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The DOI for this manuscript is doi: 10.5858/arpa.2020-0104-RA

The final published version of this manuscript will replace the Early Online Release version at the above DOI once it is available.

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Point-of-Care Testing in Rural and Remote Settings to Improve Access and Improve Outcomes

A Snapshot of the New Zealand Experience

Geoffrey C. E. Herd, MAppSci; Samarina M. A. Musaad, MB BS, MPH, FRCPA

• ***Context.***—**Three key guiding principles of rural and remote clinical services are to improve health access, improve outcomes, and reduce inequity. In New Zealand as in other countries, point-of-care testing and technologies can assist in clinical decision-making for acute and chronic conditions and can help to achieve these key health principles for people living in rural and remote locations. This report is a companion article to the other point-of-care testing topics in this special section in this journal.**

Objective.—**To provide readers with insights into where and how point-of-care testing devices and tests can be implemented to improve outcomes in New Zealand settings without on-site pathology laboratory support. The settings in which point-of-care testing devices and the success stories associated with these initiatives include general practices, pharmacies, workplaces, rural hospitals, and sexual health clinics.**

Data Sources.—**The information is extracted from published literature and also first-hand experience in remote and rural New Zealand settings. This report also outlines the regulatory and accreditation challenges relating to point-of-care testing devices in New Zealand and includes advice on the selection of devices, training, and ongoing quality assurance for this type of medical testing in remote locations.**

Conclusions.—**Point-of-care testing in rural remote settings without laboratory support can be challenging and rewarding for clinicians. It is now, and will be in the future, an even more important component of the health system to improve outcomes and reduce inequity.**

(*Arch Pathol Lab Med*. doi: 10.5858/arpa.2020-0104-RA)

Point-of-care testing (POCT) is defined as bedside or near patient medical laboratory testing and provides rapid laboratory test results to assist with clinical decision-making[1] and reduce the therapeutic turnaround time. The results obtained from POCT devices can improve access to health care[2] and are often the only means of obtaining urgent and timely medical laboratory test results in primary care settings in rural locations or remote hospitals that do not have on-site laboratory support.[3,4]

A wide range of medical testing devices are available for clinical decision-making in remote locations. These locations often do not have on-site laboratory support. These devices provide results for diagnostic, screening, and monitoring tests quickly and efficiently, when and where the results are needed. Some examples of these tests and the types of devices include but are not limited to: dip-stick urine and pregnancy test kits; drugs of abuse test kits; blood glucose, blood gas, and lactate analysis; biochemistry analytes and cardiac troponin tests; D-dimer tests; tests for infectious diseases; oral anticoagulant monitoring; urate; celiac disease tests; lipid tests; and glycated hemoglobin (HbA_{1c}).

The types of settings in which these tests and devices are used include but are not limited to: remote rural hospitals and primary care clinics, radiology practices, birthing centers, general (family) practice, community paramedical services, patients' homes, diabetes clinics, drug of abuse detoxification units, sexual health clinics, workplaces, corrections facilities, and pharmacies.

The authors are aware of other POCT services being carried out in the community, such as pharmacy-based screening for celiac disease and the use of over-the-counter devices for fertility and/or pregnancy testing and patient self-testing, including capillary blood glucose, and ketone tests and continuous transcutaneous glucose monitoring. These tests and technologies will not be discussed in this report.

REGULATION, ACCREDITATION, AND FUNDING OF POCT IN NEW ZEALAND

The 4 pillars for safe POCT services in New Zealand are: the regulation of POCT devices, the New Zealand Health and Disability Consumers Code of Rights 1996,[5] accreditation of POCT services, and the New Zealand Best Practice Guidelines for Point-of-Care Testing.[6]

Accepted for publication August 23, 2020.

From Point of Care Testing, Whangarei Hospital, Northland District Health Bard, Whangarei, New Zealand; New Zealand (Herd); and Labplus, Auckland City Hospital, Auckland, New Zealand (Musaad).

The authors have no relevant financial interest in the products or companies described in this article.

Corresponding author: Geoffrey C. E. Herd, MAppSci, Whangarei Hospital, Northland District Health Board, Maunu Road, Private Bag 9742, Whangarei 0148, New Zealand (email: Geoff.Herd@northlanddhb.org.nz).

Regulation of POCT in New Zealand

This article reflects on some of the New Zealand experience with POC medical testing in remote locations and primary care settings. It must be noted that in most clinical settings the POCT users and operators are not medical laboratory trained. Therefore, we emphasize that robust training and quality assurance systems to support these POC tests and devices are essential to ensure that the test results that are used for clinical decision-making are precise and accurate (ie, clinically reliable) at all times, when and where these tests are performed.

This is particularly important for all settings that use POCT devices in New Zealand. The reason is that, apart from the exception of urine pregnancy test kits, POCT devices are *not* regulated in this country. Musaad and Herd[7] recognized that this lack of regulation meant that POCT devices can be used for clinical decision-making in any health settings in New Zealand without appropriate validation prior to use and without ongoing quality assurance. These authors therefore proposed a regulatory framework in 2013 and in 2015, published guidance for the clinical governance of POCT in clinical settings at the provider level.[8]

The Therapeutic Products Bill[9] was released by the Minister of Health for public consultation in December 2018. The bill sets out a regulatory framework for all therapeutic devices, including POC medical testing devices. The broad provisions in the proposed bill are consistent with a revised and expanded regulatory framework for POCT devices that was described by Musaad and Herd.[10] This revised regulatory framework is designed to improve patient safety, including thorough selection of devices, validation, quality assurance, accreditation, and incident reporting.

