative, quality improvement and quality assurance. A formal review was not required.

QI LOCATION

TOH Intensive Care Unit at the General campus is a 28-bed mixed surgical/medical tertiary care unit. All TOH staff, physicians, and trainees can submit voluntary reports into an electronic database system to identify safety events. This system was created in 2010 and is called the Patient Safety Learning System (PSLS). It is meant to identify system errors to better improve patient safety. Reports range from (not inclusive to) laboratory issues, medical issues, device issues, staff issues, or other system issues including near-misses.

A retrospective review was done of all the PSLS reports submitted to the ICU at TOH between 2010 to 2018. To be considered pre-analytical, an error must have occurred at any point from when the specimen was collected until its delivery to the laboratory. It should be noted that the laboratories attempt to enter all labelling errors and specimen problems into PSLS. The inclusion criteria that were used in this study were as follows:

- Specimen contamination
- Specimen in wrong container
- Specimen improperly prepared/unusable
- Non-sufficient quantity (NSQ)
- Specimen not labelled
- No source indicated on specimen
- Specimen mislabelled (wrong patient identifier)
- Discrepancy between requisition and specimen label (includes discrepancy with patient identifier and source of specimen)
- Requisition missing information
- Specimen leaked on transit
- Specimen was not received at the laboratory

In addition to reviewing the PSLS, a prospective review of specimen labelling and processing was conducted. A walk-through was done from when a specimen was drawn to when it was delivered to the lab. Observation and interviews were conducted with physicians, nurses, clerks, laboratory technicians, and managers.

A survey was conducted with ICU nurses to identify how specimen labelling and processing could be improved, and to identify any concerns. Surveys were handed out and emailed to ICU nurses and voluntarily answered. These surveys were completed between July and August 2018. A copy of the survey can be seen in the supplement section.

RESULTS

There was a total of 2098 PSLS reports attributed to

the ICU at TOH between 2010 to 2018 (laboratory and non-laboratory related). Of those reports, 1104 (52.6%) were related to pre-analytical issues (collection, labelling, processing, preparation, and transit of specimen before analysis).

Table 1: **Break-down of pre-analytical issues in the ICU at TOH (numbers and percentages).**

Pre-analytical issue	Number (percentage) of pre-analytical related PSLS in the ICU at the General Campus (%)
Specimen contamination	118 (10.5)
Specimen in wrong container	64 (5.6)
Specimen improperly prepared/un-usable	105 (9.5)
Non-sufficient quantity	181 (16.4)
Specimen not labelled	138 (12.4)
No source indicated on specimen	168 (14.0)
Specimen mislabelled (wrong patient identifier)	118 (9.8)
Discrepancy between requisition and specimen label (includes patient identifier and specimen source)	88 (7.9)
Requisition missing information	91 (8.0)
Specimen leaked on transit	38 (3.5)
Specimen not received at the labo-ratory	27 (2.4)
Total	**1104 (100)**

A further breakdown of the 1104 pre-analytical related PSLS reports can be seen in **table 1**. The majority (52.1%) of pre-analytical errors stemmed from labelling specimen and requisition information (which included specimen not labelled, mislabelled, and requisition missing information or discrepancy with label). Specimen preparation issues accounted for 42.0% of errors (**table 1**). There appears to be a progressive increase in the portion of NSQ related errors by year, while other errors have fluctuation over the years with no trend that can be seen (**table 2**).

Table 3 shows the breakdown by type of specimen involved in the pre-analytical PSLS in the ICU at TOH. The majority of pre-analytical PSLS were related to blood specimen, including biochemistry and hematology. Data from the Cerner Millennium, the Laboratory Information System used at TOH approximates 8992 specimens are sent for biochemistry and hematology testing per year from the ICU. Pre-analytical issues in the ICU related to blood specimen occur in less than 1% of all biochemistry and hematology testing sent.

Cytology specimens were the second highest specimen type with pre-analytical issues and PSLS reports. There was an average of 530 PSLS reports per year for cytology specimens for all units at TOH .

