Point-of-Care Testing Trial in General Practice in Australia

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Abstract: A randomized controlled trial of point-of-care testing (POCT) is currently being conducted in approximately 60 general practices in urban, rural, and remote Australia. The trial will investigate clinical and cost-effectiveness, safety, benefits to patients and general practitioners, and clinical outcomes of point-of-care testing. Point-of-care tests measured as part of the trial include hemoglobin A1c, urine albumin-to-creatinine ratio, lipids, and international normalized ratio.

Key Words: point-of-care testing, general practice, hemoglobin A1c, urine albumin-to-creatinine ratio, lipids, international normalized ratio

(Point of Care 2006;5:192)

In 2002, the Australian Government commissioned a report on the role and value of point-of-care testing (POCT) in general practice in Australia.1 This report highlighted that rural and remote general practices could potentially be the main beneficiaries of POCT but that further work was needed to determine the clinical and economic benefits of POCT in general practice. As a result, the government recommended that a trial of POCT in general practice be conducted. The objectives of the trial were to investigate the clinical effectiveness, cost effectiveness and safety of POCT in general practice; to investigate the benefits to the patient and the general practitioner (GP); and to determine whether POCT led to improved health outcomes—all within a structured quality management framework. A design for the trial and an evaluation framework was developed before the commencement of the trial, as were a detailed set of standards for POCT in general practice, which incorporated trial guidelines.2,3

The 18-month randomized controlled Point-of-Care Testing Trial in General Practice commenced in 2005 and will finish in 2007. The trial is being conducted in urban, rural, and remote geographic areas, with approximately 20 general practices being recruited from each of the Adelaide, South Australia (urban), Bendigo, Victoria (rural) and Dubbo, New South Wales (remote), regions, respectively (approximately 60 practices overall). Half the general practices will conduct POCT (ie, be in the intervention group), whereas the remainder will be control sites, conducting routine laboratory testing. Approximately 5000 patients have been recruited for the trial. Patients must have a preexisting diagnosis of diabetes or hyperlipidemia or be on anticoagulation therapy. Tests to be measured as part of the trial are hemoglobin A1c and urine albumin-to-creatinine ratio (for diabetes management), lipids (for monitoring patients with hyperlipidemia who are being prescribed lipid lowering drugs), and international normalized ratio (for measuring clotting time for patients receiving anticoagulation [warfarin] therapy). The POCT devices selected for use in the trial were the DCA 2000 (Bayer Australia Ltd, Melbourne, Victoria, Australia) for HbA1c and urine albumin-to-creatinine ratio testing, the Cholestech LDX (Point of Care Diagnostics Australia Pty Ltd, Sydney, New South Wales, Australia) for lipids, and the CoaguChek S (Roche Diagnostics Australia Pty Ltd, Sydney, New South Wales, Australia) for international normalized ratio.

The trial is being delivered by 3 lead organizations, working collaboratively from an Adelaide base. They are the University of Adelaide, Flinders University, and the RCPA (Royal College of Pathologists of Australasia) Quality Assurance Programs Pty Ltd. A trial management group is responsible for day-to-day administration of the trial and for issues relating to accreditation and safety, recruitment of general practices, and evaluation of trial outcomes. A POCT Device Working Group is responsible for the development of a training manual, the delivery of initial and refresher training workshops, competency assessment for POCT operators, the implementation and maintenance of an internal quality control program for the POCT tests, and the supply of devices, reagents, quality control materials, and consumables. The External Proficiency Testing Program Group is responsible for the implementation and maintenance of an external quality assurance (proficiency testing) program for the POCT tests. All 3 groups report directly to the Australian Government Department of Health and Ageing, through a government-elected POCT Steering Committee.

REFERENCES

