A PILOT OF HOME UROFLOWMETRY IN UK PRIMARY CARE

Hypothesis / aims of study
Several countries, such as the UK, operate a ‘gatekeeper’ healthcare system where access to non-emergency specialist services requires referral by general practitioners (GPs) who follow their own investigative protocol, and may subsequently decide the need for specialist care.

The UK Government National Institute for Health and Care Excellence’s (NICE) 2012 clinical guideline 97 recommends that flow rate measurement is not used for men with lower urinary tract symptoms (LUTS) at initial assessment. NICE also estimates that over 40 % of men seen for specialist assessment for LUTS could be have been managed by GPs [1]. Service delivery change to reduce unnecessary referrals has been identified as a research priority.

We conducted a feasibility study of use of home uroflowmetry in the GP investigative protocol using a low-cost electronic device in UK primary care. We aimed to obtain feedback from patients and GPs on its use in this setting and evaluate the potential impact of access to home flow data at initial assessment on need for specialist referral.

Study design, materials and methods
Five local primary care practices took part in the study. They recruited men attending their practice due to LUTS to use a home urine flowmeter for one week. No exclusion criteria surrounding symptom severity, symptom duration, treatment status, or number of previous primary care consultations were imposed. The home flowmeter, developed and built by us, records maximum flow rate (Qmax), voided volume (Void), date, time, duration and flow rate-time graphs for all recorded voids.

Participants completed an International Prostate Symptom Score (IPSS) and a questionnaire on which they used visual scales to score the burden of home uroflowmetry (from 0 Not at all burdensome to 10 Very burdensome) and their willingness to repeat home uroflowmetry (from 0 Not at all willing to 10 Very willing).

Results
24 patients were recruited between February and September 2012. Their median (range) age was 68 (61 to 77) years, median (range) total IPSS score 12 (2 to 26) and median (range) IPSS QOL score 3 (1 to 6). Two patients failed to complete an IPSS and one failed to complete a feedback questionnaire.

The median (range) number of voids recorded by each patient using the home flowmeter was 49 (29 to 82). One patient’s flowmeter contained no data, thought to be due to incorrect use of the device.

Correlation between symptoms and home flow data
Home flow data provided objective measures of frequency, reduced flow and nocturia to allow correlation with subjective IPSS scores for these symptoms (Spearman's rank). For frequency: ρ = 0.4, p = 0.07, for weak flow: ρ = -0.3, p = 0.3, for nocturia ρ = 0.6, p = 0.009.

Patient opinion
The median ‘burden’ score was 0 (Not at all burdensome) (range 0 to 3), indicating that all participants experienced very little inconvenience when using the device at home. The median ‘willingness to repeat’ score was 10 (Very willing) (range 2 to 10); all but five patients (78 %) gave a score of 10.

Indications from home flow data
Management of patients in primary care prior to the home flow study versus indications from their home flow data are shown in table 1.

<table>
<thead>
<tr>
<th>Indication from home flow data</th>
<th>Management of patient in primary care prior to home flow study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Qmax &lt;15ml/s (BOO)</td>
<td>None conservative / α-blocker / α-blocker &amp; 5αRI / α-blocker &amp; diuretic / Antimuscarinic</td>
</tr>
<tr>
<td>Frequency ≥8 (DO)</td>
<td>3 / 1 / 0 / 0 / 0</td>
</tr>
<tr>
<td>&gt;35% urine output at night (NP)</td>
<td>0 / 1 / 0 / 0 / 0</td>
</tr>
<tr>
<td>BOO &amp; DO</td>
<td>1 / 0 / 1 / 0 / 0</td>
</tr>
<tr>
<td>BOO &amp; NP</td>
<td>2 / 2 / 0 / 1 / 1</td>
</tr>
<tr>
<td>None of the above (normal)</td>
<td>6 / 2 / 0 / 0 / 0</td>
</tr>
</tbody>
</table>

Table 1. Management of each patient in primary care prior to the home flow study versus indications from their home flow data. BOO = bladder outlet obstruction, DO = detrusor overactivity, NP = nocturnal polyuria, 5αRI = 5-alpha reductase inhibitor.

Qualitative GP feedback
‘I found the [home flow] reports useful as they were an additional diagnostic tool, enabled better evidence based treatment instead of a trial of treatment, and improved the patients’ quality of life more quickly. They also prevented the need for some referrals. Some examples: [A] 65 year old man presented with [urgency] and occasional urge incontinence. He had nocturia 3-4/night. I initially gave some lifestyle advice and tamsulosin, but [on the basis of the home flow report] I changed him to an anticholinergic,'
and reinforced evening fluid reduction. His symptoms had improved at the next appointment. I suspect I would have got there in the end with trial and error but with [the home flowmeter] I got there quicker, with fewer appointments, and less cost of medication/time. One report came back with a very high urine output so I discussed fluid intake in detail and it did appear he was drinking excessive quantities of fluids, these were reduced and symptoms improved. One result came back as fairly normal, [although] the patient reported poor flow and frequency, so they could be reassured without the need for trying medications and referral.”

“[Patients] who had previously had the pleasure of a trip to the [urine flow clinic] were very clear that it was preferable. They found it easy to use... The report was very helpful and added weight to my attempts at managing their care in primary care.”

Interpretation of results
As has already been established in large studies [2], there is poor agreement between reduced flow symptoms and objective measurement of flow rate. This could be an important contributory factor towards the high failure rate of α-blocker medication commonly prescribed in primary care on the basis symptoms where a reduced flow is unconfirmed [3]. Therefore, objective measurement of a patient's flow rate, along with its relation to voided volume and storage parameters, could be an extremely valuable early tool, particularly in deciding whether to target medicinal treatment to the bladder or outlet.

The GPs involved in the study perceived patient care benefits such as arriving at the correct management decision more quickly, improving efficiency by avoidance of ineffective medications resulting from 'trial and error', and having the confidence to reassure men whose results were normal. As exemplified by one patient with apparent advanced obstruction, early flow data may also expedite the referral of those who truly warrant it.

The vast majority of patients (96 %) provided useable data from home uroflowmetry and feedback on use of the device from both patients and GPs was extremely positive, indicating that it would be feasible to administer within primary care.

Concluding message
The addition of home uroflowmetry to primary care could be a powerful tool to guide the initial management of men with LUTS, aligned with the current drive to reduce referrals to secondary care. The success of the technology in this setting would require careful consideration and evaluation of models of implementation, particularly surrounding interpretation of the resulting data.

References
1. NICE support for commissioning for lower urinary tract symptoms in men, September 2013

Disclosures
Funding: The Wellcome Trust Clinical Trial: No Subjects: HUMAN Ethics Committee: Newcastle & North Tyneside 1 Helsinki: Yes Informed Consent: Yes