



1 Folly Bridge  
Oxford  
OX1 4LB  
England  
United Kingdom

info@whizaway.com  
<http://www.whizaway.com>  
Office + 44 (0) 1865 240572  
Fax + 44 (0) 1865 246565

## **CEP 07004: Published: 17 January 2008**

Re Whiz<sup>®</sup> CleanCatch<sup>®</sup> Midstream

<http://www.pasa.nhs.uk/PASAWeb/NHSprocurement/CEP/outputs/Genmedsocialcare.htm#urology>

### **Updated Comments as at 30 November 2009 (3e) to the CEP report**

- A. Introduction
- B. New Published Material that impacts on the CEP report
- C. General points of the CEP report at 17 January 2008: Potential to re-visit the Status<sup>1</sup>
- D. General Conclusions of CEP report
- E. General Conclusions: What CEP did not investigate and why
- F. Detail examination of CEP 07004 report and input of new evidence
  - In antenatal and other clinical areas
- G. Modeling approach: as used in CEP
- H. Contamination rates: as used in CEP
- I. Issues of Best Practice
- J. Other areas of use: approach of CEP report
- K. Interim Conclusions
- L. Suggestions

#### **A. Introduction**

1. All reports/reviews are written at a particular point in time, and products/concepts naturally move on and get updated over time. This is true of the NHS as a whole where in 2008 a number of new programmes and initiatives were adopted including but not limited to Lord Darzi's reports.
2. The CEP 07004 ("CEP report") on the Whiz Cleancatch<sup>®</sup> Midstream ("Cleancatch") was published on 17 January 2008 and it would be appropriate to estimate that it had a cut off point for the receipt of information as being four months prior to publication, ie 16 September 2007.
3. It is in the light of this and our own development and understanding of matters that we make the following comments on the CEP report. Our comments are not in any way to level a criticism at CEP or its authors. It is an attempt with the benefit of hindsight, and an evolving product as well as an evolving NHS to re-examine matters. It supercedes our report of the 20 January 2008.

---

<sup>1</sup> Jbol Ltd was informed at the time of CEP that it is within its remit to revisit a report if time and resources and or priority criteria permit and there is significant new evidence which prima facia suggests the report status could be altered.

## **B. New Published Material that impacts on the CEP report**

4. There are two new publications relating to the Cleancatch Device itself, both peer reviewed:
  - a) Letter to the Editor: BJU International, March 2008
  - b) Letter to the Editor BJU International, November 2008
5. In September 2008 Cleancatch was placed on FP10 NHS prescription by nurse or doctor. This was after an investigation that spanned some three years, and indicates the strong benefits to community use on cost and clinical base (which are the cornerstone of FP10)
6. There are numerous new Government reports on the Health Service: the key relevant ones are:
  - a) NHS Improvement Plan June 2008
  - b) Lord Darzi report: High Quality Care For All<sup>2</sup> June 2008
  - c) *Standards for Better Health*: DH document 4132991.<sup>3</sup> June 2008  
> Includes the mandatory core standards
  - d) NHS Charter
7. There were also a number of mandatory and recommendatory regulations and NSM and best practice guidelines, which although may have been published prior to September 2008 we only became fully aware of their impact in relation to procurement (we were aware of them as manufacturer) subsequent to the publication of the CEP report.
8. There were also a number of mandatory and recommendatory publications (scientific and general press) of table of occurrence, rating and contributing causes of HCAI including C.diff, MRSA, ESBL as well as Neo-natal deaths and preterm Birth in the UK during 2008.
9. There was also the growing awareness of the multiple use factor of the Cleancatch and its impact on sections of the public as well as the impact of automatic machines which can only use 10 ml containers resulting in transference of samples to secondary containers
10. There is also a key objectives of the Department of Health clearly expressed to us ie *'A key objective of Health Service procurement is that the NHS receives value for money while maintaining the highest quality and safety standards for patients'*<sup>4</sup>
11. We also became only in 2008 – as a result of an updated opinion by product liability specialists set of barrister's chambers – more aware of the fact regarding certain mandatory requirements regarding culture, regarding Pathology labs and EU directives and sterility which we could not bring to the attention of CEP at the time of the report.

