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Making sense of a haemolysis monitoring and reporting system: a nationwide longitudinal multimethod study of 68 Australian laboratory participant organisations

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Abstract

Background: The key incident monitoring and management systems (KIMMS) quality assurance program monitors incidents in the pre- and postanalytical phases of testing in medical laboratories. Haemolysed specimens have been found to be the most frequent preanalytical error and have major implications for patient care. The aims of this study were to assess the suitability of KIMMS for quality reporting of haemolysis and to devise a meaningful method for reporting and monitoring haemolysis.
Methods: A structured survey of 68 Australian KIMMS laboratory participant organisations was undertaken. Quarterly haemolysis reports (2011–2014) were analysed.
Results: Among 110 million accessions reported, haemolysis rates varied according to the reporting methods that participants used for assigning accessions (16% of participants reported haemolysis by specimen and 83% reported by episode) and counting haemolysis rejections (61% by specimen, 35% by episode and 3% by test). More than half of the participants (56%) assigned accessions by episode and counted rejections by specimen. For this group, the average haemolysis rate per 100,000 episodes was 177 rejected specimens with the average rate varying from 100 to 233 over time. The majority of participants (91%) determined rejections using the haemolysis index. Two thirds of participants (66%) recorded the haemolysis manually in laboratory information systems.
Conclusions: KIMMS maintains the largest longitudinal haemolysis database in the world. However, as a means of advancing improvements in the quality of the preanalytical laboratory process, there is a need to standardise reporting methods to enable robust comparison of haemolysis rejection rates across participant laboratories.

Keywords: haemolysis; laboratory medicine; laboratory monitoring and management systems; patient safety; preanalytical errors; quality control; specimen rejection.

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Introduction

Haemolysis refers to the breakdown of red blood cells (also known as erythrocytes) and the release of haemoglobin into the surrounding fluid [1]. Haemolysis is one of the most common causes of preanalytical errors, which can affect the integrity of a blood specimen and the reliability of laboratory results [2, 3]. The presence of haemolysed specimens has major implications for the quality and safety of patient care [4, 5], constituting an area of major importance for laboratories in Australia and around the world [2]. Benchmark data about the prevalence and variation of haemolysis across laboratories can make a valuable contribution to the development of safe practises to reduce haemolysis and potential errors in laboratory results. Reduction in haemolysis rates can enhance the effectiveness of laboratory services and their contribution to safe and quality patient care.

Benchmark data at local, regional and national level have not been widely available. In 2009, 156 European laboratories participated in a survey about practises for

identifying and rejecting haemolysed specimens [6]. The survey was launched under the auspices of the European Scientific Advisory Board (now Global Preanalytical Scientific Committee) [7]. In the United States, 772 laboratories reported their haemolysis identification and rejection practises to a similar survey conducted by Howanitz et al. [8]. Both surveys found that haemolysis practises varied widely, and about 70% of laboratories reported a haemolysis rate below 2.9%. However, these surveys provided information only at a single point in time and did not track changes over time.

The key incident monitoring and management systems (KIMMS) project in Australia has established an ongoing patient safety project to monitor laboratory incidents, including haemolysis. The project was originally developed by the Royal College of Pathologists of Australasia and was made available through the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) and funded by the Australian Department of Health via a Quality Use of Pathology Program (QUPP) grant. Laboratories from across all Australian States and Territories submit data on a quarterly basis to a centralised repository to establish a benchmark of incidents and monitor data for a variety of different types of preanalytical errors (e.g. patient misidentification, incorrect specimen labelling, haemolysed specimens and other specimen problems) and postanalytical errors (e.g. results going to an incorrect destination or recipient and amendment or retraction of laboratory results already issued). Although the programme is open to laboratories overseas, at this stage there are only Australian-based participants.

