Improving the appropriateness of laboratory submissions for urinalysis from general practice

Clodna AM McNulty*, Michael Thomasb,c, Joanne Bowena,1, Charles Buckleyd, Andre Charlette, David Gelbe, Chris Foyf, John Slossg and Stuart Smellieg


Background. Urine is the most common microbiology laboratory specimen. Submissions increase annually by 5–10%, and many specimens may be unnecessary.

Objectives. To assess the impact of guidance, implemented by interactive workshops and reinforced with modified request forms, on specimen submission.

Methods. This was a prospective randomized controlled study with modified Zelen design. The study population comprised five primary care trusts (PCTs) in Gloucestershire/County Durham/Darlington, containing 82 general practices in six geographical clusters. The six clusters were randomly assigned to urine workshop covering submission in the elderly, adults and children or a control workshop. Within these groups, half the practices were randomized to receive modified laboratory forms emphasizing the workshop messages. Practices were not aware of the study.

Results. Workshops lead to a 12% reduction in urine submissions from 16- to 64-year olds, which persisted for the 15 months but had no effect on bacteriuria rate. Workshops had no significant effect in the elderly or children. Modified forms were not associated with any reduction in submissions but were associated with an 11% reduction in detection of significant bacteriuria in 16- to 64-year olds.

Conclusions. The 12% decrease in urine submissions from 16- to 64-year olds, attained with workshops, may help counter relentlessly rising test submissions. Modified forms are currently not worth pursuing. When educational workshops are used across PCTs to change practice, the change in test submission is smaller than attained in educational initiatives involving volunteers. Workshops may be more effective if they also discuss urine submissions from asymptomatic patients and are directed at high testing practices and care homes.

Keywords. Children, education, elderly, primary care, RCT, urine testing, UTI.

Introduction

Testing activity across pathology is increasing by 5–10% per year1 and varies greatly between general practices served by an individual Trust.2 Urine is the most common specimen analysed in the microbiology laboratory and there is a wide variation in submission of specimens, which can be partly explained by different clinical management strategies of acute urinary symptoms.3 A recent qualitative study indicated that...
primary care staff were not always sure when they should use the laboratory for the investigation of urinary symptoms or when they should make use of near patient tests; staff welcomed laboratory use guidance. Recent guidance recommends that routine urine culture in the elderly, catheterized or in uncomplicated acute urinary tract infection (UTI) is unnecessary.\textsuperscript{5,6}

Guidance distributed to GPs, in paper form only or in combination with test rate feedback, has little impact on laboratory use by GPs.\textsuperscript{2,7} A Cochrane review has shown that interactive educational sessions are effective in changing health professionals management and are enhanced by audit.\textsuperscript{8,9} Verstappen et al.\textsuperscript{10,11} found that a combination of regular feedback on laboratory use and small group activities significantly reduced biochemistry and X-ray testing rates and was cost effective. Modifying request forms and asking GPs to choose a testing strategy on a request form had a significant impact on biochemistry tests submitted.\textsuperscript{12,13} None of these studies included microbiology tests.

We aimed to assess the impact of GP laboratory use guidance, implemented by interactive outreach workshops and reinforced with modified laboratory request forms on general practice laboratory use. We aimed to use a modified Zelen design\textsuperscript{14,15} which is a recognized blinding method used for randomized trials in which knowledge of the trial would influence behaviour. This is particularly valuable in trials of educational initiatives. This design is practical if data collection is not intrusive to participants or is routinely collected.

Methods

Study design

This was a prospective randomized controlled study, using modified Zelen design, examining the effect of workshops and modified request forms on clinicians’ urine specimen submission.

Study population

The study population comprised three geographical distinct clusters of general practices in Gloucestershire [two primary care trusts (PCTs), population 324 300] and three geographical clusters/PCTs in County Durham and Darlington (population 284 800) served by the microbiology departments of Gloucester Hospitals NHS Foundation Trust and Bishop Auckland NHS Trust, respectively, which are 225 miles apart.