## **C. General points of the CEP report at 17 January 2008: Potential to re-visit the Status**<sup>5</sup>

12. The CEP report was concluded and published at a time when the full impact of the Whiz CleanCatch ® Midstream was not fully recognized and at a time in which CEP itself was developing.

---

<sup>2</sup> DH 288473, of 18 June 2008

<sup>3</sup> This document is also underpinned by Legislation and in particular Section 46 of the Health and Social Care (Community Health and Standards) Act 2003 sets out the legislative basis for the Health Care Standards

<sup>4</sup> Set out in a letter from the Minister of State for Health Services of 13 January 2009 to the Rt Hon Andrew Smith MP.

<sup>5</sup> Jbol Ltd was informed at the time of CEP that it is within its remit to revisit a report if time and resources and or priority criteria permit and there is significant new evidence which prima facie suggests the report status could be altered.

13. CEP's four categories of rating did not at the time allow (even if it was considered) a split decision – eg where it is recommended for one sector of the population but has significant potential for another. While CEP's categories may still not allow this, there is the possibility now due to new evidence (see para 1-11 above) for CEP to review its report of January 2008, and to reconsider if it should on new evidence; issue a “recommend” as a status but clearly caveat for which section of the population this applies to and to indicate significant potential (if applicable) for those sectors of the population it deems it appropriate.
14. In view of the above it is important to carefully read the CEP report, as it is a concise and dense report which requires complete reading, not just the summary, and when carefully read it sets out clear issues, objectively, and it should be carefully examined for its conclusions, its caveats, its omissions (and potential reasons for this).

#### **D. General Conclusions of CEP report**

15. CEP concludes, in certain categories of patient, ie ante-natal, a recommendation to the device to be used on both clinical and cost basis. And this is a conclusion reached even if, as a sterile device, the CleanCatch, which is sterile, is compared on a non level playing field in Ante-natal to a non sterile product in terms of cost (a non sterile is 1/12 of the price of a sterile one like the CleanCatch ).
16. It is very clear that the CEP report does not suggest further studies for the CleanCatch MSU device when used in the ante-natal population.<sup>6</sup>
17. In addition CEP concludes that the CleanCatch also has significant potential in other patient groups for which further studies are recommended.
18. There is simply no doubt about this at all, indeed reference will be made to not just CEP (as per paragraphs below) but to one of its sources as well, ie Jackson et al which concluded: *“Use of this UCD should be considered for collecting all MSU samples in women, where the specimen is to be used for bacterial culture. This may be particularly important during pregnancy, where UTI may result in serious complications, including premature delivery and its associated morbidity [12]. Further studies are needed in other clinical settings in which urine culture poses a diagnostic difficulty or leads to additional complications”<sup>7</sup> [my underlining]*

#### **E. General Conclusions: What CEP did not investigate and why**

19. In addition CEP concludes there are even further benefits and cost savings that are apparent, which it has not investigated in detail. It is surmised this is because CEP had established the bona fides of the product in an objective clinical and cost scenario at the most conservative and basic level, and if the product had significant clinical and cost benefits at this level it is somewhat irrelevant to go deeper into the cost and clinical benefits. It is important therefore to state what CEP had assumed as its base level. These are:
  - (i) assumed the worst known (ie highest) contamination rate and the highest unit cost for the Cleancatch (a single unit retail price) versus the best known (ie lowest) contamination rate and unit cost (a bulk wholesale price) for current use;
  - (ii) and assumed as well the lowest test cost per test and one limited to laboratory cost only;
  - (iii) and assumed one retest only whereas guidance in ante-natal is for avoidance of false positives and false negatives and multiple retests if necessary

---

<sup>6</sup> This is a large and important group of the population. Every pregnant woman should give 12 urine samples during pregnancy (NICE guidelines). Getting a true result, ie not a false positive or a false negative in a urine sample is VITAL for the mother and unborn child. Contaminated samples are a serious and significant hazard in achieving this. *Why is it not under used in this group in terms of Maintaining the highest quality and safety standards for patients while still maintaining value for money”.*

