



Integrated Cardiovascular  
Clinical Network CHSA

# Glucose Meter Testing

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*AACB, October, 2011*

## Glucose Meters

- Available for more than 3 decades
- Revolutionised diabetes management
- Have gotten smaller, faster and more accurate over the years
- Are widely used in hospitals, outpatient clinics, emergency rooms, ambulatory medical care (ambulances, cruise ships, RFDS) and self-monitoring
- Glucose meters are utilised by a diverse population of patients representing all ages and varying acuteness of illness

## Concerns with Glucose Meters

- Meters are being used beyond their intended purpose
- Physicians not understanding limits of glucose PoCT device used in their institution – many believe results are interchangeable with laboratory results
- Use of patient meters in ICU wards
- No consensus for the analytical performance of glucose meters

## Glucose Testing Points to Consider

- It is a reasonable assumption to make that the performance requirement of glucose meters will be dependent on the intended clinical use of the meter.
- To date no meter can match the clinical performance of laboratory methods. It is not a reasonable statement to make that if a glucose meter does not match laboratory performance it should not be used, as reliance on these meters is important to the management of diabetes globally.
- Industry has the responsibility to continue improving performance of meters
- scientists and diabetes health professionals must take up the responsibility of ensuring glucose meters used in clinical environments are “fit for purpose”.

## Meter Performance

- Glucose meter performance has improved
- Technological advances have decreased operator errors
- Performance by patients (CV 7-20%) inferior to medical technologists (CV 2.5-5.9%)
- Patients failed to meet ISO criteria:  
95% of the individual results for the glucose meter shall fall within  $\pm 0.83$  mmol/L of the results at glucose concentrations  $\leq 4.2$  and  $\pm 20\%$  at glucose concentrations  $> 4.2$  mmol/L.

*Clin Chem 2002; 48:994*

## Limitations of Glucose Devices

- Less accurate than laboratory methods
  - Variation among meters
  - Glucose concentration varies between arterial, venous and capillary samples – plasma glucose higher than whole blood
  - Capillary glucose altered if reduced peripheral blood circulation eg hypotension, shock, dehydration
  - Limited measurement range
  - Accurate only within defined hematocrit range
  - Operator variability
  - Interfering factors
- [www.appn.net.au/glucose.aspx](http://www.appn.net.au/glucose.aspx)

## Clinical Use of Glucose Meters

- Point-of care glucose meters were originally developed, approved, regulated, and marketed for self-monitoring of blood glucose by outpatients with diabetes.
- Without any further regulatory review and with limited clinical assessment, devices have migrated into the hospital and critical care settings.
- Scientists continue to research inappropriate use of meters and desirable/appropriate accuracy
- Many physicians believe the accuracy of glucose meters parallels that of central laboratory devices

## Fatal Glucose Errors

**Report: Lehigh Valley Hospital gave fatal dose**

**Transplant patient died after series of hospital errors, state says.**

June 15, 2011|By Tim Darragh, OF THE MORNING CALL

Doctors at Lehigh Valley Hospital-Cedar Crest, using faulty blood sugar testing strips, this year administered an apparent fatal double dose of insulin to a patient with extremely low blood sugar levels, a critical state Department of Health report says.

A nurse monitoring the patient's status from a remote site knew that bedside blood sugar testing strips differed significantly from more reliable laboratory tests of the patient's blood, but failed to warn doctors about the discrepancy, it says.



**Australian**  
**10/02/2011**  
Page: 7  
By: Adam Creswell  
Section: General News  
Region: Australia Circulation: 136268  
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Size: 73.00 sq.cms  
Frequency: MTWTF

## Single-use needle used on 53 patients

HEALTH authorities have launched an urgent investigation after more than 50 patients at a private radiology clinic were given blood tests using a needlestick device meant for single-patient use — potentially exposing them to hepatitis B, hepatitis C and HIV infection.

All 53 patients, some of whom were undergoing tests and treatment for cancer, require testing for the viruses, and again in three months, before they get the all-clear.

The clinic on the NSW central coast, PRP Diagnostic Imaging, last night said it had written to affected patients to apologise for the mistake, which was discovered two weeks ago. The blunder occurred after the clinic

began blood glucose checks in December using the Accu-Chek Multiclix device, which fires a spring-loaded needle into a finger to produce a drop of blood.

A spokeswoman for the Therapeutic Goods Administration said they were working with NSW Health authorities to urgently investigate the matter.

Michael Jones, the chairman of PRP, which runs 17 clinics in NSW, said the device was in use only at the Gosford clinic.

Katherine McGrath, the chief executive of the Australian Association of Pathology Practitioners, said the episode illustrated the "dangers" of the push for more point-of-care testing.

ADAM CRESSWELL  
SALLIE DON

**Glucose Monitoring After Fruit Peeling: Pseudohyperglycemia When Neglecting Hand Washing Before F...**  
Hirose, Takahisa; Mita, Tomoya; Fujitani, Yoshio; Kawamori, Ryuzo; Watada, Hirotaka  
*Diabetes Care*; Mar 2011; 34; 3; ProQuest Central  
pg. 596

Clinical Care/Education/Nutrition/Psychosocial Research

BRIEF REPORT

## Glucose Monitoring After Fruit Peeling: Pseudohyperglycemia When Neglecting Hand Washing Before Fingertip Blood Sampling

Wash your hands with tap water before you check blood glucose level

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### BG measurements

Capillary BG samples were collected from the healthy volunteers in the fasting state. BG levels were recorded using a portable glucose monitor (OneTouch UltraVue, Johnson and Johnson, New Brunswick, NJ).