Ethics

The study was approved by the Gloucester Local Research Ethics Committee (LREC) (ref. number 02/52G) and Durham LREC (061/September 2002) and approved by the PCT clinical governance leads. Participating practice clinicians and managers did not know that they were part of an educational study.

Randomization

The six geographical clusters were randomly assigned by the flick of a coin to urine workshop or a control workshop focusing on genital chlamydia testing by CAMM and MT. Within these groups, half the practices were randomized by JB using random number tables to receive modified laboratory forms (Figure 1).

Workshops

All practices within the active urine workshop group were invited by their PCT to attend a standardized interactive outreach workshop in their protected PCT professional development time, during March 2003 on the clinical and laboratory diagnosis of urinary symptoms. Only the PCT clinical governance lead in Gloucestershire and the workshop lead knew that the intervention was part of a trail. Participants could have discussed their workshop content with control practices, but this was very unlikely to occur as the PCT were geographically very distinct. Workshops were based on the Health Protection Agency (HPA) urine laboratory use guidance available on the website.\textsuperscript{5,16} The workshops were designed with two Gloucestershire GPs (MT and CB), two nurses, a clinical microbiologist and a consultant in elderly care. The workshops commenced with a poster session. The posters displayed each practice urine submission rate per 1000 patient population for under 16 years, 16–64 years, greater than 64 years and catheter urines. This allowed clinicians to compare their urine specimen submission rates with other practices within their geographical cluster. Each workshop posed a series of questions to participants, covering the key messages, (Box 2) who were asked to discuss these with their neighbours. Each question was then discussed with the whole group and the evidence underpinning the answers and guidance was given. Clinical scenarios in the elderly, and catheterized, were discussed in pairs and then within the group. Participants were asked to discuss the barriers to using urine near patient tests with their neighbours and write these down. These barriers, and possible ways to overcome them, were then discussed with the whole group. At the workshop, participants were given a pot of 100 near patient tests (Multistix 8SG, Bayer Diagnostics Europe Ltd, Newbury, UK), a summary of the key messages, HPA urine guidance and practice urine submission rates. One month later, all intervention practices received, by post and Email, the workshop summary and the area’s urine submission data. The control group underwent a similarly constructed educational programme on genital chlamydia testing.

Modified laboratory forms were distributed to half of the GP practices 2 months after the workshops in Gloucester (May 2003) and 6 months after in Durham (September 2003). Requestors were asked to tick
a clinical management strategy box on the laboratory request form. These clinical strategies were summarized on the back of the form and were readily visible when the specimen was placed in the attached plastic bag (Box 1).

The back of the form also summarized the key messages covered in the workshops and emphasized the criteria for submitting urine specimens (Box 2).

Six months after the workshops, the practice managers were sent a letter that they were asked to distribute to all the doctors and nurses, highlighting the key messages covered at the workshop held in their PCT. The correspondence also contained six questions asking if the practice had discussed urine or chlamydia testing at a practice meeting, undertaken any audits on urine or chlamydia testing and if they had changed their testing behaviour. Responses in the two groups were compared by chi–square or Fisher’s exact test.

**Urine test submissions**

Laboratory data and general practice population data from April 1, 2002 to June 30, 2004 were used to determine the number of urine submissions and the number of positive results per 1000 patients. Laboratory data and general practice population data were collected for the 9 months before the intervention in all areas from April 1, 2002 to December 30, 2002.

