

Point-of-care testing in Australia: a situational assessment

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Background:

Beyond marketing approval by the TGA, there is currently no comprehensive, national framework governing the selection, implementation, quality assurance and reporting of PoCT by health services in Australia. Rather, a range of standards, guidelines and frameworks have been developed to apply to PoCT use in specified settings. These standards and frameworks, designed to ensure the utility, quality and safety of PoCT, tend to be limited in scope, and applicable in specific contexts. The aim of this review was to understand the current regulatory environment for PoCT in Australia and how this is applied to a range of clinical settings.

Methods: An academic literature search was conducted alongside an informal search of relevant Government and non-government websites limited to Australia.

Results: Several key themes emerged from the review including differences based on the setting (hospital, primary care, pharmacy etc.) and purpose of the PoCT. The NPAAC standards adopt a risk-based approach of clinical governance (including centralised laboratories and individual medical practitioners) in the absence of specific PoCT guidance which can burden medical practitioners. However, the models of successfully implemented PoCT programs in Australia vary including locally-managed, decentralised and independent governance and quality management. Additionally, there is the requirement for operational support to facilitate engagement and successful outcomes including ongoing training, data connectivity between systems, quality management processes and patient and consumer engagement for successful implementation.

Conclusion: PoCT has the opportunity to provide many benefits when there is defined clinical and/ or patient need. However, the unsupported implementation and management of PoCT brings several risks including inappropriate test selection, interpretation, and reporting, in addition to quality management issues. The findings from this review provide an overview of the current policy and practice PoCT landscape as well as considerations for potential PoCT frameworks covering test performance, healthcare system outcomes and consumer experiences.

Disclosure of Interest Statement: The Peter Doherty Institute for Infection and Immunity recognises the considerable contribution that government departments, healthcare services and researchers make to professional and research activities. We also recognise the need for transparency of disclosure of potential conflicts of interest by acknowledging these relationships in publications and presentations.