Table 2: **Break-down of pre-analytical issues in the ICU at TOH grouped by years (numbers and percentages).**

	Number (percentage) of pre-analytical related PSLS in the ICU at the General Campus (%) broken down by year								
Pre-analytical issue	2010	2011	2012	2013	2014	2015	2016	2017	2018
Specimen contamination	2 (33.3)	9 (4.4)	28 (17.8)	21 (9.1)	14 (10)	11 (9.4)	11 (8.7)	16 (17.6)	6 (25)
Specimen in wrong container	0 (0)	13 (6.3)	8 (5.1)	21 (9.1)	5 (3.6)	12 (10.2)	1 (0.8)	2 (2.1)	0 (0)
Specimen improperly pre-pared/unusable	0 (0)	17 (8.3)	13 (8.3)	14 (6.1)	11 (7.9)	18 (15.4)	17 (13.3)	10 (10.4)	5 (20.1)
Non-sufficient quantity	0 (0)	3 (1.5)	2 (1.3)	48 (20.9)	15 (10.7)	23 (19.7)	55 (43.3)	27 (28.1)	8 (33.3)
Specimen not labelled	2 (33.3)	46 (22.3)	28 (17.8)	20 (8.7)	15 (10.7)	14 (12.0)	6 (4.7)	3 (3.1)	2 (8.3)
No source indicat-ed on specimen	0 (0)	64 (31.1)	16 (10.2)	15 (6.5)	14 (10.0)	10 (8.5)	14 (11.0)	18 (18.8)	3 (12.5)
Specimen mislabelled (wrong patient identifier)	0 (0)	18 (8.7)	10 (6.4)	27 (11.7)	29 (20.7)	9 (7.7)	8 (6.3)	7 (7.3)	0 (0)
Discrepancy between req-uisition and specimen label (includes patient identifier and specimen source)	1 (16.7)	13 (6.3)	16 (10.2)	28 (12.2)	9 (6.4)	9 (7.7)	6 (4.7)	4 (4.2)	1 (4.2)
Requisition missing infor-mation	0 (0)	9 (4.2)	21 (13.4)	23 (10.0)	20 (14.3)	7 (6.0)	3 (2.4)	5 (5.2)	0 (0)
Specimen leaked on transit	1 (16.7)	11 (5.3)	11 (7.0)	8 (3.5)	4 (2.9)	1 (1.0)	1 (0.8)	0 (0)	1 (4.2)
Specimen not received at the laboratory	0 (0)	3 (1.5)	4 (2.5)	5 (2.2)	4 (2.9)	3 (2.6)	4 (3.1)	3 (3.1)	0 (0)
Total	**6 (100)**	**206 (100)**	**157 (100)**	**230 (100)**	**140 (100)**	**117 (100)**	**126 (100)**	**95 (100)**	**24 (100)**

Twenty-five surveys were voluntarily completed by ICU nurses. All the nurses stated that they experienced pre-analytical errors which included labelling issues or preparation of specimen. Only 64% of nurses who answered the survey were aware of the existence of a laboratory manual which would serve as a resource to help with preparation of specimen (**table 3**). Many of the nurses who have used the laboratory manual stated that the laboratory manual was difficult to find, lacked key information, or was not user friendly. For noteworthy quotes from the survey, please refer to the supplement section.

Table 3: **The numbers and percentage of type of specimen involved in pre-analytical PSLS.**

Type of specimen	Number (percentage) of pre-analytical related PSLS in the ICU at the General Campus (%)
Blood	648 (57.1)
Cytology	153 (12.2)
Urine	61 (5.5)
Swab	84 (7.6)
Feces	48 (4.4)
Other	2 (0.1)
Not documented	108 (9.8)
Total	**1104 (100)**

Table 4: **Survey responses by ICU nurses at TOH.**

Issues	Number of nurses (total 25)
Experienced pre-analytical errors	25
Discrepancy with orders and requisitions	19
Uncertainty of preparation	21
Aware of laboratory manual	17
Use the laboratory manual	5
Difficult accessing and/or using laboratory manual	15

Through our process mapping and surveys, we were able to identify possible causes of errors. In the ICU department at TOH there are cabinets beside the nursing stations that store patients' labels and requisitions. During admission or a room change, a previous patient's labels could still be in the cabinets and mistakenly used.

Another source of error is while labelling cytology samples and filling out requisitions. In the ICU this mostly involves a bronchoscopy or cerebral spinal fluid specimens. For the specimen to be analyzed and tested, the source on the specimen label and the requisition must be exactly the same for the laboratory to process it. If the physician fills out the requisition while the respiratory therapist or nurse labels the specimen, this poses a potential for error. If there is any miscommunication, there will be a discrepancy between the label and requisition, and the specimen will be rejected. Some of these errors can be corrected without loss of the specimen, but this still requires resources and time.

DISCUSSION

While < 1 % of specimen testing may lead to a PSLS, these errors account for > 50% of all PSLS in the ICU and represent a large absolute number per year.

Serious pre-analytical issues such as labelling a tube with the wrong patient name should be improved upon and actively prevented. Errors which involve wrong patient label on specimen and requisitions can contribute to a "never event"[5] as they can have serious consequences, (i.e., if it were to happen on a blood cross matching test).

