Whittington Health NHS

TRUST BOARD

14.00 – 16.30
Wednesday 2 November 2016

Whittington Education Centre Room 7

NHS
Whittington Health
NHS Trust

Meeting	**Trust Board – Public**
Date & time	**2 November 2016 at 1400hrs – 1630hrs**
Venue	**Whittington Education Centre, Room 7**

AGENDA

Members – Non-Executive Directors	**Members – Executive Directors**
Steve Hitchins, Chair Deborah Harris-Ugbomah, Non-Executive Director Tony Rice, Non-Executive Director Anu Singh, Non-Executive Director Prof Graham Hart, Non-Executive Director David Holt, Non-Executive Director Yua Haw Yoe, Non-Executive Director	Simon Pleydell, Chief Executive Siobhan Harrington, Director of Strategy & Deputy Chief Executive Stephen Bloomer, Chief Finance Officer Dr Richard Jennings, Medical Director Philippa Davies, Director of Nursing and Patient Experience Carol Gillen, Chief Operating Officer

Attendees – Associate Directors
Dr Greg Battle, Medical Director (Integrated Care)
Norma French, Director of Workforce
Lynne Spencer, Director of Communications & Corporate Affairs
Secretariat
Kate Green, Minute Taker

Contact for this meeting:lynne.spencer1@nhs.net or 07733 393 178

Agenda Item		Paper	Action and Timing
Patient Story			
	Patient Story *Philippa Davies, Director of Nursing & Patient Experience*	*Verbal*	*Note* 1400hrs
16/140	**Declaration of Conflicts of Interests** *Steve Hitchins, Chair*	*Verbal*	*Declare* 1420hrs
16/141	**Apologies & Welcome** *Steve Hitchins, Chair*	*Verbal*	*Note* 1420hrs
16/142	**Draft Minutes, Action Log & Matters Arising 7 September** *Steve Hitchins, Chair*	1	*Approve* 1425hrs
16/143	**Chairman's Report** *Steve Hitchins, Chair*	*Verbal*	*Note* 1430hrs
16/144	**Chief Executive's Report** *Simon Pleydell, Chief Executive*	2	*Approve* 1440hrs
Patient Safety & Quality			
16/145	**Lower Urinary Tract (LUTs) Royal College of Physicians (RCP) report and Trust response**	3	*Approve* 1500hrs

16/146	**Serious Incident Report Month 6** *Philippa Davies, Director of Nursing & Patient Experience*	4	*Approve* 1520hrs
16/147	**Safer Staffing Report Month 6** *Philippa Davies, Director of Nursing & Patient Experience*	5	*Approve* 1530hrs
16/148	**Nursing & Midwifery Revalidation Report** *Philippa Davies, Director of Nursing & Patient Experience*	6	*Approve* 1540hrs
Performance			
16/149	**Financial Performance Month 6** *Stephen Bloomer, Chief Finance Officer*	7	*Approve* 1550hrs
16/150	**Performance Dashboard Month 6** *Carol Gillen, Chief Operating Officer*	8	*Approve* 1600hrs
Any other urgent business and questions from the public			
	Lower Urinary Tract Services		
Date of next Trust Board Meeting			
	07 December at 1400hrs to 16.30hrs at the Whittington Education Centre Room 7, Magdala Avenue, N19 5NF		

Register of Conflicts of Interests:
The Register of Members' Conflicts of Interests is available for viewing during working hours from Lynne Spencer, Director of Communications & Corporate Affairs, at Trust Headquarters, Ground Floor, Jenner Building, Whittington Health, Magdala Avenue, London N19 5NF - communications.whitthealth@nhs.net.

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Whittington Health NHS

ITEM: 01
Doc: 16/142

The draft minutes of the meeting of the Trust Board of Whittington Health held in public at 1400hrs on Wednesday 5th October 2016 in the Whittington Education Centre

Present:	Stephen Bloomer	Chief Finance Officer
	Philippa Davies	Director of Nursing and Patient Experience
	Carol Gillen	Acting Chief Operating Officer
	Siobhan Harrington	Director of Strategy/Deputy CEO
	Deborah Harris-Ugbomah	Non-Executive Director
	Graham Hart	Non-Executive Director
	Steve Hitchins	Chairman
	Yua Haw Hoe	Non-Executive Director
	David Holt	Non-Executive Director
	Richard Jennings	Medical Director
	Simon Pleydell	Chief Executive
	Tony Rice	Non-Executive Director
In attendance:	Greg Battle	Medical director, Integrated Care
	Janet Burgess	London Borough of Islington
	Norma French	Director of Workforce
	Kate Green	Minute Taker
	Lynne Spencer	Director of Communications & Corporate Affairs

Patient Story

Philippa Davies introduced Anna, who been a patient of the maternity unit. Anna had already had a child by caesarean section at the Whittington, and she therefore had confidence in that procedure. Anna described her second birth at the Whittington and explained the difficulties surrounding a forceps delivery. Senior Midwife Logan Van Lessen informed the Board that she and the Clinical Director of Women's Health Chandrima Biswas had met with Anna to discuss her experience. Logan described some of the steps taken to embed learning from the lessons identified and she highlighted a new teaching video 'Footprints' which detailed mothers' feedback of giving birth at the Whittington. Simon Pleydell felt this experienced highlighted the need for better patient choice, instead of a standard medical model approach. David Holt agreed it was important to treat everyone as individuals when planning treatment.

It was noted that consideration was being given to an electronic form of consent to improve the service. Yua Haw Yoe expressed her concern that there did not appear to have been sufficient learning following her own patient story to the Board a year previously. Philippa and Richard would meet to discuss the lessons and embedding of the learning of patient stories/feedback.

16/127 Declaration of Conflicts of Interest

113.01 No member of the Board declared any conflicts of interest in the business scheduled for discussion at that afternoon's Board meeting.

16/128 Apologies and welcome

114.01 Steve Hitchins welcomed everyone to the meeting, in particular Joe Morrisroe, who had just started at the Trust as Business Planning Manager in Siobhan's team. Apologies for absence were received from Deborah Harris-Ugbomah.

16/129 Minutes, Action Log and Matters Arising

129.01 It was noted that Janet Burgess had been present at the September meeting; other than this amendment the minutes of the Trust Board held on 5th September were approved. There were no matters arising other than those already scheduled for discussion.

Actions

129.02 110.03 IM&T Strategy: A first cut of the strategy would be discussed at the forthcoming Trust Board Seminar, with the substantive item to be scheduled for discussion at a Trust Board meeting in the New Year.

160.09 Performance Dashboard: The new performance dashboard would be brought to the Board in December.

124.03 The Nursing & Midwifery Strategy had been formally approved by the Board in September; this item could therefore be closed.

16/130 Chairman's Report

130.01 Steve Hitchins began his report by reminding the Board that this month was Black History month, and there was to be an event on 28th October in N19, details of which would be circulated. This event was, as in previous years, organised by one of the Trust's security staff, and Deborah Harris was to be a guest speaker.

130.02 Steve had recently attended an Integrated Network meeting and found it of great interest; any other Board member wishing to attend one should contact Becky Owen.

130.03 On 19th October the joint youth programme initiative with Tottenham was to be launched, and on 9th November the young person's health forum (led by Collette Datt) would be launched at Arsenal.

130.04 As part of the Community Forum work, Steve announced a painting competition for school children and these will be displayed on the Trust's website with the top ten, chosen by a panel of judges and sold in aid of the Trust's charitable funds.

130.05 Board members were encouraged to sign up to the 'tea trolley rota' – an initiative whereby directors and senior managers distributed free tea and coffee to patients waiting in the outpatients departments. Several directors had already participated and found the experience to be extremely rewarding.

130.06 Steve informed the Board that non-executive director vice-chairs had now been appointed to all Board sub-committees as follows:

- Audit & Risk — Deborah Harris
- Finance & Business Development — Deborah Harris
- Workforce Assurance — Graham Hart
- Quality — Yua Haw Hoe

Concluding his report, Steve said that he was pleased to announce that Dorian Cole, head of the Improving Access to Psychological Therapies (IAPT) service had been appointed as the Trust's Freedom to Speak Up Guardian.

16/131 Chief Executive's Report

131.01 Simon Pleydell informed the Board that there was a great deal of positive work being undertaken around patient safety. This included a major focus on the promotion and uptake of the flu vaccine.

131.02 Simon was pleased to announce that ED performance was improving although the Trust was still not achieving the target of 95%. This affected the Trust's ability to access STP funding. Issues were highlighted around the impact of diverts from North Middlesex and there will be further impact on performance with the pressures of winter.

131.03 Updating the Board on the NC London Sustainability & Transformation Plan (STP) Simon reminded colleagues that the draft plan was due to be submitted to NHSI and NHSE on 21 October. The Board would receive the draft plan in its November Board meeting to consider a formal response.

131.04 NHS Improvement's Single Oversight Framework had been published at the end of September. All Trusts were to be 'segmented' into one of four categories dependent on what level of support NHSI felt they required, and Whittington Health had been categorised as Level 2; a positive ranking.

131.05 The annual staff survey had been launched the previous day, with a mixed approach of electronic and hard copies delivered to staff. Simon reported progress on recruitment initiatives and a microsite had just been launched. Norma French reported that several hundred 'hits' had been received on the button to apply for positions.

131.06 Simon and Siobhan had attended the local authority's Joint Overview & Scrutiny Committee the previous Friday, where service users of the LUTS clinic had been present to hear the Trust's plans and share their views. The Trust had given a public commitment to continuing the service, although Simon felt that the long-term future of the service would be best placed by its being sited within a tertiary setting. The RCP report was expected before the next Board meeting. Janet Burgess added that many people had contacted her to discuss the service and to make representations about its future. She had also been contacted about the planned strategic estates partnership, and fed back that there was a degree of nervousness amongst some so she would appreciate being kept informed. Simon replied that there were plans to draft an update letter to respond to questions received from the JHOSC.

16/132 Appointment of Deputy Responsible Officer

132.01 Richard Jennings reminded the Board that the office of the Medical Director had recently increased its capacity with the appointment of Julie Andrews as Associate Medical Director for Patient Safety and Rob Sherwin as Associate Medical Director for Revalidation. He now proposed that the Board formally approve Rob Sherwin's appointment as Deputy Responsible Officer; this was agreed by the Board.

16/133 Serious Incident Report

119.01 Philippa Davies informed the Board that three serious incidents (SIs) had been declared during August, bringing the total to 19 SIs recorded at the Trust since 1st April. The three declared comprised:

- a safeguarding allegation in relation to a patient
- an information governance breach concerning a handover sheet
- the never event about which the Board had been briefed in September

119.02 The paper circulated also provided details of learning arising from completed SI investigations. Philippa added that figures from the National Reporting & Learning System (October 2015-March 2016) showed a dramatic improvement in reporting and demonstrated the Trust's commitment to taking patient safety seriously. The Trust's reporting culture was undoubtedly better than average, and Richard added that this was emphasised at staff induction, where he and Julie Andrews conducted an introductory session on patient safety and our open culture. A patient safety newsletter had been launched to share learning and this had been well received by staff.

16/134 Safe Staffing Report

134.01 Philippa Davies informed the Board that with new information becoming available from the health roster system this report would be changing, and she would welcome

feedback as it evolved. The report provided details of actual versus planned staffing levels, care hours per day, shifts which triggered red and acuity levels which required adjustments to be made. Carol Gillen and all heads of nursing now received this information on a regular basis.

134.02 A graph within the report showed that levels of acuity were not typical, with the Trust having an unusually high number of 1B patients (those needing high levels of care), and Philippa reported that this explained the need for the levels of nursing employed. The report also provided detail on bank and agency usage, and was reviewed daily by the heads of nursing as part of our work to reduce agency spend.

134.03 The health roster consultation with staff had been concluded and this initiative had been supported and implemented on all wards. Staff with historical flexible working arrangements had been asked to re-negotiate to ensure the needs of the service were met.

16/135 Financial Report

135.01 Stephen Bloomer informed the Board that at the end of August the Trust had reported a £1.3m deficit and a year to date deficit of £6.8m, £3.9m worse than the planned position. The Trust had continued overspending on pay, mainly agency spend driven by a high vacancy rate. There remained some difficulty in hitting planned activity levels. Income was broadly on plan as was illustrated by the table on page 3.

135.02 Similar trends were expected in September, but a great deal of work was being carried out with the ICSUs on their CIPs; the Trust was expecting some on-recurrent income. This plus payment received from debtors meant that the Trust was likely to move closer to its financial target, but Stephen emphasised the importance of remembering this was due to non-recurrent income so there was still much to do before the position became sustainable.

135.03 In answer to a question from David Holt about whether there were revised trajectories on agency spend for the ICSUs, Stephen replied that the quarterly round of ICSU performance reviews would be starting the following week, so whilst revised trajectories had not been set, projections for the year end would be forthcoming. Norma assured the Board that her team has a very clear picture of the recruitment pipeline although she acknowledged it was difficult to enable newly-recruited staff to start quickly for a number of reasons.

135.04 Work was in hand to encourage agency staff to sign up the Trust's staff bank, with heads of nursing approaching long-standing agency staff. Norma had commissioned a piece of work to look at bank rates of pay. Recommendations had been agreed at the Trust Management Group which put Whittington health on a level playing field with neighbouring organisations. Work was underway to look at utilising staff with clinical skills who were currently working in management roles.

16/136 Performance Dashboard

136.01 Carol Gillen informed the Board that good progress continued to be made on theatre utilisation with an average use of 80%, the target being 85%. All dashboards were now in place. The PMO were upgrading Netcall to help ICSUs manage their DNA rates. Some improvement had been made to MSK waiting times; now at 60%, and there was an ongoing dialogue with the commissioners to set a more realistic target. The podiatry service had been experiencing some difficulties, however the team was now fully staffed so an improvement in waiting times was expected.

136.02 Recruitment was an issue for the Islington Reach team, with the retention of physiotherapists presenting the most challenge. The Trust had been non-compliant

with the 62-day cancer target in July, but Carol said the position had improved and she believed the September report would show that the target had been met. Emergency & Urgent Care was showing steady activity, and there had been a reduction in the number of bed management breaches.

136.03 Carol informed the Board that the week commencing 12th September had been designated the 'perfect week', the rationale being to gain an understanding of the factors impeding patient flow, issues between wards and support services, testing new ways of working, and to resolving some of the difficulties which prevent people from doing their jobs. IT and Facilities staff had acted as floorwalkers, and this had proved particularly helpful in terms of getting straightforward issues such as repairs and IT difficulties resolved quickly. An action plan had been produced, and there was a major focus in increasing medical reviews before noon.

16/137 Board Assurance Framework

137.01 Siobhan Harrington informed Board colleagues that the Board Assurance Framework (BAF) is a dynamic and will continue to be a work in progress. In updating it they had looked at all risk registers and significant risks had informed the BAF. The new format was based on the Northumberland and Good Governance models, and it grouped risks by corporate objectives. The top risks were the non-delivery of CIPs, the Trust's financial position, and the possible failure to access the capital support necessary for the redevelopment of the Trust's maternity and neonatal services.

137.02 It was suggested that at the January Board seminar there should be a session on the corporate risk register and the BAF, and these should be brought back to the Board on a six-month basis in addition to being taken to the Audit & Risk Committee and Trust Management Group.

137.03 It was noted that the final section of the document was not yet complete and the section on estates needed to be widened to cover community engagement. The next iteration of the document would be reviewed by the corporate risk sub-group. Lynne Spencer added that the risk management strategy was due to be reviewed at this time. Anu Singh assured Board colleagues the Quality Committee reviewed all quality and safety risks at each meeting. Top risks of ICSUs were discussed at the quarterly performance review meetings and at all ICSU Boards.

16/138 Draft Minutes of the 31 August Workforce Assurance Committee

138.01 Introducing the draft minutes of the Workforce Assurance Committee meeting (WAC) held on 31st August, Steve Hitchins congratulated Norma for her achievements to date as Workforce Director and in particular for her work on this sub-group. In answer to a question from Anu Singh about diversity and inclusion, Norma replied that Joy Warmington from BRAP was due to come back to a future Board seminar, however there was an improvement plan which was monitored through the WAC. She cautioned however that this affected patients as well as the workforce and as such would not fall entirely within her remit. It was agreed an update about this at a future Quality Committee will be provided by Greg Battle as Executive Lead for this area.

16/139 Draft Minutes of the 14 September Quality Committee

139.01 Anu Singh remarked on how impressed the committee had been with the nursing quality indicators which had been presented and which were, she felt, a widely appreciated tool. Of more concern had been the aggregated report of SIs, claims and complaints, where it was not clear that the Trust was placing enough emphasis on learning.

139.02 The Committee had discussed the Cancer Survey Report and had been concerned that some patients had expressed a lack of confidence in the doctors and nurses treating them. In response lead cancer nurse Karen Phillips had set up some coaching

sessions for doctors and nurses – these had been well attended by nurses but not to date by doctors. Anu was concerned at what she saw as an emerging theme, and it was suggested this was something that Richard Jennings and Philippa Davies needed to consider. Richard reminded the Board of the excellent grounding in quality and safety junior doctors received from Julie Andrews.

16/140 Any other business

140.01 Anu Singh asked what Whittington Health was doing for the national Change Day; Carol Gillen replied that there was to be a new volunteering initiative to be launched for non-clinical staff. Norma French added that a new page had been established on the intranet to support promoting quality improvements.

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Action Notes Summary

Patient Story -	Philippa and Richard would meet to discuss the lessons and embedding of the learning of patient stories/feedback	Completed	RJ PD
129.02 110.03	IM&T Strategy: A first cut of the strategy would be discussed at the forthcoming Trust Board Seminar, with the substantive item to be scheduled for discussion at a Trust Board meeting in the New Year	Closed November Board Seminar & on forward plan 2017	SB
160.09	The new performance dashboard to the Board in December	Closed	CG
124.03	The Nursing & Midwifery Strategy had been formally approved by the Board in September	Closed	PD
138.01	Joy Warmington from BRAP (equality and diversity) was due to come back to a future Board seminar	Closed Forward plan for 2017	NF
138.01	An equality improvement plan was monitored through the WAC. Update at a future Quality Committee by Greg Battle, Executive Lead	Closed QC January 2017	GB
139.02	Cancer Survey - Richard Jennings and Philippa Davies to engage doctors in future learning events	Closed	RJ, PD

Whittington Health Trust Board

2 November 2016

Title:	Chief Executive Officer's Report to the Board		
Agenda item:	**16/144**	**Paper**	**02**
Action requested:	For discussion and information.		
Executive Summary:	The purpose of this report is to highlight specific issues to the Trust Board and to update the Board on local, regional and national key issues facing the Trust.		
Summary of recommendations:	To note the report.		
Fit with WH strategy:	This report provides an update on key issues for Whittington Health's strategic intent.		
Reference to related / other documents:	Whittington Health's regulatory framework, strategies and policies.		
Reference to areas of risk and corporate risks on the Board Assurance Framework:	Risks captured in risk registers and/or Board Assurance Framework.		
Date paper completed:	28 October 2016		

Author name and title:		**Lynne Spencer, Director of Communications & Corporate Affairs**		**Director name and title:**		**Simon Pleydell, Chief Executive**	
Date paper seen by EC n/a	**n/a**	**Equality Impact Assessment complete?**	**n/a**	**Quality Impact Assessment complete?**	**n/a**	**Financial Impact Assessment complete?**	**n/a**

CHIEF EXECUTIVE OFFICER REPORT

The purpose of this report is to highlight issues and key priorities to the Trust Board.

1. QUALITY AND PATIENT SAFETY

Nursing Associate Role

We are pleased to have been chosen as 1 of only 11 test sites across England to deliver the first wave of training for 1,000 new nursing associates. We have 40 places for adult roles and 5 for children that start in January 2017 for a period of 2 years.

Well done to our bid team who received positive feedback from the HEE team:

"We appreciate the time and consideration you and your partners have put into the development of an outstanding bid"

The Nursing Associate role has been designed to bridge the gap between healthcare assistants and nurses. Health Education England (HEE) is leading the development of the initiative. The role will provide clear benefits for registered nurses, providing additional support and releasing time to provide the assessment and care.

Flu Campaign September to December 2016

We have made a good start for our 2016 uptake of the flu vaccine. To date 54% of our staff received a flu jab against a target of 75%; last year's uptake was 62%. This month we will continue our high profile campaign to ensure we protect ourselves, our families and our patients against the flu virus. We are committed to the vaccine uptake because we know it will save lives and protect the vulnerable, including children and the elderly.

MRSA Bacteraemia

We are disappointed to report our first case of hospital acquired MRSA bacteraemia case during this year. Last year we did not have any cases reported. We will continue to manage our high profile infectious control campaign across the community and hospital to ensure that this remains a single MRSA incident for the year.

Clostridium Difficile

We reported 5 cases of Clostridium Difficile up to the end of October. The target is for no more than 17 cases this year.

Cancer Waiting Time Targets

We exceeded our national cancer targets except 62 days from referral to treatment for August**.** *Reported in arrears in line with the national cancer data validation process*.

- 31 days to first treatment 100% against target of 96%
- 31 days to subsequent treatment (surgery)100% against target of 96%
- 31 days to subsequent treatment (drugs)100% against a target of 98%
- 62 days from referral to treatment 83.3% against a target of 85%
- 14 days cancer to be first seen 97.7% against a target of 93%
- 14 days to be first seen for breast symptomatic 100% against a target of 93%

Community Access Targets

MSK targets are not achievable with our current service and workforce model. We have made improvements during the year and we value our staff continuing to work extremely hard against a difficult transition period. We are liaising with Commissioners to change the targets to enable realistic achievements. We reported up to end of September:

- MSK waiting time – non consultant led patients seen 45.2% - target 95%
- MSK waiting time – consultant led patients seen 90.7% - target 95%

We are pleased to have exceeded our Improving Access to Psychological Therapies (IAPT)

- IAPT – patients moving to recovery – 51.7% - target 50%
- IAPT – patients waiting for treatment <6 weeks – 93.8% - target 75%

2. STRATEGIC

Sustainability and Transformation Plan (STP)

The health and care system across North Central London (NCL) - clinical commissioning groups, local authorities and NHS providers are working together to develop an NCL wide Sustainability and Transformation Plan (STP). The NCL STP vision is to

- improve health and wellbeing outcomes for the people of NCL and ensure sustainable health and social care services, built around the needs of local people

- develop new models of care to achieve better outcomes for all; focused on prevention and out of hospital care

- work in partnership to commission, contract and deliver services efficiently and safely

For the NHS to meet the needs of future patients in a sustainable way, we need to close the gaps in health, finance and quality of care between where we are now and where we need to be in 2020/21. In order to create a better future for the NHS, we must make changes to how local people live, access care, and how this care is delivered. This doesn't mean doing less for patients or reducing the quality of care provided. It means more preventative care; finding new ways to meet people's needs; and identifying ways to do things more efficiently.