<sup>7</sup> Jackson SR, Dryden M, Gillett P, Kearney P, Weatherall R. *A novel midstream urine collection device reduces contamination rates in urine cultures amongst women.* British Journal of Urology International 2005; 96: 360 – 364, p.364

(iv) and furthermore it stated it did not take into account risk factors for non compliance with best practice and or regulations: risk to patient, staff and risk of litigation (and costs thereto)

(v) and furthermore it did not take into account patient convenience or the principle of “*value for money while maintaining the highest quality and safety standards for patients*”<sup>8</sup>

Had CEP taken into account these five factors the cost and clinical benefits would have been much greater. We surmise that CEP held it was a futile exercise to spend further time (given its limited resources) and evaluations taking these factors into account since it is already at a base level established the clinical and cost effective benefits of the CleanCatch compared to current methods and it may have felt that its remit was not to harp on about best practice and clinical compliance, although these are clearly referenced in its final conclusions –see paragraph 24 below. It is also a better scientific approach to evaluate at the worse case scenario and if that is sufficient the rest is self-evident. If not sufficient then perhaps CEP would have investigated further which was not the case here.

20. CEP does however indicate that further savings are self-evident as having established a case for significant cost savings PER TEST, (see para 24 (e) and 24 (h) below) on contamination rates only, it did conclude that the further savings that could be achieved and places these in its conclusions as significant caveats by stating that the cost benefit already achieved by the use of the Cleancatch:

a) “*does not include the cost of treatment post diagnosis*” and this must of course include both the cost of wrong diagnosis due to a false positive or a false negative.

b) does not include the “*Resource implications of delayed diagnosis due to retesting are not included in the analysis.*”

c) does not include more than one retest, by stating “*... is also assumed that each contaminated sample is retested only once.*” One retest is not sufficient if best practice is to be carried out and indiscriminate use of broad based antibiotics to be limited. The criteria is correct diagnosis, not we will only do one retest and then if that is still contaminated give a broadbased antibiotic or do nothing risking preterm birth and neo natal death etc.

d) the fact that the use of automated machines and collection methods mean that there will be two upfront costs for two containers, and does also not include all staff time and risk in transference of the primary collection to a secondary container.

#### **F. Detail examination of CEP 07004 report and input of new evidence**

21. To provide proof in some detail although the report is quite clear, some points of clarification and or correction based on the actual CEP report (**attachment 1**)

22. What actually did CEP conclude: This appears in the main at page 16 of the report and these conclusions in the light of paragraphs 12-14 above are divided into its conclusions of ante-natal, and other areas

23. In regard to antenatal healthcare CEP held and I quote:

a) “*...use of the CleanCatch® Midstream device resulted in clinically significant relative reduction in urine contamination of 31% and 79% [20, 22] compared with conventional collection methods... Use of the CleanCatch® Midstream device could therefore lead to significant reduction of these rates [contamination rates of 15-56% per studies].*”<sup>9</sup>

b) “*...the device can significantly reduce contamination rates in MSU samples from asymptomatic females*”<sup>10</sup>

c) “*...Compared with conventional collection methods the CleanCatch® Midstream was more hygienic, significantly reducing spillage of urine*”<sup>11</sup>

<sup>8</sup> Minister of State for Health Services letter, op cit.