---

**Timeline**

3 Gloucestershire (2 PCTs) and 3 S Durham (3 PCTs) geographical clusters (88 practices) (All had website guidance)

Cluster randomisation of 6 geographical clusters to workshops

<table>
<thead>
<tr>
<th>Apr – Dec 02</th>
<th>Chlamydia Workshops/Urinalysis Controls</th>
<th>Urine Workshops/Chlamydia Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-intervention data collection</td>
<td>1 Durham cluster, 2 Gloucestershire clusters</td>
<td>2 Durham clusters, 1 Gloucestershire cluster</td>
</tr>
<tr>
<td>Gloucester and Durham</td>
<td>44 practices</td>
<td>44 practices</td>
</tr>
<tr>
<td>11 Durham (102,100) 33 Gloucestershire (227,400)</td>
<td>23 Durham (182,700), 21 Gloucestershire (106,900)</td>
<td></td>
</tr>
<tr>
<td>Mar 03</td>
<td>All workshops given</td>
<td></td>
</tr>
<tr>
<td>April 03</td>
<td>Post intervention data collection Gloucester</td>
<td></td>
</tr>
<tr>
<td>Randomisation of half practices to use modified laboratory request forms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modified lab forms</td>
<td>No forms</td>
<td>Modified lab forms</td>
</tr>
<tr>
<td>May 03</td>
<td>Gloucester forms sent out</td>
<td></td>
</tr>
<tr>
<td>17 practices (115,900)</td>
<td>16 practices (101,500)</td>
<td>10 practices (49,600)</td>
</tr>
<tr>
<td>Sep 03</td>
<td>Durham forms sent out</td>
<td></td>
</tr>
<tr>
<td>6 practices (49,900)</td>
<td>5 practices (52,200)</td>
<td>11 practices (85,100)</td>
</tr>
<tr>
<td>Jun 03- Feb 04</td>
<td>Post form data collection Gloucester</td>
<td></td>
</tr>
<tr>
<td>Oct 03-Jun 04</td>
<td>Post form data collection Durham</td>
<td></td>
</tr>
<tr>
<td>Analysed: 17 Gloucester</td>
<td>Analysed: 14 Gloucester</td>
<td>Analysed: 9 Gloucester</td>
</tr>
<tr>
<td>0 exclusions</td>
<td>2 exclusions: 1 in Gloucester closed chlamydia research</td>
<td>2 exclusions: 2 practices closed</td>
</tr>
<tr>
<td>Analysed: 6 Durham</td>
<td>5 Durham</td>
<td>10 Durham</td>
</tr>
<tr>
<td>Analysed: 9 Gloucester</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 exclusions: 2 in Gloucester chlamydia research</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 Durham</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 1** Randomization of practices to workshops and modified laboratory request forms

---

**Box 1 Modified form: codes for investigation strategies**

Urine: Urines are not routinely required for uncomplicated UTI or in asymptomatic elderly. We encourage urine culture in children.

1. Urinary symptoms (in men and women)—in non–pregnant women give antibiotics if dipstick shows leukocytes and nitrites present
2. Over 65 years—elderly: send urine if temperature above 38, dysuria or acute incontinence
3. (a) recurrent UTI
   (b) failed antibiotic
4. Catheterized—specimen unnecessary if asymptomatic
5. Pregnant
6. Suspected pyelonephritis
7. (a) renal impairment
   (b) abnormal renal tract
8. Child (15 years and under)
9. Other
(pre-intervention data) and from April 2003 to 9 months after the modified forms were issued (February 2004 in Gloucestershire and June 30, 2004 in Durham). Laboratory data were aggregated into three monthly intervals.

**Outcomes**

**Primary outcome.** Effect of workshops and modified request forms on the rate of laboratory urine specimen submissions.

**Secondary outcome.** Effect of workshops and modified request forms on the rate of significant bacteriuria per thousand population diagnosed in general practice.

**Sample size determination:**
The size of the study was fixed by the number of GP practices within the six geographical clusters. Within these parameters, we determined if this sample size would be sufficient to detect significant differences based on chlamydia submissions as these were lower than urine submissions.

**Data analysis**
We compared urine submission rates and number of significant bacteriuria diagnosed per thousand population in all practices within the geographical areas where workshops were held versus controls. We compared submissions in three age groups: children 15 years and under; 16–64 years; 65 years and older and compared submission of catheter urines in the 65 years and older group. The effect of using the modified forms on urine submission and significant bacteriuria rates was assessed by comparison of those practices that had and had not received modified forms.