In order to do this we are continuing to work together across NCL. This has resulted in the development of a second iteration of the NCL draft STP that was submitted to NHS Improvement and NHS England on 21 October 2016. The draft plan is based on the case for change reported to our Trust Board in June and developed by the STP Clinical Cabinet to ensure it reflects the best clinical expertise from a range of health and care professionals. The submission has triggered a 2 week assurance process by NHSE to review the draft STP.

Local authorities across England have shared links to draft STPs. London Borough of Camden has published at http://bit.ly/2fpDO3m.

We believe the STP is an opportunity to continue to work together over the NCL area (known as a 'footprint') and look at how we can do this better. This is a challenging piece of work, but the opportunities to improve care and the quality of health and care services are considerable. Further iterations of the STP will enable us to set out how local health and care services will transform and become sustainable over the next five years, building and strengthening local relationships and ultimately delivering the Five Year Forward View vision. We anticipate being in a position to discuss potential long term solutions from early 2017.

NHS Improvement - Single Oversight Framework

The Single Oversight Framework has been designed to help NHS providers attain, and maintain, Care Quality Commission ratings of 'Good' or 'Outstanding'. The Framework has replaced the former Monitor 'Risk Assessment Framework' and the former NHS Trust Development Authority 'Accountability Framework'. It covers 5 key themes:

- quality of care
- finance and use of resources
- operational performance
- strategic change
- leadership and improvement capability

NHS Improvement (Monitor and NTDA) released a 'shadow segment' report in October, based on information from the previous year for NHS trusts. The segment ranges from 1 to 4 and trusts are segmented according to the level of support required to continuously improve. The first official segment report will be released in November. Our Trust has been shadow segmented as a 2. NHSI has provided a summary of each segment:

Segment 1 - Providers with maximum autonomy: no potential support needs identified. Lowest level of oversight; segmentation decisions taken quarterly in the absence of any significant deterioration in performance.

Segment 2 - Providers offered targeted support: there are concerns in relation to one or more of the themes. We've identified targeted support that the provider can access to address these concerns, but which they are not obliged to take up. For some providers in segment 2, more evidence may need to be gathered to identify appropriate support.

Segment 3 - Providers receiving mandated support for significant concerns: there is actual or suspected breach of licence, and a Regional Support Group has agreed to seek formal undertakings from the provider or the Provider Regulation Committee has agreed to impose regulatory requirements.

Segment 4 - Providers in special measures: there is actual or suspected breach of licence with very serious and/or complex issues. The Provider Regulation Committee has agreed it meets the criteria to go into special measures.

Business Planning Day

We will be holding our annual business planning day on 1 November with the Executive, Non-Executive, Clinical and Operational teams. Each Executive Directorate and Integrated Clinical Service Unit will present their 2017/18 business plan to enable a Q&A session from all teams and for refining and agreeing plans that will achieve our strategic goals.

Strategic Estates Partner (SEP)

We have commenced a procurement process to identify a Strategic Estates Partner to support the delivery of our estates strategy. This is the start of a competitive dialogue and we expect to have chosen a partner by June 2017.

3. OPERATIONAL

Pressures within the emergency care pathway continue and our 4hr performance for September was 93.4% against a target of 95%. We are making steady progress with meeting our target and as we face winter we will continue to change the way we manage our patient flows. Some of these changes include focusing on improving pre noon senior clinical reviews, rolling out a minimum data set for all hospital ward white boards and opening 24 winter escalation beds on Cavell ward.

National Cancer Diagnostic Fund Bids

We are pleased that our National Cancer Diagnostic Fund bid was successful. This will enable us to progress our plans to build CT and MRI capacity for our service. We will now start to work jointly to address capacity across North Central London.

4. WORKFORCE

Staff Engagement

I am continuing to get out and about meeting different staff groups as part of an extensive programme of staff engagement events. These sessions are proving invaluable to hearing views and ideas from staff. Last week I met the endoscopy team and this week I will be meeting up with our award winning diabetes team and the finance and I&MT corporate teams. I will also be shadowing different staff and the next one scheduled will be in the community with a district nurse.

Maternity Open Day 5 November

We are hosting an open day to welcome the public and our stakeholders to our maternity unit at the hospital. This is also a great chance for parents-to-be to come along and meet our award winning clinical team, find out about the support we offer such as our active birth classes and onsite transitional services to our neo natal intensive care unit.

Allied Healthcare Professionals (AHPs) 5 November

On the same day we are holding an open day for future AHPs who would like to join our 450 AHPs (speech and language therapists, radiographers, dieticians, physiotherapists). The recruitment event forms part of a larger programme of activities to raise our profile across London to encourage potential employees to come along to meet existing staff and learn of the benefits and advantages of working for an integrated care organisation ranked ‘Outstanding for Care’ by the Care Quality Commission.

Annual Staff Survey

We launched the 2016 staff survey last month and continue to encourage those staff invited to complete the survey to feedback their important views. To date there has been an uptake of just under 20%. The analysis of the results will help us continue our action planning to tackle the top issues raised by staff.

Anti-Bullying and Harassment

We are committed to stamping out all forms of bullying and harassment. One in 4 staff reported some form of this unacceptable behaviour in last year's annual staff survey. In response we have recruited a new team of 17 specialist anti bullying and harassment advisors. These advisors are providing an impartial and confidential listening ear for staff and information and guidance on rights to enable resolution.

ED Consultant

We have recruited a substantive ED consultant for our hospital team as part of a drive to increase the number of consultants supporting the teams managing our busy emergency department.

Bank Rate Changes

New bank rates are being phased in for our clinical staffing groups. This is part of our plan for reducing costly agency expenditure and to ensure we meet the national agency cap. There are significant benefits for staff to join the bank and we anticipate a high take up. The benefits include:

- A new unsocial hours rate for doctors who work outside of 'office' hours
- Paying above the benchmark in recruitment areas that are historically problematic
- Paying comparable rates to competitive neighbouring trusts and agencies
- Offering a financial bonus scheme to staff who work additional bank hours

5. FINANCE – APRIL TO SEPTEMBER MONTH 6

We reported a £3.9m surplus up to the end of September and a year to date deficit of £2.9m; in line with our planned performance for the year. The key movements in the September were:

- Achievement of Sustainability and Transformational Fund which increased income by £3m. We are pursuing issues for £0.2m regarding meeting the ED 4hr target.
- An improvement in pay of £0.4m due to a lower spend on agency and locums coupled with high level of vacancies.
- A reduction in non-pay expenditure of £2.6m; due to commercial agreement with suppliers on disputes which created a non-recurring benefit.
- An underperformance on activity particularly in outpatients, direct access and elective care which created a £2m pressure in month. Weekly activity targets and plans are being agreed with ICSUs to catch back activity.

The underlying position at the end of month 6 was a deficit of £8.9m which is £2.5m worse than the planned position. The cash position is approximately £0.5m off plan mainly due to Haringey outstanding debtors' invoices that we expect to be settled next

month. Capital expenditure is on track but there are delays on major schemes which are being escalated for resolution via our Capital management Group.

The cost improvement programme has achieved £2.4m year to date against a target of £3.2m. This is a solid 75% achievement and we are confident that we will achieve the remaining 25% of savings by year end.

4. AWARDS

Congratulations to our Colorectal Nurse, Ann Breen in our Stoma Care team, who won the September monthly excellence award for her outstanding services supporting patients and her colleagues. Ann works tirelessly to deliver high standards of care and always demonstrates kindness and compassion.

Congratulations to Caroline Fertleman, Consultant Paediatrician, for winning the prestigious President's Medal from the Academy of Medical Educators. This special medal is given to an individual who has made an exceptional and sustained contribution to medical education - and is one of the highest accolades the AoME can bestow.

Simon Pleydell
Chief Executive Office

Whittington Health NHS

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Whittington Health Trust Board

2 November 2016

Title:	**An update on the LUTS service November 2016 Trust response to the RCP report**		
Agenda item:	**16/145**	**Paper**	**03**
Action requested:	To accept the RCP report and recommendations To approve the actions as proposed by the Trust		
Executive Summary:	The RCP report of the invited service review (on 5-6 May) to assess the Lower Urinary Tract Symptoms (LUTS) clinic was received by the Trust on 19 October. The report makes a number of recommendations in order to secure a viable and sustainable safe service for people with LUTS. This paper contains the full report. The Board are updated on progress to date against the recommendations. Feedback on the report has been obtained from commissioners and local service users. The Trust is committed to securing a sustainable future for this service.		
Summary of recommendations:	There are 27 recommendations listed within the RCP report. Some of these have already been actioned. The Board is asked to note progress to date and agree future actions.		
Fit with WH strategy:	In line with the clinical strategy in terms of securing safe and high quality services		
Reference to related / other documents:			
Reference to areas of risk and corporate risks on the Board Assurance Framework:	On BAF as corporate risk (reference BAF2)		

Date paper completed:		26 October 2016					
Author name and title:		**Siobhan Harrington Director of Strategy/ Deputy CEO**		**Director name and title:**		**Richard Jennings Medical Director**	
Date paper seen by EC		**Equality Impact Assessment complete?**		**Quality Impact Assessment complete?**		**Financial Impact Assessment complete?**	

An update on the Lower Urinary Tract Symptoms Service (LUTS) service

November 2016

Trust response to the Royal College of Physicians (RCP) report

1. This paper updates the Trust Board on the latest developments within the LUTS service. The LUTS service is a service delivered within Hornsey Central currently clinically led by Professor James Malone-Lee. The service has been subject to a number of concerns as captured within the RCP report which alongside the issue of Professor Malone Lee's retirement has led to uncertainty and anxiety for the patients attending the clinic.

2. Professor Malone Lee retired from his UCL position on 22 September and agreed to a locum consultant contract with Whittington Health from 23 September. The clinic continues. New patients are not currently being seen. The Trust is working to ensure that a sustainable and viable safe service is in place that can enable new patients to be seen.

3. The RCP invited service review was conducted on 5th and 6th May and the Trust received an interim letter with immediate feedback on 19 May and a subsequent letter outlining a potential safety concern on 9 August. The final RCP report was received on 19 October. It is an advisory document for the Trust.

4. The Trust has had an action plan in place in response to the interim letter of 19 May and improvements have been made in terms of governance.

5. The final report outlines 27 recommendations which are grouped into six themes.

5.1 Patient safety concerns. The RCP has made a number of recommendations aimed at addressing safety concerns, and identifying any possible instances of harm from nitrofurantoin, in particular, that may not yet have been identified. The Trust accepts these recommendations. Professor Malone-Lee has already conducted an initial review of patients who have been prescribed nitrofurantoin. The Trust is following the RCP's advice with regard to commissioning an external review to see if there is any evidence of any other patients having been inadvertently harmed by Nitrofurantoin.
The resource within the Medical Directors team has been strengthened with the Associate Medical Director for Patient Safety now being in post.

5.2 Patient access. Three of the six recommendations have been completed. The Trust has considered the issue of where the clinic is housed and in consultation with the service user group has agreed for it to continue for now at Hornsey with strengthened governance arrangements whilst focusing our work on securing a more sustainable solution with colleagues at UCLH.

The pathway for children is being finalised and once agreed will be confirmed with commissioners. Work continues to strengthen the MDT arrangements and this links to the issue of the succession plan being in place.

5.3 Clinical governance arrangements. There are eight recommendations in respect of improving the clinical governance arrangements of the clinic, all of which are being actioned. The Trust has worked to ensure that the clinic is operating within the policies and procedures of the Trust and that staff are all trained and aware of all the clinical governance arrangements within the Trust.
There is progress on integrating the patients' clinical records into the trust electronic patient system and this will be complete by December.

5.4 Succession Plan. There are six recommendations to support us having a clear succession plan in place with regard to the management and clinical leadership of the clinic. Progress has been made in all areas. In the short term, Professor Malone Lee returning from retirement and being employed by the Trust has secured our transitional plan with the clinic continuing and Professor Malone Lee supporting the development of a longer term sustainable solution.
The Trust accepts the recommendations. Discussions continue with commissioners, UCLH colleagues and service users to secure a tertiary service in an appropriate setting. The multidisciplinary team is now established at UCLH and arrangements continue to be strengthened. We are aiming to have an integrated service in place by the end of March.

5.5 Work with University College London (UCL). There are four recommendations in respect of UCL. The report has been formally shared with UCL. The three immediate recommendations have been addressed. UCL colleagues will be engaged in finalising the succession plan.

5.6 Private practice. This recommendation is accepted and is being actioned.

6. Service user engagement has been a priority. The Trust has met four times over the last six months with a small group of service users who have been very helpful in clarifying their concerns and influencing how we develop the service and communicate more effectively in a time of uncertainty. We have produced updates to our website and are currently writing to all patients to update them of progress to date. There has also been communication with MPs and councillors and discussion at the Joint Overview and Scrutiny Committee.

7. Feedback on the report. The Trust has received feedback from both service users and commissioners on the detail of the report. Service users welcome the commitment to strengthen the arrangements for the LUTS service; they recognised that there is much work for the Trust to complete, they also welcomed the recommendation to move the clinic to a more tertiary setting and finally are keen to see new patients accepted to the clinic as soon as possible.
Local commissioners also welcome the report and accepted the recommendations and will work with both Whittington Health and UCLH to implement the recommendations.

8. The Trust Board has previously discussed the detail of the action plan in response to the interim letter and recommendations and agreed that two criteria needed to be met in order to open the clinic to new patients
   - A succession plan having been agreed by WH, UCLH, UCL and commissioners
   - Safety and governance concerns raised by the RCP invited service review having been satisfactorily addressed from WH and local commissioners' perspectives.

   Following receipt of the final report it is proposed that these criteria remain the same. Commissioners are fully engaged and will continue to work with us to resolve any issues.

9. With regard to care for children with LUTS we are working with Great Ormond Street NHS Foundation Trust to secure a local tertiary pathway.

10. It is recognised that this has been a difficult time for the service users and clinical team. We are committed to securing the improvements needed to ensure the LUTS service is a viable and sustainable service that is open to new patients.

Royal College of Physicians

Setting higher standards

Report of the invited service review to assess the Lower Urinary Tract Symptoms clinic at The Whittington Hospital NHS Trust

On 5 – 6 May 2016

1.0 Executive summary

The Lower Urinary Tract Symptoms (LUTS) clinic is a service provided by The Whittington Hospital NHS Trust, and which also undertakes research overseen by University College London (UCL). The LUTS clinic provides treatments to patients with urinary tract infections, which include prescribing antibiotics in dosages and combinations and for durations outside of drug licensing and recognised national guidelines. This includes patients referred by GPs from within Haringey and Islington Clinical Commissioning Groups (CCGs) as well as patients referred from elsewhere in the UK.

There have been a number of written concerns expressed to the Trust about the prescribing practices of the LUTS clinic and two serious untoward incidents (SUIs) attributed to nitrofurantoin, which had been prescribed by the LUTS clinic. In response to these concerns the Trust restricted Professor Malone-Lee's practice, following which Professor Malone-Lee felt unable to work within these constraints and suspended the LUTS service. These restrictions were subsequently altered and the clinic was reopened. At the time of the review visit it had been agreed that the LUTS clinic would not accept any new referrals but would continue to treat its existing patients.

The Royal College of Physicians' invited review team was provided with a large number of relevant documents and had the opportunity to interview staff working in the LUTS clinic, other employees of The Whittington and a number of current and former patients of the LUTS clinic, and commissioners.

Based on all of the information considered by the review team it was concluded that changes need to be made to ensure the safety of patients currently being treated by the LUTS clinic. It was also concluded that some of the information being provided to patients about the risks of their treatment was not appropriate and needs revising.

Given the retirement announcement of Professor Malone-Lee, it was recognised that there was significant uncertainty over the long term future of the clinic, including concerns expressed by the CCGs over the appropriateness of the clinic and whether it should accept new referrals.

In order to assist the Trust in addressing these issues, a series of recommendations were made by the review team designed to safeguard the current patients of the LUTS clinic who cannot easily or do not wish to be referred to other services. These include the need for significant improvements in clinical governance and oversight, which have commenced but need further development. In particular the investigation of potential adverse events such as determining the incidence of pulmonary fibrosis and clostridium difficile need to be progressed and completed. The multidisciplinary team meetings to discuss cases need to be further developed, for example, with a review of core and invited members and a plan for a rotation of chair. This would help ensure the desired outcome of high quality and appropriately agreed treatments plans for patients.

Investment in terms of capacity and capability of clinical leadership and management and involvement of University College London is also required. Efforts should be made to overcome the clinic's organisational and geographic isolation and to regularise the employment of clinic staff. There should be a similar focus on the prescribing practices of the clinic and the interface with private practice.

Until these measures are put in place it was also recommended that no new patient referrals (adult or paediatric) be accepted by the clinic.

Advice about the long term future of the clinic was provided and focused particularly on involving patients in future plans and the need to work with a major tertiary centre such as UCLH (University College London Hospitals NHS Foundation) to give the clinic a new base for further development.

2.0 Introduction

Dr Richard Jennings, Executive Medical Director, at The Whittington Hospital NHS Trust contacted the Royal College of Physicians (RCP) regarding the LUTS Clinic on 25 November 2015. Dr Jennings discussed the review with Dr Peter Belfield, Medical Director for Invited Service Reviews (ISR) at the RCP. Following discussion it was agreed that an ISR would be carried out and this was arranged and took place on 5 – 6 May 2016.

The terms of reference for this ISR were:

1. **Patient experience**
   The review team will consider the views of patients who have received treatment via the LUTS clinic. This will include some contact with a small representative group of patients and carers. It will include compliments and complaints about the service and other collected measures of patient experience. Consideration will be made whether patients receive adequate information on the risks and benefits of treatment and if patients are being informed when recommended treatment falls outside accepted national guidelines and safe practice.
2. **Clinical governance and safety of the service**
   The review team will make an assessment of the clinical governance arrangements in place for the LUTS clinic by looking specifically at whether the treatment provided by the clinic is safe, appropriate and reasonable. The review will consider whether there is an appropriate system in place for the recognition and management of risk, and how the service meshes with directorate and corporate risk management systems and generally learns from things that go wrong. The recent serious untoward incident and other relevant information will be considered.
3. **Appropriate clinical audit and use of approved guidelines for antibiotic prescribing**
   The review team will seek evidence of completed and ongoing audit regarding informed consent, quality of note keeping, and any documentation of risks/benefits that are given to patients. Where guidance on treatment is available, the team will review how such guidance is implemented and how variations are agreed and documented.
4. **Translation of research into clinical practice and assessment of research governance arrangements**
   The review will assess the current research governance arrangements and whether processes are in place that clearly define activities in the service that are clinical practice, audit, service development and research. This will include the consent of patients to treatment, enrolment to ethically approved clinical trials and evidence of peer review for research initiated by the unit.
5. **Team working, leadership and managerial support**
   The review will consider if team working within the clinic is appropriate and in line with Good Medical Practice. An assessment would be made regarding the balance of clinical oversight and clinical freedom among the clinicians, and whether the allocation of roles and responsibilities are appropriate. The review will take a view on the potential fragility of the service and thoughts about succession planning. Leadership, managerial support and accountabilities of the LUTS clinic will also be considered.
6. **Internal and external relationships of the LUTS service**
   The review will consider wider team working with key Trust departments' eg diagnostic services and medicines management. Consideration of systems of formal or informal clinician peer review will be scrutinised in particular in cases that involve young children and adolescents. The review will also consider relationships with external stakeholders such as the key Clinical Commissioning Groups (CCG) that the Trust relates to, local general practitioners and other referring colleagues.

7. **Duties of the trust legally and ethically**
   Given that the LUTS clinic has been provided by Whittington Hospital NHS Trust (The Whittington) for some years, the review will consider what duties does the Trust have both from a governance point of view and from an ethical point of view to continue with regard to the services it offers to existing patients in the future. The review will consider how the service works with and learns from other clinical services, and seeks peer and other external independent reviews. Consideration will also be made of the clinical and research governance of the co-aligned private practice element of the LUTS clinic.
8. **Any other matters of concern**
   The review team will note any other significant findings and make appropriate recommendations to remedy these.

3.0 Invited Service Review Team

Dr Peter Belfield	Medical Director of Invited Service Reviews (Chair of the review team), Royal College of Physicians.
Mr Adrian Joyce	Consultant Urologist at St James's University Hospital, Leeds.
Professor Gary Ford	Chief Executive of the Oxford Academic Health Science Network, Consultant Stroke Physician at Oxford University Hospitals NHS Foundation Trust and Visiting Professor of Clinical Pharmacology, Oxford University.
Dr Peter Cowling	Consultant Microbiologist and Infection Control Doctor for Northern Lincolnshire & Goole NHS Foundation Trust, based at Scunthorpe General Hospital.
Ms Mary Porter	Lay Reviewer
Mr Steven Wakeling	Head of invited reviews, Royal College of Surgeons

4.0 Documents received and reviewed

The review team received 209 documents. A summary list of the documents can be found in section 11.

5.0 Interviews and visits to clinical areas

Wednesday 4 May 2016

- Invited Service Review introductory meeting held between ISR team, Dr Richard Jennings (Executive Medical Director) and Ms Ashleigh Soan (MD portfolio manager).

Thursday 5 May 2016

- Tour of the LUTS clinic premises
- Interviews with:
    - Professor James Malone-Lee (Professor of Medicine)
    - Dr Sheela Swamy (Clinical research fellow and PhD student 2013 to 2016)
    - Dr Dhanuson Dharmasena (Clinical research fellow and PhD student 2014 to 2017)
    - Dr Hristina Toteva (Clinical Fellow 2015 to 2016)
    - Dr Anthony Kupelian (Consultant Urogynaecologist. Quondam Clinical research fellow and PhD student 2010 to 2015)
    - Dr Tara Dhepour (Clinical attachment doctor 2015 to 2016)
    - Mr Harry Horsely (Microbiologist PhD Student 2013 to 2016, postdoctoral research fellow and laboratory support to clinical service)
    - Dr Sanchutha Sathiananthamoorthy (Microbiologist postdoctoral research fellow, Quondam MSc student, PhD student 2010 to 2015 and laboratory support to clinical service)
    - Dr Kiren Gill (Gynaecological ST4 and Quondam PhD student 2010 to 2015)
    - Dr Rajvinder Khasriya (Subspecialty trainee in urogynaecology, Quondam Clinical research fellow and PhD student 2008 to 2011)
    - Ms Liz Denver (Senior Nurse and head of health and safety, clinical governance and research governance 1999 to 2016)
    - Ms Linda Collins (Former Clinic Nurse and quondam PhD student 2012 to 2016)
    - Ms Marcia Nickle (former PA and service manager 1999 to 2016)
    - Dr Richard Jennings (Executive Medical Director)
    - Mr Simon Pleydell (Chief Executive Officer)
    - Dr Julie Andrews (Consultant Microbiologist, Director of Infection Prevention and Control and Associate Medical Director for Patient Safety)
    - Dr Peter Christian (Chair) and Ms Sarah Price (Chief Officer) of Haringey Clinical Commissioning Group
    - Ms Phillipa Marszall (Head of Patient Experience)

Friday 7 May 2016

- Interviews with:
    - Mr Dan Wood (Consultant Urological Surgeon at UCLH and external reviewer involved in the 2015 academic review of the LUTS clinic commissioned by University College London)
    - Ms Alison Blair (Chief Officer) and Dr Jo Sauvage (Chair) of Islington Clinical Commissioning Group
    - Dr Helen Taylor (Clinical Director Clinical Support Services and Head of Pharmacy)
    - Group of approximately thirty current and former patients and relatives of patients attending the LUTS clinic

- Dr Robert Sherwin (Consultant Obstetrician and Gynaecologist with a sub-speciality interest in Urogynaecology, Director of Research and Innovation and Associate Medical Director for Revalidation)
- Ms Fiona Isacsson (Director of Operations, Surgery and Cancer)
- Dr Nick Harper (Consultant Anaesthetist, Clinical Director, Surgery and Cancer and Chair of the Lower Urinary Tract Symptoms MDT)
- Dr Michael Kelsey (Consultant Microbiologist and Chair of the Drug and Therapeutics Committee)

6.0 Background

The Trust provided information to the review team explaining that the LUTS clinic was part of The Whittington and run by Professor James Malone-Lee, a consultant physician with a clinical background primarily in adult medicine and, in particular, care of the elderly medicine. Professor Malone-Lee was said to have both a research and a clinical interest in the diagnosis of urinary tract infection. His principal employer is UCL, but he has an honorary clinical contract with The Whittington Hospital NHS Trust.