The New Zealand Health and Disability Consumers Code of Rights

Patient rights documents have been developed in Australia, Canada, New Zealand, the United Kingdom, and the United States, and by the World Health Organization. The New Zealand Health and Disability Consumers Code of Rights document was published in 1996.[5] In this code, right No. 4 states that patients have a right to appropriate standards of care, and therefore POC tests are no exception to this rule. In addition, right Nos. 5 and 6 state that patients have rights to effective communication and to be fully informed.[5] Clinicians need confidence that the POCT information is clinically reliable, so that correct decisions can be made to inform patients and to explore appropriate treatment options with those patients and families.

Accreditation for POCT in New Zealand

With regard to public hospitals, 18 POCT services are accredited by International Accreditation New Zealand (IANZ),[11] as part of its medical testing accreditation program. These accredited laboratories comply with the requirements of the POCT standard, ISO 22870:2016. However, POCT services in rural clinics and in most remote hospitals and private surgical hospitals are not accredited to this standard by IANZ.

Best Practice Guidelines for POCT

In recognition of these rights and the need for quality assurance for POCT in all settings in the interest of patient safety, the New Zealand Point-of-Care Testing Advisory Group was established in 2009 and published its first set of Best Practice Guidelines for Point-of-Care Testing in 2014.[6] These guidelines were reviewed in 2018,[12] and they are used in conjunction with the Australian Government National Pathology Accreditation and Advisory Council Guidelines for Point of Care Testing (PoCT) 2015.[13] Both of these guidelines provide best practice advice and support for health providers who use POCT devices in any setting, including hospitals, the community, and rural or remote locations.

Funding for Medical Laboratory Testing

In New Zealand, publicly owned district health boards (DHBs) fund hospital and community laboratories to perform hospital- and community-based medical laboratory requests for the relevant geographic region. The 20 DHBs also support and fund POCT services within their respective hospitals as required. The existing funding frameworks have limited scope for reimbursement of POCT in the community. However, there are some examples of DHB funding for POCT services in the community. This report will outline some POC medical testing experiences in the community, rural, and remote locations in New Zealand and includes advice on the selection of POCT devices for locations that do not have on-site laboratory support.

POCT FOR CARDIOVASCULAR DISEASE RISK ASSESSMENT IN PRIMARY CARE

Background

A report published by the Ministry of Health in 2013 showed that coronary heart disease, stroke, and diabetes were the leading causes of health loss in 2006.[14] Chan et al[15] showed that the indigenous Māori people of New Zealand had the highest prevalence of cardiovascular disease (CVD), that is, 7.41% compared with non-Māori, and that the prevalence of CVD across all age groups was highest in Māori men and women. In addition, the prevalence of CVD increased with more social deprivation.[15]

The Northland District Health Board Services Plan 2012–2017 states that Northland, the northernmost region in New Zealand, has a high Māori population and has high levels of deprivation compared with the rest of the country.[16] Access to health care and visits to general practitioners (GPs, also known as primary care physicians) can be challenging for people living in rural areas with significant deprivation.

In 2011 the New Zealand government Ministry of Health prioritized CVD risk assessments (CVDRAs) and screening for diabetes. The aim was to achieve a target whereby 90% of eligible adults would receive a CVDRA by primary health organizations by July 2014.[17] Primary health organizations are not-for-profit organizations that include GPs (primary care physicians), nurses, and other allied health providers.

Guidelines for CVDRAs include triglyceride levels, total cholesterol to high-density lipoprotein ratio (lipids), and the use of a risk calculator. Screening for diabetes is also recommended using either fasting glucose or HbA_{1c}. HbA_{1c} testing is more convenient for patients than fasting glucose because HbA_{1c} level provides an estimate of average glycemia during the previous 3 to 4 months, and there is no dietary restriction, which improves compliance. The next section outlines the results of an evaluation carried out in Northland using POC HbA_{1c} testing as part of requirements completion of CVDRAs.

Evaluation of Point-of-Care Testing in Heart Health Trial

The Evaluation of Point-of-Care Testing in Heart Health (EPOCH) trial was carried out in Northland, New Zealand, in 2014 and 2015 by Wells et al.[18] In 2011, the New Zealand government made CVD risk assessments for Māori, Pacific, and South Asian peoples a national priority and set a target of 90% of eligible adults to be screened by primary health care organizations by July 2014.[18] This cluster randomized controlled trial involved patients aged 35 to 79 years enrolled in 20 primary care practices. The trial compared the impact that finger stick POCT for lipids and $HbA_{1c,}$ as opposed to conventional community laboratory testing (usual practice), would have on the completion of CVD risk assessments. A total of 10 of the 20 primary care practices used POCT for lipids and HbA_{1c}, and 10 practices used conventional laboratory testing (controls).

The practices that used POCT included 3 urban practices located in the main city of Whangarei, the regional capital of Northland, and 7 rural practices located in smaller towns throughout Northland. The distance between the 2 most remote practices was 124 miles (200 km). The primary outcome measure for the study was the proportion of completed CVD risk assessments. In addition, qualitative information on operational processes for CVD risk assessment and the feasibility of POC testing within the practices was collected through interviews with practice staff and 2 questionnaires.

The POC testing in the trial practices was carried out using equipment and consumables supplied by Roche Diagnostics New Zealand Ltd. This equipment included a Roche Diagnostics cobas b101analyzer (F. Hoffmann-La Roche Ltd), along with cartridges for lipid and HbA_{1c} testing and quality control solutions that were provided by the manufacturer. Staff training on the use of the equipment and consumables was carried out on site at each practice by Roche Diagnostics New Zealand Ltd. Individual lot numbers of test cartridges for the lipid and HbA_{1c} tests underwent acceptance quality control testing prior to use and afterwards at monthly intervals. Interlaboratory comparison samples were submitted for lipid tests, and external quality assurance samples for HbA_{1c} tests were distributed to each practice at intervals during the course of the study.[18,19] External quality assurance samples for POC HbA_{1c} testing were acquired from a national quality assurance program, the Waikato DHB Laboratory Quality Assurance (QA) Programs, which are managed by Waikato Hospital Laboratory, based at Waikato Hospital, Hamilton, New Zealand.