The dependent variables in the statistical models were the number of test submissions and the number of positive tests by practice within each 3-month period. The natural logarithm of the practice capita- tion was incorporated as a covariate in the model to allow for variations between practices. The Durham and Darlington practices submitted significantly more urine specimens than the Gloucestershire practices before the intervention [median submission rate per 1000 patients per year for 0–15-year olds, median 50, interquartile range (IQR) 39–63 versus 81, IQR 69.5–98, \( P < 0.0001 \); for 16- to 64-year olds, median 72, IQR 71–84 versus 104, IQR 88–129, \( P < 0.0001 \) and 65+ year olds, median 158, IQR 113–192 versus 296, IQR 219–351, \( P < 0.0001 \)], therefore the aggregate baseline number of submissions and positive tests were included as covariates to allow for any variation between the randomized groups of practices. To allow for the cluster randomization of workshops by area within PCTs, a multilevel model was used. The outcome variable was assumed to have a Poisson distribution and a logarithmic link function was used to enable direct estimates of the rate ratios to be obtained. The models were implemented in Stata version 8.2 and MLWin. The unit of analysis was the GP practice. The two interventions, outreach workshop and modified form, and their interaction were treated as fixed effects, as was the region (Gloucestershire or Durham and Darlington). Time since the workshop was also included in the model to enable the determination of any effect modification of workshops and modified forms with time.

**Results**
Eighty-two practices (total population 609,100) participated. Forty practices were randomized to attend urine workshops and 42 to attend chlamydia workshops (Figure 1). One practice in Gloucestershire that
closed during the study period was excluded from the analysis. Two pairs of practices in Darlington merged during the study period: each pair was treated as a single practice throughout the analysis. In 32 of 44 (74%) practices randomized to attend a urine workshop, at least one staff member attended; 21 (34%) were doctors, 25 (62%) were nurses and 4 (5%) were administrators (Table 1). Chlamydia results will be presented separately.\(^{17}\)

**Urines 16- to 64-year olds**

After the intervention, practices randomized to the urine workshop areas submitted 12% fewer urine specimens compared to the controls [ratio 0.88, confidence interval (CI) 0.80–0.97], but workshops had no significant effect on the bacteriuria rate. The findings did not differ by region, and the decrease persisted for the 15 months following the workshops. Modified forms had no significant effect on submissions (ratio 0.93, CI 0.85–1.02), but were associated with an 11% reduction in detection of bacteriuria (ratio 0.89, CI 0.80–0.99) (Table 2). There was no added effect of modified forms and workshops together.

**Urines in the elderly \(\geq 65\) years**

Workshops and modified forms had no significant effect on the submission of urine specimens or the detection of significant bacteriuria in intervention practices when compared to control practices. Workshops and modified forms also had no significant effect on the submission of catheter urines in patients over 65 years (ratio workshop: control 1.81 CI 0.97–3.38; ratio modified form: control 1.49, CI 0.79–2.79).

**Urines in children 0–15 years**

Neither workshops nor modified forms had any significant effect on urine submissions or detection of significant bacteriuria (Table 2).

Sixty-six of 82 (80%) practices completed the 6-month questionnaire. Fifty-two per cent of practices (21/40) in the urine workshop area reported that they had discussed urine testing at a practice meeting and 57.5% (23/40) reported that they had changed their urine testing or protocols, compared to 21% (9/42, \(P = 0.006\)) and 10% (4/42, \(P < 0.001\)) in the control areas. However, discussing urine testing did not have any significant effect on submission rates (ratio of submissions to those who did not discuss urine testing 0–15 years 0.94, CI 0.81–1.09, 16–64 years RR 0.95, CI 0.84–1.07; 65 years and older RR 1.00, CI 0.84–1.20); 7.5% (3/40) of practices in the workshop areas had undertaken audits on the management of urine infection in their practices compared to none in the control group (Fisher’s exact test \(P = 0.11\)).