Professor Malone-Lee's main research hypothesis was said to be that patients with chronic lower urinary tract symptoms have deep seated bladder and urethral infections, which are not demonstrable by current conventional diagnostic methods and are not responsive to standard antibiotic treatments. For these reasons the LUTS clinic was said to carry out its own laboratory based investigations and to prescribe antibiotics for a duration that is often much longer and often at a dose that is greater than those covered by the medication's license or approved by national guidelines.

The Trust was said to have received over the past two years an increasing number of written and verbal concerns from its own as well as external clinicians and external bodies about the prescribing practices of the LUTS clinic. It was also reported that the Trust was aware of two serious untoward incidents that had been identified in 2009 and 2015 relating to patients having developed pulmonary fibrosis. This was attributed to nitrofurantoin, which had been prescribed by the LUTS clinic for extended periods of time.

In response to these concerns the Trust restricted Professor Malone-Lee's practice and the clinic was thereafter suspended. These restrictions were subsequently altered and the clinic was reopened some weeks later after a period of intense public concern. At the time of the review visit it had been agreed that the LUTS clinic would not accept any new referrals but would continue to treat its existing patients.

The Whittington Trust asked the RCP to consider patient experience, patient safety and overall governance of the LUTS service and to make recommendations for their consideration as to its future development.

7.0 Information gathered by the review team

The following information represents a summary of the information gathered by the review team during the interviews held and from the documentation submitted. It is organised under the headings of the terms of reference agreed with the Trust in advance of the visit and by the themes that emerged.

7.1 Patient experience

The review team was asked to consider the views of patients who have received treatment via the LUTS clinic on their experiences of the clinic. They were also asked to consider whether patients had been provided with adequate information on the risks and benefits of their treatment and whether they had been informed when this treatment had fallen outside of accepted national guidelines and current conventional practice.

7.1.1 Patient views of the LUTS clinic

The review team received several hundred pages of letters and other statements from current or former patients of the LUTS clinic, their relatives and carers. These letters were unanimously supportive of the clinic, including the treatments that it provided and the staff that worked there. During the review visit the team also had the opportunity to hear from a number of patients on their views of the clinic.

Patients described the recognition they had received from Professor Malone-Lee and the other clinic staff. Some described feeling they had a serious medical condition, which other clinicians had refused to recognise, and resenting the implication from medical practitioners that that their symptoms were the result of a psychological condition. They described feeling relieved to have been referred to the clinic, in some cases having found it themselves and requested a referral, as their symptoms had finally been acknowledged or diagnosed.

The patients interviewed reported that they considered the treatment regimens the clinic had prescribed for them to be innovative and highly effective. They reported that their symptoms had either been cured or made much more manageable and that their quality of life had been drastically improved. It was also stated that, for some, the treatment had allowed them to continue with their normal lives whilst waiting for another curative intervention, such as surgery.

This was contrasted against their reports of other medical treatments, such as short courses of antibiotics, which they stated had not provided long lasting relief. Patients also described a positive aspect of the service as being that it did not use invasive tests or treatments, such as those they had experienced elsewhere. These patients were very positive about how the healthcare professional in the clinic treated them as equals. Of those service users interviewed, they considered they were highly informed about the clinic's rationale for diagnosis and treatment and furthermore that this rationale had been based on research.

7.1.2 Formal patient complaints

A representative of the Trust commented that they were not aware of the Trust having received any formal patient complaints regarding the conduct of the clinic provided by the LUTS service.

However, it was reported that in 2015, following the suspension of the clinic there were many patient complaints received about the suspension of the service. LUTS staff were also said to have made numerous DATIX entries of patients reporting relapse, difficulty in obtaining medication, poor communication and with a small number of patients being admitted to hospital.

7.1.3 *Accessibility and support*

Those patients who provided information to the review team were also very positive about the level of access they had to the clinic and to Professor Malone-Lee in particular. In particular patients were very positive about the clinic's use of telephone appointments, which they found to be very convenient. The physical location of the clinic in a community health centre was also said to be convenient.

A number of patients also commented that they had found it very supportive to have direct email correspondence with Professor Malone-Lee. It was commented that in some cases he had encouraged them to email the clinic regularly about side effects and that he provided very prompt responses, throughout the week and even when away on holiday. Professor Malone-Lee also had a practice of giving his patients' his mobile phone number in case they needed to contact him.

Some clinicians working outside of the clinic commented that the service was extremely accessible to patients, provided a 'great patient experience' and those patients enjoyed the very direct contact with Professor Malone-Lee. Some stated that they had referred some patients to the clinic because they were not sure what to do for them and they knew the clinic would provide them with a lot of support. Professor Malone-Lee in particular was described as being a thoughtful and caring doctor who was trying to do the right thing by his patients. Some commented that this level of care and support was 'a very powerful medicine in and of itself'.

Some interviewees did state that they were concerned that some patients could become 'dependent' on the high level of personal support Professor Malone-Lee provided. Some commented that they were unsure whether some of the LUTS clinic's patients had really benefited from their treatments as opposed to just from the high level of support they received.

7.1.4 *Information provided to patients about treatments*

The review team had the opportunity to look at a sample of clinic letters provided by the Trust as well as to see the LUTS clinic's own Artemis database, which is used to generate these letters. The team also spoke with patients and clinic staff about the information that is provided to patients about their treatments.

Patients who spoke to the review team stated that they had been informed of the risks associated with the high dose and long course antibiotics that they had been prescribed. During consultations in person and over the telephone members of the clinic's staff were reported to ask patients about any side effects they had experienced. They were also asked directed questions about specific common side effects potentially due to the antibiotics they had been prescribed.

An example was given of patients taking nitrofurantoin being asked about lung symptoms. It was stated that if a patient did report having developed a cough or shortness of breath while taking nitrofurantoin that they would be told to stop the drug. If it later became apparent their symptoms were instead due to an upper respiratory tract infection, they would then be advised to resume taking the nitrofurantoin. However, the review team noted that evidence from the most recent serious incident suggests there was a delay on acting on pulmonary symptoms despite regular review in the clinic.

The review team also reviewed a copy of the clinic's current patient information booklet. This version had been published in January 2016 and had both the Whittington and UCL logos on it. The leaflet was notable as it was both lengthy and very focused on the individual effort of Professor Malone-Lee. In effect it epitomised the work of the whole clinic, which encouraged patients to believe in the work and

safety of the clinic. It was stated that the booklet contained details about the quantified risks of the medications the clinic prescribed. The quantification of these risks was said to be based on the clinic's observation of side effects in the population of patients it had treated.

The example was given of the clinic performing a risk calculation based on the number of its patients it believed to have developed a *Clostridium difficile* (*C. diff*) infection.

The review team felt that potential risks of treatment were somewhat underplayed in this information. For example, from a review of adverse events the review team observed that some of the potential risks were described as being much less common than some information from the Trust appeared to suggest.

Patients beginning new medications were also said to be encouraged to read the patient information leaflets (PIL) for their prescribed antibiotics.

The review team asked specifically about what information was provided to patients about the licensing and guidelines associated with their medications. Clinic staff commented that, although it was not given as written information, all patients were told if their medication was been prescribed outside of published guidelines. A number of patients commented that they had also been made aware of the use of some drugs outside the terms of their licence (sometimes called 'off-label').

The Artemis database contains descriptions of each of the antibiotics used by the LUTS clinic, which have been written by Professor Malone-Lee. These descriptions were said to be 'very much influenced' by the clinic's research study findings rather than being based on the standard licensing information. The set texts being used were reported as having been approved by the LUTS MDT.

When letters are sent to patients or their GPs these descriptions are used to populate the letters, to provide information about the nature of the patients' medications and the possible side-effects they can cause. It was stated that the same information was sent to both the patient and their GP.

Members of the clinic's staff and those patients that spoke to the review team commented that they considered the clinic's patients to be very well informed. Both groups were said to be mindful of the risks associated with long term use of high dose antibiotics. It was also commented that the amount of time and information provided to patients by the LUTS clinic was far more than had been given to them by other doctors.

The review team however heard from one patient that they had previously been prescribed nitrofurantoin by their GP without being given any information about the potential risks associated with taking it. This account had not been verified with the GP in question and it was unknown as to the length of the course for which nitrofurantoin had been prescribed.

7.1.5 Suspension of the LUTS clinic in 2015

The review team was provided by the Trust with copies of correspondence relating to the suspension of the LUTS clinic in 2015. The Trust confirmed in writing in a letter dated 21 October 2015 that restrictions on Professor Malone-Lee's practice were to be imposed (these restrictions are described in more detail in a subsequent section of this report).

On the same day Professor Malone-Lee put out a statement to the LUTS clinic's patients explaining that the Trust's Medical Director had instructed him to follow 'standard guidelines published by the Trust, which are largely applicable to acute urinary infection'. It went on to state that Professor Malone-Lee

was therefore suspending the service 'until such time as further instructions are provided'. The statement advised patients to direct their queries to the Trust's medical director.

On 22 October the Trust sent out a letter from the medical director explaining to patients that the clinic's suspension had come as a result of 'concerns about possible risks to the health of patients associated with some of the antibiotic prescriptions...' The letter also explained that another letter would be sent subsequently to invite patients to an alternative clinic and that if patients experienced symptoms in the meantime they should consult their GP. The letter also provided the contact details for the Trust's patient advisory liaison service (PALS).

The review team heard that the Trust had hoped the LUTS clinic would be able to continue, working within the restrictions imposed. Once Professor Malone-Lee had taken the decision to suspend the clinic the Trust was said to have tried to put in place a service for the clinic's existing patients, with input from a multi-disciplinary team.

Patients were reported to have been supportive of Professor Malone-Lee's decision to suspend the clinic in response to the restrictions being imposed. The clinic's patients were, however, said to have felt that the suspension of the clinic had been handled very poorly by the Trust.

Patients were also reportedly unhappy when seeing the 'replacement' clinicians, as they were not willing to prescribe the same antibiotic regimens as the LUTS clinic had previously provided.

The Trust was said to have received a large number of calls and letters from patients about the clinic's suspension. As a result of the high volume of correspondence the Trust had received it funded some additional staffing support, which was put in place in December 2015.

A number of formal patient complaints were received about the suspension and about the alternative arrangements put in place. It was also said that the majority of patients were dissatisfied with the responses they received from the Trust.

The review team were also informed that some correspondence was received by the PALs team from patients saying they were glad the clinic was being stopped because of the negative experiences they had had. This correspondence was not provided to the review team. It was, however, clarified that the overwhelming majority of contact with PALS was in support of the LUTS clinic.

The Trust subsequently agreed an amendment to the practice restriction with Professor Malone-Lee on 19 November 2015. This amendment was communicated to the court dealing with an application for permission to issue Judicial Review proceedings the following day. The suspension of the LUTS clinic ended on 23 November 2015.

7.2 Clinical governance and safety of the service

The review team was asked to make an assessment of the clinical governance arrangements in place for the LUTS clinic. In particular the reviewers were asked to consider whether there was an appropriate system in place for the recognition and management of risk. A recent serious untoward incident (SUI) as well as other relevant information was included in this.

7.2.1 *Recording of adverse outcomes and serious incidents*

Members of the LUTS clinic's staff explained to the review team that the clinic's Artemis database has a box in each patient's record for recording adverse events. It was also reported that the database could produce reports on what adverse events had been recorded.

In a document entitled 'Summary of the evidence for the Lower Urinary Tract Service' (please see Appendix 12.1, figure 1) an analysis of the side effects experienced by the clinic's patients was presented. This stated that side effects had been experienced by 266 out of a total of 626 patients who had reported a total of 465 side effects (please see figure 1, appendix two). Professor Malone-Lee stated that, in his 30 years of working within the Trust, he was only aware of one serious adverse incident.

The review team was also informed that the LUTS clinic's staff also recorded any serious incidents on the Trust's Datix incident management system. It was also commented that the clinic did not receive any feedback about the Datix incidents it recorded. In contrast, it was also reported however, that the clinic had not recorded any adverse drug events on the Datix system and had really only started using the system when the clinic was "suspended".

A number of interviewees commented that there was 'distance' between the Trust's and LUTS clinical governance structures in place. This was in part due to a lack of communication between the two and was despite the LUTS clinic being part of this Trust. It was commented that the Trust had allowed the LUTS clinic to develop in isolation from the rest of the Trust with little knowledge of how many patients were being seen or even that the clinic was treating children.

One example of this given was the clinic's Artemis database, which it was reported was entirely separate from the Trust's electronic patient record (EPR) system. Furthermore it was reported that, until recently, staff working in the Whittington Hospital could not access this database. It was noted that, because of this, if a LUTS clinic patient presented at the hospital clinicians would have to rely on the patient to know which medications they were taking.

7.2.2 *Clostridium difficile* infections

A number of interviewees discussed the monitoring of patients with *Clostridium difficile* (*C. diff*) infections in particular. It was reported that over the last several years a number of local GPs who had seen patients treated by the LUTS clinic had raised concerns about their patients having developed *C. diff* infections. These concerns were said to have not been formally recorded at the time. During the ISR factual checking process, it was stated by the LUTS team that the concerns about specific patients raised by GPs had not been brought to Professor Malone-Lee's attention.

The LUTS clinic was said to be 'very well aware' of the risk of patients on long term antibiotics developing a *C. diff* infection and it was reported that the clinic tested for this, although no specific evidence was provided to the review team to confirm this. It was commented that the use of co-amoxiclavulanate was limited, wherever possible, as this was known to be associated with *C. diff* infections.

Other interviewees commented that, particularly as most patients treated by the LUTS clinic were referred from outside of the Trust's local catchment population, it was very difficult for the clinic to follow up on some of its patient's outcomes. It was stated that this limited the accuracy and reliability of the data held by the LUTS clinic on *C. diff* infection rates.

The review team was informed that the Trust had recently undertaken an analysis of 398 patients who had been recorded over a seven year period as having had *C. diff* infections. It should be noted that this does not include patients referred to the clinic from outwith the local CCGs. It was stated that 25 of these patients were individuals who had been treated by the LUTS clinic. This number of 25 differs from the stated incidents in the patient information leaflet. Further investigation of this had been delegated to senior clinical managers within the Division (Surgery and Cancer) who line manage the service and who were reported to have had insufficient time and capacity to complete the process. During the ISR factual checking process, it was stated by the LUTS team that Professor Malone-Lee had "no knowledge of the 25 patients who were diagnosed with C. diff and who have been seen at some time in the LUTS clinic" and that the LUTS staff were careful to record all cases of C. diff brought to their attention.

7.2.3 Pulmonary fibrosis

A number of interviewees commented on the risk of developing pulmonary fibrosis associated with the use of nitrofurantoin. Professor Malone-Lee commented that because he had been stopping the use of nitrofurantoin so readily if he was concerned about patients developing lung symptoms, he did not think his patients were at risk of this side effect. This view is at odds with pulmonary injury being a rare but probably the most serious adverse reaction that is associated with long term use.

A document provided by the Trust stated that there were known to be two cases of 'patients being seriously harmed as a result of developing pulmonary fibrosis after being prescribed long courses of nitrofurantoin' by the LUTS clinic. One incident from 2005 was said to have resulted in litigation against the Trust, which was subsequently settled. The second incident occurred in 2015 and led to the LUTS clinic being suspended. It was noted by the review team that the 2015 serious incident investigation was still incomplete at the time of the visit, and they considered this was of significant concern. A member of the Trust commented that they felt the Trust had not responded sufficiently to the serious incident in 2005 but it was unclear if this individual had formally raised their concerns.

Earlier in 2016, the Trust had undertaken an informatics review of its patient record systems and identified 13 patients who had previously been seen at a clinic by Professor Malone-Lee and who had received a diagnosis of pulmonary fibrosis from The Whittington. Of these 13 patients, three were noted to have received this diagnosis prior to, or shortly after, their first LUTS clinic attendance and two were known to be the subject of serious untoward incident investigations. It was noted by the review team that this did not include patients who were treated by the LUTS clinic who were referred from outside of the Trust's local catchment population and who may have been diagnosed with pulmonary fibrosis by their local respiratory team. The document (please see section 11, document 32. *Information relating to pulmonary fibrosis*) also mentions a further potential case of pulmonary toxicity highlighted at the Trust public meeting with patients in late 2015.

7.2.4 Clinical practice restrictions

The LUTS clinic was suspended by Professor Malone-Lee on 21 October 2015 following restrictions being placed on his practice by the Trust in light of the incident that occurred in 2015, described above. These restrictions were subsequently amended on 19th November 2015 after further discussion and to allow the clinic to re-open to existing patients (please appendix 11, document 19.1 for details of the restrictions).

A number of patients commented on this, stating that they felt the initial set of restrictions was totally disproportionate to the safety incident that had occurred. They also stated that those patients taking nitrofurantoin had been given no additional warning by the Trust about this particular drug being associated with the incident.

A number of the patients who spoke to the review team also raised safety concerns about the welfare of patients during the period of the time the clinic was suspended. The review team were provided with details of 191 incidents from the Trust's Datix incident reporting system, which had been logged by the clinic's staff. It was reported that the Trust was in the process of investigating 12 cases of patients who had been admitted to hospital during this period of time. The Divisional team responsible for these investigations was said to also be looking at the 25 cases of *C. diff* mentioned previously (section 7.2.2.) and that the Trust had not provided additional resources to the team to support this work.

With reference to the restrictions currently in place it was acknowledged that they did not prevent the use of many of the antibiotics being prescribed by the LUTS clinic. Restrictions on nitrofurantoin had been made but other antibiotics were being used within and outwith licence criteria. One member of medical staff described them as 'pragmatic' but 'arbitrary'.

A number of individuals commented on the restriction requiring Professor Malone-Lee to discuss the management of children with a consultant paediatrician. Professor Malone-Lee stated that he had undergone designated safeguarding lead (level three) training and that he had been treating children throughout his career. The Trust was said to have followed guidance from the Royal College of Paediatrics and Child Health regarding best practice around the treatment and safeguarding of children by someone whose predominant practice is with adults, in doing-so the Trust stipulated that there should be input from a consultant paediatrician in these instances (discussed in more detail under paragraph 7.6.4).

7.2.5 Other clinical governance processes

The review team asked about the governance arrangement relating to the microscopy undertaken by staff within the LUTS clinic. It was reported that the QA of this microscopy was done by a number of 'expert technicians'. The review team were provided with copies of the clinic's standard operating procedures relating to microscopy. These were brief and not document controlled. They described how microscopy should be undertaken but not how the quality assurance of microscopy was performed or what the process was for microscope and counting chamber calibration. It was noted that the Trust's microbiology department was not involved in monitoring the quality standard of this microscopy and no competent 'expert technicians' were in evidence at the clinic. It was stated that the doctors were principally responsible for carrying out the microscopy. It was found that none of this aspect of the investigation of urines, upon which so much of the extended off license treatment was predicated, was compliant with United Kingdom Accreditation Service (UKAS) standards or United Kingdom Standardised Microbiological Investigations (UKSMIs). It was reported that this was not in line with the Trust's Pathology service accreditation.

It was reported that the LUTS clinic was routinely sending mid-stream urine samples for culture growth by the Trust's microbiology service. It was said that, twice a year, the clinic carried out an analysis of these results, which involved counting 'the number of antibiotics reported as sensitive and the numbers that are resistant'. In the document entitled 'Summary of the evidence for the Lower Urinary Tract Service' (please see Appendix 11, document 44) a short analysis of antibiotic resistance was given. This stated that data from four visits had shown that 'the median number of antibiotics to which the isolate was resistant remained at 1 throughout'. However it noted that this analysis was not performed by the Trust's microbiology service, which was unusual because only they would have had access to the complete set of sensitivity data.

The review team were informed that the vast majority of prescriptions issued by LUTS clinic were FP10 prescriptions, which could be fulfilled by any pharmacist outside of the Trust. It was stated that before

the clinic had moved to its current location the clinic had sometimes written prescription forms to be dispensed by one of the hospital's pharmacists. The review team heard that these pharmacists had at times tried to challenge the prescribing and that this appeared to have resulted in the FP10 prescriptions being used. Some interviewees commented that it was very difficult for the Trust to keep track of what was being prescribed using this type of form. It was noted that the LUTS clinic accounted for one third of all Trust out-patient antibiotic prescribing.

Members of the Trust's staff were uncertain when asked about the financial arrangements associated with the LUTS clinic. It was said to be difficult for the Trust to get comprehensive activity data for the clinic, as information on the LUTS clinic did not always appear on the Surgery and Cancer Integrated Clinical Service Unit (ICSU) (managerially the LUTS clinic is part of this ICSU) report. There was also confusion about the contractual arrangements associated with the clinic and how the different CCGs were charged for the patients referred to the clinic from various places in the UK.

Some interviewees were also uncertain as to how the funds associated with patients being seen privately by the clinic were processed. It was commented by Professor Malone-Lee that private patients were only seen out of hours in the clinic and the funds raised were used exclusively for the benefit of the NHS clinic. While this appeared to be a small scale enterprise and taking place entirely within the auspices of the Whittington, both Professor Malone- Lee and others talked about setting up a private service for patients independent of the Trust after his planned retirement in September 2016. A number of interviewees had concerns about the governance of such a future service.

7.3 Appropriate clinical audit and use of approved guidelines for antibiotic prescribing

As part of this element of the review's terms of reference the review team was asked to consider what guidance on antibiotic treatment was available and how this guidance was implemented by the LUTS clinic as well as how variations were agreed and documented.

