

## Whittington Health Trust Board

4 January 2016

<b>Title:</b>	LUTS action plan and progress report						
<b>Agenda item:</b>	<b>16/179</b>		<b>Paper</b>			<b>8</b>	
<b>Action requested:</b>	To note progress against action plan						
<b>Executive Summary:</b>	This paper consists of a progress report and the action plan produced in response to the recommendations from the RCP invited service review of the LUTS service, which was received by the Trust on 19 October 2016. The action plan will be discussed at Quality Committee and the CQRG.						
<b>Summary of recommendations:</b>	To agree the next steps						
<b>Fit with WH strategy:</b>							
<b>Reference to related / other documents:</b>	RCP invited service review May 2016.						
<b>Reference to areas of risk and corporate risks on the Board Assurance Framework:</b>	BAF risk as corporate risk (reference BAF2)						
<b>Date paper completed:</b>	28 December 2016						
<b>Author name and title:</b>	Siobhan Harrington Director of Strategy			<b>Director name and title:</b>	Siobhan Harrington Director of Strategy Richard Jennings Medical Director		
<b>Date paper seen by EC</b>		<b>Equality Impact Assessment complete?</b>		<b>Risk assessment undertaken?</b>		<b>Legal advice received?</b>	



## Trust Board Progress update regarding LUTS service

1. This paper updates the Board on progress made against the action plan in place to meet the recommendations of the RCP invited service review of the LUTS service. The review was conducted in May 2016 and the final report received in October 2016; an interim letter was received in May 2016 which enabled key actions to be progressed.
2. The action plan is attached as appendix 1.

Overall progress has been made although there are a key number of areas where work needs to be completed. As a team we are working to conclude the actions so that we can assure the Board with regard to the two criteria set:-

- A succession plan having been agreed
- Safety and governance concerns raised by the RCP review having been satisfactorily addressed from WH and commissioners' perspectives

The LUTS service will continue and will reopen to new patients once we have secured the detail of the succession plan with UCLH colleagues and commissioners, and when the commissioners and the Trust Board are assured that safety concerns have been addressed. We are aiming to conclude the final actions by the end of March 2017.

### 3. Key areas of progress

Since the last discussion at Trust Board in November the key areas that have progressed are

- 3.1 Integrating the Artemis IT with the Trust IT
- 3.2 Continuing to strengthen the MDT working jointly between WH and UCLH
- 3.3 Identifying a paediatrician from GOSH who will work on the paediatric pathways
- 3.4 Professor Malone Lee and his team continuing the clinic and strengthening the clinical governance arrangements
- 3.5 Ongoing communication with service users, Overview and Scrutiny colleagues and responding to MP letters
- 3.6 Agreeing the detail of the review regarding Nitrofurantoin prescribing

### 4. Key risks and mitigations

There remain a number of risks in securing the future arrangements

- 4.1 The agreement on a final succession plan and sustainable and viable model of care for the LUTs clinic. There has been progress with colleagues from UCLH however this will need a reviewed focus. Through January discussions will continue with the Trust and also commissioners to secure the future sustainable model.
- 4.2 The contracting and financial arrangements of the clinic will need to be agreed with commissioners and work progressed to secure a tertiary setting for the clinic.
- 4.3 In order to allay safety and governance concerns there are a number of aspects that need to be addressed. The review of patients prescribed Nitrofurantoin will be completed. A desktop review will be completed where the various policies, audit programme and clinical governance activities will be reviewed in January. This will enable any gaps to be addressed.
- 4.4 Communication with service users and ensuring that we continue to keep local councillors and MPs informed of progress.

### 5. Proposed next steps

Through January final agreement needs to be reached with colleagues from UCLH.  
There are plans for a meeting with commissioners to discuss the detail of progress against the action plan and the future sustainable model for the clinic.  
The review of Nitrofurantoin patients will commence and aim to conclude by the end of February.  
A desktop review of the clinical governance arrangements will be conducted with the Medical and Nursing Director and ICSU so that any potential gaps can be addressed.  
Further service user meetings will be held.  
A final report will be brought to the March Trust Board on actions completed and an assessment of achievement of the criteria previously set to enable the clinic to reopen.