### Study design

Capillary blood samples were collected in the fasting state from healthy volunteers 1 h after they had peeled one of any of several kinds of fruits (orange, grape, or kiwi), followed by no hand washing no alcohol swab (Table 1, row 2), hand washing with tap water (Table 1, row 3), rubbing the fingertip with an alcohol swab once (Table 1, row 4) or five times

**OBJECTIVE**—To examine whether hand contamination with fruit results in a false blood glucose (BG) reading using capillary fingertip blood sample.

**RESEARCH DESIGN AND METHODS**—The study subjects were healthy volunteers with normal glucose tolerance test. Capillary BG samples were collected from the fingertip after peeling orange, grape, or kiwi fruit, followed by no action, washing hands with tap water, or rubbing the fingertip with an alcohol swab, then analyzed with glucose monitors.

**RESULTS**—The BG levels measured after peeling any of the fruits, followed by washing hands, were similar to the control subjects (no fruit handling), but the levels after fruit peeling, followed by no washing, were abnormally and significantly high, even when the fingertip was cleaned once or five times with an alcohol swab before blood sampling.

**CONCLUSIONS**—To avoid overestimation of blood glucose using portable monitors, the hands should be washed before monitoring capillary BG, especially after fruit has been handled.

## How Can We Determine How Accurate Should Glucose Measurements Be?

- Expert opinion – conferences
- Opinion of Clinicians
- Regulation
- Biological Variation

## Questions to Consider

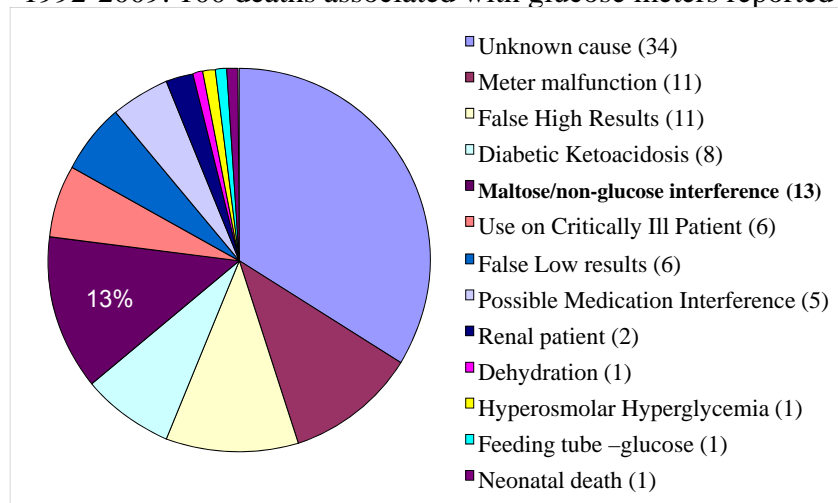
- If glucose meters are used for patients of all ages with varying acuteness of medical conditions is it reasonable to assume that a meter will be suitable for all patient ages and varying acuteness of illness??
- With such widespread use of glucose meters, are glucose meters being used effectively in patient management??
- Is there overuse of glucose meters and potential to not achieve desired outcomes - inappropriate management, and increased cost of health care??

## FDA Glucose Meeting

- In 2010 the FDA held a public meeting to discuss precision and accuracy issues in Washington.
- The purpose of the meeting:
  - raise public awareness
  - obtain input about the accuracy and clinical use of blood glucose meters
  - share ideas on the challenges associated with their use
  - work towards identifying solutions

## Adverse Events - Deaths

1992-2009: 100 deaths associated with glucose meters reported



FDA Medical Device Reporting Database

## IFCC Glucose PoCT WG Aims

To investigate the quality specifications required for glucose PoCT meters as glucose testing is used in a wide range of health care settings including:

- Hospitals – Adult: A&E, medical wards, intensive care – Paediatric: A&E, medical ward, intensive care
- General practice/physicians office
- Specialists
- Ambulances
- Air Ambulances
- Patients/Carers – self monitoring
- Nursing Homes
- Population surveys - screening

## Current IFCC Projects

- To develop allowable analytical error (including bias and imprecision) recommendations for different clinical situations.
- To develop recommendations about suitability of instruments for different clinical situations.
- To define training standards for both health workers and patients.
- To develop clinician derived quality specifications for critically ill patients.
- To develop clinician derived quality specifications for general practice.
- To develop clinician derived quality specifications for ambulances/Air Ambulances/Emergency Departments.
- To establish epidemiologists derived quality specifications for population surveys.
- To develop patient derived quality specifications for self/testing.
- To develop paediatric derived quality specifications for paediatric patients.

## ICU Specifications

- Literature review has confirmed no quality specifications for ICU setting have been published.
- Plan is to survey ICU physicians and nurses to establish how they use glucose results.

