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Point of Care Testing (PoCT) in Health Care: A Rapid Review

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A report of findings from a rapid review on Point of Care Testing (PoCT) safety and quality issues in Australia and internationally, prepared for the Australian Commission on Safety and Quality in Health Care.

EXECUTIVE SUMMARY

INTRODUCTION

The National Pathology Accreditation Advisory Council (NPAAC) defines Point of Care Testing (PoCT) as **pathology testing performed in close proximity to a patient by a healthcare worker**, usually outside the precincts of a traditional laboratory. Testing is undertaken at the time of, and for use during, a consultation or episode of care.

The benefits of PoCT include rapid result availability enabling decreased turnaround time compared to central laboratories; immediate and informed clinical decision-making regarding patient diagnosis and management; proximity to care enabling clinicians to have results close to patient care, assisting in diagnosis and disposition assessment; and convenience and accessibility, particularly in rural and remote areas. However, the safety and quality risks of PoCT must also be acknowledged and understood.

OBJECTIVES AND RESEARCH QUESTIONS

The three key objectives of this rapid review were to provide a summary on: 1) Pathology PoCT safety and quality issues that are relevant to the Australian context and relate to the areas covered by the *Requirements for Point of Care Testing (Second Edition 2021);* 2) Standards on pathology PoCT and how they compare to the *Requirements for Point of Care Testing (Second Edition 2021)*; and 3) Training resources in Australian healthcare on the use of PoCT devices. To address these objectives this rapid review is structured around the following questions:

Question 1. What pathology PoCT devices are used in Australia? What are their trends and issues?

Question 2. What are the safety and quality issues with the use of pathology PoCT?

Question 3. How does the *Requirements for Point of Care Testing (Second Edition 2021)* compare to similar standards on pathology PoCT from reputable organisations?

Question 4. What training resources exist in Australian healthcare on how to use PoCT devices?

METHODS

To address Questions 1 and 2, a structured search strategy was applied in Medline (via Ovid) and Embase (via Ovid). The search strategy was devised to focus on identifying peer-reviewed literature on PoCT quality and safety over the last five years (Jan 2019 to Jan 2024)(Table 1). Handsearching of targeted reputable healthcare websites was utilised to identify relevant sources of evidence to address Questions 3 and 4.

FINDINGS

Pathology PoCT devices used in Australia are listed in Table 2. PoCT use in Australia has widely expanded in the past decade and during COVID-19. PoCT is used in a range of health care settings, including hospitals (emergency departments, intensive care units, operating theatres, wards), emergency medical services (ambulance, medevac), general practice, Indigenous medical services, community, pharmacies, and sports clinics, across urban, rural, and remote areas, as well for self-testing.

QUESTION 1. WHAT PATHOLOGY PoCT DEVICES ARE USED IN AUSTRALIA? WHAT ARE THEIR TRENDS AND ISSUES?

PoCT issues discussed in the identified Australian peer-reviewed literature are summarised in Table 3, with more detailed summaries regarding trends and issues from each publication provided in Appendix 2. These

include issues related to: i) Accuracy; ii) Competency; iii) Total Quality Assurance; iv) Traceability; v) Connectivity; vi) Infrastructure; vii) Workflow; and viii) Funding.

QUESTION 2. WHAT ARE THE SAFETY AND QUALITY ISSUES WITH THE USE OF PATHOLOGY PoCT?

The safety and quality issues related to the use of PoCT are summarised in Table 4 (and further detailed in Appendix 3) under the following headings: i) Governance; ii) Management Systems; iii) Training and Competency; iv) Pre-analytical Considerations; v) Analytical Considerations; vi) Post-Analytical Considerations; vii) Environment; and viii) Workplace Health and Safety.

QUESTION 3. HOW DOES THE *REQUIREMENTS FOR POINT OF CARE TESTING (SECOND EDITION 2021)* COMPARE TO SIMILAR STANDARDS ON PATHOLOGY PoCT FROM REPUTABLE ORGANISATIONS?

The *Requirements for Point of Care Testing (Second Edition 2021)* standards are largely comparable with national and international guidelines (Table 5 and Table 6). Notable differences revolve around areas of governance, connectivity, and post-analytic considerations around standardisation of results reporting.

The current update of the ISO standard, *ISO 15189:2022 Medical Laboratories Requirements for Quality and Competence* has structured guidelines around areas of risk and common errors relating to PoCT. In addition to stronger definition and delineation of responsibility for governance of PoCT programs formalised by Service Level Agreements (SLAs), the following areas have been identified as potential sources of error that require greater focus: environmental conditions; insufficient operational documentation and oversight of assets; analytical considerations including measurement uncertainty and measurement accuracy; clinical decision limits; monitoring the validity of results; acceptable quality control performance; External Quality Assurance (EQA) participation (where available); comparability of results; and a renewed emphasis on continuity and emergency preparedness planning in instances of PoCT service failure.

QUESTION 4. WHAT TRAINING RESOURCES EXIST IN AUSTRALIAN HEALTHCARE ON HOW TO USE PoCT DEVICES?

A variety of training resources were found ranging from accredited/nationally recognised training, training kits, device training guides, case studies, professional learning modules, competencies, and documents. The format of training resources included videos, webinars, documentation (forms/templates) and guidelines, with some resources requiring a user/staff login for access.

There is a vast array of PoCT training resources available which are broadly dispersed across a range of providers within Australia. The majority of resources appear to be provided online by NSW Health Pathology and Flinders University (and its associated PoCT programs/collaborations). Others, like Pathology Queensland (QLD), have internal systems. Resources are available in a wide range of formats ranging from simple documents (forms, procedures, posters) to online training modules and videos. Whilst many resources are in the public domain (e.g., New South Wales Health Pathology (NSWHP) YouTube channel), other providers require a user account/login to access training (e.g., Australian Point of Care Practitioners Network (APPN)) or only provide training to staff at specified centres (Flinders University PoCT programs in the Northern Territory (NT)/Western Australia (WA)).

CONCLUSION

The findings from the rapid review highlight the widespread adoption of pathology PoCT devices in Australia, accompanied by significant benefits but also notable safety and quality challenges. Effective governance, robust management systems, adherence to standards, and comprehensive training are essential to address these challenges and ensure the reliability and accuracy of PoCT results. Continued efforts towards standardisation, connectivity, and quality assurance are crucial to enhance the effectiveness and safety of PoCT in healthcare delivery.