The Waikato DHB Laboratory QA Program is a New Zealand–wide external quality assurance scheme that uses human matrix to circumvent potential limitations that may be associated with artificial matrix (eg, lyophilized material) that other (international) schemes use. During the time of the EPOCH trial, it was not possible to obtain the Waikato DHB Biochemistry Program samples for lipid tests. Therefore, third-party commercial quality control material was used to challenge the POC lipid tests. This quality control material used was the BIO-RAD Liquichek Unassayed Chemistry Control (Human).

The quality management system included thorough validation of the total cholesterol, high-density lipoprotein cholesterol, triglyceride, and HbA_{1c} assays on the cobas b101 analyzer prior to the commencement of the study and again after a manufacturing fault relating to the HbA_{1c} assay. This validation testing was carried out by IANZ-accredited medical laboratories.[18,19]

Three weeks after commencing the EPOCH trial it was halted. The manufacturer notified the investigators about imprecise and inaccurate HbA_{1c} values on the cobas b101 analyzer and activated a global recall. The initial quality control data showed acceptable results. The batches of HbA_{1c} cartridges received after commencing the trial showed test results that differed from the conventional laboratory results for HbA_{1c} by 0.9% to 2.0% (+6 to −14 mmol/mol) at the clinical cutoff points of 5.8% to 6.7% (40–50 mmol/mol), respectively.[19] Ten faulty batches of HbA_{1c} testing discs were recalled worldwide.

The root cause of the inaccurate HbA_{1c} values was a manufacturing problem, which was eventually rectified, and the HbA_{1c} test was revalidated by the laboratories prior to recommencement of the EPOCH trial. For a full review of the validation process and quality control testing relating to the HbA_{1c} testing issues, and the rationale for recommencing the trial, see Kenealy et al.[19] The trial resumed after retraining of staff and additional acceptance testing of the new HbA_{1c} kits.

EPOCH Trial: Outcome, Key Lessons, and Discussion

The quantitative results of the trial showed that CVD risk assessments were recorded for 7421 patients in the 10 practices that used POCT, whereas in the 10 control practices, 6217 patients had CVD risk assessments recorded. There were major external factors that affected the results of the trial, including: that by July 2014, practices had completed CVD risk assessments in 90% of eligible people in Northland; there was a guideline update on the CVD risk assessment published in late 2013; and the fact that the trial had to be halted soon after commencement.[18] This interruption to the trial resulted in a lengthy delay until the trial resumed, which meant that most practices had achieved their CVDRA screening targets with the time frame set by the Ministry of Health.[18] As a result of this interruption to testing, nursing staff needed to be retrained on how to use the POC analyzer.[18] Nurses noted the time pressure associated with the POC lipid and HbA_{1c} testing, which was an additional nursing task. Other disadvantages included the 5-minute waiting times for the lipid results, followed by another 5 minutes for the HbA_{1c} test results; the requirement for monthly quality control testing; and the lack of adequate space so that the POC analyzer was available for all nurses to use. Other responses to the questionnaire showed that POCT in the practice was perceived as an additional task that had not been integrated with the clinical procedures. The authors concluded that use of POCT devices to enable patient engagement for cardiovascular risk assessments and preventive care need to be fully integrated into the clinical setting.[18]

However, the authors used questionnaires and interviews and showed that for some patients, the POC lipid and HbA_{1c} tests were acceptable, particularly for young people ages 45 to 55 years, and also that Māori men liked the "instant result." Of 10 staff, 7 responded that finger stick testing was more acceptable to patients than venipuncture and that it was beneficial for those who have difficulty attending primary care physician (GP) appointments and to visit a laboratory for blood testing. The use of the POC lipid results and HbA_{1c} information along with other health screening parameters meant that a discussion about the meaning of CVD risk assessment could be completed at the

time of the consultation. Rigorous validation of POCT devices and quality control are essential prior to implementation and also on an ongoing basis while devices are in use in clinical settings.[18,19]

Health Screening and Diabetes Checks in a Workplace to Improve Access to Health Care

This pilot study, a workplace health check and diabetes screening initiative, was carried out at the AFFCO NZ Ltd meat processing plant in Moerewa, Northland, New Zealand, on June 24–26, 2019.[20] The town of Moerewa is situated in central Northland and has a high deprivation rating. This pilot program was funded by the Northland District Health Board (NDHB) with the initial aim of increasing the number of CVDRAs for 35- to 44-year-old Māori men who have not had a CVDRA in the past 5 years. Funding was approved by the NDHB for use in collaboration with the Te Tai Tokerau Primary Health Organization (now known as the Mahitahi Hauora Primary Health Entity) to provide staffing and to purchase POC HbA_{1c} equipment for the health and diabetes screening.

The POCT equipment used during the study included a capillary blood glucose meter CareSens Nano (i-SENS Inc, Seoul, Korea) and a Siemens DCA Vantage HbA_{1c} analyzer (Siemens Healthcare GmbH, Erlangen, Germany). The analytic performance of the DCA Vantage analyzer was verified using the manufacturer's optical calibration equipment, quality control solutions, and test cartridges prior to commencement of the study. Two registered nurses were trained and certified to use the instrument.

The equipment, study materials, identification numbers, and data recording forms were set up in the human resource managers' office on the premises at the meat processing plant. However, on the day prior to the commencement of the health screening and diabetes testing, an employee, when asked if he was willing to participate, replied that he was "too old" and therefore outside the age group. This had the effect of narrowing the offer of workplace health testing. Therefore, it was immediately decided to provide health checks to all employees rather than restrict these checks to the equity target of 35- to 44-year-old Māori men. This "on the spot" decision improved access to the screening, was more equitable for other age groups and other ethnicities, and also included access to the screening for female employees.