Appendix 1: Action Plan re RCP Review LUTS clinic. December 2016

Task No	Action	Timescale as per RCP report received 19 October	Progress
1.	At the conclusion of the review visit, the review team provided immediate feedback to the Trust regarding potential patient safety concerns that required intervention. This feedback was confirmed in a letter sent to the Trust by the medical director for Invited Service Reviews on the 19 May 2016. This was followed up by an additional letter highlighting potential concerns about further cases of pulmonary fibrosis associated with nitrofurantoin in LUTS patients.	<p><b>0-3 months</b></p> <p>Review will be completed by March 2017.</p>	<ul style="list-style-type: none"> <li>• RJ created draft action plan for this task and received feedback from key stakeholders.</li> <li>• James Malone-Lee reviewed the LUTS database on the 13 patients who also had a diagnosis of pulmonary fibrosis, and wrote a report, with additional information, on 28.08.2016.</li> <li>• RJ wrote to the Head of Medicines Management for Islington CCG and internal Trust experts for specific advice about thresholds for investigation.</li> <li>• RJ identified an independent respiratory physician to complete the review.</li> <li>• RJ wrote to the Head of Medicines Management for Islington CCG about an expert on pharmacovigilance, on 22.11.2016.</li> <li>• Review to be completed by March 2017.</li> </ul>
2.	The Trust must provide sufficient resource and focus to investigate these and other potential safety concerns raised by its own governance systems, our review and its principal commissioners.	<p><b>0-3 months</b></p> <p>Resource identified.</p>	<ul style="list-style-type: none"> <li>• Internal project resource identified.</li> <li>• IT resources to integrate Artemis (stand-alone LUTS clinic record system) with the central Trust patient record system and this will be done by 31.12.2016.</li> <li>• Clinical audit requirements for the LUTS clinic review complete and agreed:               <ul style="list-style-type: none"> <li>○ Control Audit due in February 2017</li> <li>○ Document and Consent Audit due in August 2017.</li> <li>○ Patient Experience Audits to be confirmed.</li> </ul> </li> </ul>
3.	The Trust should continue to provide access to the LUTS clinic for those patients already registered with it and until such a time that long term succession plans have been agreed and implemented. It may be appropriate for some patients to subsequently be referred to other services but there are likely to be a significant number of patients who will need to continue to access the service.	<p><b>0-6 months</b></p> <p>Continuity of service in place.</p>	<ul style="list-style-type: none"> <li>• Continuity of service provision in place.</li> <li>• The MDT is now established at UCLH and arrangements continue to be strengthened.</li> <li>• Discussions continue to take place with UCLH, commissioners and service user to ensure a sustainable and viable safe tertiary service.</li> </ul>
4.	The management of these patients, including the medication prescribed, its doses and durations, should be reviewed,	<p><b>0-6 months</b></p>	<ul style="list-style-type: none"> <li>• MDT in place with WH and UCLH.</li> <li>• NH now chairing the MDT.</li> </ul>