7.3.1 Antibiotic prescribing regimes used by the LUTS clinic

The review team was provided with a copy of the notes from a Joint Antimicrobial Steering Group and Drug and Therapeutics Committee (D&TC) extraordinary meeting, which was held on 4 August 2015. These notes included a 'Protocol for management of patients with chronic lower urinary tract symptoms with clinical evidence of urinary tract infection – Whittington Lower Urinary Tract Symptoms Clinic'. This included details of the different lines of prescribing as follows:

- Protocol – first line
    - Nitrofurantoin Macrocrystals CR 100mg BD to 100mg QDS
    - Trimethoprim 200mg BD to 400mg BD
    - Cefalexin 1g BD to 1g QDS
- Protocol – second line
    - Azithromycin 500mg OD for 3 days and then thrice weekly, with an increase back up to 500mg OD if the patient's response dips between doses
    - Doxycycline 100mg BD (particularly in the presence of urethral or prostate pain)
    - Pivmecillinam 400mg BD to 800mg TDS
    - Amoxicillin 500mg BD to TDS
    - Co-amoxiclav 500mg BD to TDS
    - Methenamine Hippurate (said to be used for most patients on long term regimens)
    - Clotrimazole vaginal pessary 1 thrice weekly (to be used in response to candida infections identified by urinary yeasts)

- Fluconazole 100mg OD for 7 – 14 days (to be used in response to candida infections identified by urinary yeasts)

- Protocol – third line
  - Fosfomycin 3g thrice weekly (only when combined with another agent)
- Protocol – fourth line
  - Ciprofloxacin 500mg BD (noted to be used for short-term use)
- Protocol – fifth line
  - Ertapenem 1g IV over 30 minutes daily for five days
  - Gentamicin 7mg/kg OD IV for five days (if penicillin intolerant)

The outcomes of this internal review were recorded alongside the details of the medication being prescribed by the LUTS. For many of the antibiotics described it was noted that no treatment duration was stated in the protocol. For some it was noted that the dosages described exceeded the licensed dose and for some others it was commented that the drugs were not recommended for patients with UTIs or had not been approved by the D&TC. It was also stated that the LUTS clinic's protocol did not reflect the Trust's recognised template and that, as none of the drugs were suitable for combination therapy, the protocol should clearly explain a 'distinct stepwise progression from first line drugs to second line and so on'.

Additional information about the LUTS clinic's prescribing was provided in the document entitled 'Summary of the evidence for the Lower Urinary Tract Service' (please Appendix 11, document 44). This included a table (figure 2 below) showing the percentage of the clinic's prescribing practice accounted for by the different antibiotics being used.

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Amoxicillin	2.2	3.8					0.2		0.1	0.3	0.8	1.3
Azithromycin										26.0	19.9	17.0
Cefuroxime											1.5	1.1
Cephalexin	31.1	15.4	22.2	10.4	36.2	28.6	32.3	27.0	12.5	20.1	22.8	22.9
Ciprofloxacin	4.4	11.5	6.7	10.4	10.3	10.5	5.6	5.0	3.6	3.6	2.7	0.7
Clarithromycin							1.6	0.1	5.1	1.7	0.2	0.1
Co-amoxiclav	6.7	10.3	17.8	29.2	5.2	3.8	6.7	15.1	16.7	9.8	6.0	3.8
Co-trimoxazole									0.5	0.6	0.6	0.2
Doxycycline		6.4	6.7	2.1	1.7		3.6	5.7	12.2	3.0	1.7	2.2
Ertapenem								0.4	2.9	1.2	0.2	
Fosfomycin								3.0	5.6	4.0	2.0	1.7
Gentamicin		1.3				1.0	0.4	0.7	0.4	0.4	0.1	
Levofloxacin											0.1	
Meropenem												
Methenamine								3.4	8.6	2.8	27.5	35.7
Nitrofurantoin	51.1	34.6	42.2	41.7	43.1	54.3	48.0	36.3	22.4	22.1	11.9	10.1
Nofloxacin	2.2	5.1		4.2			1.1	0.7	0.7			

Figure 2. Annual antibiotic prescribing practice percentages.

Also provided was a list (figure 3 below) of the most commonly used antibiotic combinations prescribed by the LUTS clinic. The document also states that combination treatment was 'encouraged because we recognised partial response to a single agent but found that we could improve the response by adding another agent. We verified the need for both antibiotics by trial of treatment withdrawal.'

2015	Percent	Cumulative %
Methenamine & Cephalexin	21.6	21.6
Methenamine & Azithromycin & Cephalexin	13.7	35.2
Methenamine & Nitrofurantoin	9.8	45.1
Methenamine & Azithromycin	8.9	54
Azithromycin & Cephalexin	6.2	60.2
Methenamine & Co-Amoxyclav	4.4	64.6
Methenamine & Nitrofurantoin & Cephalexin	4.2	68.8
Methenamine & Azithromycin & Nitrofurantoin	3.6	72.3
Methenamine & Trimethoprim	2.2	74.5
Methenamine & Pivmecillinam	2	76.5
Azithromycin & Nitrofurantoin	1.6	78.1
Methenamine & Azithromycin & Doxycycline	1.4	79.5

Figure 3. Most common (top 80%) antibiotic combinations prescribed in 2015.

Regarding the choice of antibiotics prescribed the document entitled 'Summary of the evidence for the Lower Urinary Tract Service' (please Appendix 11, document 44) stated that the LUTS clinic had, in 2004, drawn 'on published guidelines on UTI'. It was stated that patients had reported that 'low-dose prophylactic treatments were unreliable' and so higher doses had been used. It was stated that as of 2010 doxycycline had been used more and azithromycin from 2013.

Professor Malone-Lee commented that he had previously had a patient who had been admitted to hospital and treated for pneumonia with azithromycin. He stated that during this time it had "cured her infection" and as a result he had begun to prescribe it in the LUTS clinic. He also said that he had seen literature on its use for non-specific GUM infections. Upon questioning, Professor Malone-Lee commented that the patient had likely been given a combination treatment which would have included an agent more associated with successful treatment of UTI, and that it may have been clarithromycin rather than azithromycin that she was prescribed. During the ISR factual checking process the LUTS team stated that the patient "was not cured , her symptoms had returned after discharge but responded on re-exposure to a macrolide (azithromycin) and this proved consistent through a sequence of stop/start cycles."

Other interviewees commented that Professor Malone-Lee had in the past clearly stated that he had based some treatment decisions on anecdotal experience and that this had given rise to some concern.

Regarding the LUTS clinic's treatment protocol it was stated that the clinic decided what treatment regimen to start a patient on based on the patient's symptoms when they were first seen. It was said that the clinic would use first line antibiotics wherever possible. Member of the clinic's staff were also clear in stating that the decision to change a patient's treatment was based primarily on the patient's symptoms. It was understood that any changes in antibiotic prescribing were determined by symptom response rather than any empiric microbiological data and that different combinations of treatments could be used and separate to the protocols in place.

7.3.2 Completion of treatment

The review team were informed that some patients of the LUTS clinic were discharged more quickly than others. The document entitled 'Summary of the evidence for the Lower Urinary Tract Service' (please Appendix 11, document 44) reports that for a sub-group of 225 patients who had finished their treatment and had been discharged, the average length of treatment was 383 days. There was reported to be a large variance in treatment duration amongst this group. It was reported that there was still a large number of patients under continuing long term follow up of the clinic.

Some patients who had been discharged were said to have later asked to be readmitted to the service. All patients who were discharged from the clinic were said to be given open access for six months after which they would need a new referral.

Patients were said to be discharged when their chronic symptoms had gone. It was said that some still had acute episodes of symptoms but that these could be managed with standard treatments. Some patients who had been discharged were reported to have recurrences of their chronic symptoms after 'a couple of years' at which point their GPs may refer them back to the LUTS clinic.

7.3.3 Concerns about treatment protocol

A number of interviewees stated that they knew treatment being prescribed by the LUTS clinic was outside of published guidelines and outwith the medication licensing. It was noted that the majority of

the medications being prescribed were 'conventional antibiotics' but that they were used in higher doses, for longer durations and in combinations that were not considered to be active in treating UTI.

It was commented that concerns had been raised a number of times about the clinic's prescribing and Professor Malone-Lee himself acknowledged that this practice did not occur elsewhere in this country. It was also stated that some of the patients being treated by the LUTS clinic might have been able to be treated with other 'standard' treatments. Common practice amongst urologists, for example, would be to use antibiotics in treating such patients in doses and for lengths of time (eg six weeks) that would also be outside normal licensing but for a planned limited period. Dosage regimes, combinations and the length of prescribing (months) commonly seen in the LUTS clinic would be considered as an outlier.

These concerns were said to have led to a number of discussions amongst local GP commissioners about ending the commissioning of the service (although it was never formally commissioned to begin with). Some GPs and consultants were also said to have stopped referring any of their patients to the LUTS clinic.

A specific concern was raised about the LUTS clinic's use of intravenous gentamicin for several days without appropriate serum concentrations being monitored. The regimen of 7mg/kilogram body weight mandates the daily measuring of the serum concentrations and should have followed a protocol for determining gentamicin dosage frequencies. Not to do so would have resulted in an additional risk of adverse reactions to gentamicin. In the document entitled 'Summary of the evidence for the Lower Urinary Tract Service' (please Appendix 11, document 44) it is stated that five-day courses of IV Gentamicin (and Ertapenem) had been used between 2009 and 2013 but as Professor Malone-Lee found this not to be 'curative', the clinic no longer uses this approach.

Other concerns were also raised about the use of IV Tazocin and the possible use of Tigecycline. It was clarified that Professor Malone-Lee had discussed the use of Tigecycline with a colleague but that the LUTS clinic had never prescribed this drug. No additional information on the use of Tazocin was provided at the time of the review. However, during the ISR factual checking process additional comments were provided by LUTS team. It was stated by them that the IV regimens were "adopted in consultation with microbiologists" and it was confirmed that the team followed a "guideline for once daily gentamicin published by Gloucester Hospitals". Tazocin and Tigecycline were reported to have been used because of culture sensitivity data, and this was done in consultation with microbiologists and under their supervision (it was noted by the LUTS team that both treatments could not be dispensed otherwise). It was commented that these were used in "rare isolated circumstances for particularly sick patients". In early 2014, it was reported the LUTS team found a way of avoiding IV interventions.

The LUTS clinic reported they had tried to 'accommodate' the safety concerns that had been raised about some of the treatment regimens used in clinic patients. The document entitled 'Summary of the evidence for the Lower Urinary Tract Service' (please Appendix 11, document 44) comments on some of the changes that had been made. It is reported that the use of nitrofurantoin had been reduced over time reflecting the clinic's 'concerns about the threat of rare, but serious adverse events associated with protracted use'.

7.3.4 Clinical audits

During the review visit a member of the LUTS clinic's staff commented that the clinic gathered a lot of data but that the number of 'defined audits' undertaken was very low. It was noted that one of the issues was perceived to be the clinic's lack of resources.

The Trust provided the review team with a document entitled 'centrally recorded LUTS audits'. This included just one audit, which was titled 'Clinical Audit of Fresh Urine Microscopy (July 2014 – October 2014)'.

The review team were also provided with a number of audits the clinic had carried out, which had not been centrally recorded with the Trust. The subjects of these audits include the following:

- Antibiotic resistance and the treatment of chronic UTI (January - September 2015)
- LUTS in diabetics audit (June – August 2013)
- Record Keeping and Clinic Notes Audit (18 - 22 April 2016)
- Psychology Survey (February – March 2016)

7.4 Translation of research into clinical practice and assessment of research governance arrangements

The review team were asked to assess the current research governance arrangements and whether there were clear definitions as to those aspects of the service which constitute clinical practice, and those which are research. Included in this are contractual and appraisal arrangements shared between the Trust and University College London (UCL).

7.4.1 Research publications

The review team was provided with copies of a number of research publications that had been authored by members of the LUTS clinic's staff. The titles of the publications, many of which were conference abstracts included:

- Can urodynamics distinguish between urethral strictures and Benign Prostatic Hyperplasia (BPH)?
- Urinary ATP as an indicator of infection and inflammation of the urinary tract in patients with lower urinary tract symptoms
- Urinary ATP and visualization of intracellular bacteria: a superior diagnostic marker for recurrent UTI in renal transplant recipients?
- An encapsulated drug delivery system for recalcitrant urinary tract infection
- Enterococcus faecalis Subverts and Invades the Host Urothelium in Patients with Chronic Urinary Tract Infection
- Spectrum of Bacterial Colonization Associated with Urothelial Cells from Patients with Chronic Lower Urinary Tract Symptoms
- Discrediting microscopic pyuria and leucocyte esterase as diagnostic surrogates for infection in patients with lower urinary tract symptoms: Results from a clinical and laboratory evaluation
- Lengthy antibiotic treatment to resolve recalcitrant oab[1]
- The problems affecting the diagnosis of urinary tract infection
- The Inadequacy of Urinary Dipstick and Microscopy as Surrogate Markers of Urinary Tract Infection in Urological Outpatients With Lower Urinary Tract Symptoms Without Acute Frequency and Dysuria

The review team observed that the majority of the studies that had been published were related to the diagnostic aspects of the LUTS service, identifying and diagnosing urinary tract infections. It appeared

[1] overactive bladder symptoms (OAB).

that very little research into the various antibiotic protocols chosen or a review of outcome data with regards to quality of life had been undertaken.

The review team were informed that any research studies that were sponsored by The Whittington would be audited by the Trust. All of the research studies, which had been conducted by the LUTS clinic, were said to have been sponsored by UCL, the principal employer of Professor Malone-Lee. The Trust was said to have given 'site approval' for the LUTS clinic's studies.

7.4.2 Sediment cultures

It was stated that part of the diagnostic research undertaken by the LUTS clinic involved urine sediment cultures. These cultures were said to have been previously done in the laboratory sited at the Eastman Dental Institute (part of UCL) but were now reported to be carried out in the Centre of Nephrology at the Royal Free Hospital (part of the Royal Free London NHS Foundation Trust, which is a member of the UCL Partners academic health science centre). The review team had no real data on how many urine samples were sent from the clinic in a calendar year to either of these sites. In addition no material transfer agreement appeared to be in place in relation to transfer of samples between Whittington Trust and UCL/Royal Free.

It was commented that until 2013 these urine sediment cultures had provided data, which were used to influence clinical management decisions for the LUTS clinic's patients. It was stated that this stopped being the case when the laboratory change-over occurred. It was also stated by clinic staff that this had been 'leading us down a route of using cocktails of medications that were quite worrying'. The review team received no evidence that ethical approval and Trust approval to use the results of these research assessments to influence patient management had been in place.

When asked how the use of these research-based urine sediment cultures had been explained to patients, Professor Malone-Lee said that patients had been told 'that this was something new we were using in our laboratories'. He also commented that he had not been aware that the clinic had required formal ethical approval to use these cultures for this purpose.

7.4.3 Efficacy of treatment regimens

Information provided to the review team in the document 'Summary of the evidence for the Lower Urinary Tract Service' (please Appendix 11, document 44) states that since April 2013 the LUTS clinic had been using plots (see figure 4 below) of urinary epithelial cell counts and pyuria[2] over time. It was commented that it had become 'evident that the oscillations in the patients' symptoms did not necessarily imply treatment deficiency'. There was said to have been an observation of 'fluctuations in symptoms, pyuria and urothelial cells counts of decreasing amplitude, recognised as "damped oscillations"' As a result of this observation the clinic was said to have learned 'to maintain the same antibiotic regimen, despite symptom variance, provided that the overall trend was downwards'. This was stated to show treatment efficacy as illustrated in a graph plotting pyuria, frequency and symptoms scores over time (figure 5 below).

[2] pyuria is the condition of urine containing white blood cells or pus.

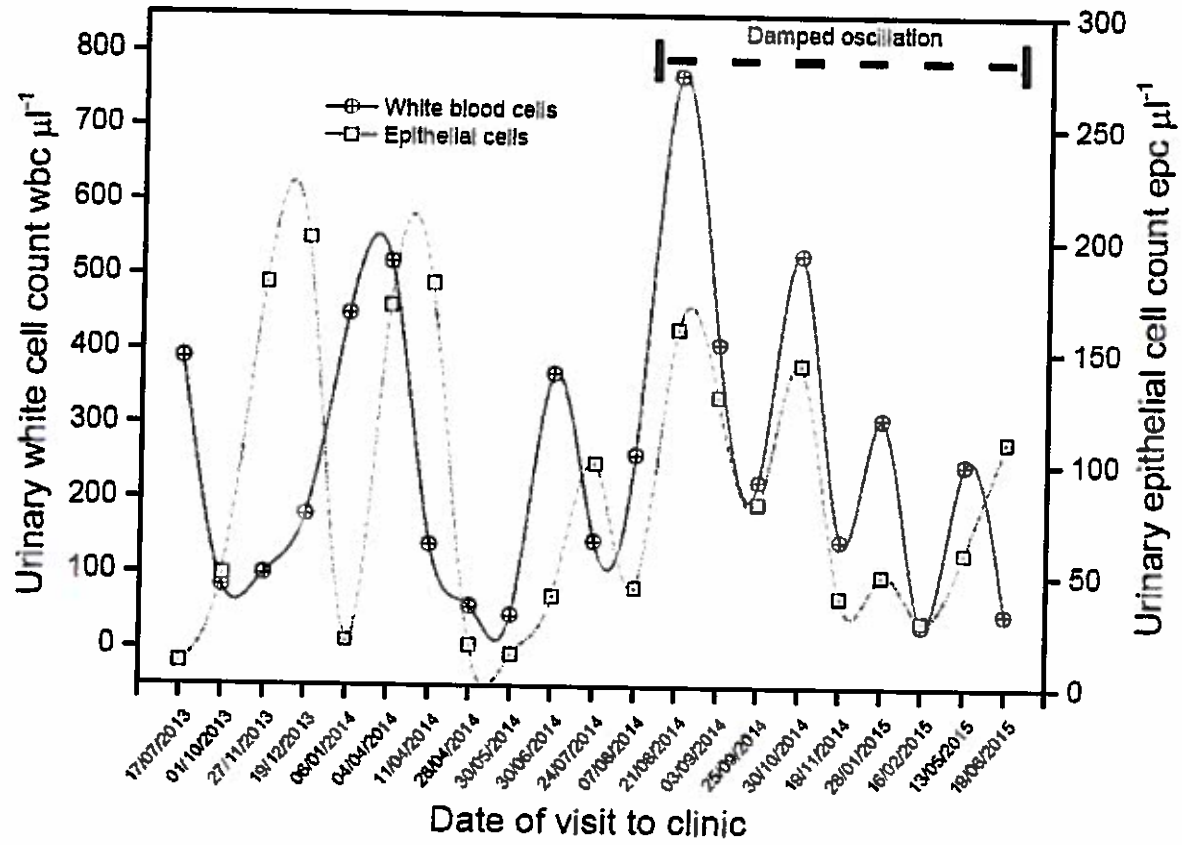

Figure 4. Pyuria and epithelia cell count over time.

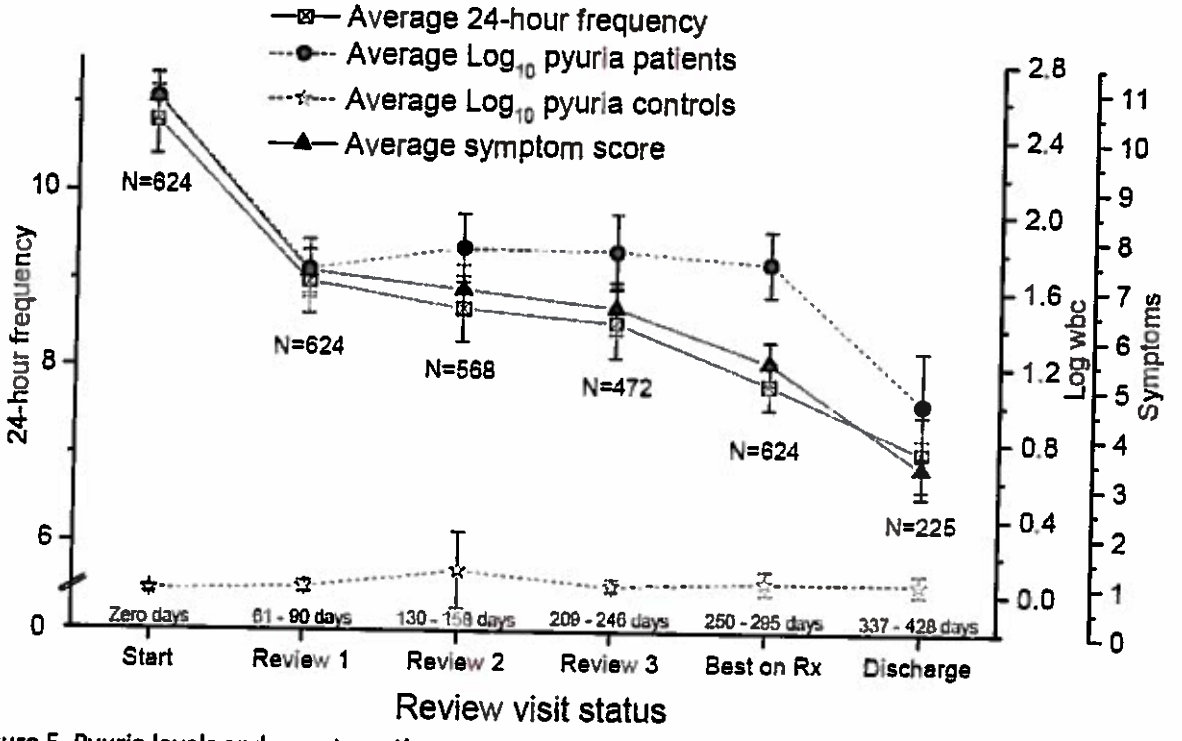

Figure 5. Pyuria levels and symptomatic scores over time.

In discussing this data during the review visit it was stated that statistical analysis had confirmed correlation between the pyuria levels and patients' symptom scores. It was also explained that all patients being treated by the LUTS clinic went through a test cessation of their medication once their pyuria level reached zero. The document 'Summary of the evidence for the Lower Urinary Tract Service' (please Appendix 11, document 44) states that for a group of 858 patients who had their medication stopped 633 restarted taking medication due to symptoms relapsing.

The symptom scores used by the LUTS clinic were said to have 'evolved' from the free text descriptions the clinic had previously used. When asking about measuring patients' quality of life, the review team were told that one member of the LUTS clinic's staff was also said to have collected a significant number of patient 'biographies' for use as part of their PhD study. It was stated by a number of interviewees that Professor Malone-Lee had chosen not to use a validated quality of life survey to gather information from patients, as he did not 'believe in them'.

7.4.4 Randomised controlled trials

The review team asked about what consideration had been given to conducting randomised controlled trials (RCTs) involving patients being treated by the LUTS clinic. It was said that the clinic had twice tried to develop a protocol to carry out an RCT.