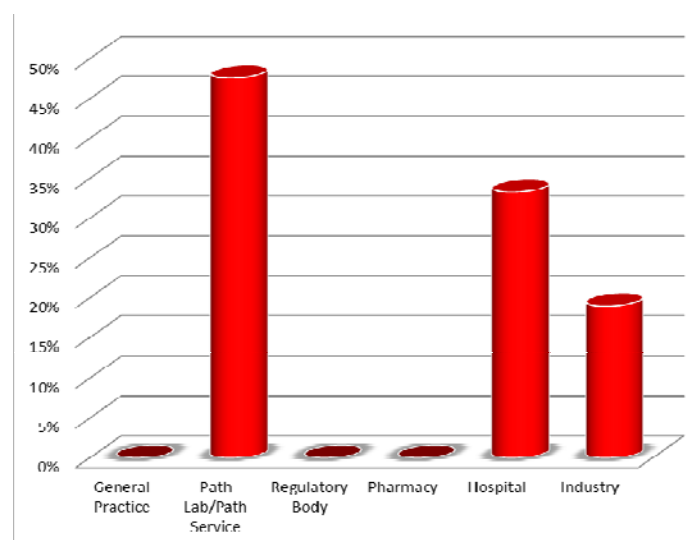
## Comments

- Glucose meters are being used in a variety of places for multiple medical reasons ranging from self monitoring to TGC
- In many instances meters are not “fit for clinical purpose they are being used for” which may not be the “clinical purpose the meter was intended for”
- Education is important for all device users from patients to physicians
- Meters that result in an accurate treatment decision – this may differ in different situations
- AACB PoCT working committee held a glucose workshop earlier this year to identify issues

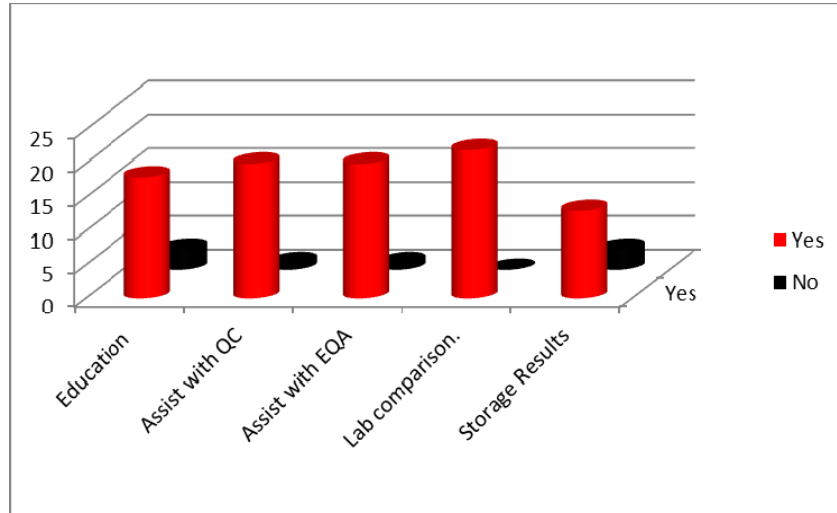
## Outcome of Glucose Workshop

- Participants were asked to fill out a questionnaire on glucose testing
- Results would assist PoCT working committee to develop some recommendations around glucose meters – input/endorsement from endocrinologists/Diabetes Australia
- 23 questionnaires were returned (45% response rate)

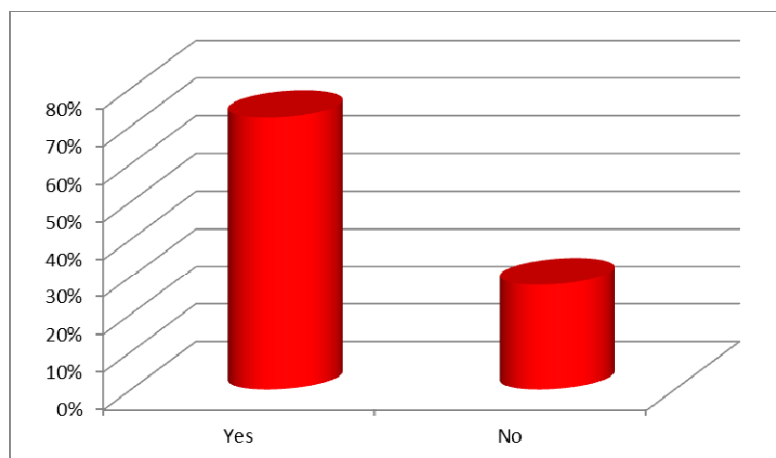
## Organisation



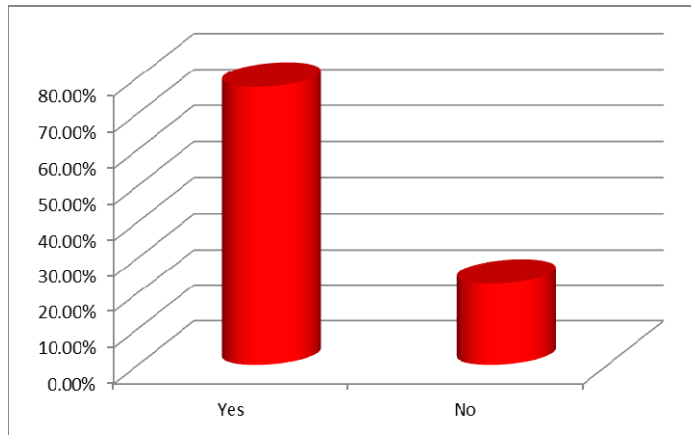
## Should Pathology Laboratories/Services have a role in maintaining glucose meters



