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Safeguarding women's health: national briefing note

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"Urine testing is an area of increasing importance in the medical diagnosis of common conditions such as Urinary Tract Infection (UTI) and antenatal screening for healthy pregnancies," says Giovanna Forte, CEO of Forte Medical. "Yet there is no protocol for its collection, leading to inaccurate diagnoses and treatment as well as untold misery for millions of women every day."

Giovanna is co-founder of Forte Medical, a company set up to realise the invention of her brother and co-founder Dr Vincent Forte BA (Cantab), MBBS (Lond), MRCP, MSc, DA., an NHS GP of over 20 years. His invention was designed to make urinalysis more accurate and treat women with UTI first time, with the right antibiotics.

Accurate urine diagnoses will result not only in reducing many women's prolonged suffering from UTIs and quicker more reliable antenatal care, but also in fewer antibiotic prescriptions therefore reducing risk of Antimicrobial Resistance (AMR). These are at least four good reasons to take a closer look at current hit-and-miss practices and the significant cost savings that could be achieved by revising the protocols surrounding a urine test.

1. Urinary Tract Infection impacts almost 3m women every year in the UK alone;
2. Antenatal urine screening is critical to the health of both woman and child;
3. Accepted sample collection methods for these tests are unreliable, negatively impacting diagnoses and treatment;
4. False-positive results lead to unnecessary antibiotic prescribing, putting women on the frontline of AMR.

Little is being done to ameliorate these problems, causing prolonged suffering to many.

Nuffield Department of Primary Care Health Services:

"1 in 10 women see their GP each year because they have a Urinary Tract Infection, or UTI. When someone goes to see their GP with UTI symptoms they are often asked to provide a urine sample..... However, up to 30% of urine samples are contaminated by bacteria which normally live on the body. A contaminated sample cannot rule out infection or prove there is an infection. Another sample will need to be sent, and the delay may increase the length of time a patient will experience symptoms and mean they take extra courses of antibiotics, which could result in infections resistant to antibiotics in the future. If every contaminated urine culture was repeated this would cost over £14 million annually in England and Wales."

Digesting the stats (not including essential antenatal urine screening)

Some statistics that relate to UTI, the area of female health which my company has been seeking to ameliorate (at worst) and improve (at best)

27m adult women in the UK:

2.7m GP visits for UTI annually

2.7m urine samples dipped or cultured

Average of 540,000 (20%) failed tests that need to be repeated (and if not, why not?) (1)

972,000 of younger women suffer recurrent UTI (2)

Additionally.

50% of the global rise of anti-microbial resistance (AMR) has a urinary source (3)

25% of Sepsis cases originate from the urogenital tract (4)

45-49% of Gram-Negative blood infections have a UTI source (5)

Unlike a blood test, where great care is taken in collection and analysis, urine has no protocol attached to its collection for accurate analysis, diagnosis and treatment, and yet it has the same diagnostic parity. Guidelines for midstream or clean-catch urine are left to the GP to request and for the patient to be able to deliver.

Regardless of urine specimen quality, routine Primary Care pathway for UTI is to use a dipstick to identify problem bacteria in the urine sample; an increasingly discredited practice which dates from the 1950s. A positive dip, and indeed a false-positive dip resulting from contamination, will usually trigger the prescribing of a broad-spectrum antibiotic, an empirical practice recommended by NHS and PHE guidelines and yet contrary to UK and global guidelines to tackle AMR, which recommend identifying problem bacteria for targeted prescribing. These guidelines have not been aligned causing confusion at Primary Care point of care testing and treatment.

A broad-spectrum antibiotic will either cure the infection, ease the symptoms temporarily or have no effect at all. If the UTI recurs it necessitates a repeat GP visit where a further sample will be taken and sent to a laboratory to be cultured in order to establish the problem bacteria and identify the antibiotic needed. A contaminated sample cannot be read, even in the laboratory. Throughout this process, the woman will be suffering.

In extreme cases, the untreated infection can lead to sepsis, as happened to me.

The global threat of AMR is worsening, forecast to be a greater threat to public health than Covid-19 and indeed also fueled by the virus. (7)

Despite real-world clinical evidence our technology to improve urine specimen collection has been dismissed by policy makers and leadership as being unimportant. Our evidence demonstrates improved outcomes for women presenting with UTI *and* pregnant women for whom accurate urine screening is essential for their own health and that of their child. It also points to reduced antibiotic prescribing, better infection control and improved patient care. In addition, our evidence demonstrates significant cost savings which run well beyond the required outlay. The digitisation of dipstick technology overlooks urine specimen quality. Any such technology that relies on a potentially unreliable specimen merely amplifies the diagnostic process that is already letting women down.

A recent approach to a leading London Institute for Women's Health requesting evaluation of our technology and its outcomes yielded a response from those running the Institute stating that that this is "*not an area of clinical or research interest that we can prioritise*".

When we approached a leading Royal College of primary care medicine to offer to run an e-learning module on the benefits of accurate urine collection (without mention of our technology), the coordinator, instructed by the Medical Director, dismissed the opportunity with: "*Our concern is that the method to collect urine safely can only be done utilising your*

device, therefore we feel it may point to promoting your product. This may seem subtle but our membership [are] sensitive about such things and we do have to manage this carefully."

The reason given by many in the Health Service and the media for not embracing a practical solution to the issue of UTI and AMR is the reluctance to be seen to be promoting a product. Such qualms do not seem to impact the pharmaceutical industry, whose medicines are announced and named, even in unproven concept stage.

If almost 3m men passed pins and needles through their urethra each year, something would have been done about the lack of integrity around analysis, diagnosis and treatment which boils down to hit-and-miss collection, relying on patient dexterity (6) and creates such high unreliability rates.

The NHS has spent millions instructing us to wash our hands, yet still sees nothing wrong in asking women to soil their hands when providing a urine specimen from which almost a third will not be diagnosed.

This attitude fails the mothers, sisters, partners, daughters and female friends of those that dismiss UTI as unimportant *and* those GPs who prescribe antibiotics that are not targeted to the problem bacteria and may prove useless. These practices contribute to wasted laboratory time processing pointless urine samples *and* millions in NHS funds being quite literally flushed down the loo.

"Appropriate use of antibiotics - Antibiotic use must improve to reduce the drivers of drug-resistant infections, through evidence-based, optimised use **and the development and uptake of diagnostic tools.**" Wellcome, November 2020 (8)

The overarching solution to this global women's issue is for the introduction of a protocol and appropriate aligned methods for urine collection to reduce contamination risk for all dipped and cultured samples, whether traditionally or digitally analysed. **Women's health and safety in the GP surgery must come into focus.**

- **Names of institutions and clinicians have not been given in this Briefing but can be made available to any serious enquiries.**
- **Dr Vincent Forte is now retired.**

1. 2016 Freedom of Information request to NHS Trust for urine volumes and contamination rates - average = 20%
2. <https://www.bjfm.co.uk/recurrent-urinary-tract-infections>
3. NHS Improvement
4. <https://www.ncbi.nlm.nih.gov/books/NBK482344/>
5. <http://www.unplannedadmissionscommittee.com/news>
6. https://www.england.nhs.uk/wp-content/uploads/2020/08/Taking_a_urine_sample.pdf
7. <https://www.bmj.com/content/369/bmj.m1983>
8. <https://wellcome.org/sites/default/files/wellcome-global-response-amr-report.pdf>

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