It was reported that at one time the clinic had attempted to undertake a study of the use of nitrofurantoin after receiving advice from the Medicines and Healthcare products Regulatory Agency (MHRA) to limit the study to a single drug. Following further advice from an ethics committee the study was said to have been designed as a crossover trial[3] using a placebo coupled with a recovery drug. The study was reported to have not been carried out as the clinic had found that none of its patients would agree to be involved in any study which may give them a placebo drug. Other reasons heard were that the pharmacy costs to do so would be high and that also the Ethics Committee reportedly said that the clinic could not put patients on placebo if they had an infection.

The review team was informed that in the future the LUTS clinic planned to undertake a 'long term observational cohort study'.

A number of interviewees commented that they believed the LUTS clinic should have undertaken randomised controlled trials to demonstrate the efficacy of its treatments. One noted that the clinic needed to put out some publications related to its treatments, as this was a 'difficult field to take on without published evidence'.

7.4.5 Research governance

It was stated that the responsibility for the governance arrangements around the LUTS clinic's research lay with UCL. Responsibilities for the supervision of the PhD students working in the LUTS clinic were said to be shared by Professor Malone-Lee and their supervisors at UCL.

The Trust's Medical Director was said to have held discussions with Professor Mark Emberton, Dean of Faculty of Medical Sciences for UCL, regarding the recent issues concerning the LUTS clinic.

The review team were provided with a copy of a report, commissioned by UCL, looking at some of the research completed by the staff of the LUTS clinic. This UCL review did not look at the overlap between clinical and research practice and whether appropriate research protocols for such an overlap had been followed. The ISR team observed that the governance role of UCL appeared to have been limited. The

[3] a longitudinal study in which subjects receive a sequence of different treatments

report clearly states that its remit was limited to look at research rather than clinical practice. The outcome of this review was that no concerns were identified 'relating to the design, conduct, completion or publication of the research work undertaken'.

It was commented to the review team that the Trust had been disappointed by the oversight of the LUTS clinic that UCL had provided, with the review conducted by an NHS employee without involvement of UCL research governance staff. The review was said by the Trust to also have been prompted by the LUTS service being in the bottom quartile of research output and it was also said to 'fall well short' of what the Trust had hoped to learn from it about the clinic's practice.

During the ISR factual checking process, the LUTS team sought to provide further clarification to the review team around the UCL commissioned review. It was stated that, other than staff from the LUTS team, no staff from the Whittington trust attended the UCL review. It was also re-emphaised that the review panel also had access to statements of support of the LUTS team from collaborating academics. Further positive comments were made by the LUTS team about this UCL review but these did not relate specifically to points of factual accuracy in this report.

It was stated that the arrangements for Professor Malone-Lee's annual appraisal were not entirely satisfactory. There had not been any joint appraisal between the Trust and his employer UCL.

Professor Mark Emberton was invited to attend the RCP's review visit to discuss matters relating to the LUTS clinic's research but was not available to attend.

During the ISR factual checking process, the LUTS team stated on Professor Malone-Lee's behalf that he considered the UCL managers had been "supportive to him and have looked after him well".

7.5 Team working, leadership and managerial support

The review team were asked to consider if team working arrangements within the clinic were appropriate and assess the allocation of roles and responsibilities amongst clinicians. The review was also asked to consider how fragile or otherwise the current leadership arrangements in the clinic are.

7.5.1 Roles and responsibilities

It was explained to the review team that new patients were seen and assessed by a clinic doctor. The doctors planned to take a patient history, ask about medications and the patient's history of side effects, to go through the clinic's symptoms scoring process and to undertake fresh urine microscopy. Every patient was then said to be discussed with Professor Malone-Lee, either in person, by telephone or by video conference.

Those patients who were viewed to potentially benefit from Botox injections for treatment of an overactive bladder were said to be referred to the clinic's nurse. When asked as to whether the clinic could make more use of nursing staff the review team were told that it had taken many years for a nurse specialist to be trained in the clinic's work and so it would not be easy to achieve this.

7.5.2 Delegation of responsibilities

Professor Malone-Lee informed the review team that none of the doctors working in the LUTS clinic were 'allowed to do anything without me checking it', this was said to include sending emails out to patients. It was explained that, as most of the treatments prescribed by the clinic fell outside of medication licensing, Professor Malone-Lee wanted to take responsibility for all actions being taken. It

was said that he had hoped to hand over more responsibilities but that in his opinion the other, more junior doctors were nervous about taking on this responsibility.

During periods when Professor Malone-Lee was away from the clinic on leave he was said to call in daily to discuss some of the clinic's patients with the most complex conditions. It was also reported that in difficult consultations the doctor seeing the patient would sometimes make a video conference call to Professor Malone-Lee when he was off site so that he could speak to the patient over the internet.

The review team noted that all the junior doctors they met deferred to Professor Malone-Lee in part as he was or had been helpful in their careers and in part because this was "how the clinic worked".

7.5.3 Staff appointment and contracts

The review team were informed that Professor Malone-Lee was responsible for finding and appointing all of the staff that worked with him. It was commented that the process he followed for doing this was 'not too dissimilar to how other academics would do it'. It was also highlighted that the junior doctors in the clinic were not in formal educationally recognised training posts.

At the time of the review visit there were three non-consultant grade doctors working for the LUTS clinic, each of whom was in the process of finalising their PhDs. They were said to be employed on fixed term contracts held by the Trust, which had recently been renewed for an additional six months. This process was said to be frustrating on all sides – the Whittington as employer not getting much notice of changes and the doctors having last minute renewal of contracts. It was noted that at times it was difficult for the Trust to keep track of how many staff were working in the LUTS clinic.

It was also reported that in the past there had been a number of other, 'transient' doctors working in the clinic, who had been employed by UCL. It was known that no junior doctors in clinical training were rotated into the clinic.

7.5.4 Support given to staff

A number of interviewees commented that Professor Malone-Lee was very supportive of the staff working alongside him. He was said to have a 'very nurturing nature' and to be very supportive of the academic work of the PhD students working with him. There was also said to be a 'good team atmosphere' amongst those staff working in the LUTS clinic.

There were, however, some concerns raised about the more junior staff working in the LUTS clinic being 'beholden' to Professor Malone-Lee and not being in a 'secure position' should they wish to challenge his practice. Others noted that these junior members of staff were very loyal to Professor Malone-Lee and that they were concerned some lacked a wider perspective of alternative practice in other services treating patients with lower urinary tract symptoms.

7.6 Internal and external relationships of the LUTS service

In this area the review team were asked to consider the team working between the LUTS clinic and other Trust departments, such as diagnostic services and medicines management as well as external stakeholders including Clinical Commissioning Groups and local GPs. Consideration was also given to systems of clinician peer review, particularly for cases involving children.

7.6.1 *Relationships with the microbiology service*

There was reported to have been a 'mixed history' in the relationships between the Trust's microbiology service and the LUTS clinic.

Professor Malone-Lee's relationship with one of the consultant microbiologists was said to have previously been quite good, as the two had worked together on some research. More recently they were said to have 'drifted apart'. Professor Malone-Lee's relationship with another consultant microbiologist was said to have been more limited and there were reported to have been some significant difficulties between the two. It was reported that Professor Malone-Lee's behaviour had at times been seen as patronising towards this individual.

The review team also heard that the LUTS clinic's staff had not always been satisfied with the communication they received from the Trust's microbiology service. It was commented that the clinic sometimes received culture reports back, which simply read 'mixed growth', which was described as not being helpful. One interviewee stated that it would be helpful to work with a microbiologist who 'agreed with the treatment' that the clinic used. In response to these issues it was said that the Trust's microbiology service reported on cultures 'as a normal laboratory would do' and that if something more was required by the clinic then this had not been communicated.

At the time of the review visit the involvement of microbiology in the treatment planning of the LUTS clinic was said to be 'very little'. It was commented that a lot of MSU samples were received from the clinic but that there was little contact with the clinic's staff. The Trust's microbiology service was said to have no knowledge of the research being undertaken by the clinic or the antibiotic sensitivity testing being carried out (other than the laboratory's routine testing), as this was not done in the Trust's laboratory.

7.6.2 *Relationships with medicines management service*

It was stated that there had previously been some significant difficulties between Professor Malone-Lee and some of the Trust's pharmacy staff. It was reported that he had in the past acted "aggressively towards some of them" and that there were now some who would no longer speak to him. The review team understood these difficulties to have arisen due to disagreements about dispensing medications prescribed by the LUTS clinic to its patients.

At times when Professor Malone-Lee was away and the Trust's medicines management service had communicated with the other members of the LUTS clinic's staff, these interactions were said to have been appropriate and the relationships with these staff were reported to be 'okay'.

7.6.3 *Multi-disciplinary team meetings*

Following the resumption of the LUTS clinic on 23 November 2015 the Trust put in place arrangements for a LUTS multi-disciplinary team (MDT) meeting. A document dated 26 November 2015 was provided to the review team, which set out the core membership of this MDT including Professor Malone-Lee, a consultant microbiologist, an antimicrobial pharmacist, Dr Peter Christian (who is a local GP and a member of Haringey CCG), Mr Amalin Dutt (Head of Medicines Management at Islington CCG) and the MDT's coordinator. The review team heard that Mr Nick Harper, a consultant anaesthetist and the Clinical Director of Surgery, was chairing the MDT meetings.

The terms of reference for the LUTS MDT were documented as including the discussion of:

- Cases which Professor Malone-Lee thinks it would be helpful to discuss

- Those patients about which other clinicians had expressed concerns
- Patients who have been taking nitrofurantoin for more than six months
- Any cases for which the LUTS clinic has proposed treatment outside of the antimicrobial treatment limits set on 19 November 2015.

It was also clearly stated that the MDT meetings would not be used as forum for the discussion of the clinical management of children.

Meetings were set to be held fortnightly from 7 December 2015 with the frequency of meetings reviewed thereafter. The Trust provided the review team with the minutes of MDT meetings that had taken place on 23 December 2015, 9 February 2016 and 17 February 2016.

A number of interviewees commented that they felt it was a positive step that MDT meetings had been introduced to support the LUTS clinic and to allow for opportunities to 'debate the management of these patients'. It was, however, also stated that the meetings held to date had not followed the normal format that would be expected of an MDT meeting. The review team heard that Professor Malone-Lee explaining the 'philosophy' behind the LUTS clinic had largely taken up the first meetings.

More recently the MDT meetings were said to have included discussion of specific cases, but it was noted that cases brought to the meeting had been those patients with particularly complex conditions, which Professor Malone-Lee had reportedly described as representing about 10% of the LUTS clinic's practice. It was commented that there was a need for more typical cases to be presented, representing the 'bulk' of the clinic's patients. The review team was also informed that some discussion had 'quickly escalated' and had become very tense. It was described that the MDT discussion around his patients' was dominated by Professor Malone-Lee and that members of the MDT had found it difficult to have an educated discussion about these patients. These interviewees reported that, it was their view, Professor Malone-Lee had found it difficult to accept challenge from his peers or to reflect on his practice.

7.6.4 Management of paediatric patients

The management of children within the LUTS clinic was highlighted by many people to be problematic. It was observed that it was not until the clinic's suspension that senior managers at the Trust became fully aware that a small number of children were being seen at the clinic.

Part of the revised restrictions placed on Professor Malone-Lee's practice was the requirement that he discuss the management of children with a consultant paediatrician. When Professor Malone-Lee was asked if he thought a physician trained in caring for older people should be managing children, Professor Malone-Lee stated that he had worked with children for 35 years and in the past had been part of a community enuresis service. Professor Malone-Lee had recently undergone/refreshed the necessary Trust child protection training.

The review team was informed that the arrangement recently put in place after the clinic suspension was that Professor Malone-Lee would brief Mr Nick Harper, the Clinical Director of Surgery, on his paediatric patients and that Mr Harper would then relay this information to a consultant paediatrician working in Birmingham. The paediatrician would then provide any feedback to Mr Harper who would then pass the information on to Professor Malone-Lee.

It was stated that the Trust had considered that it was unlikely to be sustainable for one of the Trust's consultant paediatricians to be involved in these cases or for Professor Malone-Lee to correspond directly with the paediatrician in Birmingham.

Professor Malone-Lee stated that, should he have been required to, he would not have objected to undertaking clinics jointly with a consultant paediatrician. Some interviewees reported that there was reluctance by the local paediatric team to work with Professor Malone-Lee due to his perceived difficult working relationships and unusual treatment plans.

7.6.5 Other clinical engagement

It was reported to the review team that when the LUTS clinic had been based in its previous location, at The Archway Campus opposite The Whittington Hospital, there had been more links between it and the rest of the Trust. Following the movement of the clinic to the Hornsey Medical Centre maintaining these links was said to have been more difficult. A number of interviewees commented that this move had made the clinic more 'isolated'.

Professor Malone-Lee's practice was also said to have become more 'isolated' as it had become more sub-specialist. It was commented that he had previously been part of the general medical on-call rota but had come off in approximately 2009. He was also said to have previously provided urodynamic testing for urogynaecology patients but, following disagreements about these tests, this was reported to have stopped in around 2010 or 2011.

The review team heard from one individual that they felt a more robust governance structure needed to be put in place, agreed by all parties, providing an integrated service alongside microbiology, pharmacy and other relevant clinical groups.

Professor Malone-Lee reported that he made a point of taking difficult cases to national and international conferences for discussion. He stated that he had found it very useful and reassuring to talk through problems with other national and international experts. He did, however, comment that the difficulty was that some other international groups were working with animal models and that the clinic's work was so specialised that there was a 'danger of being isolated'.

The review team met representatives of the two main CCGs (Haringey and Islington) that work with the Whittington hospital. Both groups described very good relationships with the Whittington Trust but very problematic ones with the LUTS clinic. Although the LUTS clinic had never been clearly commissioned by the CCGs (it was part of a block outpatient contract with the Trust) there had been very significant public concern when discussion had commenced about its "decommissioning". Local general practioners had felt unable to continue some treatment regimes and had questions about rationale and potential side effects. For example a GP in one of the CCGs had recently noted a potential patient safety incident of a patient with microscopic haematuria who had been seen in the LUTS clinic. The review team advised that this recent concern should be raised with the Trust.

7.7 Duties of the trust legally and ethically

The review team was asked to consider what duties the Trust has both from a governance point of view and from an ethical point of view to continue to provide services to the existing patients of the LUTS clinic.

7.7.1 Continuation of the LUTS clinic

The Trust was reported to be conscious of a need to resolve the current situation regarding the concerns that had been raised about the LUTS clinic in a way that was ethical with respect to the clinic's current patients. It was acknowledged that the clinic treated a group of patients who felt that it had offered them hope of their conditions being cured.

Some interviewees stated that they felt that the clinic should be closed due to concerns about the safety of the treatments it prescribed, but that they were concerned about what effect this would have on its patients. Others commented that if the clinic was to continue it would need to be treating patients with recognised clinical conditions and offering treatments accepted by the wider medical community.

There were some interviewees who suggested that a proportion of the clinic's patients may be able to be referred on to other services. It was, however, recognised that no other clinicians would be willing to adopt the LUTS clinic's model of prescribing. As such, those patients who felt as though they had already tried all other treatment options would be unlikely to accept referral to any service other than the LUTS clinic.

One of the patients who spoke to the review team commented that some patients had, during the time the clinic was suspended, gone onto the internet to source the antibiotics they had previously been prescribed. It was commented that if the clinic were to close then it was likely there would be some who would attempt do the same in future.

At the time of the review visit the clinic was not accepting referrals of new patients, due to the restrictions that had been imposed on Professor Malone-Lee's practice. A number of interviewees, including some of the patients who wrote or spoke to the review commented that they felt that this was ethically problematic for the Trust as they felt the service should be opened up to new patients again. Some clinicians, however, stated that whilst they could support the ongoing treatment of existing patients (under Good Medical Practice) they would not be willing to refer new patients to the LUTS clinic.

7.7.2 Succession planning

Professor Malone-Lee discussed with the review team that it was currently his plan to retire from practice in the Trust in September 2016. A number of other interviewees, including staff and patients, made reference to this and all acknowledged that this raised questions about the future of the LUTS clinic. It was commented that it would not be justifiable for the Trust to shut down the clinic purely because Professor Malone-Lee had retired, given that a large number of patients were still being treated.

The review team heard that Professor Malone-Lee had on a number of occasions attempted to discuss with the Trust how the LUTS clinic might be managed once he had retired. He was said to be in favour of one of the doctors who had worked in the clinic while earning their PhD returning to manage the service. It was, however, noted that although many of these individuals were interested in working in this field they did not want to work in the LUTS clinic due to concerns about how Professor Malone-Lee felt he had been treated by the Trust. Some interviewees also noted that it was unlikely that any other clinician who took on the clinic would be able to spend the time communicating with patients or be as accessible outside clinic appointments to patients as Professor Malone-Lee had been and that this may lead to some patients becoming dissatisfied.

It was stated that the Trust was not currently in a position to appoint a substantive clinician to replace Professor Malone-Lee due to all of the unresolved concerns about the efficacy and safety of the service. The review team were also informed that UCL were unlikely to replace Professor Malone-Lee's post.

The Trust was however very interested to discuss with tertiary NHS partners, such as UCLH, as to how to take the service forward.

Professor Malone-Lee also commented to the review team that, once he had retired from NHS practice, he planned to continue seeing some patients privately until such time as another doctor was able to take over this practice also. It was noted that this would likely require the private LUTS practice to move out from the Hornsey Medical Centre and any governance arrangements by the Whittington Trust.

7.7.3 Tertiary service referrals

It was commented that over time patients from a variety of places had either been referred to the LUTS clinic or had found it through their own initiative. The review team was informed that of the approximately 900 patients, who were being treated by the LUTS clinic, 100 were from within Haringey CCG and 131 were from within Islington CCG. The rest of the patients were from other parts of London or others parts of the UK.

A number of interviewees stated that The Whittington Hospital NHS Trust was not set up to manage a tertiary referral service, as the LUTS clinic had evolved to be. Some stated that if the clinic was to continue it would be more appropriate for it to be managed by a large trust that already managed other tertiary referral services and who had a mix of the relevant specialities for multidisciplinary working, such as UCLH.

8.0 Conclusions

The following conclusions are reached on the basis of the documentation reviewed (as set out in section 11) and the interviews held with staff at the Whittington Hospital NHS Trust (as described in section 5 above).

8.1 Overall conclusions

Based on all of the information considered by the review team it was concluded that significant changes need to be made to ensure the safety of patients currently being treated by the LUTS clinic. Much stronger governance oversight of the activity, outcomes, side effects and adverse events associated with the clinic is required. Investment in capacity and capability of management associated with the clinic is required to achieve this and to ensure integration with Trust processes. It was also concluded that some of the information being provided to patients about their risks of their treatment was not appropriate and so needs revising.

There is a great deal of uncertainty about the future of the clinic given the forthcoming retirement of Professor Malone-Lee, the clinic's lead clinician. This will need to be resolved with a plan put in place to ensure continuity of care for those patients receiving ongoing treatment who are not able or willing to be transferred to other services.

The review team also concluded that there was further uncertainty about the long term future of the clinic, including whether it would resume accepting new patient referrals. The fact that the LUTS clinic has not been able to carry out randomised controlled trials or high quality observational studies assessing clinical outcomes means it has not been able to provide verifiable evidence that its treatment is effective. It is also noted that the treatment regimens have not been based on published data from other centres.

There are questions about whether local CCGs will wish to commission the service and whether a tertiary centre would be better placed to support a service like the LUTS clinic. The review team were of the view this could be achieved in a tertiary centre such as UCLH that would have the necessary range of contributing specialties to manage complex patients. Such a centre would be able to tackle the funding flows associated with this complex small volume service. A fresh start to the clinic would be beneficial as there is a breakdown of trust between a significant number of existing patients and the management at the Whittington.

8.2 Patient Experience

Those patients who provided their views to the review team were very supportive of the LUTS clinic and the benefits they feel they have received from the treatment the clinic has provided. Many came to the clinic feeling they had been let down by previous medical treatment and that the clinic provided recognition not afforded to them elsewhere. Some feel as though the clinic has transformed their lives by drastically improving their quality of life. The review team was, however, conscious that it has only heard from a subset, albeit a large one, of all of the clinic's patients and that there may be some others who are less content with the service.

Although they were said to be very convenient for patients, the review had some concerns about the appropriateness of the clinic using so many telephone and virtual appointments. This poses the risk of not affording the doctors the opportunity to appraise patients comprehensively in person, allowing them to identify any physical symptoms or signs, or adverse reactions to medications.

Patient accounts to the review team were that they have received detailed information from the clinic about their treatment and the risks associated with it. In many cases there is good individual scrutiny of care in such a personalised service. However, having looked at the information given, the review team concluded that the benefits of treatment are well described, but that risks and adverse effects are not given sufficient emphasis considering the use of so many medicines outside the terms of their licences.

The experience of patients following the temporary closure of the clinic was poor. Members of the Trust management team and Professor Malone-Lee as clinical lead should have worked together more collaboratively to ensure more effective lines of communication with patients.

8.3 Clinical governance and safety of the service

The clinical governance arrangements for the clinic are of serious concern as there is not robust evidence of the efficacy of the treatments provided, patient outcomes, or comprehensive data on the complications patients have experienced. The clinic is monitoring side effects included diarrhoea but there was no evidence of a robust process for monitoring rates of *Clostridium difficile* infections, which is likely to be especially difficult given that the great majority of the clinic's patients come from across the UK and not from the local CCG or Whittington natural catchment area. Similarly, work on identifying other patients potentially harmed by nitrofurantoin with pulmonary fibrosis needs taking forward urgently.

The fact that the clinic has based some of the information it gives to patients on the risks of complications on the observed incidence rate for licensed use coupled with poor recording of outcomes was also of concern.

The review team heard a number of anecdotes of safety issues, including the serious untoward incident, which triggered the review. It is not possible to be sure that all such issues have been recorded as the clinic has operated entirely separately from the Trust's governance structure for some time. Indeed without the clinic suspension and access to its bespoke and previously autonomous clinical database the Trust had no information on patient care. Most of the LUTS clinic's audits that were provided to the review team had not been filed centrally with the Trust.

Recently the Trust has taken a more active role, and begun investigating some safety issues but it has not allocated the necessary resources to investigate these issues expediently. As a result the investigation of the recent serious untoward incident was still incomplete at the time of the review visit. The information the review team received suggested that the current Division clearly lacks the necessary resources to undertake this work and a strong case can be made for use of additional and separate corporate resource here to give transparency and independence.

Also concern was raised as to the arrangements for urine microscopy in the clinic that currently do not satisfy UKAS accreditation with potential risk to the Trust's overall microbiology service accreditation.

8.4 Appropriate clinical audit and use of approved guidelines for antibiotic prescribing

The clinic's patients receive individual treatment plans but, while information provided to the review team gave an indication of the sorts of treatments prescribed, there does not appear to be a recorded standard protocol setting out the range of antibiotic treatments that are being used, or the indication for each antibiotic or combination of antibiotics.