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	discussed and agreed at properly constituted and well managed MDT meetings with additional resources committed to it as required.	Joint UCLH/WH MDT in place	<ul style="list-style-type: none"> <li>• TOR's for UCLH/WH MDT to be formalised and approved by both Trusts.</li> <li>• First MDT meeting was held on 14.07.2016, 6 MDTs have been held so far. Each MDT is held on the second Thursday of every month.</li> </ul>
5.	The information provided by the LUTS clinic to its patients on the treatments and their associated risks should be reviewed to ensure its accuracy. It will be necessary to provide patients with updated information on the risks of their medications and discuss further their preference in terms of on-going treatment.	<b>0-6 months</b>	<ul style="list-style-type: none"> <li>• Information in place.</li> <li>• Desktop review to be conducted.</li> </ul>
6.	The existing restriction for a requirement of consultant paediatrician input for current paediatric patients should remain in place with oversight being provided by a consultant paediatrician. It would be beneficial to ensure these patients are discussed in the LUTS MDT meeting with input from the consultant paediatrician involved.	<b>0-3 months</b>  In place	<ul style="list-style-type: none"> <li>• Progress has been made with colleagues from GOSH and JML. A Consultant Paediatric Nephrologist from GOSH has agreed to be involved in the Paediatric Pathway.</li> <li>• This has the support of the Medical Directors of both WH and GOSH.</li> <li>• The restriction around the treatment of patients by the LUTS clinic remains in place.</li> <li>• Detail on pathway with GOSH to be agreed in January.</li> </ul>
7.	The Trust should review the LUTS clinic's current use of telephone and virtual review appointments and prepare a clear policy on its expectations about how patients are reviewed.	<b>0-6 months</b>	<ul style="list-style-type: none"> <li>• Policies to be reviewed as part of desktop review in January.</li> </ul>
8.	The Trust should consider where the clinic should be housed in the short term until longer term succession plans have been agreed. It should seek to locate it more clearly within its own hospital premises to allow the Trust to better support and oversee the clinic.	<b>0-6 months</b>  Complete	<ul style="list-style-type: none"> <li>• The Trust has consulted with the service user group and has agreed for the service to continue for now at Hornsey.</li> </ul>
9.	The clinic should undertake audits of patient outcomes and of consent to unlicensed treatments.	<b>6-24 months</b>	<ul style="list-style-type: none"> <li>• Audit programme being agreed.</li> </ul>
10.	To ensure that treatment is provided in a safe manner the	<b>0-6 months</b>	<b>In order to strengthen governance within the service, the</b>

	<p>Trust should put in place robust clinical governance processes to monitor the outcomes, side effects and any adverse effects experienced by the clinic's patients. The Trust will need to resource these measures appropriately.</p>	<p>Resource in place</p> <p>Clinical Governance process</p> <p>IT access to records</p>	<p><b>Trust expects the service to deliver within the policies and clinical governance processes of the Trust. The service requires:</b></p> <ul style="list-style-type: none"> <li>• <b>Regular audit - Support has been offered and accepted in completing any national and Trust-wide audits for the service. Infection Control and Record Keeping Audits due February and August 2017 respectively.</b></li> <li>• <b>Robust arrangements to gain and record informed patient consent to treatments</b></li> <li>• <b>Incident reporting</b></li> <li>• <b>Mandatory training – The clinic is up-to-date on all Mandatory and Statutory training</b></li> <li>• <b>Patient safety</b></li> <li>• <b>Protocols in place – protocol received 29 August</b></li> <li>• <b>Information Governance training complete</b></li> <li>• <b>Records Management</b></li> <li>• <b>Trust I.T integrated Artemis, Datix etc – I.T systems will be in place by end of December</b></li> </ul>
<p>11.</p>	<p>If any serious incidents, associated with the LUTS clinic, were to be identified by the Trust these should be appropriately escalated and investigated utilising the Trust's established clinical governance processes. The Trust would need to consider the outcome of any such investigations to determine if the continuation of the existing clinic is considered safe.</p>	<p><b>0-6 months</b></p> <p>Ongoing</p>	<ul style="list-style-type: none"> <li>• <b>There has been one logged Serious Incident– the investigation is complete but awaiting completion of actions.</b></li> <li>• <b>The Serious Incident report has been completed – RCA report has been shared with the family.</b></li> </ul>