<sup>9</sup> Idem, p.16

<sup>10</sup> Idem, p.4

- d) “For routine MSU collection in an antenatal setting when culture and microscopy are undertaken for all MSU specimens, the CleanCatch® Midstream urine collection device can provide savings in terms of staff time, and in terms of the additional resources required for repeat collection and testing of MSU samples due to contamination. There might be additional benefits not captured in the cost impact analysis, such as the value of enhanced compliance with best practice and national guidelines, and how this might impact on local risk assessment strategies.”<sup>12</sup>
- e) And in the economic assessment re ante-natal, the report concludes “...using the CleanCatch® Midstream for antenatal screening instead of a conventional universal container saves £1.69 per patient, per completed diagnostic episode, when all samples are cultured and all contaminated samples are retested.”<sup>13</sup> But this is when there is not a level playing field ie when the sterile CleanCatch at £1.12 is compared to the non sterile container at £0.09 – see Table 4.<sup>14</sup> When like for like ie the cheapest sterile container available on the NHS list is compared the savings increase per test to £2.22 after having paid the full £1.12 for the CleanCatch.
- f) One can perhaps stress again here that the use of a non-sterile container dramatically increases the risk factor (which has cost implications from a ration of 1<sup>(-6)</sup> to 1<sup>(-1)</sup> or in plain terms from “improbable” risk to “one in two ie 50/50” risk.<sup>15</sup> Even a product that is aseptic and where the aseptic manufacture is maintained and guaranteed has a risk factor of 1<sup>(-3)</sup> or “frequent”
- g) Another important conclusion is that “...(the cleancatch) minimises variation in the sample collection procedure...” The Dept of Health and Lord Darzi’s report stress the need for uniformity and standardization to improve the delivery of health care to all. That is not to have some areas providing much better healthcare than others due to services compliance failure.
- h) And another conclusion was that in general the CleanCatch “...improves Methods of urine collection and urine analysis ...
- i) If however regulations, standards and best practice were followed then the economic benefits would change and I quote from the conclusions of the CEP report: “Replacing the conventional universal container with the 30ml sterile Uripot collection device at £0.55 [23], in accordance with the National Standard Method for Investigation of Urine would increase the savings attributable to use of the CleanCatch® Midstream for antenatal screening to £2.22 per patient per completed diagnostic episode”

24. In a careful reading of the report there is not one single negative comment or caveat of the Cleancatch when used in ante-natal care. It is repeatedly recommended.

25. In fact what the CEP report did not mention but could have was the conclusion of Jackson et al which concluded unequivocally that: “Use of this UCD should be considered for collecting all MSU samples in women, where the specimen is to be used for bacterial culture. This may be particularly important during pregnancy, where UTI may result in serious complications, including premature delivery and its associated morbidity”<sup>16</sup>

---

<sup>11</sup> Idem

<sup>12</sup> Idem

<sup>13</sup> Idem, p.14

<sup>14</sup> Idem, p.13

<sup>15</sup> these risk factors are established in UK law under International Standard 14971: 2007 (*Medical devices — Application of risk management to medical devices*)

<sup>16</sup> Jackson et al p.364

26. Furthermore although CEP points out that 100% of clinicians preferred the device to current methods it does not cite the reasons as expressed in Jackson et al for this preference which was “*time-saving and improved hygiene as the main reasons for their preference*”<sup>17</sup>
27. Furthermore CEP makes no calculation or mention of the cost impact on urine collection on patients or if the patient **is a child their family**. Government and NICE reports show that the cost to recall and retest is around £400 .And the emotional stress can be seen from the comments of one team leader at a NHS hospital (**attachment 2**). This too is not factored into the equation of costs by CEP.
28. Furthermore CEP does not factor in the assistance either financially, legally or patient wise that the Cleancatch can and does offer to in the fight and reduction of HCAI such as C.difficile and MRSA. If the use of the Cleancatch reduced this incidence by a factor of 1 even per 10,000 urine tests it would be an amazing and important saving. **Attachment 3** is a publication of November 2008 in the BJU International which is a peer reviewed letter published and which shows how the Cleancatch can and may assist in the control and reduction of C.difficile.<sup>18</sup>**Attachment 4** refers to a 2008 publication of a clinical trial which shows urine spillage as a real and potential cause of the spread of MRSA (if the urine is contaminated already by MRSA) and also refers to how the Cleancatch can assist in the reduction of MRSA.
29. While the CEP report mentions the potential of the Cleancatch to improve both clinically and cost on patient safety issues it does not quantify this in terms of cost.
30. The cost of HCAI is estimated at a minimum of £1billion per annum in the NHS. The HCAI research network states: “**IMPACT on the UK NHS** □ *As well as affecting patients, HCAI is also a serious burden on the NHS. These infections are costing the NHS an estimated £1 billion a year and they are having a major impact on the availability of beds because infected patients have to spend, on average, an extra 11 days in hospital. Furthermore, infected patients cost 3 times more to treat than uninfected patients and infections are becoming difficult to treat because of an increase in antimicrobial resistance.* □ □ *Some of the other costs to the NHS include:* □ - *Staff workload,* □ - *Treatment for staff; and* □ - *Extra costs.* □ □ **Preventing Healthcare-Associated Infection** □ *Unfortunately, not all HCAI can be prevented as they are often the price we pay for advances in medicine. But with good practice and careful hygiene it has been estimated that around 15% to 30% could be avoided*”<sup>19</sup>
31. Good practise includes using fit for purpose devices. and reducing contamination, which has a direct impact on the reduction of antimicrobial resistance by reducing indiscriminate antibiotic prescriptions.