The KIMMS database provides an opportunity to investigate existing laboratory practises for identifying and reporting haemolysis and to establish benchmark data over time. One of the barriers preventing the aggregation of benchmark data is the wide variation of criteria for the identification and rejection of haemolysed specimens currently used by laboratories in KIMMS. The aims of this study were thus (1) to assess suitability of KIMMS for quality monitoring of haemolysis across laboratories and (2) to devise a standardised reporting and analysis method to examine the prevalence and variations in practise of haemolysis rejection.

Materials and methods

Study design and participants

This was a retrospective cohort study utilising the haemolysis data collected in the KIMMS database from 2011 to 2014. In the KIMMS database, the term "participants" can refer to either a single physical laboratory or a group of affiliated laboratories at one or more physical locations. Each participant enroled and submitted aggregated quarterly reports of all individual laboratories within the participant organisation to the KIMMS database.

Haemolysis

The KIMMS database recorded instances when any specimens where one or more tests were not performed or one or more results were rejected or not reported due to haemolysis. It should be noted that not all haemolysed specimens are necessarily rejected. Participants considered many factors when deciding whether or not to reject a specimen, including the types of tests that were requested on a specimen and the test assay's sensitivity to haemolysis. Terminology used in the KIMMS database, such as accession, is defined in Table 1.

Structured survey

There were a variety of methods that laboratory participants used for accessioning and for counting haemolysis rejections. Participants variously assign accessions by episode, where multiple specimens and tests to be conducted for a single patient were all grouped into a single accession number, or by specimen, where each specimen was assigned its own accession number (even if it belonged to the same episode as other specimens with different accession numbers). Similarly, participants variously counted haemolysis rejections according to the number of episodes affected by haemolysis, according to the number of specimens affected by haemolysis, or according to the number of tests affected by haemolysis.

Because of this variety in the way different laboratories record their data, not all this information was consistently captured in KIMMS. We devised and conducted a structured survey (see Table 2) to clarify these parameters and gain an understanding of how laboratories captured their data in practise. The survey asked participants to describe: (a) the source of the majority of specimens arriving at their laboratories and whether most specimens were collected by laboratory phlebotomists or clinical staff, (b) the definition used for assigning accessions, (c) what method was used to detect haemolysed specimens, (d) whether haemolysis rejections were identified in the specimen reception area (SRA) or within each laboratory department, (e) how these rejections were recorded in laboratory information systems (LIS) and (f) how rejections were defined for the numerical counts submitted to KIMMS.

Data and data linkage

Data were extracted from the KIMMS database across 16 quarterly data reports covering a total period of four calendar years (2011–2014). The survey data were linked with the KIMMS quarterly data by de-identified laboratory participant numbers. Ethical approval was obtained from the UNSW Australia and the Macquarie University Human Research Ethics Advisory Panels (9_13_037).

Table 1: Definitions of terms used in the KIMMS database.

Term	Definition
Test	An individual laboratory assay request to be processed by the laboratory
Specimen	Broadly defined as a container of tissue for which one or more tests have been requested. Examples of tissue are blood, urine, faeces, pus, and other body fluids and solid tissue. Containers with specific preservatives would normally be regarded as different specimens from the same episode However, in this article, as we are dealing with haemolysis of blood samples, we generally use the term to mean a blood specimen, unless otherwise specified
Episode	A collection of one or more tests, to be conducted on one or more specimens, that constitute a single request (order) for a single patient, generally taken at a single point in time
Accession	An accession is a laboratory identification number assigned by the laboratory to allow identification, tracking and reporting of results in laboratory information systems [9] for one or more tests. Accessions can be typically assigned (i) by episode – which can include multiple individual blood specimens drawn at the same time or over a short period, or multiple tests run for the same patient; – by laboratory department, (ii) or by specimen – multiple individual specimens can be taken at once, but in this case they are each assigned different tracking numbers; – and this may vary between laboratories and organisations

Table 2: KIMMS participant survey questions.