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12.	The current corporate provision of serious incident investigations needs significant enhancement to provide timely and comprehensive investigation. Investment in the medical directorate structure is also required and robust processes put into place to ensure learning from clinical incidents is shared.	<b>0-6 months</b> Complete	<ul style="list-style-type: none"> <li>• <b>Two Associate Medical Director posts were created in 2015/16. Mr Robert Sherwin was appointed to the role of Associate Medical Director (AMD) for Revalidation on 01.02.2016. Dr Julie Andrews was appointed to the role of AMD for Patient Safety on 01/02/2016.</b></li> <li>• <b>The Trust Board receives Quarterly Safety and Patient reports; the last two reports were received by the Board on 01.06.2016 and 07.09.2016.</b></li> </ul>
13.	The Trust should conclude the serious incident investigation regarding nitrofurantoin toxicity and share the findings and recommended actions with the patient who was harmed and the clinic team ensuring lessons are learned. Similarly, the Trust should review patient admissions to secondary care during the period in which the LUTS clinic was “suspended”, other potential harms with nitrofurantoin and the true incidence of <i>Clostridium difficile</i> should be completed.	<b>0-6 months</b> Complete	<ul style="list-style-type: none"> <li>• <b>An SI involving Nitrofurantoin – this investigation has been completed and the RCA report has been shared with the family.</b></li> <li>• <b>Review of emergency admissions during the suspension of the LUTS service complete.</b></li> <li>• <b>If a C.Diff case was associated with a LUTS patient this would be highlighted by the Post Infection Review that is completed on each case, which would then be highlighted through the ICSU and clinical team associated with the patient.</b></li> </ul>
14.	A clear definition of the involvements of the Trust's microbiology services in the LUTS clinic's work should be put in place to include UKAS accreditable performance of the clinic's arrangements for urine microscopy.	<b>0-6 months</b> Complete	<ul style="list-style-type: none"> <li>• <b>The microbiology laboratory will continue performing investigations on LUTS clinic patient using the standards outlined in the UK agreed standard document.</b></li> <li>• <b>JML is currently in discussion with NICE regarding urine testing techniques.</b></li> </ul>
15.	A review of the LUTS clinic's method of prescribing should be carried out and a clear policy put in place as to how medications should be prescribed and dispensed.	<b>6-24 months</b>	<ul style="list-style-type: none"> <li>• <b>Policy is in place.</b></li> </ul>
16.	The Trust should ensure that information held by the LUTS clinic about its patients is fed in to the Trust's central electronic patient records system and that there are clear	<b>6-24 months</b>	<ul style="list-style-type: none"> <li>• <b>IT system integration will be completed by the end of December 2016.</b></li> </ul>

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	flows of information in each direction.		
17.	The Trust should identify who can take over the management of the LUTS clinic in the short term, once Professor Malone-Lee retires later this year. The issue of oversight and development of independent practice for junior doctors and nurses in the clinic needs attention and should be encouraged in line with good medical and nursing practice.	<b>0-3 months</b>  Plan from September for Clinical Leadership and Consultant input	<ul style="list-style-type: none"> <li>• <b>JML has agreed to 4 clinical sessions a week. His contract has just been extended for a further 3 months from December 2016 to March 2017.</b></li> </ul>
18.	A succession plan should urgently be developed in direct dialogue between the Trust and Professor Malone-Lee. This should include direct high-level dialogue with neighbouring tertiary centres such as UCLH or other tertiary centres. Succession should focus on the development of multi-disciplinary team working to ensure resilience in the service, and to overcome the reliance on any one individual. The Trust should ensure they take steps to regularly update the patient representatives and service users on these plans as they develop.	<b>0-6 months</b>  NOT YET COMPLETE  Ongoing communication and engagement of JML and Patient Representatives	<ul style="list-style-type: none"> <li>• <b>Clinical Collaboration meetings are being held with UCLH colleagues.</b></li> <li>• <b>Final succession plan will require the approval of the CCG's.</b></li> <li>• <b>Progress on the succession plan includes identification of some additional WH consultant support and UCLH consultant support.</b></li> <li>• <b>The Trust is currently negotiating extra support from UCLH.</b></li> <li>• <b>A letter was sent out to all LUTS clinic patients on 20<sup>th</sup> November 2016.</b></li> <li>• <b>Service users group regularly meeting. Since May there have been 5 meetings with the last one in December 2016.</b></li> <li>• <b>Communication with Overview and Scrutiny Committees and MPs continues.</b></li> </ul>
19.	The Trust should engage in direct, high-level dialogue with local clinical commissioning groups and with neighbouring tertiary centres to agree a strategy for the long-term future of the LUTS clinic. This should include a review of what treatments are likely to be commissioned, whether the clinic should open to new patients, which providers are best placed to offer them and whether the treatment to be offered would be part of the research framework.	<b>6-24 months</b>  NOT YET COMPLETE	<ul style="list-style-type: none"> <li>• <b>A meeting will be held in January 2017 with commissioners to discuss the strategy for the long-term future of the clinic.</b></li> </ul>
20.	The future of the clinic would be safer and better regulated with a fresh start in a tertiary centre such as UCLH that has a mix of appropriate specialties, and could offer true disciplinary working. Clinicians working in such an environment will safeguard care of patients by peer review, good teamwork	<b>6-24 months</b>  NOT YET COMPLETE	<b>See box 18 and 19 above.</b>