**Discussion**

**Main findings**

Despite seventy-five per cent practice representation at the urine workshops, they only had an effect on specimen submission in one age group, leading to a 12% reduction in urine submissions from 16- to 64-year olds. Workshops had no significant effect in the elderly or in children. The modified forms were not associated with any changes in submissions, but were associated with an 11% reduction in detection of significant bacteriuria in 16- to 64-year olds.

**Interpretation of results**

Although the workshops covered all three age groups, they commenced and concentrated most on patients in the 16- to 64-year-old age group with symptoms of acute uncomplicated UTI. This emphasis on acute symptoms and the adult age group may have led clinicians not to absorb the other messages, to reduce specimens in the elderly and to increase specimens in children. With such good workshop attendance, we may have expected a greater fall in submissions in the

<table>
<thead>
<tr>
<th>Table 1</th>
<th>General practice attendance at urine workshops</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gloucestershire Sedgefield/ Darlington Total chlamydia workshop areas</td>
</tr>
<tr>
<td></td>
<td>Number</td>
</tr>
<tr>
<td>Practices represented</td>
<td></td>
</tr>
<tr>
<td>Clinical role of participants</td>
<td></td>
</tr>
<tr>
<td>GP</td>
<td>16</td>
</tr>
<tr>
<td>Nurse</td>
<td>25</td>
</tr>
<tr>
<td>Administrator</td>
<td>4</td>
</tr>
</tbody>
</table>

**Table 2** Effect of urine workshops and modified forms on urine submissions and infections detected per 1000 patients per year in the three age groups

<table>
<thead>
<tr>
<th>Ratios of submissions and 95% CIs in intervention areas versus controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine workshop</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Urine submissions per 1000 population</td>
</tr>
<tr>
<td>0–15 years</td>
</tr>
<tr>
<td>16–64 years</td>
</tr>
<tr>
<td>65 years and over</td>
</tr>
<tr>
<td>Catheter urines</td>
</tr>
<tr>
<td>65 years and over</td>
</tr>
<tr>
<td>Significant bacteriuria detected per 1000 population</td>
</tr>
<tr>
<td>0–15 years</td>
</tr>
<tr>
<td>16–64 years</td>
</tr>
<tr>
<td>65 years and over</td>
</tr>
</tbody>
</table>
16- to 64-year-old age group. Recent data now suggest that two-thirds of the urines submitted to the laboratory for culture are not from patients with acute urinary symptoms. Doctors may send in urine specimens for reasons other than suspected infection (e.g. suspected haematuria, investigation of incontinence or other urinary symptoms) or to rule out infection in patients with diagnostic difficulties, e.g. non-specific abdominal pain, or confusion in elderly. Future workshops should address all reasons for submission of urines.

In the 16- to 64-year age group, the modified forms did not lead to a change in the rate of submissions but were associated with a change in the type of urine specimen, as demonstrated by the reduction in detection of significant bacteriuria. The modified forms encouraged clinicians not to send urines in uncomplicated UTI, situations that have a high bacteriuria rate (urines are not routinely required for uncomplicated UTI). This may have resulted in a greater proportion of specimens from asymptomatic patients, leading to the lower significant bacteriuria rate. Future workshops should also address submission of urine specimens from these asymptomatic adults. The modified forms had no effect on overall urine submissions in any age groups. This may be because clinicians have already taken the decision to submit a specimen when they read the modified forms. We had hoped that the messages would inform the clinicians’ future specimen submission—but this was not the case.

**Study strengths**

Unlike most of the participants in previous studies included in systematic reviews examining the effect of workshops on professional practice and health care outcomes, the practice staff in this study were not aware that they were participating in a study and were not volunteers. Our sample size was large, included practice staff in different geographical regions of England and controls, and we collected data for longer than in most other studies (12 months before and 15 months after) and from all practices, not just those attending the workshops. Therefore, the results give a much more realistic indication of the true value of outreach workshops to reduce diagnostic tests across a whole PCT.