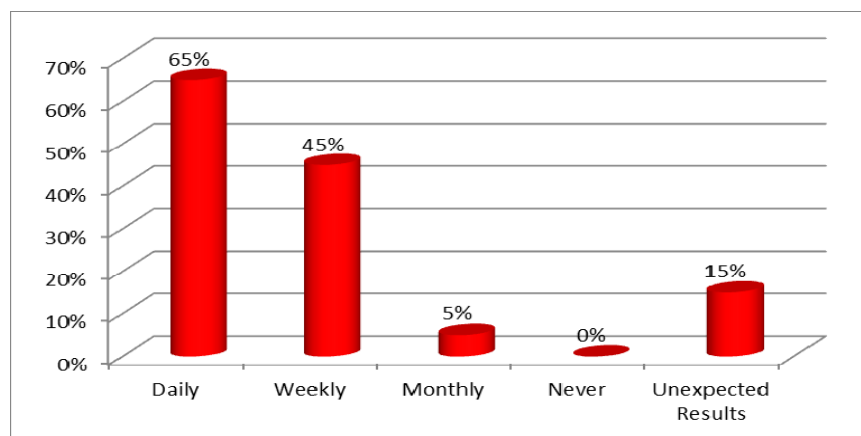
## Are glucose meters you are involved in part of a EQA program



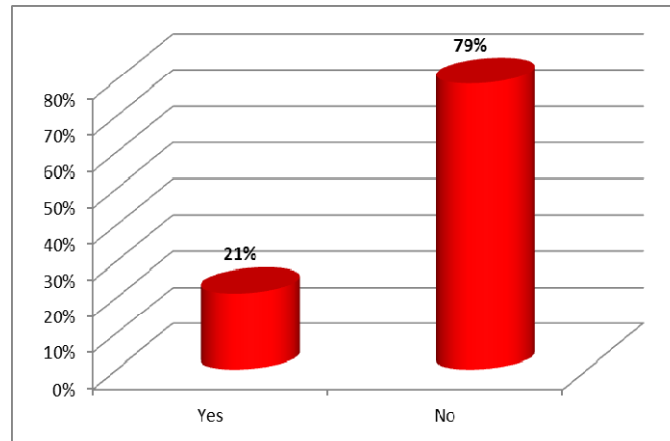
Should all glucose meters used to provide results to a patient/client be enrolled in an EQA program



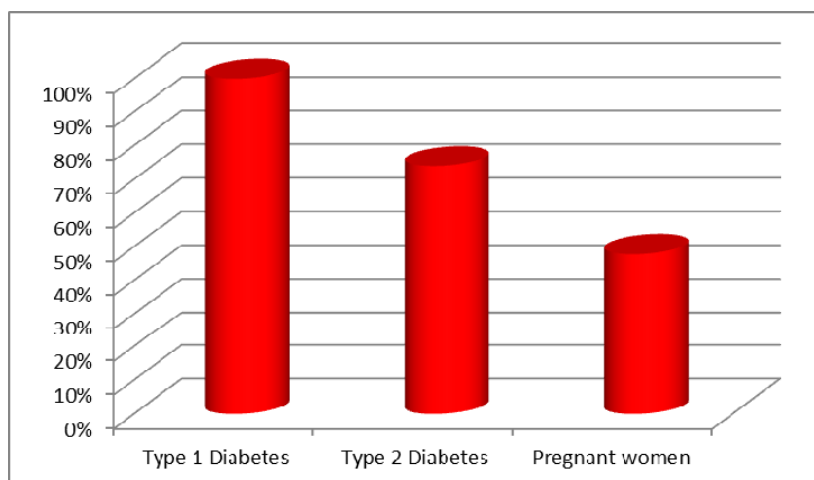
How often should quality control be run on glucose meters?



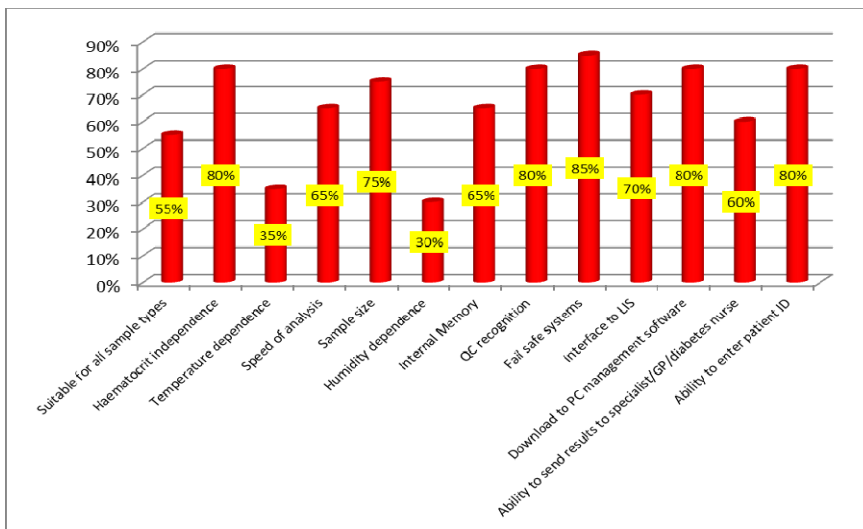
Should meters used by patients for self monitoring be used in hospital acute facilities?



