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CXBLADDER COMMERCIAL EVALUATION CONFIRMS CLINICAL OUTPERFORMANCE

Peer reviewed publication of further independent, real-world clinical evidence highlights the effectiveness, safety and long term clinical utility from inclusion of Cxbladder in a new standard of care in mainstream clinical use.

Cancer diagnostics company, Pacific Edge Limited (PEB: NZX) provides an overview of an independent publication by one of New Zealand's largest public healthcare providers, which highlights the sustained outperformance of a new clinical standard of care that utilises Cxbladder. This real-world outperformance highlights the significant gains in clinical utility that are being derived from the mainstream use of Cxbladder by the Canterbury District Health Board (CDHB) in New Zealand.

The new standard of care that was implemented by the CDHB in February 2018, incorporates Cxbladder Triage as the sole urine test to be used in combination with imaging for investigation of all patients who have blood in the urine, a key indicator of bladder cancer (haematuria).

A previous publication by the CDHB in 2019 on the use of Cxbladder, for all patients who present with haematuria, highlighted that this new clinical pathway detected all invasive urothelial carcinomas and that approximately one-third of patients could have safely avoided the need for an invasive cystoscopy with negligible risk of a bladder cancer being missed.[1]

This latest publication is a review of the effectiveness of this new standard of care, and also includes a follow-up of all the patients who were ruled out by the new pathway as not having bladder cancer. The outcomes described in this paper were consistent with the previous CDHB publication in 2019 and confirmed that the new clinical pathway is an effective standard of care for investigation of haematuria. No patients, who were negative to Cxbladder Triage and imaging, and were therefore ruled out from any further work-up, were found to have a tumour over a follow-up period (21 months on average).

CEO of Pacific Edge, David Darling, said: "The results from this latest independent clinical audit provide further real-world evidence for the use of Cxbladder in everyday commercial practice as a rule-out test for both low and high-risk patients undergoing investigation for haematuria.

"The validation that comes from having further independent clinical evidence, drives successful inclusion in guidelines and positive coverage policy decisions for reimbursement. This is very supportive for those urologists who have adopted Cxbladder and those who are considering the use of Cxbladder as a mainstream component of their standard of care. It demonstrates that Cxbladder is consistently able to correctly identify those patients who can be assessed in primary care without the need for a secondary care referral to undertake flexible cystoscopy.

"For those urologists looking to increase their commercial adoption of Cxbladder, this real-world published evidence on the evaluation of patients who test negative over a 21-month follow-up period, provides the extra evidence supporting the effectiveness of Cxbladder as a mainstream diagnostic test in urology."

[1] Davidson PJ, McGeoch G, Shand B. Inclusion of a molecular marker of bladder cancer in a clinical pathway for investigation of haematuria may reduce the need for cystoscopy. N Z Med J.2019; 132(1497):55–64.

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Clinical Publication Overview and Summary:

The new standard of care requires that all patients receive Cxbladder and imaging for evaluation of haematuria at primary care where only those who test positive are referred to secondary care. The effectiveness and safety of the new pathway was evaluated in a real-world setting where approximately 900 high and low risk haematuria patients received this standard of care and 53% were successfully and accurately ruled out from referral to the urologist.

- The new standard of care uses Cxbladder Triage as the cornerstone test in the evaluation of all haematuria patients and shows significant outperformance over the previous standard of care.
- The evaluation of the effectiveness and long term safety of this new standard of care on all high risk and low risk haematuria patients, had a sensitivity of 98.1% and a negative predictive value of 99.9% to detect a bladder cancer.
- All patients removed from referral to secondary care, by testing negative to the new standard of care were monitored over a median 21 months follow-up period, with no tumours occurring in these patients.
- Review of all new bladder cancers diagnosed in the 15 months following the study showed that none had been missed in the haematuria assessment using the new clinical pathway.
- Of the 884 haematuria patients undertaking the new clinical pathway only a single low-risk low-grade cancer (Ta) was missed.
- The adoption of the new pathway successfully ruled out 53% of all haematuria patients enabling 39% of all patients to be fully cared for in primary practice thereby avoiding any further unnecessary referral to secondary care.
- Patients were only referred for a full urological assessment and cystoscopy by secondary care physicians, if their Cxbladder result was positive and/or their imaging showed a bladder or other urinary-tract abnormality.
- The combination of Cxbladder Triage and imaging reliably identifies those patients who have presented to clinic with haematuria, who can be managed safely in primary care without the need for a secondary care referral and a flexible cystoscopy.

The authors Davidson, Shand and McGeogh conclude that, 'this outcome significantly reduces the burden of invasive and expensive cystoscopic evaluations and spares patients the potential risks, discomfort and anxiety from having a cystoscopy, without compromising detection rates for bladder cancer'. It also allows healthcare resources to be better focused on patients most in need.

Read the full New Zealand Medical Journal paper here:
https://www.nzma.org.nz/journal-articles/assessment-of-a-clinical-pathway-for-investigation-of-haematuria-that-reduces-the-need-for-cystoscopy-open-access

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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 Cxbladder suite of non-invasive, simple to use and accurate diagnostic tests provide actionable results, and better detection and management of urothelial cancer. The company is developing and commercialising its range of Cxbladder bladder cancer tests globally through its wholly owned central laboratories in New Zealand and the USA. The company's products have been tested and validated in international multi-centre clinical studies.

ABOUT Cxbladder Triage www.cxbladder.com
Cxbladder Triage combines the power of the genomic biomarkers with additional phenotypic and clinical risk factors to accurately identify 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 carcinoma.

ABOUT Cxbladder Detect www.cxbladder.com
Cxbladder Detect enables the non-invasive detection of bladder and other urinary tract cancers from a small volume of a patients' urine. Cxbladder Detect provides clinicians with a quick, cost effective and accurate measure of the presence of the cancer as an effective adjunct to cystoscopy.

ABOUT Cxbladder Monitor www.cxbladder.com
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 (UC) whose Cxbladder Monitor score shows that they have a low probability of recurrent urothelial carcinoma. 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.

ABOUT Cxbladder Resolve www.cxbladder.com
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.