# CHEMICAL PATHOLOGY

# The application of glucose point of care testing in three metropolitan hospitals



Lynda Sharp<sup>1</sup>, Ian Farrance<sup>1</sup> and Ronda F. Greaves<sup>1,2</sup>

<sup>1</sup>School of Health and Biomedical Sciences, RMIT University, and <sup>2</sup>Centre for Hormone Research, Murdoch Children's Research Institute, Melbourne, Vic, Australia

# Summary

The application of glucose point of care testing (PoCT) in hospitals has been a contentious subject for many years. No information is available regarding the extent to which glucose PoCT is used within the Australian hospital system and whether such testing is fit for its intended purpose. The aim of this study was to investigate the extent to which glucose PoCT is used within three teaching hospitals and whether testing procedures operate within a framework of quality management. Eighty operators of glucose PoCT participated in a descriptive electronic survey. Specific training in glucose PoCT was limited, with 26% of respondents reporting no specific training in glucose PoCT and 52% of respondents reporting no specific on-going competency assessment for glucose PoCT. The application of quality control (QC) for hand-held meters was generally good, with the majority of respondents indicating that QC was performed on a regular basis. However, 17% of respondents reported that QC was done irregularly or not at all. Electronic reporting of results was limited with 77% of respondents reporting they enter results manually into paper records. The survey obtained data not previously available. It established that glucose PoCT would benefit from a closer adherence to a quality management framework.

Key words: PoCT; glucose meters; hospital; guidelines; quality management.

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# INTRODUCTION

Innovative technical developments with improved patient outcomes has resulted in the increased application of point of care testing (PoCT) in hospitals, with blood glucose being the most widely used PoCT performed in hospitals today.<sup>1</sup> In a market survey conducted in 317 United States hospitals during 2007–2008, it was found that 100% of the surveyed hospitals performed blood glucose PoCT.<sup>1</sup> This market survey also established that glucose PoCT was performed in a number of separate departments within a hospital. This finding is not surprising, as the worldwide prevalence of diabetes is continuing to increase at a significant rate.<sup>2,3</sup> A hospital PoCT for glucose is frequently conducted using a hand-held meter, or in some situations as

part of a blood gas analysis. Hand-held meters, initially designed for the self-monitoring of diabetic patients, are now widely used in many hospital departments and critical care settings.<sup>4,5</sup>

Since the introduction of the Ames reflectance meter in 1970, but more particularly since the first generation glucose PoCT devices developed by Ames (Ames Glucometer) and Boehringer Mannheim (Reflomat),<sup>6</sup> there has been controversy regarding the use of such devices within the hospital environment.<sup>7,8</sup> The hospital use of hand-held glucose meters certainly pre-dates the development of recognised standards or guidelines, which were largely developed as a result of questionable meter performance. However, in recent years many of the problems relating to meter performance and their clinical application have been addressed through technical developments and the publication of professionally based standards and guidelines. Even so, the use of glucose meters in the hospital setting remains contentious as the analytical performance required for a particular clinical purpose may not be achieved in a consistent manner.8

The International Organization for Standardization (ISO) and the Clinical and Laboratory Standards Institute (CLSI) in the USA have both produced documents to address many of the perceived operational and technical issues.<sup>10,11</sup> The international standard for point-of-care testing in a hospital or clinic is ISO 22870: Point-of-care testing - requirements for quality and competence.<sup>10</sup> This ISO standard gives specific requirements applicable to PoCT and is intended to be used in conjunction with ISO 15189: Medical laboratories – requirements for quality and competence.<sup>12</sup> The requirements of ISO 22870 'apply when POCT is carried out in a hospital, a clinic, or healthcare organisation providing ambulatory care'. In addition, local regulatory agencies such as the United Kingdom Medicines and Healthcare Products Regulatory Agency provide policy statements,<sup>13</sup> and professional associations such as the Australasian Association of Clinical Biochemists (AACB), the Association of Clinical Biochemists of Ireland (ACBI) and the National Academy of Clinical Biochemistry (NACB) in the USA, provide information in the form of operational guidelines for PoCT<sup>14-19</sup> with specific guidelines for glucose PoCT.<sup>20</sup> As multiple performance goals for hand-held glucose meters have been proposed, performance targets vary widely and considerable confusion exists.<sup>18</sup>

In an environment which can produce numerous opportunities for error, questions are continually asked as to

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whether hospital based glucose PoCT meters are fit for their intended purpose.<sup>4,21</sup> This has led to the recommendation that when a blood gas analyser is present, it is the preferred method for glucose PoCT.<sup>20</sup> In addition to meeting defined technical performance standards, it is also recommended that glucose PoCT systems (both hand-held meters and blood gas analysers) should operate within a framework of quality management principles as described in the ISO standard, or the various professional guidelines.

