

Pushing innovation in bladder cancer diagnosis: how the UK is leading new discoveries.

Rethinking bladder cancer diagnosis and surveillance is necessary to provide better solutions to patients as well as a more cost-effective approach for the NHS.

Q: What makes ADXBLADDER different to the other urine biomarkers we've all come across?

Mr McCracken:

ADXBLADDER is a real game changer in the field of bladder cancer testing. Our data demonstrates this test has one of **the highest sensitivities and negative predictive values of any urine test for bladder cancer diagnosis** and offers innovative features, such as the result being unaffected by urinary tract infections, inflammation or the presence of visible blood in the urine. Additional benefits are that the test uses standard ELISA methods, available in almost every hospital laboratory, requires only 10mls of urine, and takes only four hours to achieve a binary "yes/no" result.

Mr Dudderidge:

This test has a fantastic biological rationale. ADXBLADDER measures MCM5, which is directly linked to cellular growth. The key to the new test is that healthy cells which line the bladder are terminally differentiated and so do not contain MCM5, while cancer cells are replicating cells and therefore do contain MCM5, so when these cells are shed into the urine MCM5 can be detected in the urine of cancer patients, but not in normal urine. I agree with Stuart that it's a strong plus that infections, inflammation and haematuria doesn't cause false positives. We have worked on building the **most robust clinical data to support this test with the largest trials of any similar marker and the strongest results as well**. These results reflect real life, with unselected haematuria patients and follow-up patients in our recurrence study. The results are consistent and nearly all clinically significant tumours are detected. The negative predictive value is 99%.



Mr Tim Dudderidge

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Mr Stuart McCracken

Consultant Urological
Surgeon and Honorary
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Sunderland Royal Hospital
and Newcastle University.

Q: How do you envision ADXBLADDER fitting into the BC pathway?

Mr McCracken:

The mainstay of cancer diagnosis in patients with haematuria remains cystoscopy for all patients, together with appropriate imaging and often urine cytology. We know cystoscopy alone can lead to up to 30% of bladder tumours being missed. We also know that urine cytology is limited by its poor sensitivity and false positives due to benign conditions. There is therefore an unmet need for a non-invasive and cost effective test, such as **ADXBLADDER, that has now been shown in two separate large studies to outperform urine cytology in both the diagnosis and surveillance of bladder cancer**. In the diagnosis of pT1 tumours and above, ADXBLADDER has been shown to have a very high sensitivity and negative predictive value of 97% and 99.8%, respectively. I would suggest that any centres performing urine cytology as part of their diagnostic protocol should consider switching to ADXBLADDER.

Mr Dudderidge:

Regarding NMIBC surveillance, personally I would favour looking at **reducing the number of follow up cystoscopies, i.e. increasing the interval between tests and replacing some cystoscopy appointments with ADXBLADDER tests**. In reality I think we should start by running tests in parallel so that staff gain familiarity with the test and so that local audit can confirm our trial observations. This will help demonstrate possible reductions in invasive procedures and the significant financial savings that could be achieved.