### G. Cost modeling approach as used in CEP

32. Furthermore the cost benefit as indicated in CEP is quite conservative in its table of calculations: It is based on a test cost of £5.87 (lab) or total test cost of £8.87 (see table 4 p.13 of the CEP report). However these appear as conservative figures if not impossible figures to maintain if a full economic assessment of a urine test is made. Important UK studies show the true cost of a urine test in GPs is £25.65 and the cost to a hospital out patient is £104.85 for each urine test. This is from the researched and authoritative Whiting et al, 2006<sup>20</sup> at page 116. (**attachment 5**) It places lab costs at £16.00 for pyuria/bacteriuria only and dipslide and lab culture being £2.60 each and then add nitrate and glucose etc.
33. However even Whiting et al does not take into account emergency microbiology which is £12.00 not £8.00 as stated in Nice CG54 table 11 page 20. (**attachment 6**)

<sup>17</sup> Idem

<sup>18</sup> To date, ie 30 November 2009, no adverse comments have been received by either of authors regarding the conclusions drawn.

<sup>19</sup> HCAI research network at <http://www.hcainetwork.org/about%20hcai.htm>. Accessed at 091130

<sup>20</sup> Whiting P, Westwood M, Bojke L et al. Clinical effectiveness and cost effectiveness of tests for the diagnosis and investigation of urinary tract infection in children: a systematic review and economic model. Health Technology Assessment 2006; 10 (36)

34. CEP uses in its modeling that to explain to a patient how to take a proper MSU will take approximately 5 min of the nurse's time. And allocates a cost of this as £2.08. This may well be the time taken to explain it to certain sectors of the population but not to the populations as a whole. Nice CG54 at para 3.1.12 (p.19) believes at least in relation to explaining to a parent the time required to be 20 minutes and a cost of £8.20 –see **attachment 6**. CG54 also relies on the cost figures of Whiting et al for its calculations.
35. **Attachment 7** lists some data of saving with cost and economic savings using Whiting et al test cost figures. Again in defence of the CEP report they did have with the report an interactive spreadsheet where contamination rates and costs can be altered. In a nutshell:
- Using Garcia et al and GP environment i.e. CleanCatch contamination rate of 4%; test cost of £25.45 (Whiting et al), Cleancatch Cost of £1.12 and a non sterile universal used in conventional of £0.09 then the savings even after paying £1.12 including VAT is £17.00 per test with only one retest
  - Using Lifshitz et al and hospital environment i.e. CleanCatch contamination rate of 4%; test cost of £104.85 (Whiting et al), Cleancatch Cost of £1.12 and a non sterile universal used in conventional of £0.09 then the savings even after paying £1.12 including VAT is £30.81 per test with only one retest
36. In a single environment that does say 30,000 tests per annum this could be a saving of some £500,000 minimum per annum excluding the extra health benefits to patients of accurate diagnosis and costs relating to HAI etc and when the comparison is not on a level playing field.
37. There is no mention of the number of tests done per annum in the UK. This is approximately 70 million of which 70% are women. In ante-natal alone at a birth rate of 900,000 there is approximately 10 million tests if best clinical practice is followed. Yet despite the best clinicians in the world the UK has the highest rate of preterm birth (**Attachment 8**) in the world. There could be a substantial change in these figures if best practice was followed in the collection of the sample, avoiding in pregnant women the issues and dangers which are a contributing cause of preterm birth and neo natal death of false positives and false negatives