The aim of this study was to investigate whether the application of glucose PoCT in hospitals actually operated within a quality management framework as specified in the ISO standard or a given set of professionally developed guidelines. To achieve this aim, a survey was developed to collect responses from key users of glucose PoCT in three teaching hospitals. The responses obtained create a snapshot of current operational procedures in the use and quality management of glucose PoCT.

## METHODS

## Questionnaire

A descriptive electronic survey comprising 36 questions was constructed using Qualtrics survey software (Qualtrics, Australia). The survey questions were developed based on the ISO standard and published recommendations for the use of glucose PoCT in hospitals. They reflect many of the published concerns regarding the application of glucose PoCT.<sup>4,10,11,17,20</sup> The cross sectional survey comprised a variety of question formats including yes/no, multiple choice, multiple response, and open-ended questions, with several questions having space for further comment. A section for glucose measured on a blood gas analyser was also included.

The survey questions were aimed at prompting responses in relation to adherence to the peer reviewed published guidelines and the questions did not vary between institutions. In developing the survey we did not look at the presence of, or adherence to, a local institutional or departmental policy.

#### Hospital selection and ethics approval

The hospital profiles were selected from the 'MyHospitals' website, an online gateway for the National Health Performance Authority.<sup>22</sup> The three hospitals, each with a capacity of over 500 beds, were non-specialist tertiary teaching hospitals incorporating a variety of specialist medical units. The rationale for choosing these hospitals was to maximise sample size and to collect responses from a range of clinical departments. To de-identify the facility and the respondents, the hospitals were assigned a random designation (HA, HB, HC). The ethics committees in each of the three hospitals approved the study.

#### Distribution

This survey was distributed in 2013. Participation was entirely voluntary and respondents were assured that complete anonymity would be preserved. After consultation with senior hospital management and departmental heads, appropriate departmental staff were identified and contacted by email. Departmental managers were invited to electronically distribute the survey to potential users of glucose PoCT within their department. Whilst this network distribution approach provided a mechanism to collect the broadest range of responses, including staff on shift work, the approach did not allow for tallying the total number of survey participation requests distributed. The survey circulation was staggered between the three hospitals, with responses recorded between April 2013 and October 2013.

#### Data analysis

The survey responses contained both quantitative and qualitative data, together with some text-based comments. Numerical data were compiled to provide descriptive statistics. To quantify the data, results are presented as the percentage (%) of participants providing a particular response (n = numerator), compared to the total number of participants who responded to the particular question (d = denominator). Some survey questions allowed for multiple responses and the denominator will reflect the addition of all responses made in these instances. That is, where multiple responses were solicited, the denominator may show a total response greater than the actual number of survey participants. This analysis was conducted within the Qualtrics survey software.

Figure 1 describes the planning, implementation and analysis process for the glucose PoCT survey.

# RESULTS

The survey generated a total of 80 responses across the three hospitals with 77 responses providing sufficient useable data. The first three questions were specifically designed to stratify the respondents:

- Q1. Hospital of employment: HA (49%, n = 38, d = 78), HB (29%, n = 23, d = 78), or HC (22%, n = 17, d = 78). Two respondents did not answer this question.
- Q2. Clinical setting: Clinical settings varied considerably across the hospitals with the largest cohort of responses from general wards (27%, n = 22, d = 81) and emergency departments (14%, n = 11, d = 81). Three respondents did not answer this question and four respondents indicated two departments. Table 1 outlines the range of departments from which the responses were generated.
- Q3. Position employed: 77 people responded to this question. The greater proportion of overall respondents were registered nurses (32%, n = 25, d = 77), nurse unit managers (18%, n = 14, d = 77), or associate nurse unit managers (18%, n = 14, d = 77). These employment categories were provided as free text entries and are summarised in Table 2.

The three participants who did not answer all of these questions, also did not answer any further questions and hence their participation was invalid. This accounted for approximately 4% of the survey responses.

#### Types of meters and number of tests performed

Glucose PoCT using hand-held devices was performed by nearly all respondents (95%, n = 73, d = 77). Four respondents, all medical scientists (including the one PoCT coordinator), indicated that PoCT glucose testing did not occur in their pathology department.

The number of glucose PoCT instruments held within a department was generally between one and eight, with departments such as an intensive care unit reporting '20 plus instruments'. A high percentage of respondents from each hospital reported that more than 30 PoCT blood glucose measurements were performed in their departments every week; with some estimates ranging from 50 to 350, others estimating 'hundreds', '800 or more', or in one case 1000. Nursing staff were the sole operators of the hand-held glucose meters in the majority of responses (59%, n = 41, d = 70), with a mixture of medical and nursing staff being the next most popular response (36%, n = 25, d = 70).

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