Participant number: _____
(1) How are KIMMS accessions assigned?
(a) per sample (b) per episode
(2) What Disciplines do you collect accessions from? _____
(3) Are these the same as those you collect KIMMS data from? Yes/No
(4) Approx. proportion of accessions for each discipline _____
(5) Has the KIMMS data been consistently counted since 2011? Yes/No
(6) What proportion of your accessions come from?
(a) public hospital _____ (b) private hospital _____
(c) GP/specialist/other____
(7) What proportion of your accessions are collected by:
(a) your employees _____ (b) other _____

Haemolysis rejections
(8) How do you count Haemolysis rejections?
(a) per tube (b) per test (c) per department (d) per episode
(9) Where do you decide the haemolysis rejections?
(a) specimen reception area (SRA) (b) destination laboratory department (c) mix
(10) How do you decide haemolysis rejections-haemolysis index (HI)? Yes/No
(11) Recorded in the LIS
a) automatically (b) manually (c) mix

Statistical analysis method for reporting haemolysis

When examining the characteristics and practises of participating organisations, we included all accessions in the analysis. However, occasionally, participant organisations failed to report haemolysis data within their overall KIMMS submission, so only those quarterly submissions with data submitted by a laboratory on its haemolysis reporting were included in the haemolysis-related analyses. The haemolysis rejection rate was calculated by dividing the number of haemolysis rejections by the number of accessions (variously defined, see earlier) reported by the participant for a given time period. It was not appropriate to calculate an overall haemolysis rejection rate for the entire KIMMS data set because participants assigned accessions and counted haemolysis rejections using a variety of definitions (as described above). The haemolysis rejection rates and their 95% confidence intervals (CIs) were calculated for participants for each of the five different combinations of accessioning practises and methods for counting haemolysis. Data analyses were conducted using SAS software, Version 9.4 of the SAS System for Windows. Copyright © 2002–2012 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA.

Results

KIMMS laboratory participants' characteristics

A total of 1017 quarterly reports were submitted to KIMMS from 68 participants across Australia from 2011 to 2014. On average, 7,103,487 accessions per quarter were reported (a total of 113,655,796 accessions). The majority of participants (n = 57; 84%) reported accessions by episodes, the rest (n = 11; 16%) by specimens. Table 3 shows that the majority of participants (n = 51; 75%) received most of their specimens from inpatients in government public hospitals; this group accounted for more than one third of all accessions (37%) and three participants who received an approximately equal number of accessions from inpatients in both public and private hospitals. Another group

Table 3: Source of the majority of specimens.

Specimens collected from	No. of participants	% of participants	No. of accessions	% of accessions
Other (outpatient, referred patient, etc.)	13	19	65,079,684	57
Hospital-public	51	75	41,579,102	37
Hospital-public and private	3	4	5,985,420	5
Hospital-private	1	1	1,011,590	1
Total	68	100	113,655,796	100

Table 4: Staff type which collected the majority of specimens.

Specimen collector	No. of participants	% of participants	No. of accessions	% of accessions
Laboratory phlebotomist	47	69	81,288,155	72
Both	3	4	8,259,610	7
Clinical staff	11	16	8,169,686	7
(Missing/unknown)	7	10	15,938,345	14
Total	68	100	113,655,796	100

of participants (n = 13; 19%) reported that most of their accessions came from other sources (outpatient, community patient, referred patient etc.). This group accounted for over half of all accessions in the KIMMS database (57%). A total of 47 participants, accounting for 72% of all accessions, reported in the survey that laboratory phlebotomists did most of the specimen collections (Table 4).

Haemolysis

Almost all quarterly reports (n = 1002; 99%) included haemolysis rejection data (Table 5). A total of 230,845 haemolysis rejections were reported. Forty-two participants (62%) counted their haemolysis rejections by specimen, 24 (33%) by episode and two by test (3%). Two thirds of participants recorded the haemolysis rejections by manually entering them into the laboratory information system (LIS) (n = 45; 66%), and only one quarter were automatically recorded by the analysing equipment that interfaced with the LIS (n = 18; 26%), and three participants (4%) reported using both recording methods.