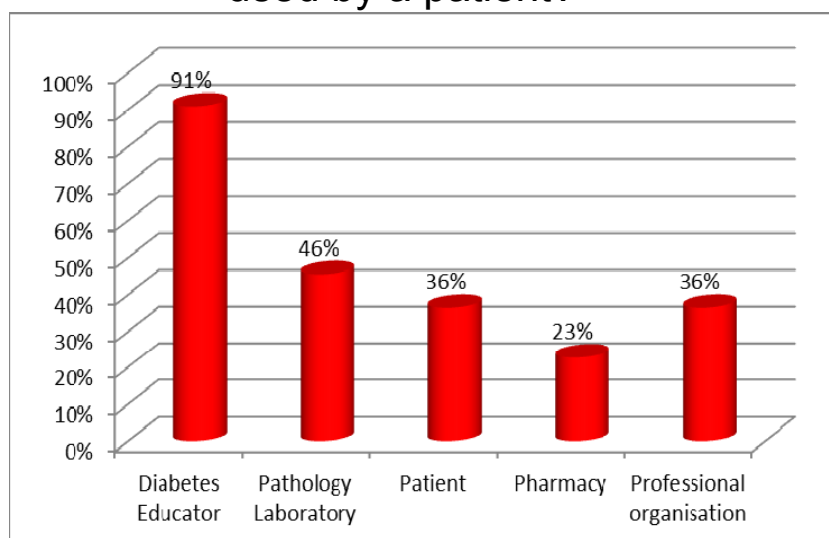
Who needs a glucose meter?



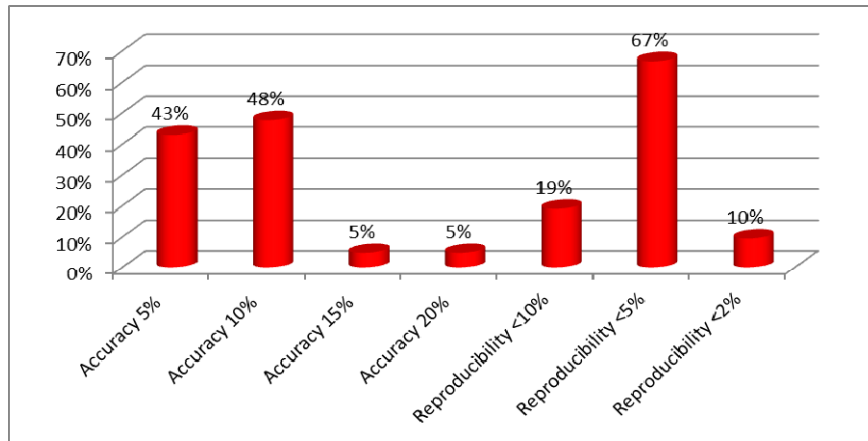
## What features are important to you/your organisation when selecting a glucose meter?



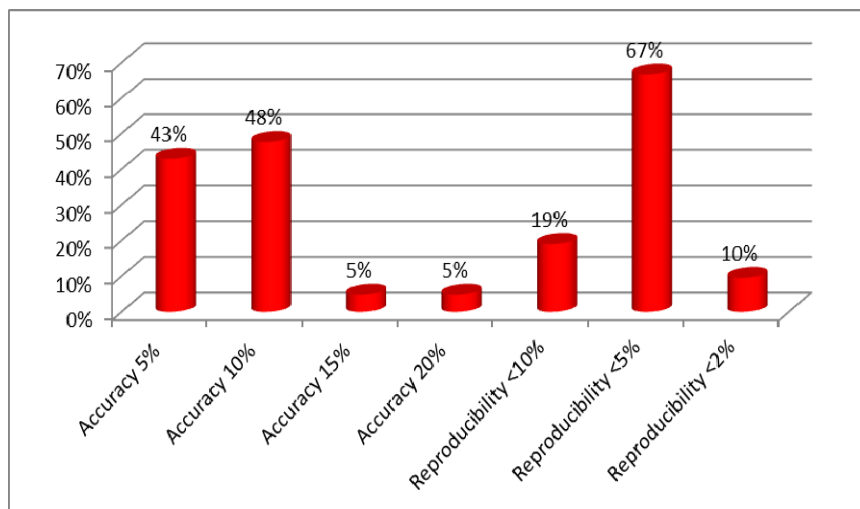
## Who should choose what type of meter is used by a patient?



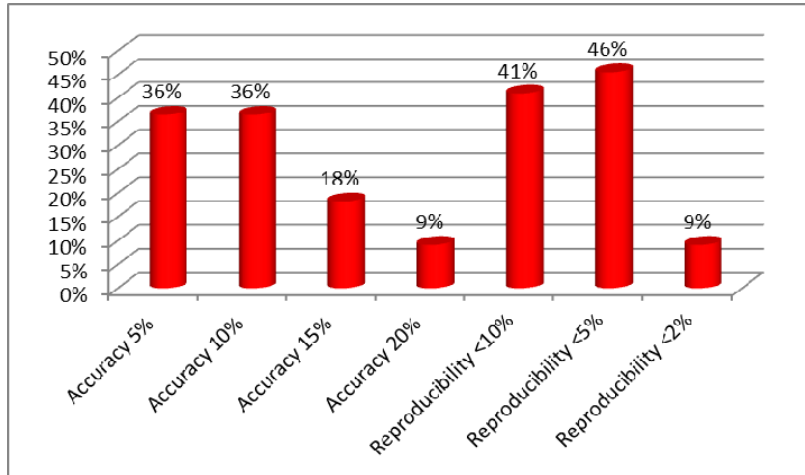
What do you consider acceptable analytical performance for a meter used on a patient (eg hospital ward, general practice, community health)?



