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A NOVEL MIDSTREAM URINE-COLLECTION DEVICE REDUCES CONTAMINATION RATES IN URINE CULTURES AMONGST WOMEN

Sir,

With reference to this article by Jackson *et al.* [1], the authors found significant reductions in contamination rates of urine samples of 31% and of spillage of urine (on hands, clothes and floor) of 41%. The authors found these reductions occurred with the use of the CleanCatch™ Midstream, a novel midstream urine-collection device, that is sterile (10^{-6} probability of non-sterile unit, PNSU). However, the authors did not investigate what happens once a contaminated sample has been identified, or the link, if any, between contamination rates and the incidence of hospital-acquired infections (HAI) including *Clostridium difficile* infection (CDI).

In fact, current investigation shows a potential profound link between contamination rates and the incidence of HAI, and we suggest that the procurement officer plays a central role in influencing the incidence of HAI (including CDI). Has the role of the procurement officer one that has hitherto been overlooked?

It is a clearly accepted view that broad-based antibiotic prescription increases the incidence of HAI. BSOP 10 states: 'The incidence of [CDI] has been shown to decrease once antibiotic therapy is controlled' [2]. What influence does the procurement officer have on the rate of broad-based antibiotic prescription? This issue has not been addressed in any papers to date.

Informal discussions with some 30 clinicians show that when faced with a contaminated sample they will normally prescribe rather than retest, and such prescription would be a broad-based antibiotic. This is especially true in busy environments and is even the case where re-testing is mandatory under National Institute of Health and Clinical Excellence (NICE) guidelines [3], because a false-positive result coupled with a broad-based antibiotic prescription can have adverse effects leading to premature birth. (A false-positive result can lead to a HAI outbreak, as it will lead to unnecessary treatment for some of the patients, e.g. trimethoprim and/or ciprofloxacin. This treatment will cause side-effects, needing further treatment in a proportion of patients, i.e. piriton for the rash, fluconazole for thrush, metronidazole for CDI. If you are really unlucky, the CDI will escalate into an outbreak).

The question now arises as to what causes these contaminated samples? Leaving aside faulty collection procedures and substandard laboratory practice, this is where the role of the procurement officer becomes crucial. The procurement officer decides what equipment is purchased and so is faced with a simple cost choice: a sterile container (10^{-6} PNSU) at ≈£1.00 retail or a non-sterile container (≤10^{-3} PNSU) at ≈20 p retail. (European Standard EN 554: 1994 defines a sterile product as one that is 'free from viable micro-organisms'). With some hospitals doing ≈100 000 tests annually, choosing the cheaper non-sterile unit can amount to substantial 'unit cost savings' (especially if there is a bulk discount for the non-sterile product).

We draw evidence from two sources to support the importance of the procurement officer, one obviously being the results of the clinical trials conducted by Jackson *et al.* Second is the experience of the Oxford Radcliffe Hospital (ORH); during the trials by Jackson *et al.* the ORH used a sterile container (costing £1.13 per unit) but in 2007 the procurement officer issued instructions to change to a non-sterile container (costing 6p per unit). (The use of non-sterile containers for urine sample collection is strictly forbidden by UK and European Union legislation). By the end of the year the CDI rate at the ORH had, according to press reports, increased by 30%, while at the same time the contamination rates had increased by >22% (Freedom of Information requests, FOI). The ORH has refused further FOI requests to supply information on the data that might assist in interpreting these values (subject to an appeal to the FOI commissioner, which can take 2 years).

Whilst there is no confirmed direct link between the increase in contamination rates and CDI rate, there is no doubt that a contaminated sample will meet with one of two results, i.e. a re-test or antibiotic prescription. There are no data on the number of re-tests, with most laboratories simply treating the re-test as a new test, but the preponderance of replies is clearly that clinicians will prescribe a broad-based antibiotic rather than re-test. Thus a reduction in contamination will lead to a reduction in the incidence of CDI.

Incidence of contamination when a sterile device (10^{-6} PNSU) vs an aseptic device (10^{-3} PNSU) is used is highly significant. The BSI standard [4] sets out the semiquantitative probability range in table D4, where in common terms the scales for probability can include 'probability of harm per use' and 'probability of harm per device'. An aseptic rating of 10^{-3} PNSU translates as 'frequent' whereas 10^{-6} translates to 'improbable'. Sterile means that it is controlled to a guaranteed level of contamination rate of 1 per million. It is then, by definition of control, 'improbable' that there will be any contamination in the container that is sterile (improbability = >1 per million). Aseptic means that it is controlled to a level of contamination rate of 1/1000. It is then, by definition of control, 'frequent' that there will be contamination in the container that is aseptic (frequent = >1/1000 and to ≤1/10 000). Sometimes with *in vitro* devices the term 'clinical clean' is used, but this term has no sterility significance and is probably a marketing term. It is equivalent to unsterile and not to aseptic, which has a sterility reference.

It is possible that readers might indeed have statistics or would like to clinically trial the

issues set out here, based on the facts accumulated. First, what does the clinician do in terms of percentages when confronted with a contamination urine sample: re-test or prescribe? (To do nothing is not an option under NICE Guidelines.) Second, will a reduction in contaminated samples result in a reduction in broad-based antibiotic prescription? The authors would welcome any comments from readers either via the journal or directly, to set in motion a fuller investigation, if not a trial, on these issues.

Historically most collection points (i.e. hospitals) used sterile containers for urine collection in microbiological examination. The trend, introduced by procurement officers, has been to move away from sterile containers towards non-sterile containers, despite the European and UK regulations making sterility mandatory when culture of the specimen is involved. This appears to be matched by an increase in HAI (including CDI). A FOI request to the NHS Supply chain showed that in 1999, 80.62% of urine sample collections were non-sterile, while in 2007 this had increased to 91.97%. Between 1999 and 2007 the incidence of CDI increased dramatically. (Data before 1999 were not available)

In accordance with the *BJU Int* code of conduct we wish to declare an interest in the subject, in that Orde Levinson is the inventor of the CleanCatch Midstream device used in the clinical trials by Jackson *et al.* Furthermore, Joseph Delo, while currently a medical student at Oxford University, has taken a summer job during 2008 with the company of the CleanCatch Midstream. Other than this, no influence was or could have been brought to bear on the information above.

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1 **Jackson SR, Dryden M, Gillett P, Kearney P, Weatherall R.** A novel midstream urine collection device reduces contamination rates in urine cultures amongst women. *BJU Int* 2008; **96**: 360–4
2 **Health Protection Agency.** *National Standard Method for Processing of Faeces for* Clostridium difficile. BSOP 10; January 2008
3 **NICE.** Guidelines: Antenatal care: Routine care for healthy pregnant women. Clinical Guidance 6; October 2003
4 **BSI.** Medical devices. Application of risk management to medical devices. BS EN ISO 14971: 2007; April 2007.