From the outset, the investigators were keen to ensure that the health screening was carried out in a culturally sensitive and appropriate manner. To that end, a Kaiāwhina (Māori translation: helper) welcomed and informed all participants about the health screening checks and testing and that the results would be sent to their GP. Testing was carried out during 3 days, with the second day reserved as a "ladies' day." This program of alternate day screening was designed to ensure that the health screening was carried out in culturally sensitive manner and one which was acceptable to both male and female employees. The participants completed consent forms before 2 registered nurses commenced the health screening checks, which included height, weight, and waist circumference measurements and body mass index (BMI) calculation. Additional screening checks included blood pressure measurements, smoking assessment, previous history of cardiovascular disease and family history of diabetes, nonfasting capillary blood glucose, and POC HbA_{1c} tests. In total, 57 employees (39 men and 18 women) participated in the 3-day pilot study. The predominant ethnic group was Māori 64.9%, followed by New Zealand European 26%, Tongan 5.7%, African 1.7%, and Indian 1.7%. The average age for the men was 49.5 years (range, 23–68 years), and for the women it was 43.1 years (range, 24–69) years. A total of 23.8% of the Māori men were within the initial target age group of 35 to 44 years.

The mean body BMI values for the men and women were 32.2 and 31.1 kg/m^2, respectively. The Ministry of Health–recommended BMI for healthy weight cutoff point is 18.5 to 24.9 kg/m^2 for adults.[21] A previous history of CVD was reported by 14 of the participants (24.5%). Blood pressure measurements showed that 19 of the 39 men (50.0%) and 11 of the 18 women (61.1%) exceeded the Ministry of Health–recommended systolic and diastolic blood pressure levels (ie, 120 and 75 mm Hg).[22] The range of blood pressure values for the men was 110/60 to 154/110 mm Hg, and the blood pressure range for the women was 102/68 to 160/88 mm Hg.

A family history of diabetes was reported by 30 of 57 participants (52.6%). The nonfasting capillary blood glucose results ranged from 90.1 to 369.4 mg/dL (5.0–20.5 mmol/L; reference interval, 63.1–198.2 mg/dL [3.5–11.0 mmol/L]). The mean HbA_{1c} level for all participants was 5.7% (38.4 mmol/mol; reference interval, 4.3%–5.8% [24–40 mmol/mol]). The participants' HbA_{1c} test results ranged from 4.7% to 10.3% (28–89 mmol/mol). Two participants reported they had type 1 diabetes, and 1 had type 2 diabetes. One man with type 1 diabetes had a glucose level of 264.9 mg/dL (14.7 mmol/L), and his HbA_{1c} was 10.3% (89 mmol/mol). Another man with type 1 diabetes on dietary control had a glucose level of 127.9 mg/dL (7.1 mmol/L), and his HbA_{1c} was 7.4% (57 mmol/mol). One woman with type 2 diabetes had a glucose level of 369.4 mg/dL (20.5 mmol/L), and her HbA_{1c} level was 9.9% (85 mmol/mol). A total of 6 men and 2 women, who were not known to have diabetes, had HbA_{1c} levels >5.8% (40 mmol/mol).

It was not possible for a primary care physician to be present in the workplace to provide treatment advice at the time of the health screening. Therefore, copies of the results of the health screening checks and the HbA_{1c} tests were sent to the participants' primary care physician for follow-up. Clinical management and actions based on the results were left to the discretion of the primary care physician.

A total of 56 of 57 participants (98.3%) completed questionnaires that were designed to assess their impressions and gain feedback about the study. One participant did not receive a copy of the questionnaire. Participants were asked how they found the testing and what they liked about the testing. A total of 32 of 57 participants (56.1%) stated that the health and diabetes and testing was: "ok/good/easy/great/cool/awesome." In addition, 10 of 57 participants (17.5%) reported that the health and diabetes and testing was a "good idea." There were no negative responses to these questions. A total of 98.3% of participants answered that they would recommend this program to their family and friends, and 98.3% stated they would participate if the program was repeated in 2020.

There is evidence that this pilot study helped to improve access to health care and reduce barriers to accessing health services. A total of 14 responses from 56 participants (25%) below provided real-world insights and comments of examples of the barriers to accessing health care that these people were experiencing in their day-to-day lives. Participants stated that the screening in the workplace was more

convenient for them and that it was difficult to meet appointments with doctors outside working hours.

The major limitations of this pilot study were the fact that there were only 57 participants, the limited time available for the health screening, which meant that it was not possible to carry out lipid tests, the less than optimal physical setting for the health screening, which was carried out in an office, and that a primary care physician was not available to provide immediate treatment advice.

In conclusion, the results of this pilot study demonstrate that the health checks and diabetes screening for employees in a workplace are both culturally and clinically acceptable to these people and their management. The results are an example of the integration of expertise and resources between the NDHB and primary health care. In addition, this study demonstrates a high quality of clinical service and improves access to health care, with a focus on reducing barriers, meeting the health needs of Māori and Pacific people, and addressing inequity in Northland. The health providers and the employer, AFFCO New Zealand Ltd, are encouraged by the outcome of this pilot. There are opportunities to repeat this health screening initiative at the AFFCO Moerewa meat processing plant next year and at other workplaces in Northland in the interests of improving access to health care for these people.

