## I factsheet

## The Truth about 'Gold Standard' Testing

There are two diagnostic tests for urinary tract infection (UTI); the dipstick, with its familiar different coloured squares, and 'mid-stream urine' (MSU) cultures, tested at a lab. Peer-reviewed research has discredited these tests for over 30 years, yet they are described as 'gold standard'. Recent biostatistical studies from University College London (UCL) show that these tests **miss at least 50 percent of genuine infections**. The medical authorities ignore these substantive concerns. National Institute for Health Care and Excellence (NICE) guidelines disregard the failures; the British Infection Association stipulates that a UTI can only be diagnosed after positive test results. Why they ignore them remains a mystery. But clinicians continue to tell countless sufferers of chronic bladder conditions that, because their tests are negative, they have no infection.

In 2014, a world-leading microbiologist, **Dr Paul Schreckenberger** of Loyola University, Chicago, told the American Society of Microbiology:

"We basically have to relearn everything about the urinary tract because we were misled. Our beliefs were unfounded. We are now, with the new science, realising everything we were taught is probably wrong. The clinicians that we work with are quite distraught over this."

### **Urinary Dipsticks**

When a patient visits their GP and reports symptoms of a UTI, a urinary dipstick is the first tool the doctor will use to help with the diagnosis. If a dipstick finds signs of infection, a sample will be sent off to the lab for a culture. The problem with dipsticks is studies in the 1990s found that they are highly insensitive and will miss up to 50 percent of infections. Dipsticks identify white blood cells only 55 percent of the time and nitrites (another indicator of infection) just 10 percent of the time. Studies concluded dipsticks are useful to confirm infection, but SHOULD NOT be used to exclude infection.

#### **MSU Culture**

If a dipstick has found signs of infection, a doctor will send a urine sample to the lab for a mid-stream urine (MSU) culture to identify the bacteria. These cultures use thresholds that researchers believe are seriously flawed. They are based on studies conducted by Edward Kass in the late 1950s and referred to as the

'Kass Criteria'. In simple terms, Kass stated that, for a UTI to be present, the growth of a single, previously classified urinary 'bug' must reach a 'set colony count' of 10^5 colony forming units (cfu) or greater.

### What are the flaws in the 'Kass Criteria'?

- 1) Kass' report was never intended or validated for diagnosing acute UTI. It was based on a small and highly unrepresentative sample of women with an acute kidney infection—which is very different from an uncomplicated UTI. For some reason, the Kass Criteria became widely adopted for acute UTI diagnosis, perhaps faute de mieux.
- 2) The base Kass assumption is that healthy, un-infected urine is sterile. This assumption has recently been debunked after numerous researchers have found the bladder has its own bacterial community, similar to that of the gut.
- 3) The Kass Criteria requires concentration of a single urinary bug. This mistaken criterion linking an infection



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to a single microbe was formulated in 1884 and is disproven. Multiple bacteria (poly microbial) are thus discounted, as are bacteria not currently classified as 'known urinary' bugs. Anything but the Kass classification is regarded as a contaminated sample, and automatically ignored.

4) The lab culture is for just 24-hours. Thus it misses slower growing bacteria, bacteria which don't culture well outside the body and low bacterial growth due to a diluted urine sample.

### Dr Schreckenberger on Kass:

"That's another myth—the fact that infections are present only when the bacteria are present at 10^5 or greater. And that was never the intent of Kass' original report. The amount of bacteria... in people that have UTI varies. When you get up... the urine has been concentrated during the night, sure it can be 10^5. But ... when you've had coffee and urinated ... it can be 10^2 and that's also significant. But labs aren't culturing at 10^2 ... we miss a lot of true UTIs by setting cut-off limits based on dogma [ie Kass] that we think needs to be trashed".

### What other UTI indicators are there?

Labs also look for white blood cells (known as leukocytes or pus cells). The leukocyte threshold for diagnosing UTI was set by Cuthbert Dukes almost 90 years ago. In setting it, a fundamental statistical error by Dr Dukes meant that the threshold was set too high. This error was somehow 'baked' into subsequent studies, and even now labs continue to accept it.

1) Even though the white blood cells' function is to fight infection, they are only accepted as indicators of UTI if the Kass Criteria for bacterial growth (see first page) has been met.

- 2) When there is no bacterial growth, leukocyte counts below the (false) Duke threshold are regarded as 'normal'; those above are described as 'contamination' or 'sterile pyuria'. (Pyuria is urine containing white blood cells/pus; 'sterile' means no infection present.)
- 3) Leucocytes survive poorly outside the body. Thus a leucocyte level which might have indicated infection when first taken may have fallen significantly by the time the sample is cultured—even if only a few hours later and when refrigerated.

### **Epithelial Cells**

The epithelium is a thin tissue which lines the bladder and most of the urinary system. Research has established one of our first line defences against urinary infection is to shed this lining to rid the bacteria. Thus higher levels of epithelial cells are expected when coupled with bacterial growth that reaches the existing criteria.

If a sample shows high levels of epithelial cells without positive bacterial growth, it is still assumed to be contamination. Research has shown, however, that the level of shedding reflects the severity of infection and possibly the strength of the immune response. The automatic assumption of contamination is baseless.

**Professor James Malone-Lee**, Emeritus Professor of Nephrology at UCL, and Head of the Community LUTS Service, Whittington Hospital, in 2016 said:

"Many women with the appropriate symptoms are dismissed as not suffering from an infection when they do in fact have one. This controversial view is supported by much published literature. I am sorry to record this, because in doing so I identify a worrying deficiency in our diagnostic protocols, but the evidence is out there for everyone to read."