Haemolysis detection location and methods

Out of 68 participants, the majority (n = 62; 91%) reported that the haemolysis detection process occurred when the specimen arrived in the destination laboratory department; five other participants (7%) reported that the haemolysis detection process occurred in the SRA or the destination laboratory departments and the one remaining participating organisation did not report where the detection occurred.

Similarly, 62 participants (91%) decided rejection using the haemolysis index (HI) and five other participants (7%) made these decisions without the index, i.e. visual inspection, including the use of a colour chart. The one remaining participating organisation did not report how they made these decisions.

Table 5: Haemolysis rejections by reporting groups.

Accession assigned by	Haemolysis counted by	No. of participants	No. of quarterly submissions	No. of haemolysis rejections	No. of accessions	Rate, number of rejections per 100,000 accessions (95% CI)	Percentage of haemolysis rejections of all accessions
Per specimen	Per specimen	4	27	15,190	18,505,638	83 (81–84)	0.08%
	Per episode	7	110	69,052	5,300,854	1303 (1293–1313)	1.30%
Per episode	Per specimen	38	579	70,605	39,997,983	177 (176–178)	0.18%
	Per test	2	32	3,466	22,147,372	16 (15–17)	0.02%
	Per episode	17	254	72,532	26,928,824	270 (268–272)	0.27%
Total		68	1002	230,845	112,880,671		

Prevalence and variation of specimens rejected due to haemolysis

Given different methods were used for accessioning and for counting haemolysis rejections, the haemolysis rejection rates were reported separately (see Table 5) for the five groups using different combinations of accessioning practises and methods for counting haemolysis. The largest group of participant organisations (n = 38) with the most accessions reported (~40 million) who defined accessions assigned by episode and haemolysis rejections counted by specimen reported a mean haemolysis rejection rate of 177 rejections per 100,000 accessions. The second largest group of participant organisations (17 organisations with ~27 million accessions, accessions assigned by episode, haemolysis rejections counted by episode) reported a mean haemolysis rejection rate of 270 rejections per 100,000 accessions.

To examine the haemolysis rejection rates over time, we focused the subsequent analysis on the 38 participant organisations who used the most common method of accessioning and counting haemolysis rejections, i.e. accessions assigned by episode, haemolysis rejections counted by specimen. Haemolysis specimen rejections per 100,000 episodes for each quarter and year of the study period are presented in Figure 1. The quarterly haemolysis rejection rate between 2011 and 2014 fluctuated between 100 and 233 rejections per 100,000 accessions. The variations of haemolysis rejection rates between 38 participant organisations were very similar over time as shown in the 95% CIs in Figure 1.

Discussion

To our knowledge, KIMMS maintains the largest existing longitudinal haemolysis data set in the world. The results of this study revealed considerable variation between participants with respect to where the majority of accessions came from, which type of staff performed the actual specimen collections, what method was used for haemolysis detection, where it occurred in the laboratory process and how rejections for haemolysis were counted. Broadly speaking, the prototypical KIMMS participant organisations received most of the specimens from inpatients in public hospitals, received a majority of specimens that had been collected by phlebotomists, identified haemolysed specimens within each laboratory department using the HI result generated by a chemistry analyser, assigned accessions according to the episode, counted haemolysis rejections per specimen and recorded this information manually in LIS.

This study also identified areas that could improve the quality of future reporting and monitoring of haemolysis rejections. First, the most important conclusion