POCT TO SUPPORT ACUTE CARE IN A RURAL HOSPITAL WITHOUT AN ON-SITE LABORATORY

Hokianga Health Rawene Hospital is a rural hospital in Rawene, Northland, New Zealand, that provides an accident and emergency service, as well as maternity and acute patient treatment. The nearest major hospital, Whangarei Hospital, Northland, New Zealand, is located 2 hours by road transport from Rawene. Each year there are approximately 700 acute admissions to Hokianga Health Rawene Hospital; patients present with general medical problems and injuries. In addition, there are high rates of diabetes, chronic respiratory disease, ischemic heart disease, heart failure, gout, and cancers. Added to this clinical demand are increasingly complex presentations, with many patients who have multiple comorbidities and medications. Maternity services, including antenatal, birthing, and postnatal care, are also provided. Approximately 25% of the patients are transferred to Whangarei Hospital.[3]

Hokianga Health Rawene Hospital does not have an on-site laboratory service. Specimens for nonurgent investigations are sent by road to Northland Pathology Laboratory in Whangarei. These specimens are dispatched Monday to Friday at 10:00, and the test results are available electronically by late afternoon. It is not possible to send samples for laboratory tests after 10:00 on Friday or on weekends and public holidays. This lack of laboratory support placed patients at risk and compromised decision-making.[3]

An Abbott i-STAT analyzer (Abbott Point of Care Inc, Chicago, Illinois) was installed in 2008 to provide POC blood gases and lactate, electrolytes, urea, creatinine, glucose, cTnI and BNP. This POCT service was supported by the Northland District Health Board (NDHB) POCT quality management system, which includes a staff training and certification program, along with internal and external quality control tests. The quality management system is carried out by registered nurses on site at Hokianga Health Rawene Hospital and is overseen by the NDHB POC coordinator based in Whangarei Hospital.

This Abbott i-STAT POCT service was evaluated by Blattner et al.[3] A total of 269 POC tests were undertaken for 177 patients. These authors showed that use of the device improved diagnostic certainty from 2.5 diagnoses pretest to 1.3 diagnoses posttest ($P < .001$). The use of POCT changed patient disposition for 43% of patients ($P < .001$), by reducing transfers to the Whangarei Hospital by 62% (52 pretest and 20 posttest) and increased discharges by 480% (7 pretest and 34 posttest). Substantial treatment changes occurred in 75% of cases, with some change in 22% and no change in 3% of cases. During the first year of operation, the overall cost to Hokianga Health Rawene Hospital was NZ $90,222. This cost included the POCT implementation, treatment costs, and more and longer bed stays for patients. Note: prior to the POCT service being implemented, these patients would have required transfer by road ambulance to Whangarei Hospital for treatment. The net savings in reduced transfers and costs to Whangarei Hospital was NZ $362,138. The additional benefits include better continuity of care and the fact that patients are not separated from family. The authors concluded that the use of POCT allowed clinicians to obtain test results in a clinically relevant turnaround time, and it helped to both improve the provision of health care in a disadvantaged community and reduce inequity.[3]

CHALLENGES IN IMPLEMENTING POC HEMATOLOGY IN A RURAL LOCATION

In December 2015, following on from the successful installation of the Abbott i-STAT analyzer, Hokianga Health Rawene Hospital installed an Abbott Cell Dyn Emerald 22 hematology analyzer (Abbott Diagnostics). It was expected that the types of presentations that would benefit from POC hematology results include emergencies and acute cases with potential for deterioration, and where a full blood count could add critical diagnostic information (eg, early sepsis, a poorly differentiated patient, possible neutropenic sepsis in patients receiving chemotherapy, gastrointestinal bleeding, and bleeding in a patient on anticoagulants). The analyzer measures hemoglobin, hematocrit, red blood cell parameters, white blood cell counts with a 5-part white blood cell differential, and platelet counts, which provide timely POC hematology results to support decision-making. The analyzer is supported by an internal quality control program using control material supplied by the manufacturer, and the service was also enrolled in the Waikato Hospital Laboratory Quality Assurance Survey for Hematology. This survey was supplied by the Waikato Hospital Laboratory, Waikato Hospital, Hamilton, New Zealand.

Blattner et al[23] reviewed the clinical effectiveness of this hematology analyzer at the POC in a prospective observational study. This mixed-methods study included quantitative and qualitative assessments of the clinical impact and a cost-benefit analysis.

Data on differential diagnoses and disposition were collected from February to April 2016 and June to August 2016. In total, 97 of 116 POC care hematology tests were included for the study. A total of 94 of the 97 tests (97%) were performed on patients with acute undifferentiated presentations. Most of these tests, 70 of the 97 (72%), were performed on weekends, evenings, and overnight, and of

the 97 tests, 69 of the tests (71%) were performed on patients with Māori ethnicity.

The analysis of data showed that the use of POC hematology results reduced the average number of differential diagnoses from 2.43 pretest to 1.7 posttest (χ tests $P < .05$). In addition, there was a reduction in the number of patients transferred and an increase in the number of patients who were discharged home (χ tests $P < .05$). Prior to hematology testing, 25 of the 97 patients (26%) would have required transfer to Whangarei Hospital. This number was reduced to 11 of 97 (11%). Prior to on-site hematology testing, 59 of the 97 patients (61%) would have been admitted to Hokianga Health Rawene Hospital, whereas this number was reduced to 14 (14%) posttest, and 4 patients were transferred to another hospital.

With regard to change in treatment, the clinical staff stated that in 60 of the 97 cases (61.8%), the hematology tests changed clinical management and that there was a "significant change" in treatment in 9 of 97 patients (9.2%). For example, the POC hematology results confirmed the presence of neutropenia in a febrile patient on chemotherapy. Another example showed that the hematology results assisted a decision not to start antibiotic treatment.