Other types of pre-analytical errors drain resources, through time to report the error, time to contact treating team to resend samples, and the need for additional supplies for the new sample. PSLS reviewers need time to review the multitude of reports. This could take away resources from other safety issues in the PSLS if the system is being overwhelmed with pre-analytical issues. Given the absolute number of errors (520 PSLS reports per year), it becomes a huge burden for the laboratory and ICU. As one technologist for cytology says: "it does use significant resources for us to reject a specimen since we have to phone the unit to advise of the problem and how to correct it, fill in a rejection letter explaining the problem, complete the PSLS, and order a transportation worker to come pick up the specimen to return to the unit." Pre-analytical issues also affect nurses and physicians who must divide resources and time to recollect samples and follow up with the laboratory. These errors also have a financial effect. Eastern Ontario Regional Laboratory Association (EORLA) estimates the cost of each phlebotomy (blood drawn from patient) approximately $11.

The people most affected by pre-analytical issues are the patients, who have to provide another sample and potentially stay in the hospital longer because of testing

result delays. With any additional procedure (including but not limited to phlebotomy, bronchoscopy, and biopsy) the patient undertakes additional risk of bleeding, infection and other complications.

The most common cytology specimens in the ICU are bronchoscopy and cerebral spinal fluid samples. Sample rejection due to pre-analytical errors cause two potential problems: cost to the healthcare system and difficulty in collecting a second sample.

Based on the surveys conducted, nurses explain that when there is confusion with how to prepare a specimen, which tubes to use, and how many tubes to send, there is no one single resource for them to review. At TOH there are lab manuals that provide some information on how to prepare specimen for specific tests however. The lab manual itself, however, is hard to find and access, difficult to navigate, and sometimes lacks essential information (i.e., which tubes, and how many tubes to use). There are also times in which there are discrepancies between what is in the manual and what the laboratory technicians require for the test.

Miscommunication can cause errors in sample testing. For example, there may be discrepancies between physician orders and the actual test intended, due either to orders in short hand form or to physician-written orders not found on a requisition. However, the introduction of a new electronic medical record (EMR) system at TOH may have positive effects on pre-analytical errors. This error might be deemed Type 2 error (i.e. tolerated) since for now there is change planned for the future versions of the EMR which should reduce this issue.

Non-sufficient quantity represents a significant percentage of pre-analytical issues as well as progressive increase in the proportion of the errors. The majority of NSQ are for INR and PT testing in blood. For these tests to be meaningful, the sample tube must be filled with blood to a specific amount. If there is too much or too little blood mixed with the prefixed anticoagulant in the tube, it cannot be processed. Since the results of this study have been made available, the hospital has started using new tubes with double lines acting as a guide for filling INR sample tubes. The results of this initiative are still unclear and will need further investigations. It is important to note that NSQ samples are rejected automatically by the machine and not by a human, which was a popular misconception on the unit. There could be some benefit in educating ICU staff members of this fact to improve communication and avoid sending samples that are NSQ. This is a type 1 error (i.e. able to fix) and would address 16.4% of PSLS pre-analytic reports.

A limit of this study is the voluntary nature of PSLS (though the policy at the laboratory at TOH is to input to the PSLS all specimens which are rejected or returned for any reason). For study purposes, we assumed that the number of errors correlated with the number of PSLS reports. However, not all errors may have been reported and therefore the number of pre-analytical errors may be underestimated by PSLS. Due the nature of the PSLS reports, we were unable to attribute adverse events/harm based on the reports. Another limitation of the study is its scope; we focused only on one department in one campus of The Ottawa Hospital. This issue is likely wide-spread, but not all issues and potential solutions can be applied to the entirety of the units and departments in the hospital. Lastly, the sample size for our surveys was small. We only collected 25 surveys from nurses. However; the issues and comments were fairly consistent across the surveys.

We would argue that specimen preparation issues occur frequently and, based on surveys, can be reduced with an improved lab manual, implementation of a new EMR system (which occurred in 2019), more education, and the introduction of new tubes. We would argue that mislabelling that requires recollection of specimen—especially for difficult and invasive specimens (eg. bronchoscopy specimens, cerebral spinal fluids specimens)—should be never events. The rejection and recollection of these samples places a large burden on ICU staff, laboratory staff, and the patient themselves. In the future we plan to work with the laboratory to produce a user-friendly manual, and we plan to expand this work to other units and departments. We are currently working towards building a website that can house the laboratory manual which would help to enable better access. The hope with the website is to clarify the preparation process of specimens (such as type of tubes, amount needed) so they can be properly analyzed in the laboratory and to make labeling process more clear. It is unclear what the effects of the implementation of the new EMR system at TOH has had on pre-analytical errors. More research and

study will need to be done with the new EMR system.

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