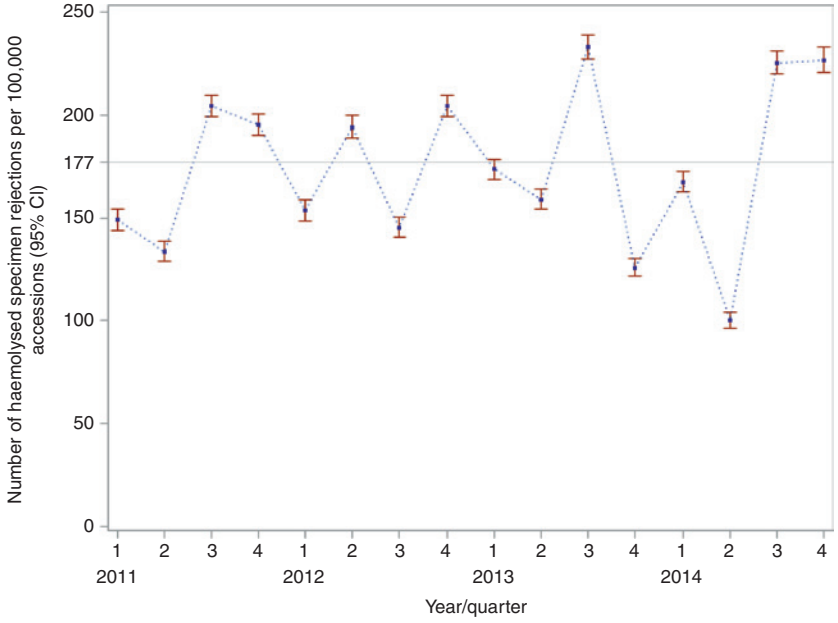

Figure 1: Numbers of haemolysis specimen rejections per 100,000 episode accessions from the first quarter (Q1) of 2011 to the fourth quarter (Q4) of 2014 for the 38 KIMMS participants who assigned accessions per episode and counted haemolysis rejections per specimen (overall mean = 177 specimen rejections per 100,000 episode accessions as shown by the horizontal line, i.e. 0.18% of all accessions).

is that there is a need to standardise reporting methods among the KIMMS participants. Of 68 participating organisations, a variety of methods were used for accessioning and counting haemolysis rejections, this systematically influenced the haemolysis rejection rates and made it inappropriate to compare haemolysis rejection rates between laboratory participants that had used different methods. Without standardisation of these recording metrics, deriving useful comparisons, benchmarks and targets will not be possible. Participants varied both in how they assigned accessions (whether it was according to the specimen or to the episode, definitions see Table 1) and how they counted haemolysis rejections for submission to the KIMMS database (by episode, by specimen or by test). Episodes can contain multiple specimens upon each of which multiple tests might be requested. Because the haemolysis rejection rate was calculated by dividing the number of haemolysis rejections by the number of accessions processed by the participant for a given period, differences in how these were defined systematically altered the resultant rates. Participants who counted haemolysis rejections per test recorded a lower rate of haemolysis rejections (16 rejections per 100,000 accessions for two participants) compared with other participants, but this low rate is probably an artefact of how they capture and report their data.

Second, KIMMS participant laboratories did not report haemolysis detection methods and their operational haemolysis cutoff parameters, including the criteria used for haemolysis rejections. Nor did they report the assay methodology and/or the instrumentation that was used, which may determine the point at which haemolysis interferes with the accuracy of a result. These factors would have influenced the rate of haemolysis rejection reported.

Third, we identified a need for the KIMMS participants to report blood specimen accessions separately. Haemolysis mainly affects blood specimens, while participants contributing data to the KIMMS database reported their activity by the number of accessions for all types of specimens (including tissue specimens, and faeces, etc., for which haemolysis was not necessarily relevant). Although the majority of the specimens collected in the laboratories were blood specimens and haemolysis is one of the most common causes of preanalytical errors [2, 3], laboratories' haemolysis rates would be systematically affected by the proportion of their activity that was performed on other than blood specimens. When the haemolysis rate is calculated using the total number of accessions (regardless of specimen type), laboratories whose activity was dominated by tests on blood specimens would report artificially higher rates of haemolysis than laboratories that did a smaller proportion of tests on blood specimens.

Fourth, providing regular feedbacks to laboratory participants will help them to track their performance over time, to enable comparison and benchmarking with their peers. We devised a reporting and analysis method to examine the haemolysis rates for participants. Based on participants' reporting methods, five haemolysis rejection rates were calculated by dividing the number of haemolysis rejections by the number of accessions.