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	and integration with Trust governance processes.		
21.	Until the future of the service has been determined by the Trust and commissioners, no new patient referrals should be accepted into the LUTS clinic.	<b>0-6 months</b>  NOT YET COMPLETE	<ul style="list-style-type: none"> <li>• <b>On 02.11.2016 the Trust Board agreed that new referrals would only be accepted by the LUTS clinic if the following criteria were met:</b> <ul style="list-style-type: none"> <li>- <b>Quality and safety concerns have been resolved</b></li> <li>- <b>A clear succession plan in place</b></li> </ul> </li> </ul>
22.	In view of the significant patient interest, reputational risk, and pressure on individuals, the Trust should invest in significant project management to provide additional capacity and capability to deliver both strategic and operational work including governance improvements for the LUTS service.	<b>0-6 months</b>  Under review	<ul style="list-style-type: none"> <li>• <b>Project management support has been in place and is currently being reviewed.</b></li> </ul>
23.	Support must be offered to Professor Malone-Lee during what will likely be a very difficult and stressful period of time for him personally prior to his retirement.	<b>0-3 months</b>  Ongoing	<ul style="list-style-type: none"> <li>• <b>The Trust has continually offered support during this period; this offer was reiterated during the last meeting of 15<sup>th</sup> November 2016 and also in December 2016.</b></li> </ul>
24.	UCL should be urgently reminded of their employer responsibility regarding provision of this clinic that is entirely focused around one individual they employ who has an honorary contract with the Trust.	<b>0-3 months</b>  Complete	<ul style="list-style-type: none"> <li>• <b>RJ shared the report with the Dean of UCL Faculty of Medical Sciences, on 21.10.2016.</b></li> </ul>
25.	UCL should be urgently engaged to fulfil its responsibilities regarding oversight of the LUTS clinic's research and the use of research data to make individual patient treatment decisions and how the research findings published by Professor Malone-Lee have been translated in to clinical practice in the LUTS clinic. Any new information should be utilised in conjunction with the Trust to plan the future of the service.	<b>0-3 months</b>  Complete	<ul style="list-style-type: none"> <li>• <b>See box 24 above.</b></li> <li>• <b>Research governance arrangements have been confirmed with UCL and WH research teams in December 2016.</b></li> </ul>
26.	UCL should state its intentions regarding carrying out further research in the field of the lower urinary tract infection and the Trust should discuss with them what its intentions are for the future delivery of the clinic, including the acceptance of new patients.	<b>6-24 months</b>  Complete	<ul style="list-style-type: none"> <li>• <b>UCL's Vice-Dean for Research and UCL's Dean of the Faculty of Medical Sciences have responsibility for the research that is on-going in the LUTS clinic. UCL statement received.</b></li> </ul>
27.	When Professor Malone-Lee retires and if he then continues to practice privately, there would need to be formal discussion with his new Responsible Officer or the regulator the GMC, to	<b>0-6 months</b>	<ul style="list-style-type: none"> <li>• <b>Professor Malone-Lee has offered assurance to the Trust that all private sessions take place not on Whittington Health premises. JML is working at a</b></li> </ul>

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	ensure any future private practice arrangements are safe.		<b>private clinic which is listed as a Designated Body and has an RO. However, JML's RO continues to be WH RO and his NHS practice is subject to arrangements with WH RO.</b>
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