Many of the drugs prescribed are in higher doses than is licensed and the clinic does not appear to enforce a maximum duration for any of these medications. A number of patients are taking

combinations of two, three or more antibiotics at the same time and there are more than twelve different combinations currently in use. The majority of the antibiotic regimens used are not recommended by any accepted guideline and while some urology services, for example, may prescribe outside these norms for a small group of complex patients this is not at the dosage, duration or combinations used in the LUTS clinic or in such a large number of patients. This makes the process around patient information and consent absolutely vital but there was a lack of evidence of the clinic having completed audits of patient outcomes or of patient consent.

The Clinic was said to have responded to concerns by reducing the use of nitrofuratonin, the drug associated with the recent serious untoward incident. However, the review team were unclear about the actual number of patients still taking this drug.

Many patients are taking these medications for years at a time, the average length of treatment being 383 days. This is concerning because some serious adverse reactions such as pulmonary fibrosis are associated with durations of increasing length, as is the emergence of antibiotic resistance.

It was also concerning that the record keeping system that the clinic uses had for a long time been separate from the Trust's electronic patient records. This means that an acute admission of a LUTS patient at the Whittington (or any other hospital) would leave doctors unable to review what medications the patient was taking. The team understands some staff at the Trust can now access this separate database but this is not a sufficiently reliable solution to this issue. Recording of adverse events does not appear to be systematic with local systems being used but no systematic central recording or learning is apparent.

8.5 Translation of research into clinical practice and assessment of research governance arrangements

There did not appear to be clear definition of which aspects of the LUTS clinic are research-related and those that are clinical practice. Professor Malone-Lee's hypothesis about a sub-epithelial cell infection may be tenable and, if correct, this condition may be what has caused a number of the clinic's patients' symptoms. This may, however, not be the case for all of the clinic's patients and there did not appear to be a distinct process for the diagnosis of patients with one condition or another and all patients seem to be treated with high dose, long term antibiotics. The risks and benefits of this treatment regimen to patients remain very unclear in the absence of evaluation in clinical trials.

The great majority of the research that has been published relates to the diagnostic aspects of the service. This is not clear to all patients, an example being that the information leaflet carries the UCL logo which encouraged patients to believe that UCL had approved the work and safety of the clinic. The clinic's process for monitoring patients' conditions relies primarily on the use of fresh urine microscopy - as a purportedly more sensitive test for UTIs - as well as on a series of patient symptom scores the clinic has devised. It should be noted that microscopy is subject to observer variability and bias and there was not a clear process in place for the standardised performance or quality assurance of this process.

Regarding the effectiveness of the antibiotic treatment regimens used in the clinic, graphs of changing pyuria levels and patient symptom scores were provided with reference to these demonstrating the improvement that had been achieved. The review team noted that in figure 5 (section 7.4.3) pyuria scores do not appear to have improved between days 61 and 296 of treatment. After an initial decline during a more standard antibiotic prescribing timeframe no further changes were seen until the 337-428 day range. Patient symptom scores are obviously also potentially affected by other factors.

The inability of the clinic to carry out any randomised controlled trials means that it has not been able to provide verifiable evidence to convince others that the treatments used are safe and effective. The clinic has also not used a validated, standard quality of life measure to demonstrate the benefits of its treatments to patients. This is not to say that the review team feels there is evidence that the treatment is not effective in some patients and indeed the reviewers were moved by the considerable number of detailed patient accounts provided. However, without reliable clinical research evidence it will be difficult for other clinicians to accept that these unorthodox treatments are sufficiently effective,

The review team also did not see evidence of robust oversight on the part of UCL of the research being undertaken, the use of research data to make individual patient treatment decisions or how the research findings published by Professor Malone-Lee have been translated in to clinical practice in the LUTS clinic. Given that many of the treatments utilised are not those recommended by guidelines and/or fall outside the licensed use, the review team would have expected UCL, as Professor Malone-Lee's employer, to be involved with the Trust in reviewing this practice. It was extremely disappointing that the review team was not able to meet with a member of UCL who could speak to these issues.

8.6 Team working, leadership and managerial support

The LUTS clinic is very much led by Professor Malone-Lee and there appeared to be little evidence of independent practice undertaken by the other doctors. This appeared to be influenced in part by Professor Malone-Lee's desire to take on all of the responsibility and liability associated with the out of license prescribing the clinic uses. There also appeared to be a low level of nursing involvement in the clinic's ways of working which was again surprising as much of the care could be protocol driven.

The clinic is therefore very fragile given that it relies so heavily on the input of one senior clinician, who the review team heard will be retiring in September 2016. When he is away from the clinic, telephone and internet video calls are used, which serve to further reinforce this dependency.

It was also apparent to the review team that the Trust has little involvement in the appointment and management of the clinic's staff. At times there appeared to have also been a lack of clarity on the Trust's part as to the exact role some of some of the staff working in the clinic other than to grant honorary contracts. These factors make members of the clinic's staff dependent on Professor Malone-Lee more so than the Trust for their employment.

The review team found that loyalty was clearly visible but for some of the junior staff in particular, they considered this may have affected some of their behaviour and ability to reflect/question their own practice e.g. their very limited broader team working with the rest of the hospital.

8.7 Internal and external relationships of the LUTS service

The LUTS clinic is geographically and organisationally very isolated within the Trust and there appears to have been very little clinical scrutiny or supportive challenge from the Trust senior management team, until very recently.

In response to the recent Serious Untoward Incident (SUI) the Trust has introduced a multi-disciplinary team meeting to discuss some of the clinic's patients. This MDT had only met on four occasions and the meetings are therefore in evolution. The review team noted that the core membership lacks the input of a consultant urologist and a consultant uro-gynaecologist. Furthermore it appeared that there was a lack of clarity in terms of the criteria for selecting cases to be presented at this forum. There was varying feedback from attendees of this meeting as to how effective they were, and there was little evidence that the MDT was significantly influencing the treatment regimens being used. The review team noted

that good practice in similar MDTs would be to include a review of a random sample of patients as well as patients identified with issues for discussion, and furthermore for cases to reviewed and presented by an independent clinician.

There is very little communication between the LUTS clinic and the Trust's microbiology services. A lack of agreement about what the clinic expects from these services in terms of the reports being provided seems to have led to some frustration amongst clinic staff. Interpersonal relationships between microbiology consultants and the clinic are at low ebb for understandable reasons. There was also no evidence that the microbiology service was being included in the analysis of sensitivity and resistance data.

Following changes to the methods of prescribing used by the LUTS clinic, interactions with the Trust's medicines management and pharmacy teams are limited and this is unsatisfactory. This clinic should not be so reliant on the use of FP10 prescriptions that are harder to supportively challenge, scrutinise or regulate.

A number of staff were said to have experienced poor personal working relationships with the LUTS clinic and in particular Professor Malone-Lee, with some staff reporting having been distressed by some of their past interactions.

The arrangements currently in place to provide oversight of the clinic's existing paediatric patients still leave them without the direct input of a consultant paediatrician. This raises a number of concerns about clinical oversight and safeguarding.

8.8 Duties of the trust legally and ethically

The review team was clear that the Trust has a responsibility to ensure the patients already under the care of the LUTS clinic continue to receive care and support. It may be that some patients can be satisfactorily transferred to the care of other services but there is likely to be a relatively large number of those patients who have come to depend on the LUTS clinic. For the immediate future these patients will require ongoing care of the sort that the clinic currently provides and will likely benefit from management by a multidisciplinary team.

The long term provision of a clinic of this nature would undoubtedly be more suitably housed within a tertiary centre such as UCLH or another tertiary centre with additional resources and facilities to support it. Such a clinic based on proper multidisciplinary working (in particular with involvement of urology and gynaecology) could have a fresh start taking small numbers of patients, being clear on referral protocols, diagnostic pathways and agreed treatment plans. Integration with Trust governance processes would safeguard patients and those involved in running the clinic.

In terms of the potential for private practice the review team felt that some thought would need to be given to how a private clinic could operate within a recognised governance framework if the private LUTS practice was indeed to move out from the Hornsey Medical Centre

The review team had genuine concern for the welfare of Professor Malone-Lee who is a thoughtful, caring doctor but who is also currently experiencing considerable pressure in leading the LUTS clinic. The review team was concerned about what support he was receiving from both The Whittington and University College London in terms of his current work but also in planning for his forthcoming retirement.

9.0 Recommendations

This section is the key part of the report. The following recommendations are for Whittington Hospital NHS Trust to consider. In considering these recommendations it will be of upmost importance that the Trust ensures that the clinic's existing patients are consulted.

For ease of reference the review team have tried to link the findings of the report to the recommendations. Where possible an indication of timescales for implementing the recommendations have been made and in general these would apply from the date of receipt of the final report. Those recommendations relating to immediate patient safety concerns should have already been taken forward following our immediate feeback letters (see appendix 12.2 and 12.3).

Immediate actions required to address potential patient safety concerns

9.1. 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 (see appendix 12.2). This was followed up by an additional letter highlighting potential concerns about further cases of pulmonary fibrosis associated with nitrofurantoin in LUTS patients. (see appendix 12.3).
Immediate (0-3 months)

9.2 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 e.g. case of microscopic haematuria highlighted at the visit.
Immediate (0-3 months)

If, following the work undertaken to review the above, potential patient safety risks have been identified then the Trust will need to ensure that appropriate action is taken to address these. The RCP will provide further advice as required once this information is clear.

LUTS clinic and patient access in the short term

9.3 The Trust should continue to provide access to the LUTS clinic for those patients already registered with it and until such time that long term succession plans have been agreed and implemented. It may be appropriate for some patients to subsequently (wherever possible being seen first) 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.
Short term (0–6 months)

9.4 The management of these patients, including the medication prescribed, its doses and durations, should be reviewed, discussed and agreed at properly constituted and well managed multi-disciplinary team meetings with additional resources committed to it as required (please see section ten, references 1 and 2 for further guidance on good practice for multidisciplinary team working and good governance). In addition to LUTS clinic staff, core invited members at these meetings should include as a minimum; urology, uro-gynaecology, microbiology and pharmacy input. They will require administrative resource to produce agendas, minutes and document actions.
Short term (0–6 months)

9.5 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 following this review to provide patients with updated information on the risks of their medications and discuss further their preference in terms of on-going treatment.
Short term (0–6 months)

9.6 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 also be beneficial to ensure these patients are discussed in the LUTS MDT meeting with input from the consultant paediatrician involved.
Immediate (0–3 months)

9.7 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.
Short term (0–6 months)

9.8 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.
Short term (0–6 months)

Clinical governance arrangements

9.9 The clinic should undertake audits of patient outcomes and of consent to unlicensed treatments.
Medium term (6–24 months)

9.10 To ensure that treatment is provided in a safe manner the 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.
Short term (0–6 months)

9.11 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.
Short term (0–6 months)

9.12 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.
Short term (0–6 months)

9.13 Specifically, 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 *Clostridium difficile* should be completed.
Short term (0–6 months)

9.14 A clear definition of the involvement 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.
Short term (0–6 months)

9.15 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.
Medium term (6–24 months)

9.16 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 flows of information in each direction.
Medium term (6–24 months)

Succession planning

9.17 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.
Immediate (0-3months)

9.18 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.
Short term (0–6 months)

9.19 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 a research framework.

9.20 We recommend that 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 multidisciplinary working. Clinicians working in such an environment will safeguard care of patients by peer review, good teamwork and integration with Trust governance processes.
Medium term (6–24 months)

9.21 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.
Short term (0–6 months)

9.22 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.
Short term (0–6 months)

Professor Malone-Lee and UCL

9.23 Support must be offered to Professor Malone-Lee during what will likely to be a very difficult and stressful period of time for him personally prior to his retirement.
Immediate (0-3months)

9.24 UCL should be urgently reminded of their employer responsibilities regarding provision of this clinic that is entirely focused around one individual they employ who has an honorary contract with the Trust.
Immediate (0-3months)

9.25 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 Whittington to plan the future of the service.
Immediate (0-3months)

9.26 UCL should state its intentions regarding carrying out further research in the field of the lower urinary tract infection and The Whittington should discuss with them what its intentions are for the future delivery of the clinic, including the acceptance of new patients.
Medium term (6–24 months)

Private practice

9.27 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 ensure any future private practice arrangements are safe.
Short term (0–6 months)

Responsibilities of the Trust in relation to these recommendations

This report has been prepared by The Royal College of Physicians for submission to The Whittington Hospital NHS Trust. It is an advisory document and it is for the Trust concerned to consider any conclusions and recommendations reached and to determine subsequent action.

It is also the responsibility of the Trust to review the content of this report and in the light of these contents take any action that is considers appropriate to protect patient safety and ensure that patients have received communication in line with the responsibilities set out in the Health and Social Care Act 2008 (Regulated activities) Regulations 2014, Regulation 20.[4]

[4] The Health and Social Care Act 2008 (Regulated Activities) Regulations, 2014: http://www.legislation.gov.uk/uksi/2014/2936/contents/made

10.0 References

1) The Characteristics of an Effective Multidisciplinary Team (MDT) http://www.nhsiq.nhs.uk/media/2444560/ncatmdtcharacteristics.pdf (particularly relevant are sections on governance, logistics and support)
2) Ten principles of good interdisciplinary team work http://www.human-resources-health.com/content/11/1/19

11.0 Documents received and reviewed

1. Organisational structure chart – Whittington Health (April 2016
2. Professor Malone-Lee's latest agreed job plan
3. Professor Malone-Lee's Whittington appraisal completed 12 February 2013
4. Professor Malone-Lee's Whittington appraisal completed 12 November 2013
5. Professor Malone-Lee's Whittington appraisal completed 10 February 2015
6. Professor Malone-Lee's UCL appraisal completed 2011
7. Professor Malone-Lee's patient and colleague feedback
8. Professor Malone-Lee's CPD certificate for 2014/15 and for the latest five year cycle

8a. Professor Malone-Lee's safeguarding mandatory training and highlighted concerns regarding safeguarding training

8b. Example of 20 paediatric case notes

9. Protocol for management of patients with chronic lower urinary tract symptom with clinical evidence of urinary tract infection – Whittington Lower Urinary Tract Symptoms Clinic (updated November 2014)

9a. Notes of the Joint Antimicrobial Steering Group (ASG) and Drug & Therapeutics Committee (D&TC) meeting on the 4 August 2015

10. Strategic and business plans for the LUTS clinic and the division of medicine

11a. Clinical Audit Policy (October 2013)

11b. Risk Management Strategy (October 2015-2018)

12. Minutes of trust's Serious Incident Executive Advisory Group (SIEAG) meeting on 27 November 2015

12a. Notes of LUTS meetings held during the suspension of the clinic 21 October – 23 November 2015.

13. Screenshots of Artemis system

14a-f. Anonymised examples of clinical letters to patients taken from the Artemis system (14b not provided)

15. Patient information sheet – LUTS clinic *The treatment of lower urinary tract symptoms in Professor Malone-Lee's centre* (January 2016)

16. Safety comments for the use of azithromycin, ciprofloxacin and other quinolones, co-amoxiclav, and nitrofurantoin (5 March 2016)

17. UCL academic research report

- James Malone-Lee research report – commissioned by UCL (15 January 2016)
- Bishara et al. *Can urodynamics distinguish between urethral strictures and Benign Prostatic Hyperplasia (BPH)?* Journal of Clinical Urology (2015, Vol 8(4) 274-278)
- Gill et al. *Urinary ATP as an indicator of infection and inflammation of the urinary tract in patients with lower urinary tract symptoms.* BMC Urology (2015; 15:7)
- Kelley et al. *Urinary ATP and visualization of intracellular bacteria: a superior diagnostic marker for recurrent UTI in renal transplant recipients?* SpringerPlus (2014; 3:2000)

- Labbaf et al. *An encapsulated drug delivery system for recalcitrant urinary tract infection.* Journal of the Royal Society Interface (28 October 2015)
- Horsley et al. *Enterococcus faecalis Subverts and Invades the Host Urothelium in Patients with Chronic Urinary Tract Infection.* PLOS ONE (December 2013, vol 8, issue 12)
- Khasriya et al. *Spectrum of Bacterial Colonization Associated with Urothelial Cells from Patients with Chronic Lower Urinary Tract Symptoms.* Journal of Clinical Microbiology (July 2013, vol 51, p. 2054-2062)
- Kupelian et al. *Discrediting microscopic pyuria and leucocyte esterase as diagnostic surrogates for infection in patients with lower urinary tract symptoms: Results from a clinical and laboratory evaluation.* BJU International (112, 231-238)
- Swamy et al. *Lengthy antibiotic treatment to resolve recalcitrant oab*[5] (619)
- Dacheva et al. *The problems affecting the diagnosis of urinary tract infection.* Aging Health (2012, 8(5), 537-545)
- Khasriya et al. *The Inadequacy of Urinary Dipstick and Microscopy as Surrogate Markers of Urinary Tract Infection in Urological Outpatients With Lower Urinary Tract Symptoms Without Acute Frequency and Dysuria.* Journal of Urology (Vol. 183, 1843-1847, May 2010)

18. Research and development permissions for the LUTS service
19.1 Chronology of issues – LUTS clinic
19.2 Email correspondence from 2014 – meeting to discuss antibiotic prescribing for chronic LUTS
19.3 Email correspondence regarding Professor James Malone-Lee prescription Pip/taz
19.4 Suspension of the clinic
19.5 Joint Health Overview and Scrutiny Committee – Addendum Deputation Statement (27 November 2015)
20. Telephone conversation with Richard Jennings (Medical Director) and the daughter of a former clinic patient (now deceased) regarding concerns about the patient's medication (22 January 2016)
21. Concern raised by patient regarding continuing prescription issued by the LUTS service (23 March 2016)
22. Complaints from private patients of Professor Malone-Lee's being unable to access NHS treatment following the restriction on new referrals (March 2016)
23. Serious Incident StEIS reference 2015.33773
24. Claim reference Lt 11/11, Datix ID 210
24a Prescribing report relating to patient involved in serious incident reference 2015.33773
25. Linked datix incidents reports
25a. Proposed process for the review of datix incidents submitted by the clinic between 22 February 2016 and 8 March 2016
25b. Consultation on the proposed process for the review of datix incidents submitted by the clinic between 22 February 2016 and 8 March 2016
26. Letters of support from patients or relatives/carers of patients of the clinic
27 and 27b Letters of support from other professionals
28. Submission from patient representatives for RCP review
29. Patient and Public Engagement Strategy, toolkit and action plan (July 2014)
29a. Transcript of the public meeting held on 12 November 2015 for LUTS patients, carers and relatives
29b. Trust response to the consultation with patients on the terms of reference for the RCP invited service review
30. LUTS clinic activity analysis
31. HSMR data for urinary tract infections within Urology

[5] overactive bladder symptoms (OAB).

31a. Information relating to *Clostridium difficile*-associated diarrhoea
32. Information relating to pulmonary fibrosis, including 13 cases of patients.
32a. Hospital admissions during the 5 week period of the LUTS clinic suspension (21 October 2015 – 23 November 2015)
33. LUTS MDT meeting minutes and terms of reference
34. Centrally recorded audit 'Clinical Audit of Fresh Urine Microscopy'
34b. Additional audits completed by LUTS service not registered with the central clinical governance team
35. Details of quality improvement initiatives
36. Dr Sheela Swamy, Clinical research fellow and PhD students educational and appraisal documentation
37. Dr Dhanuson Dharmasena, Clinical research fellow and PhD student educational and appraisal documentation

Additional information provided by Professor James Malone-Lee

38. *The Role of Antibiotics in the Treatment of Chronic, Recalcitrant Lower Urinary Tract Symptoms* – a paper for the RCP external review. Sheela Swamy, Maria De Lorio, William Barcella, Kiren Gill, Anthony Kupelian, Rajvinder Khasriya, James Malone-Lee (Division of Medicine UCL and the Department of Statistics UCL, 6 March 2016)
39. Complaints following LUTS clinic closure (October 2015-April 2016)
40. Database, Protocols, Consent Forms and Patient Information Sheets
41. The criticisms of the LUTS clinic
42. Abstracts
43. Review articles and peer review papers
44. Summary of the evidence for the Lower Urinary Tract Service
45. Compliments, support letters and biographies (Patients)
46. LUTS clinic audits and surveys
47. UCL Academic review (15 January 2016)
48. Affidavits from colleagues
49. Case review for RCP review of the LUTS service
50. The story of the LUTS clinic
51. Case history for RCP review
52. Clinical paper on treatment methods LUTS clinic
53. Clinical evidence summary for RCP review

Information received from the patient support group

54. Patient evidence and patient submission

Additional information provided by Professor James Malone-Lee

55. *The Role of Antibiotics in the Treatment of Chronic, Recalcitrant Lower Urinary Tract Symptoms* – a paper for the RCP external review. Sheela Swamy, Maria De Lorio, William Barcella, Kiren Gill, Anthony Kupelian, Rajvinder Khasriya, James Malone-Lee (Division of Medicine UCL and the Department of Statistics UCL, 6 March 2016)
56. Complaints following LUTS clinic closure (October 2015-April 2016)
57. Database, Protocols, Consent Forms and Patient Information Sheets
58. The criticisms of the LUTS clinic
59. Abstracts
60. Review articles and peer review papers
61. Summary of the evidence for the Lower Urinary Tract Service
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63. LUTS clinic audits and surveys
64. UCL Academic review (15 January 2016)

65. Affidavits from colleagues
66. Case review for RCP review of the LUTS service
67. The story of the LUTS clinic
68. Case history for RCP review
69. Clinical paper on treatment methods LUTS clinic
70. Clinical evidence summary for RCP review

12.0 Appendix

12.1 Figure 1

Side Effect	Frequency	Percent
Intolerant	155	32.6
Rash	43	9.1
Diarrhoea	42	8.8
Intolerant	40	8.4
Joint pain	39	8.2
Short of breath	39	8.2
Nausea	33	6.9
Liver	28	5.9
Headache	17	3.6
Itch	13	2.7
Cough	11	2.3
Constipation	5	1.1
Allergic	4	.8
Vomiting	4	.8
Paraesthesia	2	.4
Total	**475**	**100.0**

12.2 Letter to trust with immediate feedback 19 May 2016

Dr Richard Jennings
Medical Director
Whittington Hospital NHS Trust

BY EMAIL ONLY

19 May 2016

Dear Dr Jennings,

I am writing to you to confirm the immediate feedback that I provided to you on Friday 6 May 2016, the final day of the invited review of the Trust's Lower Urinary Tract Symptoms (LUTS) Service.

I would note that this discussion represented the invited review team's immediate feedback at the conclusion of the interviews held and was based on the information that was available to the reviewers at that time. It should be recognised that at that stage there had been limited time to consider in detail all the extensive information gathered.

The review team's immediate feedback broadly based on the eight agreed terms of reference was as follows:

- Many of the problems we identified go back a long time and are part of the inherent fragility of the service which is unduly dependent on one individual, Professor Malone-Lee.