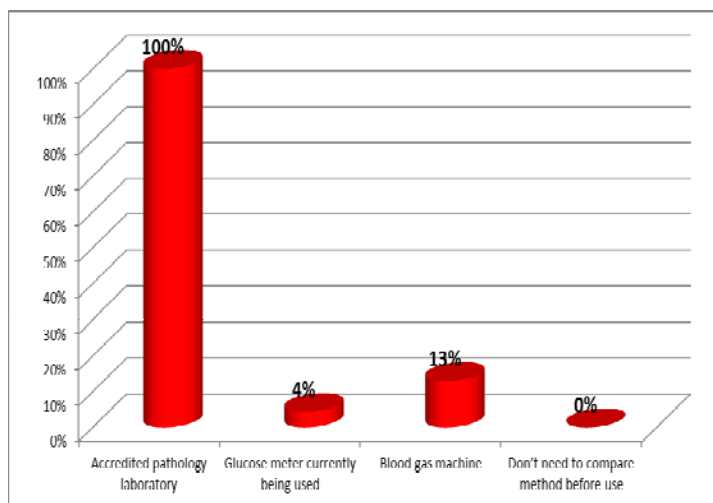
What do you consider acceptable analytical performance for a meter used in ICU?



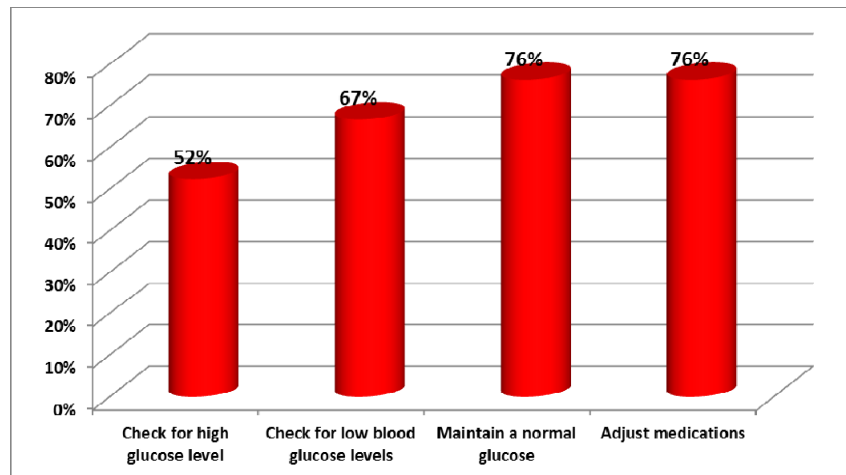
What do you consider acceptable analytical performance for a meter used for self monitoring?



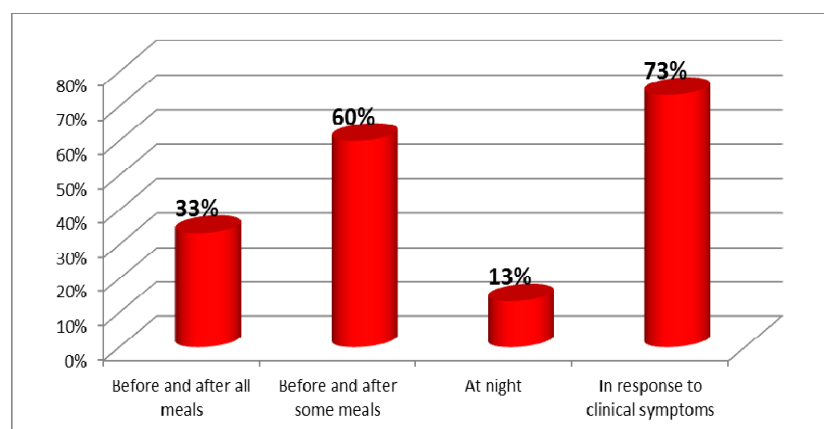
What would you consider a suitable comparative method to when evaluating a glucose meter?



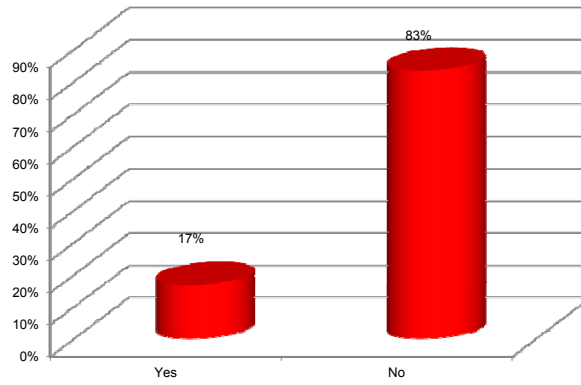
## What is the most important reason for glucose testing?