In terms of financial benefit, the introduction of the hematology analyzer showed significant savings to the health system. The financial analysis showed that costs of the analyzer, running costs, overheads, and staff time to support the device were $36,500 per annum. The direct savings were based on the average cost per hospital admission. The savings to Whangarei Hospital were estimated to be $87,500 per annum, and they were $62,500 per annum for Hokianga Health Rawene Hospital.[23]

The intangible benefits for the use of the hematology analyzer included the ability to provide care closer to home for patients in the Hokianga area in Northland, which avoids the need to transfer them to another hospital. This in turn reduces stress on patients and their families. The availability of the hematology results improved decision-making and communication with clinicians at the referral hospital and also improved job satisfaction for the clinical staff at Hokianga Health Rawene Hospital.

There were significant challenges for the nursing staff that related to managing and supporting the analyzer within a rural hospital without on-site laboratory support. The authors noted that this type of technology does increase clinician workload because of additional responsibilities, for example the need for training and conducting quality assurance, and this needs to be considered from the outset.[23] It is to the clinicians' credit and commitment that the hematology test results were clinically reliable and without their commitment, the clinical outcomes of this study would not have been realized. These authors also noted the importance of clinical governance, oversight, and quality management systems relating to projects of this nature.[23]

Other POCT tests provided by Hokianga Health Enterprise Trust, a not-for-profit primary care organization, are POC international normalized ratio (INR) tests for warfarin management at 6 remote clinics in the district. These tests are performed using Roche CoaguChek XS Pro INR analyzer (Roche Laboratory, Meylan, France) and are subject to regular quality control tests, which are performed centrally at the Hokianga Health Rawene Hospital.

STRENGTHENING DIAGNOSTIC AND DECISION-MAKING PRIMARY CARE (GENERAL PRACTICE)

The Waitemata District Health Board Rural Point of Care Testing Service (R-POCT) was implemented in all rural primary care practices (general practices) across both the Auckland DHB and Waitemata DHB areas.[24] The rationale for this POCT service in rural general practices is to enable rapid decision-making from assessment and diagnosis to treatment. The goal is to reduce unnecessary emergency department presentations and/or hospitalizations and help provide appropriate care at the right time and in the right place, either at the patient's primary care practice or by referral to hospital.

The Rural Alliance group of general practices identified the 4 most clinically valuable POCT tests for the management of people presenting acutely unwell in a rural setting. The R-POCT tests carried out by the rural practices include troponin I and INR on the Abbott i-STAT analyzer, D-dimer on the Roche h232 analyzer (Roche Diagnostics, F. Hoffmann-La Roche Ltd), and a full blood count on the QBC STAR Hematology Centrifugal Analyzer (Drucker Diagnostics, Philipsburg, Pennsylvania). The Waitemata DHB Laboratories POCT team oversees and manages the R-POCT service on behalf of both Auckland and Waitemata DHBs. This ensures that quality assurance and control measures are consistent across all primary care practices that are members of the Rural Alliance.[24]

POCT IN A SEXUAL HEALTH CLINIC FOR DETECTION OF INFECTIOUS DISEASES

The Northland District Health Board (NDHB) operates a sexual health clinic in Whangarei, New Zealand, and manages clients with sexually transmitted infections and other related conditions. For some conditions, the rapid-availability POC medical laboratory test results can help with the diagnosis and treatment options and inform advice for clients. The POC tests offset the delay in obtaining test results when samples are sent to a conventional laboratory for testing. The types of clinical conditions for which POC tests are used in the clinic include urine dipstick tests for suspected urinary tract infection, urine pregnancy tests, and whole blood tests for human immunodeficiency virus (HIV) antibodies and antibodies to *Treponema pallidum*, the causative agent of syphilis.

As part of the quality control program, the urine pregnancy test kits are subject to regular quality control checks by the NDHB POCT Team based at Whangarei Hospital. In January 2020, the Sexual Health Service commenced using the SD BIOLINE HIV/Syphilis Duo test kit (SD Standard Diagnostics Inc, Yongin-si, Republic of Korea). This testing is performed in accordance with an NDHB clinical protocol.

The SD BIOLINE HIV/Syphilis Duo test kit uses an immunochromatographic method to detect antibodies to the HIV 1 and 2 viruses and also antibodies to *Treponema pallidum* simultaneously. A blood sample is used to test for the antibodies, and the test takes 15 to 20 minutes. The results are easy to interpret, and the rapid availability of the test results helps with diagnosis and with providing advice and counseling to clients.

The BIOLINE HIV/Syphilis Duo can be used with whole blood or serum samples and was evaluated by NDHB using a panel of 20 serum samples with known reactivity for HIV 1/2 antibodies and *Treponema pallidum* antibodies (unpub-

lished data). The results obtained were consistent with a report by Van del Heuvel et al.[25] These authors evaluated 4 rapid diagnostic tests for HIV and syphilis that included the BIOLINE HIV/Syphilis Duo kit. In that study, the sensitivity for anti–HIV 1/2 was 100%, and the specificity was 99.5%. The sensitivity for *Treponema pallidum* antibody was 87% and the specificity 99.5%.[25]

The SD BIOLINE HIV/Syphilis Duo test system used at the clinic is supported by a robust quality assurance program in accordance with the recommendations of the New Zealand Microbiology Network.[26] This includes training and certification of staff and quality control tests on the test kits using known reactive samples. This POCT service is enrolled in the Royal College of Pathologists of Australasia Quality Assurance Program for Anti-HIV1+2 and Syphilis serology.

The SD BIOLINE HIV/Syphilis Duo test is used as a screening test. In addition, the kit cannot detect HIV antigen; therefore, all clients have blood samples sent to the laboratory for follow-up testing for both infectious agents. This follow-up testing is also used as an ongoing real-time quality assurance program whereby the results of the SD BIOLINE HIV/Syphilis Duo tests are compared to results from conventional laboratory assays.

