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CLINICAL STUDY SUPPORTS ADOPTION OF CXBLADDER INTO NEW CLINCAL PATHWAY

Canterbury DHB publishes real-world clinical study with cementing evidence supporting the adoption of Cxbladder into the new clinical pathway

The latest published clinical paper for Pacific Edge's Cxbladder bladder cancer tests reveals the cementing evidence behind the introduction of new guidelines for the assessment of haematuria[1] by one of New Zealand's largest public healthcare providers, Canterbury District Health Board (DHB).

The independent, real-world study has highlighted the benefits of using Cxbladder Triage (CxbT) in conjunction with imaging for initial assessment of all patients that present to the clinic with haematuria for investigation for bladder cancer. The results show that this new clinical process would allow approximately one-third of patients to be managed within the community by the primary care provider, avoiding the need for an invasive and expensive cystoscopy.

The majority of haematuria patients treated in secondary care within the New Zealand health system are seen through publicly funded hospitals and out-patient clinics (with access to services tightly managed to capacity using strict criteria and careful review of referrals), supported in the community by a robust and competent primary care sector.

The 13-month study by Canterbury DHB of 571 patients with haematuria, looked to examine the performance of new guidelines, that included CxbT as the only urine test to be used in combination with imaging, to the clinical pathway for investigating haematuria.

The results were published in the New Zealand Medical Journal[2] and provide compelling evidence supporting the adoption of Cxbladder into Canterbury DHB's new clinical pathway.

In the look-back study, all significant bladder cancers were diagnosed by the new guidelines, combined use of imaging and CxbT, before cystoscopy was undertaken, provided a performance with sensitivity of 97.7% and a negative predictive value (NPV) of 99.8%.

This look-back study concluded that:

- The new proposed clinical pathway has the potential to save considerable amounts of physician and clinical resources without compromising patient safety.
- The high negative predictive value (NPV) of this new clinical pathway would allow approximately one-third of patients with haematuria to be managed without cystoscopy, a net cost saving of approximately 30% of cystoscopies.
- Those patients with a negative CxbT test score could remain in primary care without being referred to secondary care for specialist review thereby freeing up secondary care resources.
- Canterbury DHB estimated that this would free up approximately 200 patient consultations per year and allow management of conditions that might not otherwise reach the thresholds for referral.
- Importantly, patients with haematuria would also safely avoid the social disruption and discomfort of a secondary care clinic visit for cystoscopy.
- The new pathway should be applicable in any health system with effective general practice or primary care and the ability to inform GPs of locally recommended assessment and management of haematuria.

[1] Haematuria is blood in the urine and a key indicator of urothelial and bladder cancer.
[2] NZMJ 21 June 2019, Vol 132 No 1497 ISSN 1175-8716 © NZMA http://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2019/vol-132-no-1497-21-june-2019/7915

The findings have resulted in the adoption of new local guidelines for all Canterbury DHB haematuria patients, which require that patients who present to their primary care physician in the first instance, receive CxbT and imaging. Patients negative to CxbT and imaging will not now progress to secondary care with its invasive and expensive treatment options.

This new haematuria assessment algorithm was adopted into the Canterbury Community Health Pathways in February 2018 and continuous audit of a further 890 patients has been carried out over the last year to provide a further look-back on utility, performance and patient compliance and safety.

CEO of Pacific Edge, David Darling, said: "The Canterbury DHB look-back study should be essential reading for all large healthcare organisations which are looking to better allocate limited resources and ensure quality patient care. A rapidly growing library of clinical evidence demonstrating the benefits and clinical utility of our Cxbladder tests is being published in respected medical journals, and key opinion leaders are supporting the use of Cxbladder in clinical settings. For a cancer diagnostics company commercialising new medical technology, such as Pacific Edge, the long and arduous pathway to peer reviewed publications provides the lifeblood in achieving clinical acceptance and positive reimbursement outcomes for our products."

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OVERVIEW www.pacificedge.co.nz www.pacificedgedx.com
Pacific Edge Limited (NZX: PEB) is a New Zealand publicly listed, cancer diagnostic company specialising in the discovery and commercialisation of diagnostic and prognostic tests for better detection and management of cancer. Its non-invasive, simple to use and accurate Cxbladder tests enable the detection of bladder and other urinary tract cancers from a small volume of a patients' urine. Cxbladder provides actionable results and better detection and management of urothelial cancer. The company is developing and commercialising its range of Cxbladder tests globally and has two wholly owned accredited laboratories in New Zealand and the USA. The company's products have been tested and validated in multiple international clinical studies.

ABOUT Cxbladder Triage
Cxbladder Triage accurately identifies patients with haematuria who have a low probability of bladder cancer and may not require a more extensive urological evaluation. Cxbladder Triage is a tool for use by clinicians and physicians in primary evaluation of patients with haematuria and is intended to reduce the need for an expensive and invasive work-up in patients who have a low probability of having urothelial cancer.

ABOUT Cxbladder Detect
Cxbladder Detect provides clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy. Is often used in conjunction with Cxbladder Triage to provide greater rule-out and resolution of patients who have UC.

ABOUT Cxbladder Monitor
Cxbladder Monitor allows urologists to monitor bladder cancer patients for recurrence of the disease. Bladder cancer has a recurrence rate of 50-80% and requires life-long surveillance. Cxbladder Monitor accurately identifies patients with a prior history of urothelial cancer whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial cancer. Cxbladder Monitor is designed to be used as the preferred adjunct test to cystoscopy in the management of patients for ongoing evaluation of recurrent bladder cancer.

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ABOUT Cxbladder Resolve

Cxbladder Resolve identifies those patients who are likely to have aggressive or more advanced bladder cancer. Cxbladder Resolve, when used as part of the primary evaluation of haematuria and/or in conjunction with other Cxbladder tests (Triage, Detect), is designed to assist clinicians by accurately identifying patients with a high probability of having high grade or late stage bladder cancer, for whom alternative or expedited treatment options may be warranted, or who can be prioritised for further investigation in high throughput settings.

Refer to www.cxbladder.com for more information.