#### H. Contamination rates approach: as used in CEP

38. The contamination base rate in the CEP report of 16% for current usage and 11% for the Cleancatch are based on very conservative contamination rates and even with these highly conservative rates (and unrealistically low for any area outside ante-natal) the Cleancatch saves money as the CEP report shows
39. However with the new evidence of the Letter to the Editor of March 2008 in the BJU international (**attachment 9**) the rate of 16% on current usage in antenatal (it is much higher elsewhere) is incorrect on contamination rates and its usage of these in CEP's calculations. It should be 22% in Ante-natal as a minimum. Valenstein et al as CEP demonstrates shows that a 16% contamination for women is unrealistic, let alone the best case scenario
40. And in regard to chosen as base for the Cleancatch ie 11% this is worse case scenario. The subsequent to Jackson et al trial ie Dryden et al shows the CEP contamination rate of 4%, a view echoed by the team leader in the ante-natal clinic of a NHS hospital (**attachment 2**). CEP does refer to Dryden et al and mentions this but prefers (correctly) to use the worst known contamination rate of the Cleancatch to generate a minimum savings.
41. Furthermore while CEP are correct to take the lowest contamination rate available at the time for the current method in ante-natal ie 16% it cannot transpose these rates to the known rates in other sectors of the population. It is a fact as CEP points out that in the GP environment contamination rates are 56% (quoting Garcia et al) and a National Average of 31 % (quoting Lifshitz et al) and even in reports from labs a median of 18% for men and

women (quoting Valenstein et al , who point out that for women contamination rates are much higher).

### I. Issues of Best Practise

42. Lord Darzi's report of June 2008 clearly requires the implementation of best practice and three key areas are relevant to this CEP report: These are:

a) *"Getting the basics right first time, every time. We will continue to seek improvements in safety and reductions in healthcare associated infections."*<sup>21</sup>

b) *Introducing new responsibilities, funds and prizes to support and reward innovation. Strategic health authorities will have a new legal duty to promote innovation. New funds and prizes will be available to the local NHS. authorities will have a new legal duty to promote innovation.*

c) *Ensuring that clinically and cost effective innovation in medicines and medical technologies is adopted. We will strengthen the horizon scanning process for new medicines in development, involving industry systematically to support better forward planning and develop ways to measure uptake. For new medical technologies, we will simplify the pathway by which they pass from development into wider use, and develop ways to benchmark and monitor uptake."*<sup>22</sup>

43. The CEP report does not evaluate the CleanCatch in terms of these Government policies and or on quality. The Cleancatch without a shadow of doubt is best practice and best quality and innovative. It is a quantum leap ahead of current methods: Key established factors of are:

100% of clinical staff at the front line preferred it (Jackson *et al.*)

8 out of 10 patients preferred it to other methods (Jackson *et al.*)

75% of first-time patient users and 100% of second-time patient users preferred it (Jackson *et al.*)

73% reduction in general contamination (Dryden *et al.*)

70% of first-time patient users rated it an improvement over current methods (Jackson *et al.*)

60% reduction in heavy mixed growth contamination (Jackson *et al.*)

41% reduction in urine spillage (Jackson *et al.*)

28% reduction in retests (Jackson *et al.*)

6% improvement in the number of UTI detection (Jackson *et al.*)

5% improvement in number of clinically non-significant growth (Jackson *et al.*)

CleanCatch® Midstream contamination rate 4% (Dryden *et al.*)

The CEP key conclusions about the benefits of using the CleanCatch are set out in paragraph 52 below and are not repeated here.

44. And the legal risk for not following best practice is not evaluated in CEP, even not to the consideration that the Health and Social Care (Community Health and Standards) Act 2003<sup>23</sup> imposes a "Duty of Quality" and a "Quality in Health care" **Attachment 10** is an extract from the act.