- Those patients who have chosen to provide their view to us have been very supportive of the clinic and the benefits they feel they have received from the treatment the clinic has provided. Many feel that the clinic has transformed their lives. Patient accounts to us were that they have received detailed information from the clinic about their treatment and the risks associated with it. In many cases there is good individual scrutiny of care in such a personalised service. However, having looked at the information given we think benefits are well described, but that risks and adverse effects are not given sufficient emphasis with the use of so many medicines outside the terms of their licences.

- The clinical governance arrangements for the clinic are of serious concern as there is not robust evidence of the efficacy of the treatments provided, patient outcomes, or comprehensive data on the complications patients have experienced. We have heard a number of anecdotes of safety issues, including the serious untoward incident (SUI), which triggered the review. It is not possible to be sure that all such issues have been recorded as the clinic has operated entirely separately from the Trust's governance structure for some time. Recently the Trust has taken a more active role, and begun investigating some safety issues but it has not allocated the necessary resources to investigate these issues expediently eg the SUI investigation is still incomplete. The information we received suggests the division lacks the resources to undertake this work. Independent corporate resource in terms of capacity and capability is required to rapidly review safety matters eg true incidence of *Clostridium difficile*. Also of concern were the

arrangements for urine microscopy in the clinic that would not satisfy UKAS accreditation with potential risk to the Trust's overall microbiology service accreditation.

- The clinic's patients' receive individual treatment plans but there does not appear to be a recorded standard protocol setting out the range of antibiotic treatments that are being used, or the indication for each antibiotic or combination of antibiotics. There is also a lack of evidence of the clinic having completed audits of patient outcomes or of patient consent. It was also concerning that the record keeping system that the clinic uses had for a long time been separate from the Trust's electronic patient record. It is a positive development that Trust staff can now access this database.

- There did not appear to be clear definition of which aspects of the LUTS clinic are research-related and those that are clinical practice. The great majority of the research that has been published relates to the diagnostic aspects of the service rather than the effectiveness and safety of the antibiotic treatment regimens used in the clinic. This is not clear to all patients. We have also not seen evidence of robust oversight on the part of University College London (UCL) of the research being undertaken, use of research data in individual patients to make individual treatment decisions, and how the research findings published by Professor Malone-Lee have been translated in to clinical practice in the LUTS clinic. Given that many of the treatments utilised are not those recommended by guidelines and/or fall outside the licensed use, we consider UCL as employer of Professor Malone-Lee should have been involved with the Trust in reviewing this practice. It was extremely disappointing that the review team was not able to meet with a member of UCL, Professor Malone-Lee's employer, who could speak to this issue.

- The LUTS clinic is very much led by Professor Malone-Lee and there appeared to be little independent practice undertaken by the other doctors. There also appeared to be a low level of nurse involvement. The clinic is therefore very fragile given that it relies so heavily on the input of one senior clinician, who the review team heard was retiring in September 2016. Virtual technology is used extensively to provide a further mechanism for oversight of the clinic; however when things become an emergency the clinic does not integrate well with the rest of the NHS.

- The LUTS clinic is geographically very isolated within the Trust and there appears to have been very little clinical scrutiny or supportive challenge from the Trust senior management team, until very recently. We met a number of staff who had poor working relationships with the service and some staff who were distressed by this. In response to the recent SUI the Trust has introduced a multi-disciplinary team (MDT) meeting to discuss some of the clinic's patients. This MDT has only met on four occasions and the meetings are therefore still being developed. There was varying feedback from attendees of this meeting as to how effective they were, and there was little evidence that the MDT was significantly influencing the treatment regimens being used.

- Commissioners we met locally have responsibility for about a third of all patients attending the clinic. While they were positive about the Trust as a whole, significant numbers of general

practitioners had concerns about the prescribing from the clinic and the safety of the treatment regimens used.

- It was very clear to the review that the Trust has a responsibility to ensure the patients already under the care of the LUTS clinic continue to receive care and support.

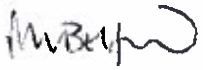
- The review team had genuine concern for the welfare of Professor Malone-Lee who is a thoughtful, caring doctor but is extremely stretched and concerned about his imminent retirement and the future of the service. His employer UCL needs to take a key role in supporting him.

- To this end the review team made the following recommendations for the Trust to act upon in the immediate future while the RCP's invited service review report is being prepared:

    - The Trust should continue to provide access to the LUTS clinic for those patients already registered with it. It may be appropriate for some patients to 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.
    - To ensure that this is done in a safe manner the Trust should put in place robust clinical governance processes to monitor the safety of prescribed treatment regimens and outcomes for these patients. The Trust will need to resource these measures appropriately.
    - 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.
    - A succession plan should urgently be developed in direct dialogue between the Trust, Professor Malone-Lee and patient representatives. This should include direct high-level dialogue with neighbouring tertiary centres.
    - UCL should be urgently reminded of their employer responsibilities regarding provision of this clinic that is entirely focused around one individual they employ who has an honorary contract with the Trust.
    - Until such time as a succession plan can be put in place no new patients should be accepted in to the LUTS clinic.
    - We recommend that the existing restriction for current paediatric patients should remain with oversight being provided by the external consultant.
    - The LUTS MDT should be further developed with additional resources committed to it as required.
    - The Trust should consider where the clinic should be housed in the near future. It may be beneficial to seek to locate it within the Trust's hospital premises so that it can be overseen more directly.
    - In considering all of this the Trust should ensure that the clinic's patients are consulted.

I hope this letter is clear and helpful in summarising the review team's immediate feedback on these matters at the conclusion of the review visit. The team will now work to prepare and finalise the invited service review report, which will be sent to you as soon as possible.

Yours sincerely,



Dr Peter Belfield
Medical Director of Invited Service Reviews

cc. Mr Simon Pleydell, chief executive officer

12.3 Letter to trust with outlining potential patient safety concern. Dated 9 August 2016

Dr Richard Jennings
Medical Director
Whittington Hospital NHS Trust

BY EMAIL ONLY

9 August 2016

Dear Dr Jennings,

I am writing to you further to our letter dated 19 May 2016 which set out the review team's immediate feedback to you on the final day of the invited review of the Trust's Lower Urinary Tract Symptoms (LUTS) Service.

Since this time, the review team and I have been working to bring together and triangulate all of the information provided to us during the course of the interviews and from the substantial documentation provided by the Trust, the LUTS clinic and the patient group. The review team received much of this documentation just before and during our visit.

As you know, the report draft is now at an advanced stage and will shortly be going through our quality assurance process. However, we are writing to you now because during the process of reconsidering the information provided to us, a potential patient safety concern about the use of nitrofurantoin has been identified that we did not emphasise in our letter of 19 May 2016. Given the potential serious nature of this, we considered it was important to draw this to your attention for further investigation and prior to the issue of the final report.

In a document entitled *Appendix 32 – pulmonary fibrosis* (copy enclosed for your reference), it was noted that the Trust in 2016 undertook a review of its patient record systems and identified 13 patients who had previously been seen at the LUTS clinic and who had also received a diagnosis of pulmonary fibrosis at The Whittington. Of these 13 patients, three were noted to have received this diagnosis prior to, or shortly after, their first LUTS clinic attendance. We also had access to redacted clinic letters (also called Appendix 32) of these patients. This informatics review also highlighted a potential discussion with you and a family member about a patient who had attended the clinic and who had died with a potential diagnosis of pulmonary fibrosis.

The review team were of the view that this is a relatively high rate of incidence of pulmonary fibrosis amongst this group of patients. This was especially pertinent given that the Trust's review of this issue to date has only considered those patients who were diagnosed with pulmonary fibrosis at The Whittington and did not consider those patients who may have been diagnosed with pulmonary fibrosis at another healthcare organisation.

We note that, at the time of the review, Professor Malone Lee stated that he had reduced his use of nitrofurantoin in recent years.

Therefore, it is our recommendation that the Trust now take steps to ensure that all instances where LUTS patients were known to have been diagnosed with pulmonary fibrosis at The Whittington are fully investigated and reviewed. An independent chest physician with managerial support may be appropriate to undertake this work.

In addition, the Trust should undertake a programme of work to establish if there are any patients of the LUTS clinic who may have had a diagnosis of pulmonary fibrosis at another healthcare organisation. In terms of the non-local patients there is a case to follow up those patients prescribed nitrofurantoin for more than 2 weeks and through contacting their GP to establish whether any had a diagnosis of pulmonary fibrosis. We would consider that this process would need the expertise and involvement of an external group of people with skills and experience in patient safety and/or pharmacovigilance. We appreciate that there are some obvious challenges and difficulties in how this is undertaken.

Given the circumstances, we consider it would be appropriate for the Trust to also notify the two local CCGs and the local GP practices highlighting the potential concern relating to the possibility of the pulmonary fibrosis.

We would be grateful if you could confirm receipt of this letter and to provide us with confirmation of the actions the Trust intends to take to address this issue. Clearly the findings of such work would inform subsequent action to be taken by the Trust.

Yours sincerely,

Dr Peter Belfield
Medical Director of Invited Service Reviews

cc. Mr Simon Pleydell, chief executive officer

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The Whittington Hospital NHS Trust
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Whittington Health

November 2016

Title:	Serious Incidents – Month 6 Update Report		
Agenda item:	**16/146**	**Paper**	**04**
Action requested:	For Information		
Executive Summary:	This report provides an overview of serious incidents (SI) submitted externally via StEIS (Strategic Executive Information System) as of the end of September 2016. This includes SI reports completed during this timescale in addition to recommendations made, lessons learnt and learning shared following root cause analysis.		
Summary of recommendations:	None		
Fit with WH strategy:	1. Integrated care 2. Efficient and Effective care 3. Culture of Innovation and Improvement		
Reference to related / other documents:	• Supporting evidence towards CQC fundamental standards (12) (13) (17) (20). • Ensuring that health service bodies are open and transparent with the relevant person/s. • NHS England National Framework for Reporting and Learning from Serious Incidents Requiring Investigation, • Whittington Health Serious Incident Policy. • Health and Safety Executive RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013).		
Reference to areas of risk and corporate risks on the Board Assurance Framework:	**Corporate Risk 636.** Create a robust SI learning process across the Trust. Trust Intranet page has been updated with key learning points following recent SIs and RCA investigations.		
Date paper completed:	24/10/2016		

Author name and title:		**Jayne Osborne, Quality Assurance Officer and SI Co-ordinator**		**Director name and title:**		**Philippa Davies, Director of Nursing and Patient Experience**	
Date paper seen by EC		**Equality Impact Assessment complete?**	**n/a**	**Risk assessment undertaken?**	**n/a**	**Legal advice received?**	**n/a**

Serious Incidents Monthly Report

1. Introduction

This report provides an overview of serious incidents submitted externally via StEIS (Strategic Executive Information System) as of the end of September 2016.

The management of Serious Incident's (SIs) includes not only identification, reporting and investigation of each incident but also examples of recommendations following investigation and dissemination of learning to prevent recurrences.

2. Background

The Serious Incident Executive Approval Group (SIEAG) comprising the Executive Medical Director/Associate Medical Director, Director of Nursing and Patient Experience, Chief Operating Officer, the Head of Integrated Risk Management and SI Coordinator meet weekly to review Serious Incident investigation reports. In addition, high risk incidents are reviewed by the panel to ascertain whether these meet the reporting threshold of a serious incident (as described within the NHSE Serious Incident Framework (March 2015).

3. Serious Incidents

3.1 The Trust declared 6 serious incidents during September bringing the total of reportable serious incidents to 25 since 1st April 2016.

Following completion of level 2 comprehensive Root Cause Analysis (RCAs), the Trust has requested de-escalation of two Serious Incidents. In these two cases RCA investigations have not identified contributory care and service delivery problems:

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The Trust declared a Never Event in September for Maternity Services: retention of a foreign object (swab) following forceps delivery and tear repair. This incident is currently under investigation. The Trust has no overdue SI investigations.

All serious incidents are reported to North East London Commissioning Support Unit (NEL CSU) via StEIS and a lead investigator is assigned to each by the Clinical Director of the relevant Integrated Clinical Support Unit.

All serious incidents are uploaded to the NRLS (National Reporting and Learning Service) in line with national guidance and CQC statutory notification requirements.

3.2 **The table below details the Serious Incidents currently under investigation**

Category	Month Declared	Summary
Safeguarding Incident Ref:13782	May 16	Safeguarding incident in relation to a patient on a current caseload.
Unexpected Admission to NICU- Baby Ref: 17074	June 16	Admission of term baby to the neonatal unit following a category 1 emergency caesarean section.
Safe Guarding Incident Ref: 21646	Aug 16	Safeguarding allegation in relation to an inpatient.
Information Governance Breach Ref: 21713	Aug 16	Confidential information contained on a clinic handover sheet was recovered by a member of Trust staff .

Never Event.- Retained foreign object post-procedure Ref: 22867	Aug 16	Retention of a foreign object (swab) following forceps delivery and tear repair.
Intrauterine Death Ref: 23372	Sept 16	Intrauterine death at 32 weeks diagnosed by ultrasound scan.
Information Governance Breach Ref: 23932	Sept 16	A patient list was found off hospital grounds by another staff member.
Intrauterine Death Ref: 23903	Sept 16	Intrauterine death at 38+1 weeks diagnosed by ultrasound scan.
Unexpected death Ref: 25397	Sept 16	Unexpected death of patient with bilateral pulmonary embolism.
Delayed Diagnosis Ref: 25413	Sept 16	A delayed ultrasound scan resulting in delayed diagnosis of an active bleed.
Retained PICC Line. Ref: 25401	Sept 16	Patient discharged with a PICC line in situ.

The table below details serious incidents by category reported to the NEL CSU. The Trust reported 6 serious incidents during September 2016.

STEIS 2016-17 Category	Apr	May	June	July	Aug	Sept	Total
Safeguarding	0	1	1	0	1	0	3
Confidential information leak/loss/Information governance breach	1	2	1	0	1	1	6
Diagnostic Incident including delay	2	1	0	0	0	1	4
Failure to source a tier 4 bed for a child	0	0	0	1	0	0	1
Maternity/Obstetric incident mother and baby (includes foetus neonate/infant)	1	1	1	0	0	2	5
Maternity/Obstetric incident mother only	0	0	0	0	1	0	1
Slip/Trips/Falls	0	0	0	1	0	0	1
Unexpected death	0	1	0	1	0	1	3
Retained foreign object	0	0	0	0	0	1	1
Total	4	6	3	3	3	6	**25**

4. Submission of SI reports

All final investigation reports are reviewed at weekly SIEAG meeting chaired by an Executive Director (Trust Medical Director or Director of Nursing and Patient Experience) comprising membership from the Chief Operating Officer, Executive Operational Team and Integrated Risk Management. The Integrated Clinical Support Unit's (ICSU) Operational Directors or their deputies are required to attend each meeting when an investigation from their services is being presented.

The remit of this meeting is to scrutinise the investigation and its findings to ensure that contributory factors have been fully explored, root causes identified and that actions are aligned

with the recommendations. The panel discuss lessons learnt and appropriate action, both immediate if applicable, and planned, to prevent future harm occurances.

On completion of the report the patient and/or relevant family member receive a final outcome letter highlighting the key findings of the investigation, actions taken to improve services, what has been learnt and what steps are being put in place . A 'being open' meeting is offered in line with duty of candour recommendations.

The Trust has executed its duties under the Duty of Candour for the investigations completed and submitted during September 2016.

Lessons learnt following the investigation are shared with all staff and departments involved in the patient's care through various means including the 'Big 4' in theatres, 'message of the week' in Maternity, Obstetrics and other departments. Learning from identified incidents is also published on the Trust Intranet making them available to all staff.

4.1 **The Trust submitted 1 reports to NELCSU during September 2016.**

The table below provides a brief summary of lessons learnt and actions put in place relating to the serious incident investigation report submitted in September 2016.

Summary	Actions taken as result of lessons learnt
• **2016.17076 IG Breach**	**Confidential information inappropriately sent out in group email list**. • An information governance case seminar was held to inform staff of the seriousness of this IG Breach and to remind them of their responsibilities when sending emails and the safety aspects of sharing patient information.

5. Sharing Learning

In order to ensure learning is shared widely across the organisation, a dedicated site has been created on the Trust intranet detailing a range of patient safety case studies.

6. Summary

The Trust Board is asked to note the content of the above report which aims to provide assurance that the serious incident process is managed effectively and lessons learnt as a result of serious incident investigations are shared widely.

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Whittington Health Trust Board

2 November 2016

Title:	Safe Staffing - Nursing and Midwifery – September data		
Agenda item:	**16/147**	**Paper**	**05**
Action requested:	For information		
Executive Summary:	This paper summarises the safe staffing position for nursing and midwifery on our hospital wards in September 2016. Key issues to note include: 1. A reduced fill rate for Registered Nurses displayed in the UNIFY report 2. Increase in the use of special shifts required because of high numbers of vulnerable patients September (215) vs August (201) 3. Reduction in the number of Red Shifts reported in September (3) compared to August (10) 4. CHPPD measure during the month was reduced compared to last month Sept (8.84) compared to August (9.01) 5. The continued use of agency and bank staff to support safe staffing		
Summary of recommendations:	Trust Board members are asked to note the September UNIFY return position and processes in place to ensure safe staffing levels in the organisation. Unify is the online collection system used for collating, sharing and reporting NHS and social care data.		
Fit with WH strategy:	Efficient and effective care, Francis Report recommendations, Cummings recommendations and NICE recommendations.		
Reference to related / other documents:			
Reference to areas of risk and corporate risks on the Board Assurance Framework:	3.4 Staffing ratios versus good practice standards		
Date paper completed:	October 2016		

Author name and title:		**Dr Doug Charlton Deputy Director of Nursing& Patient Experience**		**Director name and title:**		**Philippa Davies – Director of Nursing and Patient Experience**	
Date paper seen by EC		**Equality Impact Assessment complete?**		**Risk assessment undertaken?**		**Legal advice received?**	

Ward Staffing Levels – Nursing and Midwifery

1.0 Purpose

1.1 To provide the Trust Board with assurance with regard to the management of safe nursing and midwifery staffing levels for the month of September 2016.

1.2 To provide context for the Trust Board on the UNIFY safe staffing submission for the month of September 2016.

1.3 To provide assurance of the constant review of nursing/midwifery resource using the newly implemented Health roster.

2.0 Background

2.1 Whittington Health is committed to ensuring that levels of nursing staff, which include Registered Nurses (RNs), Registered Midwives (RMs) and Health Care Assistants (HCAs), match the acuity and dependency needs of patients within clinical ward areas in the hospital. This includes an appropriate level of skill mix of nursing staff to provide safe and effective care.

2.2 Staffing levels are viewed alongside reported outcome measures, patient acuity, 'registered nurse to patient ratios', percentage skill mix, ratio of registered nurses to HCAs and the number of staff per shift required to provide safe and effective patient care.

2.3 The electronic HealthRoster (Allocate) with its 'SafeCare' module is utilised across all inpatient wards. The data extracted, provides information relating to the dependency and acuity of patients. This, in addition to professional judgement is used to manage ward staffing levels on a number of occasions on a daily basis.

2.4 Care Hours per Patient Day (CHPPD) is an additional parameter to manage the safe level of care provided to all inpatients. This measure uses patient count on each ward at midnight (23.59hrs). CHPPD is calculated using the actual hours worked (split by registered nurses/midwives and healthcare support workers) divided by the number of patients at midnight (for September data by ward please see Appendix 1).

2.3 Staff fill rate information appears on the NHS Choices website www.nhschoices.net. Fill rate data from 1st – 30th September 2016 for Whittington Hospital was uploaded and submitted on UNIFY, the online collection system used for collating, sharing and reporting NHS and social care data. Patients and the public are able to see how hospitals are performing on this indicator on the NHS Choices website.

2.4 Summary of Staffing Parameters

Standard	Measure	Summary
Patient safety is delivered though consistent, appropriate staffing levels for the service.	Unify RN fill rate	Day - 94.5% Night - 98%
	Care hours per Patient Day - CHPPD	Overall CHPPD was 8.84 for September and is lower than last month but the RN delivered care continues to be consistent
Staff are supported in their decision making by effective reporting.	% of Red triggered shifts	0.2% of shifts triggered red in September 2016 this was a decrease from that of August 2015 (0.7%)
	% of shifts that remained partially mitigated (Amber shifts)	68 shifts i.e. 5% of all shifts in month. This was a decrease on August's figure. These consisted of shifts mainly during the day distributed between early and late.

3.0 Fill rate indicator return

3.1 The 'actual' number of staffing hours planned is taken directly from our nurse roster system (Allocate). On occasions when there was a deficit in 'planned' hours versus 'actual' hours, and additional staff were required, staff were reallocated to ensure safe staffing levels across our organisation. Staff are also reallocated to ensure wards/areas are staffed to a safe ratio of permanent to temporary staff.

3.2 Appendix 1 details a summary of fill rates 'actual' versus 'planned'. The average fill rate was 94.5% for registered staff and 107.8% for care staff during the day and 98% for registered staff and 121.7% for care staff during the night.

3.3 Nine wards reported below 95% fill rates for qualified nurses. Eight wards had above 100% fill rate for unqualified nurses. Five wards had above 100% fill rate for qualified nurses.

3.4 The UNIFY report show some wards with unusual percentage fill rates; for example, Mercers ward at (HCA) 56.1%, and Coyle ward at HCA (74.3%). This is due to the managed process of ensuring all wards are staffed to a safe and effective level for the acuity of the patients and the availability of staff on different days. Where the percentages are low for Registered Nurses they are correspondingly high for Healthcare Assistants and vice versa. This is a professional decision which is taken by the Matron depending on the needs of the specific patient group.

3.5 Some wards (Montouchi, Mary Seacole South and Nightingale) have high levels of Healthcare Assistants. This is due to the recent introduction of European nurses waiting for their PIN numbers before they are allowed to work as registered nurses.

Day		Night	
Average fill rate registered Nurses /Midwives	Average fill rate Care Staff	Average fill rate registered Nurses/Midwives	Average fill rate Care Staff
94.5%	107.8%	98%	121.7%

4.0 Additional Staff (Specials 1:1)

4.1 When comparing September's total requirement for 1:1 'specials' with previous month, the figures demonstrate a decrease in the number of shifts required (Appendix 2). September saw 215 requests for 1:1 specials compared to 201 requests in August. The requests made for this level of care were to ensure the safe management of particularly vulnerable groups of patients.

4.2 The number of RMN 'specials' used to care for patients with a mental health condition was higher in September (46) compared to August (28). All requests for registered mental health nurses are validated by the Heads of Nursing and a clinical assessment made as to the therapeutic need. These requests may then be downgraded to provide an HCA rather than an RMN.

4.2 There continues to be a high level of need for specialling patients with mental health conditions and for managing patients who require constant supervision to prevent falls.

5.0 'Real Time' management of staffing levels to mitigate risk

5.1 Safe staffing levels are reviewed and managed three times daily. At the daily 08.30am bed meeting, the Director of Nursing/Deputy Director of Nursing in conjunction with matrons, site managers and other senior staff review all registered and unregistered workforce numbers by ward. Consideration is given to bed capacity and operational activity within the hospital which may impact on safe staffing. Actions are agreed to ensure all areas are made safe. Matrons and Heads of Nursing review staffing levels again at 13.00 and 17.00 to ensure levels remain safe.