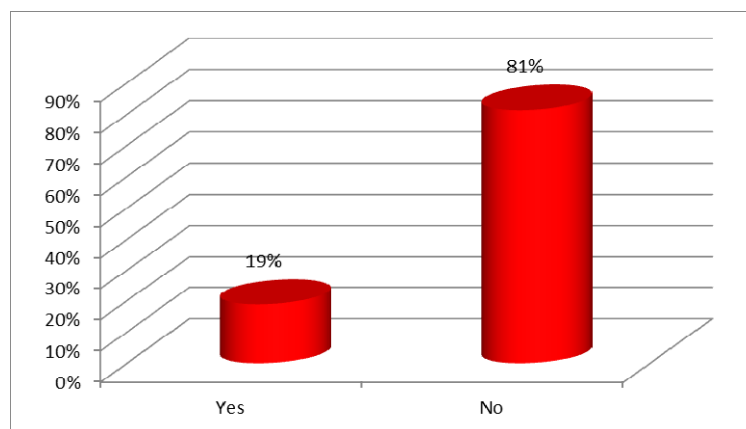
## When should glucose testing be performed?



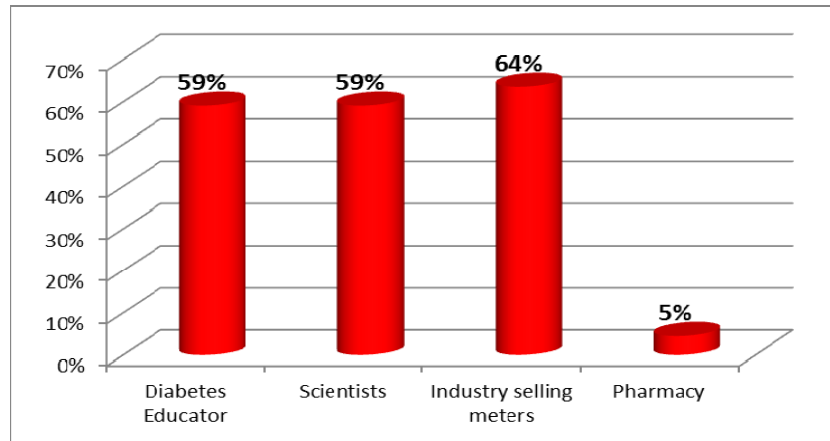
Is adequate training provided for glucose meters to health professionals?



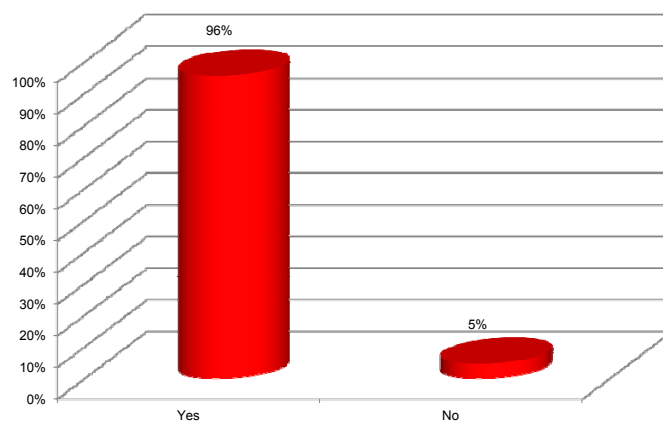
Is adequate training provided for glucose meters to patients?



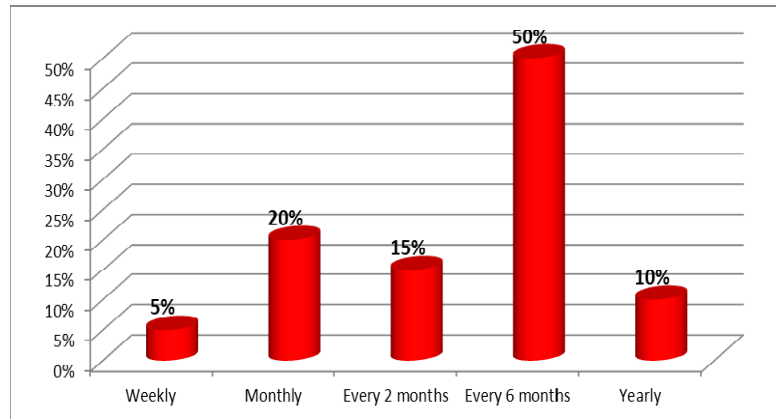
## Who should provide training to nurses testing patients?



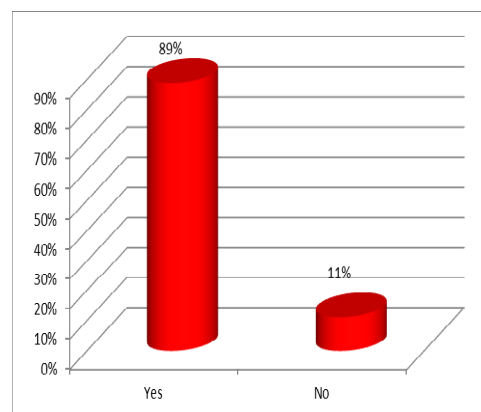
## Should patient self-testing glucose meters be checked regularly against laboratory glucose method?