45. DH policy is concerned about "*maintaining the highest quality and safety standards for patients*" ie not just best practice (which is a minimum) but while no direct mention is made in the report of how the Cleancatch achieves the best practice it does have a leitmotif on this for example by putting it in the negative that best practice is not followed but does not follow this conclusion through by saying the Cleancatch would improve or conform to it. These statements appear on page 16 of the CEP report and are:

---

<sup>21</sup> <http://www.ournhs.nhs.uk/wp-content/uploads/2008/06/dh-darzi-summary-report.pdf>, tp.7. This report is the "Final report of Lord Darzi's NHS Next Stage Review. It responds to the 10 SHA strategic visions and sets out a vision for an NHS with quality at its heart." Department of Health, UK June 2008

<sup>22</sup> *ibid* p9

<sup>23</sup> *National Standards, Local Action* Health and Social Care Standards and Planning Framework, DH 4086058 2005/06–2007/08 , 21 July 2004 updated June 2008

- a) "...sterile containers are required for urine culture, but best practice might not always be followed" (my underlining) <sup>24</sup>
- b) "...best practice might not always be followed in obtaining repeat urine specimens where contamination is found in the initial sample"
- c) "...patient instructions for conventional urine collection can vary considerably and can have a significant influence on the quality of the MSU sample collected" <sup>25</sup>
- d) "...the cleancatch) minimises variation in the sample collection procedure...."
- e) and that the cleancatch "...improves Methods of urine collection and urine analysis ... " <sup>26</sup>

46. If all these factors were taken into account in terms of economic value or abiding by the requirements of maintaining highest quality and safety, then there Cleancatch would based on the conclusions of CEP be in the recommended category without any doubt.

### J. Other areas of use: approach of CEP report

- 47. The CEP report does also recommend the use of the Cleancatch for the elderly by clearly indicating that the benefits found in antenatal as set out in para 24. (i) and (ii) above applies. But CEP indicates this was a small survey
- 48. What are the other areas where further evidence is required: use by men, for example, use in A&E, use for Arthritic persons – I attach a short memo – **Attachment 11** on why accurate sampling is so important for the arthritic. And **attachment 12** indicates some other areas of use which CEP did not investigate where the Cleancatch can have significant potential. We accept CEP cannot investigate each and every one, but its report should not be read that it is not recommending. What it was doing was recommending further evidence should be done in other areas as there is significant potential of the device in other areas – it was not we believe as can be seen from a correct reading of the report saying that there is significant potential in ante-natal.
- 49. When it comes to the use of the device in the GP environment CEP refers to the publication Garcia et al. <sup>27</sup> In the conclusions CEP point out that following patient instructions to follow the correct procedure ‘... have a significant influence on the quality of the MSU sample collected (e.g as described by Garcia).’ <sup>28</sup> Garcia studied tests in the GP environment where the average contamination rate is 56%. <sup>29</sup> If one examines Garcia, then if the patient follows the staff instructions carefully and a sterile container is used it does result in a drop of 22%, from 56% contamination to 41%. Thus for staff and patients to clearly follow instructions does have an impact in reduction of around 22%.
- 50. CEP confirms these steps/instructions used in Garcia as: “...a nurse explained how to collect midstream urine and also provided an explanatory leaflet. The instructions covered collection of the first urine in the morning, washing of hands and genitals, taking care not to touch the inside of the container and closing the lid straight after collecting the urine.” While CEP is accurate in terms of the nurse explanation and in calculation of nurse time it is not the full set of instructions in Garcia regarding the collection.
- 51. However Garcia is more detailed and states: “The women in the Control group were given a sterile receptacle in which to place the urine and an appointment for delivering the sample, without any comment being made on the urine collection method. An assistant nurse (always the same person) explained

<sup>24</sup> Idem, p.16

<sup>25</sup> idem

<sup>26</sup> Idem

<sup>27</sup> Cabedo García V, Novoa Gómez C, Tirado Balaguer M, Rodriguez Morquecho N, Rodriguez Bailo M, Solá Sandtner A. Is the technique used to collect urine important in avoiding contamination of samples? *Atencion Primaria* 2004 Feb 28; 33 (3): 140-144

<sup>28</sup> Idem p.16

<sup>29</sup> NYS et al confirms the high contamination rate of Garcia as GP's but in relation to the use of disptick which are prone to a 50/50 success rate for appropriate evaluations.