Lastly, we identified the lack of information about KIMMS participants and their haemolysis detection and reporting practises. We conducted a survey to retrospectively collect the missing information (Table 2). This information should be reported when participants begin to report to KIMMS and then regularly updated (e.g. on a quarterly basis). The findings from this study highlight the need for newer data collection methods for haemolysis identification reporting, which take advantage of the widespread use of electronic LIS in laboratory services. We found that two thirds of KIMMS participants recorded the haemolysis rejections manually in their LIS. A 2014 survey of Australian biochemistry laboratories reported that 97% of respondents were using an electronic LIS [10]. Using routinely and automatically collected and recorded data from the LIS reduces the likelihood of errors in the data submitted [11, 12] and facilitates the process of sharing data with the KIMMS database, potentially allowing for more frequent update intervals and a faster feedback loop. Various electronic laboratory systems, while undoubtedly useful, are yet to embrace all of their potential because of problems with the interoperability between systems and the aggregation of data [13, 14]. Aggregating data across these multiple systems, and from laboratories employing different criteria and definitions, would greatly facilitate the monitoring of laboratory quality performance and provide a valuable means to generate research evidence.

Despite the limitations of KIMMS data, the overall haemolysis rates, ranging from 0.02% to 1.3% depending on the ways of reporting (Table 5), concur with other literature. Based on the data from the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the median haemolysis rates varied from 0.270% to 0.850% during the period of 2009–2013 [15]. A literature review located 37 studies published between 2000 and 2014, which reported an overall rate of haemolysis and methods used to detect haemolysis (HI and/or visual inspection) [16]. A considerable variation in haemolysis rates reported in the literature was identified. Seven

studies reported a haemolysis rejection below 1% of all accessions [17–23], six between 1% and 3% [24–29], 20 between 3% and 20% [9, 30–48] and another four above 20% [49–52]. Haemolysis detection methods, and free plasma haemoglobin levels used for this detection, are likely to be partly responsible for this variation, in addition to the differences in study designs and study populations. Although further research is called for to understand these factors related to variation of haemolysis rates, future studies should aim to generate benchmark data of haemolysis rates with consideration of the haemolysis detection methods used.

As noted above, the wide range of practises in use for recording both accessions/specimens and haemolysis will confound the development of useful benchmarks and standards for good laboratory practise. As a consequence of this study, a guideline on managing and reporting of haemolysed specimens [53] has already been developed by the Australian Association of Clinical Biochemists and KIMMS custodian, the Royal College of Pathologists of Australasia, and was made available through the RCPAQAP. It is anticipated that this guideline will find its way into routine pathology practise across Australia, and through this, the ability to set appropriate standards for haemolysis, and for laboratories to be able to measure their performance against these standards, will become possible.

This study provided a foundation for further thorough investigation of all other quality indicators, i.e. pre- and postanalytical errors, recorded in KIMMS. Haemolysis is one of 21 quality indicators recorded in KIMMS. The research methods used in this study can be applied to assess other KIMMS quality indicators and potentially generate other benchmark data. Standardisation of haemolysis detection and reporting criteria would make it possible to compare KIMMS data with the other established international data, such as the data from the IFCC [54, 55]. Similarly, standardised detection and reporting facilitate laboratories by tracking their performance and improving the safety and efficiency of laboratory processes and, consequently, patient care through targeted interventions to reduce errors.

Limitation

The recall bias could affect the survey results because the information about KIMMS participants and haemolysis detection and reporting were not recorded in KIMMS. However, this information does not change frequently according to the custodians of KIMMS.

Conclusions

The KIMMS project has established a unique repository to benchmark incidence and monitoring data over time for a variety of different types of pre- and postanalytical errors, including haemolysis. However, there is a need to standardise reporting methods to enable comparisons of haemolysis rejection rates between different laboratories. Since haemolysis can affect the integrity of the specimen and the reliability of laboratory results, standardised reporting of the occurrence of haemolysis may support the improvement of the quality and efficiency of the preanalytical laboratory process.

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