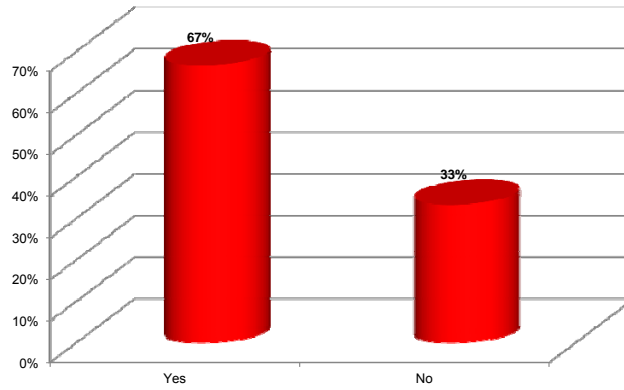
If yes, how often should meter be compared to laboratory method?



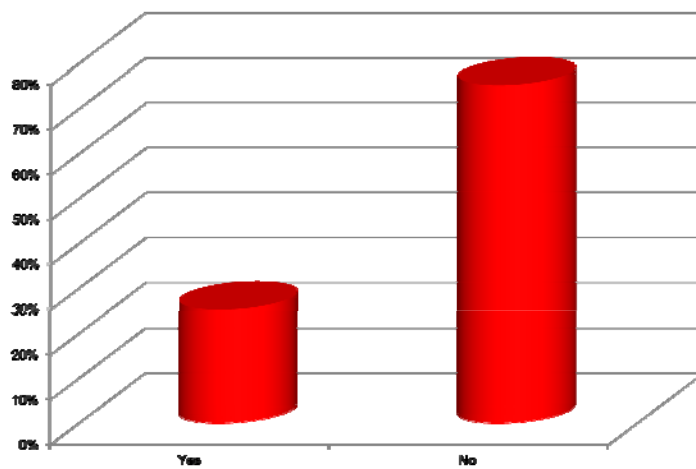
Should the current ISO15197 standard criteria for glucose meter accuracy be tightened?



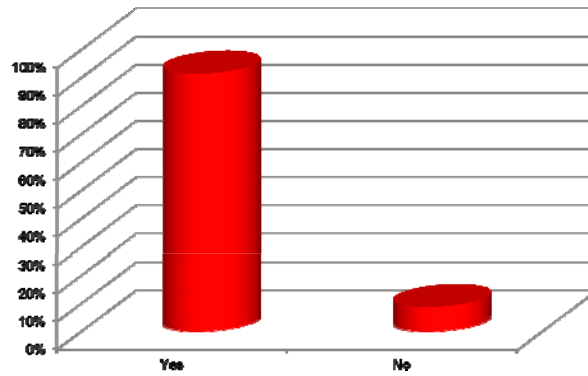
Before selecting a glucose meter for use in hospital wards, is an evaluation of the device performed?



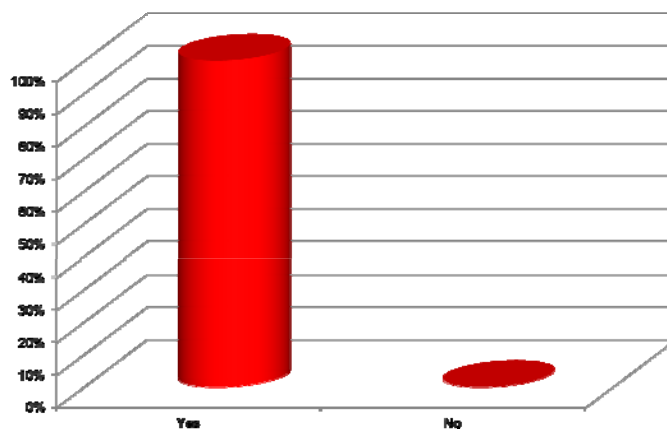
Should patient glucose meters be used for tight glycemic control?



Should evaluations of glucose meters involve patients performing some of the comparisons to give a true indication of quality of results in the patient's hands?



Should patients using glucose meters be encouraged to run quality control samples on their glucose meters?



## Conclusions

- Pathology laboratory should be involved with maintenance of glucose meters
- 79% of participants believed that glucose meters designed for self-monitoring should not be used in acute hospital facilities
- Diabetes educators should select meter used by patient
- Reproducibility of <5% for glucose meters used in patient care areas – GPs, wards, ICU and 5-10% for self-monitoring
- Glucose meter performance should be against an accredited lab method

## Conclusions

- Training for both health professionals and patients is **not** adequate.
- Clear governance structure should be available for who is responsible for training
- Patient glucose meters should be checked against laboratory method every 6 months
- QC should be run daily
- Evaluation of glucose meters should involve patients
- Patients should be encouraged to run QC

## Next Steps

- Glucose working group including all stakeholders to be set up to look at improving awareness of glucose issues and developing guidelines for use.
- Meeting with decision makers to advocate for resource allocation to help improve use of glucose meters to prevent deaths from misuse.

***Lets be proactive instead of reactive***

## Members of PoCT Committee

- Renze Bais
- Andrew Francis
- Janice Gill
- Briony Glastonbury
- Victoria Hauke
- Brian Heffernan
- George Koumantakis
- Cameron Martin
- Mark Shephard
- Rosy Tirimacco (chair)
- Janet Wale
- Les Watkinson
- Rob White
- Michelle Williamson
- Noelene Wilson
- Andrew St John – Consultant

- If you want to participate in discussion on glucose meters: visit [www.appn.net.au](http://www.appn.net.au) forum area where we will be setting up a discussion group.

Thankyou