Note: the SD BIOLINE HIV/Syphilis Duo kit is also used at drop-in clinics supported by the New Zealand Aids Foundation. The Body Positive Inc is a peer support organization that provides care and support for all people living with HIV/AIDS. This organization uses the bioLytical *INSTi* Multiplex HIV-1/HIV-2/Syphilis Antibody Test (bioLytical Laboratories, Richmond, Canada) for screening clients. To best of the authors' knowledge, these POCT programs for HIV and syphilis testing have not been systematically evaluated by accredited New Zealand laboratories.

POCT IN THE PHARMACY TO IMPROVE ACCESS TO ANTICOAGULANT MONITORING

The New Zealand Community Pharmacy Anticoagulation Monitoring Service (CPAMS) was established in 2010 to support patients on warfarin therapy and to improve the accessibility and convenience of monitoring and managing warfarin. The CPAMS program is helpful for patients who have difficult venous access, those who cannot attend primary care physicians for dosing advice, or those who have poor compliance with treatment.[27] The CPAMS program is consistent with the Ministry of Health policy of "better, sooner more convenient health care in the community."[28]

Pharmacies are reimbursed by local DHBs to perform the testing. Trained pharmacists carry out capillary blood INR testing using a Roche CoaguChek XS Plus analyzer and then calculate and dispense warfarin dosages using the INROnline decision support system. There are currently 162 pharmacies managing around 6600 patients on warfarin (Keryn Smith [product manager, Point of Care, Roche Diagnostic New Zealand Ltd], personal email communication, January 20, 2020).

Pharmacies must recruit a minimum of 45 patients who must not have antiphospholipid syndrome or the lupus anticoagulant, or be on chemotherapy. The pharmacies must carry out internal quality control tests and also participate in an external quality assurance program. CPAMS is supported by quality management systems based on the requirements of ISO 22870:2016.[1] Pharmacies enrolled in the CPAMS program within the Canterbury District Health Board catchment are also included in the Canterbury Health Laboratories scope of accreditation for POCT by International Accreditation New Zealand.[11] District health boards require primary care physicians to sign off on standing orders for each patient and require the pharmacist to request a primary care physician review for INRs <1.5 or >4.0. The warfarin dose adjustments are made using INROnline decision support system.

A review of the initial CPAMS pilot by Shaw et al included 671 patients.[29] The mean time in therapeutic range for all 671 patients was 78.6%, rising to 79.4% and 80.2% for patients who had been enrolled in the CPAMS program for 16 weeks and 26 weeks, respectively. The review showed that all pharmacies in the pilot study achieved a mean time in therapeutic range for their respective patients in excess of 70% (range, 71.4%–84.1%), well above the recommended target of 60%.[29]

Patient satisfaction questionnaires were completed by 430 of the 693 enrolled patients (62%).[29] This survey by Shaw et al showed that 98.1% preferred capillary blood testing over venipuncture, 96.9% of patients found the service more convenient, and 93.6% stated that it saved time. Some patients felt that the INR monitoring process was less fragmented, there was less likelihood of miscommunication, and they felt more involved in their treatment.[29]

In the same report,[29] 35 of 41 participating pharmacists (85%) were surveyed. All reported the CoaguChek XS Plus easy to use and that they would continue to offer the service for patients on warfarin; 97% were confident the CoaguChek XS Plus results were reliable, whereas 94% felt that, through access to INR POC testing, they could also assist patients with additional health issues. General practitioners associated with CPAMS also completed questionnaires. A total of 28 of 115 GPs (24%) responded. A total of 25 (89%) of the respondents were confident that pharmacists could manage patient's treatment safely and the test results were reliable.[29]

Other pharmacy-based POCT activities in New Zealand include capillary blood urate tests for the treatment of gout and screening tests for antibodies found in patients with celiac disease. To the best of the author's knowledge, the impact of these programs has not been evaluated.

POC TROPININ TESTING IN RURAL HOSPITALS

Rural hospitals, of which there are 33 in New Zealand,[30] rely on POC cardiac troponin (POC-cTn) for management of acute coronary syndrome; some use it after hours when the hospital laboratory is closed, but most (88%) rely on it 24 hours a day. Troponin results form the basis for discharge or transfer to larger hospitals. In 2014 the New Zealand Ministry of Health mandated an accelerated diagnostic pathway (ADP)[30] for triaging and management of acute coronary syndrome in emergency departments. This pathway relied on the use of a high-sensitivity Tn assay and was adopted by all urban and large hospitals because they have access to these assays in their laboratories. Rural hospitals were unable to adopt the ADP because the POC-cTn has lower sensitivity and higher imprecision compared with high-sensitivity Tn assays.[30]

In 2017 a clinical pathway adapted to POC-cTn was proposed by Miller and Nixon.[31] This pathway was partly based on recommendations by the Australasian Association

of Clinical Biochemists[32] and supported the use of lower cut-points for POC-cTn assays to increase sensitivity.

Miller and Nixon[31] surveyed rural hospitals in New Zealand to determine the use of POC-cTn testing, what cutoff value was being used, and if an ADP was being used for the assessment of chest pain. The survey[3] demonstrated that only one of the rural hospitals had adopted an ADP pathway adapted for POC-cTn, a few were using the Ministry of Health ADP after lowering the cutoffs for their POC-cTn assays, a practice that is not recommended, and the remainder did not use an ADP.

This illustrates that the POC-cTn assays do not meet current clinical requirements, limiting their effective use particularly in rural hospitals. In the end, the rural hospital clinicians are forced to use the POC test results as best they can while aware of their limitations. Improved POC-cTn assays are needed.