**Study weaknesses**

We have no way of determining if the workshop participants were responsible for the submission of urine samples from the practices involved. Urines may be submitted by district nursing staff, nursing homes or dropped off at the practice by patients themselves. Involvement of all staff and practices with greater urine submissions may have a greater effect. For ease of workshop organization and blinding of clinicians, the study was randomized by area rather than practice. It was up to each practice if and how they cascaded the workshop messages to the rest of their practice staff. This will have varied in each practice as it would within any PCT not involved in a trial. As clinicians did not know they were part of a trial, they were free to discuss the workshops with control practices. However, we believe that exchange of information between intervention and control practice staff about the workshops is unlikely, as they were in geographically distinct areas, with no work-related contact between practice staff at educational meetings or during on-call rota shifts. If discussions did occur, the differences between intervention and controls may be underestimated. The urine testing workshops aimed to decrease submissions in adults, and chlamydia workshops aimed to increase them; participants attending the chlamydia workshop may have taken on board the message to increase all laboratory submissions, and therefore submitted more urine samples, therefore reducing the difference between control and intervention groups. However, we do not think this occurred as changes in test submissions were specific to the areas covered in the workshops, for example chlamydia testing of over 25-year-old women in chlamydia workshop practices did not increase. Furthermore, the contents of the workshop were very condition specific and did not include general advice on sampling policy.

**Other work in this area**

The systematic review of the effect of interventions on professional practice and health care outcomes found that studies like ours that used small group discussions were more likely to be effective in improving professional practice. The smaller magnitude of our findings support the hypothesis that some educational studies may overestimate effects through enrolment of interested volunteers in trials. In our study, data were collected from across the PCT and the practices did not know that they were part of a trial. Our chlamydia workshops (described elsewhere) led to a 33% increase in chlamydia submissions in the intervention areas. The chlamydia workshops had fewer key messages, suggesting that simple key messages may be an important factor determining success. Indeed interventions in the systematic review were more effective in attaining change if they were less complex. Thomas et al. used a multifactorial design and similar to our study, practices received feedback on submission of nine different tests. Overall, their total test requests fell, but did not reach significance for six of the nine tests studied, again suggesting that increasing complexity of the message can reduce effectiveness of the intervention.

Although 75% of general practices were represented at our urine workshops, only one-third of participants were doctors, compared to two-thirds at control chlamydia workshops. Although over 50% of
practices reported that they had discussed urine testing at a practice meeting and had changed their urine testing protocol, these practices did not submit fewer specimens than those who did not discuss urine testing. Nurses and administrators may be less able to change a whole general practice staff approach to test submission than doctors. Also more staff are involved in sending urine specimens than chlamydia specimens, so it may be more difficult to change the behaviour of all these staff involved. Although our modified request forms had no effect on submissions, computer-based, guideline-driven requests in primary care can lead to significant savings, and with computerization this may be a simple way to implement guidance.20

Implications to practice
The 12% decrease in urine submissions from 16- to 64-year olds, attained with the workshops, may help to counter the relentless rise in test submissions,1 especially if it was sustained beyond 15 months. Workshops may be more effective if they include the submission of urines from patients without acute urinary symptoms, and target high testing practices, care homes and staff submitting specimens. Modified request forms in hardcopy format are not worth introducing, as a means of changing specimen submission.

Acknowledgements
We wish to thank practice staff who attended the workshops; Dr Ian Donald, Dr Sulaimen, the continence nurses, Jill Whiting, HPA medical illustration and all the PCT professional development teams for their input in the design and help at the workshops. Wally Palmer in Gloucester and Kate McGill in Durham for collecting the laboratory data.

Declaration
Funding: None. Financed by Health Protection Agency core funding.
Ethical approval: The study was approved by the Gloucester LREC (ref. number 02/52G) and Durham LREC (061/September 2002) and approved by the PCT clinical governance leads.
Conflicts of interest: Dr CAMM writes the Health Protection Agency quick reference guide for primary care covering UTIs.

References