*the RLMM method to the patients in the Intervention group and delivered to them an explanatory leaflet with the standards which had already been verbally provided and which included the taking of the first urine sample in the morning, washing one's hands and then one's genitals with soap and water, both behind and in front, rinsing with lots of warm water and drying with a clean towel. This was to be followed by opening the sterile receptacle, by unscrewing the lid without touching the inside of it or the receptacle and without leaving it open for any longer than the time necessary to take the sample and then collecting the urine midstream sample, by discarding the first urine released and closing the receptacle (fig. 1). Lastly, the patients were given a sterile receptacle in which to collect the urine and an appointment for delivering the sample.”<sup>30</sup>*

52. CEP calculates the nurse time at 5 min to explain all this. It might be far higher: indeed some 20 minutes as indicated in NICE's CG54 mentioned above. And even if explained there is no guarantee that it will be followed or can be followed by the patient in the privacy of the cubicle when the sample is given. This issue is explored in the publication of March 2008 BJU International (**attachment 9**).

53. It should be apparent that this is a double bind situation regarding the benefits of the Cleancatch. If proper procedures are not followed, then contamination rates are likely to increase by at least 22% and there is the substantial risk of litigation if best practice is not followed. If they are followed a great deal of time is taken up by staff (which is a cost) and which may not have any effect once the patient is in the privacy of the WC. It could be many, many times that of CEP's calculations

## K. Interim Conclusions

54. Some of the clinical benefits are set out in paragraph 41 above and need not be repeated here

55. The factors concluded by the CEP report are set out in para 54 below under interim conclusions

Saves significant amount of money per test: a minimum £1.69 per test done (with CleanCatch cost included at £1.12 versus current non regulatory at £0.09

**Standardises tests, improves health delivery etc – see parag**

56. FILL IN

57. Ffff

58. Ff

## L. Suggestion:

1. Aside from implementing best practice as a starter we would like to suggest the CEP report be officially updated with a time scale to complete of 3 months and that it evaluates the issues above mentioned in relation to the Cleancatch Midstream especially but not limited to:

A) Ante-natal

b) other areas as set out in this memo

c) evaluate fully cost savings to include the omissions not done ie

---

<sup>30</sup> Garcia et al, as per CEP 07004, official UK EU appointed translator: original is “*A las mujeres del grupo control se les facilitaba un recipiente estéril para depositar la orina y una cita para entregar la muestra, sin que se hiciera ningún comentario sobre el método de recogida de la orina. A las pacientes del grupo de intervención, una auxiliar de enfermería (siempre la misma) les explicaba el método de RLMM y les entregaba un folleto explicativo con las normas que ya había facilitado verbalmente y que incluía la toma de la primera orina de la mañana, lavarse las manos y posteriormente los genitales con agua y jabón, de delante hacia atrás, enjuagar con abundante agua tibia y secar con una toalla limpia. Abrir el recipiente estéril desenroscando la tapa sin tocar el interior de ésta ni del frasco y no dejándolo abierto más que el tiempo necesario para la recogida. Recoger la parte media de la micción desechando el primer chorro y cerrar el frasco (fig. 1); finalmente, se les daba el recipiente estéril para la recogida de la orina y una cita para entregar la muestra.”*

- d) evaluate impact/savings on changes in contamination rates based on published studies in ante-natal, GP and national average rates
- e) best practice
- f) legislation

and it be allowed to give a split decision ie recommended in some areas if so included and significant potential in others etc.

Oxford

30 November 2009 v.3e.

© Jbol Ltd 2009

---

Attachment 1	CEP 07004 report
Attachment 2	Comments Team Leader NHS hospital
Attachment 3	British Journal Urology International publication Nov 2008
Attachment 4	MRSA and Urine spillage and Cleancatch: Ref MRSA infection in Urine- a urological perspective D.J. Dryhurst 1, P. Patel 1, A.D. Mackay 2, M. Ahmed, Princess Royal University Hospital, Bromley, 2008
Attachment 5	Whiting et al p.116
Attachment 6	Nice CG5 p.20
Attachment 7	Some costing figures and calculations based on CEP report
Attachment 8	Press report High pretern birth and neo natal deaths in UK
Attachment 9	British Journal Urology International March 2008
Attachment 10	Extract from 2003 Act
Attachment 11	Arthritic patients and Cleancatch
Attachment 12	Other users and Cleancatch