BARRIERS TO POCT IN REMOTE AND RURAL LOCATIONS

The World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONCA) Special Interest Group (SIG) (2015) lists the barriers to implementation of POCT, and these include the cost of devices, lack of reimbursement, staff training and retention, the accuracy of POC tests, logistics and accommodation, the costs of quality control and accreditation requirements, and lack of expertise relating to implementing POCT.[33] With regard to perceived accuracy of POC tests, the experiences listed in the present report show that clinically reliable test results can be obtained provided that rigorous quality assurance programs are implemented. The WONCA SIG also states that the lack of support from suppliers is a barrier to implementing POCT. In contrast, the experience of the authors is that in New Zealand, technical and logistic support from suppliers of POCT devices and equipment has been very good and is essential for the successful implementation of POCT.

In New Zealand, funding frameworks are geared toward funding conventional laboratory testing, which is a barrier to implementing POCT. However, DHBs have recognized that the results of the Hokianga Hospital implementation of POCT and the CPAMS program are cost-effective and show improved access and improved outcomes. These examples will in time hopefully encourage other funding initiatives for POCT in remote and rural locations and help bridge the reimbursement barrier.

The survey by Miller and Nixon[31] shows that 17 of 23 rural hospitals (74%) were using POC-cTn assays but were not using an ADP. This suggests that rural hospitals are trying to "make do" with the currently available POC-cTn assays while being aware of the limitations of these assays. This experience demonstrates that knowledge of the limitations of an assay will allow it to be used in a clinically effective manner and, importantly, that there are barriers to implementing the ADP clinical pathway and guidelines.

SELECTION AND IMPLEMENTATION OF POCT TECHNOLOGIES

These programs describe what is possible in terms of POCT in remote or rural locations without on-site laboratory support. These programs do take time and effort to establish and implement with regard to selection of devices, validation, quality assurance, and training. In addition, the cultural appropriateness of testing and the setting also need to be considered.[4]

The selection of devices for remote locations needs to include assessments of usability and acceptability by the operators. The devices must be "easy to use, so that it is easy to get it right and hard to get it wrong." In terms of acceptability, there must be minimal maintenance and regular quality control requirements. The reliability of test results must also be clinically acceptable for the clinicians and to the patients or clients. Sustainability of POCT services in remote locations can also be challenging, especially those relating to staff turnover, logistics, and cold chain storage for supplies. It is imperative that clinicians and operators have easy access and support from reputable suppliers, experienced POCT scientists, and pathologists for technical and clinical advice.[4]

DISCUSSION

The examples described in this report demonstrate that POCT devices can be used safely in remote settings and rural locations without on-site laboratory support if performed by competent personnel with quality assurance oversight. A quality framework for POCT in any setting helps to ensure that patients' rights are treated with respect and dignity. POCT improves access to health care, and the rapid availability of the right information at the right time enables clinicians working in remote locations to meet standards of care, all of which are consistent with the Health and Disability Consumers Code of Rights 1996.[5]

Clinically reliable test results need to be available at all times and to be produced by all personnel who use POCT devices in these remote settings. Reliable test results can only be obtained when (1) devices which are selected for POCT are appropriate for the setting, (2) the user interface ensures that the device is "easy to use and hard to get it wrong," (3) the devices are correctly integrated into the clinical workflow,[18] (4) there are sustainable quality control, training, and certification programs in place,[18,19] (5) approved devices are available for use,[10] and (6) personnel are able to seek advice on the selection of POCT devices, troubleshooting and quality assurance as and when required.[8,13]

The use of POCT in remote settings for chronic conditions, as is the case with the EPOCH trial and the workplace health screening and diabetes initiative at AFFCO in Moerewa, are examples of how POCT also provides opportunities for on-the-spot patient-clinician interaction, joint discussion, and decision-making with regard to discussions around lifestyle changes and treatment options.[34] Schnell et al[34] noted that HbA1c testing at the POC has the potential to improve compliance with testing, improve patient education and motivation, and also improve the early detection of prediabetes. Indeed, the pilot study work at AFFCO Moerewa found 6 employees who were not known to have dysglycemia but had HbA_{1c} levels above 5.8% (40 mmol/mol),[20] the cutoff for impaired glucose tolerance in New Zealand.[19]

In an acute care setting, the clinicians at Hokianga Hospital have the right information in order to discuss treatment and management options for acutely ill patients, including discharge or transfer to a major hospital. The availability of POCT in the Hokianga Hospital setting has improved acute care and is more equitable for all people living in this rural location. The experiences at Hokianga

Hospital with the use of POCT for both biochemical and hematologic tests have been cost-effective and have shown significant savings to the health system.[3,23]

Another acute primary care setting where POCT assists with clinical diagnosis is the R-POCT service implemented by the Waitemata DHB in the Auckland and Waitemata DHB rural practices.[24]

Shaw et al showed that the CPAMS program improved the time in therapeutic range for ambulant patients on warfarin up to 80%.[29] It is expected that this improved time in therapeutic range will help to reduce the risk of bleeding and thrombotic complications for these patients. Other benefits of the CPAMS program are that the pharmacists reported improved job satisfaction, they have the opportunity to be more involved with the patients and other health conditions they may have,[29] and the service is also more accessible for patients.[27] This POCT program improves access to health care[2] and is consistent with the New Zealand government policy of "better, sooner, more convenient"[29]; it also helps improve the multidisciplinary management of patients on warfarin in the community, and it helps reduce the workload of medical practitioners.[28]

The New Zealand POCT landscape welcomes the enactment of the Therapeutic Products Bill[9] so that POCT devices are subject to regulation. Regulation of POCT devices and the appropriate accreditation requirements for their use will improve the safety of POCT in public hospitals, private hospitals, clinics, general practice, and their use in remote and rural locations. To that end, the New Zealand Point-of-Care Testing Advisory Group will continue to provide advice and guidance on POCT issues in the interests of improving access, improving outcomes, and reducing inequity for all people.

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