5.2 Ward shifts are rated 'red' 'amber' or 'green' according to numbers of staff on duty, taking into account patient numbers, acuity and dependency.

- Green shifts are determined to be safe levels and would not require escalation as these constitute the levels expected through the agreed ward establishment.

- Amber shifts are determined to be at a minimum safe level and are managed in conjunction with patient dependency and acuity. The matron will be alerted, and take appropriate action. Staff will prioritise their work and adjust their workload through the shift accordingly, with a continual review of any changes to the acuity and dependency of patients.

- Red shifts are determined to be at an unsafe level. Mitigating actions will be taken, and documented, which may include the movement of staff from another ward and utilisation of supernumerary staff within the numbers or reducing the number of patients on the ward to match the staff availability.

5.3 Red Shifts

During September 3 shifts triggering red from of a total of 1395. When compared to August, this was a decrease. Staff were reallocated by Senior Nurses to ensure safe ward cover.

Month	% shifts triggering red in month	Actual number of red shifts
September	0.2	3
August 16	0.7	10
July 16	0.65	9

5.4 Wards triggering red shifts

5.5

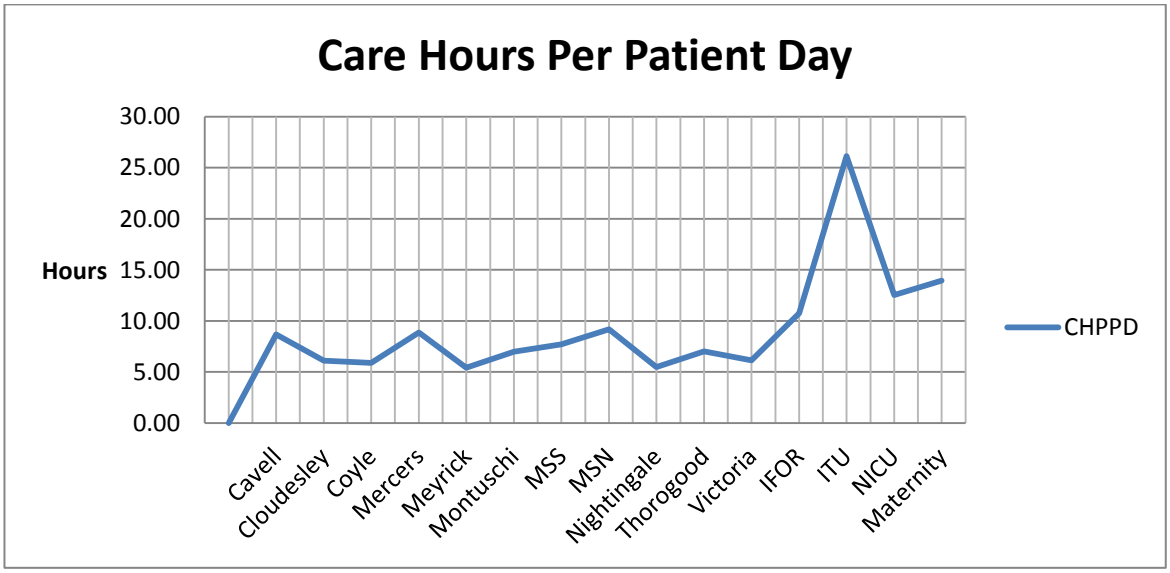
	Initial Red Shifts				
Wards	**Early**	**Late**	**Night**	**Number of shifts where staffing initially fell below agreed levels**	**% of shifts where staffing fell below agreed levels and triggered a red rating**
Mercers	0	0	1	1	**1.1**
Coyle	1	1	0	2	**2.2**

Summary of factors affecting red triggering shifts

a. Temporary staffing fill
b. Vacancy rate – Nurse Vacancy rate at ward level remains high and continues to impact on temporary staffing requirement.
c. 'Specialing' requirement
d. Additional beds opened to increase bed base capacity

6.0 Care Hours per Patient Day (CHPPD)

6.1 Care hours per patient day is calculated using the patient count on each ward at midnight (23.59hrs). CHPPD is calculated taking the actual hours worked (split by registered nurses/midwives and healthcare support workers) divided by the number of patients at midnight. The graph below shows the average individual care hours per patient for each clinical area. ITU have the most care hours (26.12) and Meyrick ward have the least (5.41).



6.2 The average number of hours of Registered Nurse time spent with patients was calculated at 6.65 hours and 2.19 hours for care staff. This provides an overall average of 8.84 hours of care per patient day.

	CHPPD
Registered Nurse	6.65
Care Staff	2.19
Overall hours	8.84

6.3 The total care hours per patient day is one of the metrics used on a daily basis by the Senior Nursing Team to monitor the level of nursing man hours required to delivery care on our inpatient wards.

6.4 The new SaferCare module of the Healthroster system provides an estimate of the total time required to provide the necessary care using the acuity and dependency of patients and calculates the available nursing time.

6.5 The early data from CHPPD indicates the total amount of care hours delivered to patients over the last four months has remained similar. Each ward maintained a high level of care delivery when comparing the total registered nurses hours available.

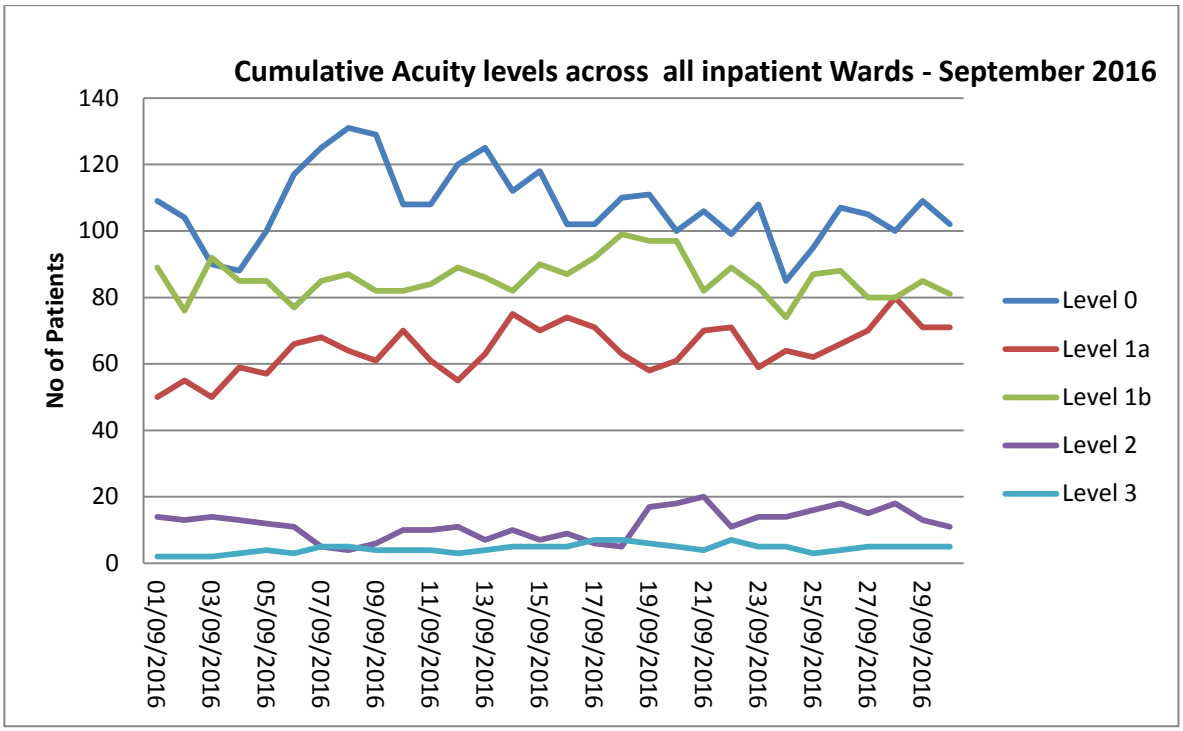
6.6 The table below shows the CHPPD hours for each in patient ward over the last four months and indicates the level of need remained stable overall. There is a slight decrease in hours of care delivered in September compared to August.

Ward Name	Sept	Aug	July	June	May
Bridges	8.66	7.74	closed	8.39	6.78
Cavell	closed	closed	7.78	6.48	8.10
Cloudesley	6.10	6.14	5.85	5.51	5.37
Coyle	5.88	5.88	6.46	7.43	7.01
Mercers	8.86	6.98	7.55	7.77	7.57
Meyrick	5.41	5.46	5.55	5.97	5.99
Montuschi	6.99	6.23	6.52	6.42	6.74
MSS	7.72	8.34	7.90	8.72	8.00
MSN	9.17	10.04	9.91	9.75	8.39
Nightingale	5.47	5.81	5.50	5.96	5.71
Thorogood	4.28	9.08	9.38	7.57	8.83
Victoria	6.15	6.56	6.14	6.41	6.27
IFOR	10.74	12.76	10.02	12.87	10.55
ITU	26.12	24.95	25.15	25.81	23.79
NICU	12.53	10.33	10.69	11.35	11.93
Maternity	13.95	16.19	11.73	13.73	13.47
Total	8.84	9.01	8.52	8.97	8.68

7.0 Patient Acuity

7.1 The acuity of patients is dependent on their care requirements. Those patients requiring a low level of care are assigned level 0 and those requiring intensive care are assigned level 3. The trust is experiencing a high number of patients with levels of acuity at level 1b. This level indicates a patient is requiring a high level of nursing support. Many patients required total support with their activities of daily living which would include washing, toileting and feeding. These patients require two staff to care for their daily needs.

7.2 The graph below demonstrates the level of acuity across inpatient wards in September. As expected, there are a low number of level 3 patients and a high number of level 0 patients. The number of level 1b patients remains high. This increased number of dependant patients requires a greater nursing support.



8.0 Temporary Staff Utilisation

8.1 Temporary staff utilisation (nursing and midwifery) is monitored daily by the Deputy Director of Nursing. All requests for temporary staff (agency) are reviewed by the Head of Nursing/Midwifery. A further review and final authorisation is then made by the Deputy Director of Nursing.

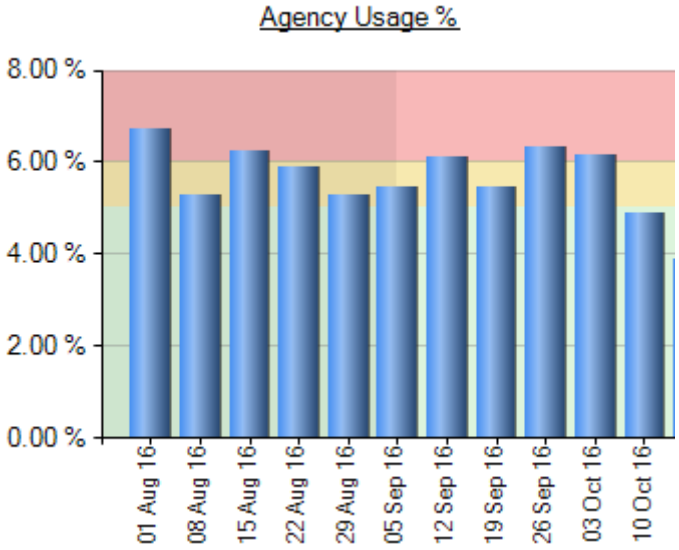
8.2 Monitoring the request for temporary staff in this way serves two purposes:

a) The system in place allows for the most appropriate use of high cost temporary agency staff across the organisation and provides a positive challenge mechanism for all requests.

b) The process allows for an overview of the total number of temporary staff (agency) used in different clinical ward areas and provides a monitoring mechanism for the delivery of safe quality care.

9.0 Agency Usage Inpatient Wards (September to date)

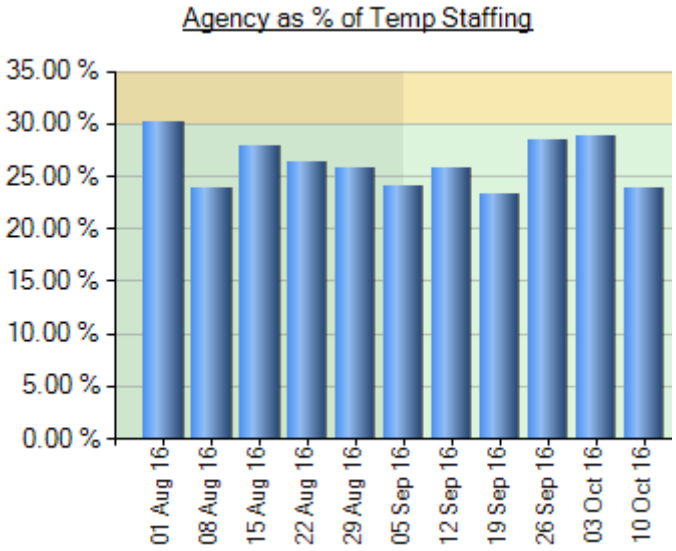
9.1 The utilisation of agency staff across all inpatient wards is monitored using the Healthroster system. The bar chart below graphically represents total usage of agency staff on inpatient wards September to date (this is cumulative data captured from roster performance reports).



9.2 A key performance indicator (KPI) of less than 6% agency usage was set to coincide with the NHS England agency cap. September data demonstrates a positive position in the second and subsequent weeks of September.

9.3 Temporary staff usage across the inpatient wards fluctuates depending on nurse vacancies and the need to provide additional support for 1:1 care or additional beds.

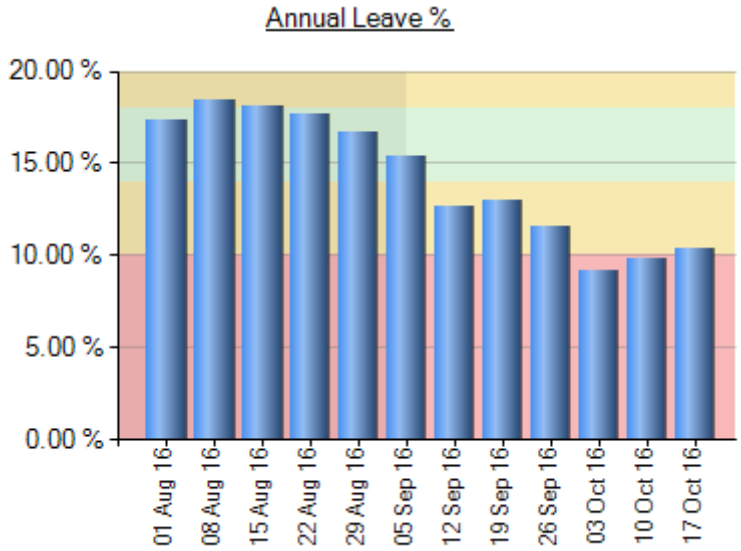
9.4 Temporary staffing usage (Bank and Agency) across inpatients wards remains high and fluctuates between 20 – 24%. Recruitment to reduce the current vacant posts is ongoing.



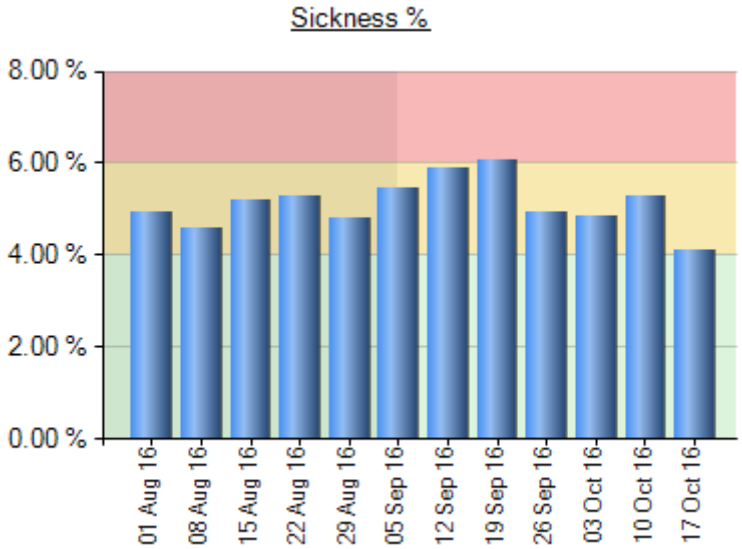
10.0 Managing Staff Resource

10.1 Annual leave taken from September to date is below the set tolerance of 15 -17%. This tolerance level ensures all staff is allocated leave appropriately and ensures an even distribution of staff are available throughout the year.

10.2 Heads of Nursing are aware of the need to remind staff to request and take holiday. This will monitor this closely over the next couple of months to ensure sufficient staff take annual leave in a more consistent way.



10.3 Sick leave reported in September was above the set parameter of less than 4%. Heads of Nursing ensure all individuals reporting back from sick leave undergo a sickness review. The data for sickness also includes staff seen by Occupational Health, who are on a 'phased return' programme following a period of sickness.



11.0 Conclusion

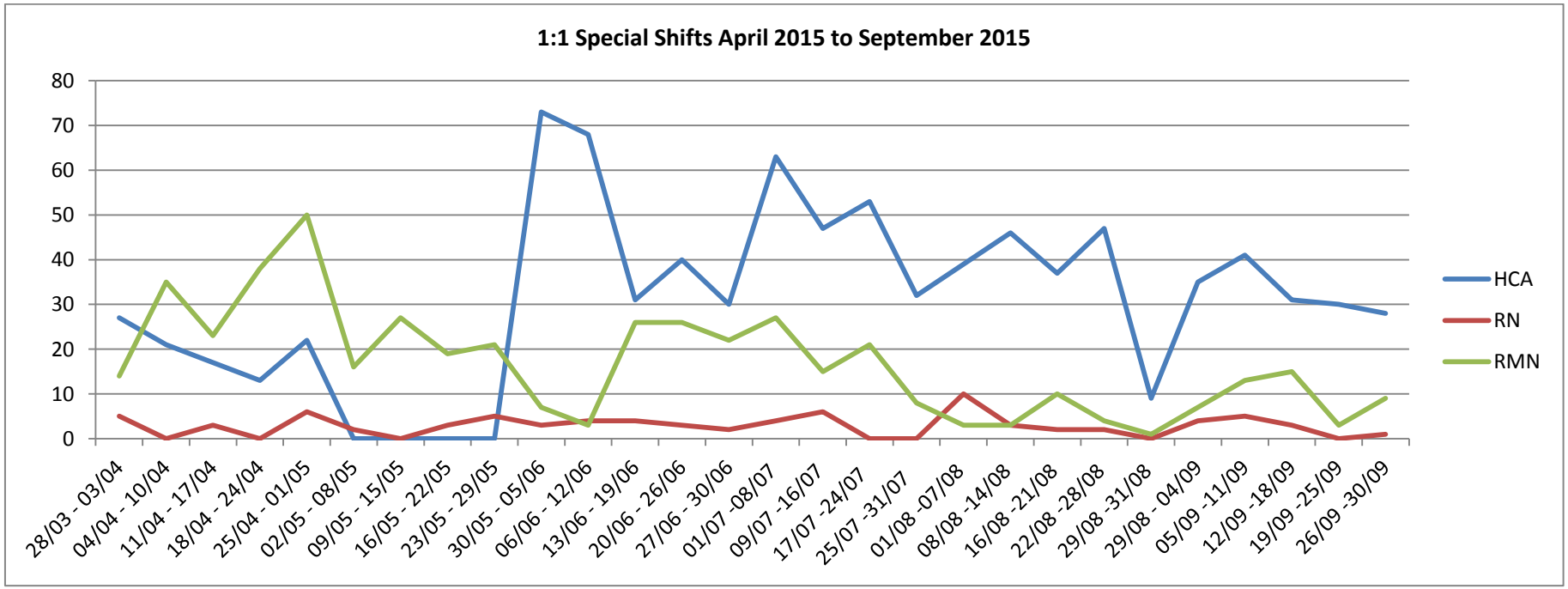
11.1 Trust Board members are asked to note the work currently being undertaken to proactively manage the nursing/midwifery resource across the ICO and the September UNIFY return position.

Fill rate data - summary
September 2016

Day				**Night**				**Average fill rate data- Day**		**Average fill rate data- Night**	
Registered nurses/ midwives		Care staff		Registered nurses/ midwives		Care staff		Registered nurses/ midwives	Care staff	Registered nurses/ midwives	Care staff
Planned (hrs)	Actual (hrs)	Planned (hrs)	Actual (hrs)	Planned (hrs)	Actual (hrs)	Planned (hrs)	Actual (hrs)				
32377	30603	9609	10358	26333	25815	6749	8213	94.5%	107.8%	98.0%	121.7%

Care Hours per Patient Day
September 2016

Total Patients at Midnight/Month	CHPPD Registered staff	CHPPD Unregistered staff	Average CHPPD (all staff)
8487	6.65	2.19	8.84


1:1 Special Shifts April 2015 to September 2015
80
70
60
50
40
30
20
10
0
28/03 - 03/04
04/04 - 10/04
11/04 - 17/04
18/04 - 24/04
25/04 - 01/05
02/05 - 08/05
09/05 - 15/05
16/05 - 22/05
23/05 - 29/05
30/05 - 05/06
06/06 - 12/06
13/06 - 19/06
20/06 - 26/06
27/06 - 30/06
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29/08 -31/08
29/08 - 04/09
05/09 -11/09
12/09 -18/09
19/09 -25/09
26/09 -30/09
HCA
RN
RMN

Average fill rate for Registered and Unregistered staff day and night

	Day		Night	
	Average fill rate RN & RM	Average fill rate Care Staff	Average fill rate RN & RM	Average fill rate Care Staff
Ward Name	%	%	%	%
Cavell	98.6%	89.4%	99.6%	121.3%
Cloudesley	91.3%	121.6%	114.8%	140.9%
Coyle	85.9%	74.3%	136.4%	105.7%
Mercers	117.6%	56.1%	156.6%	59.7%
Meyrick	94.3%	101.3%	98.1%	99.9%
Montuschi	98.6%	195.3%	101.4%	
MSS	90.3%	125.8%	91.7%	149.8%
MSN	84.8%	103.0%	100.5%	189.4%
Nightingale	77.0%	180.1%	75.1%	199.5%
Thorogood	97.4%	80.0%	97.8%	149.3%
Victoria	90.8%	123.7%	93.0%	121.1%
IFOR	92.8%	100.0%	94.0%	100.0%
ITU	100.0%		100.0%	
NICU	84.2%	100.0%	84.0%	
Maternity	102.2%	105.8%	94.1%	94.8%
Average	94.5%	107.8%	98.0%	121.7%

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The Whittington Hospital NHS Trust
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Trust Board

2 November 2016

Title:	Nursing & Midwifery Revalidation Update		
Agenda item:	**16/148**	Paper	**06**
Action requested:	To note contents and actions taken		
Executive Summary:	1. Revalidation of registered nurses and midwives (registrants) was mandated nationally from April 2016 by the Nursing and Midwifery Council (NMC). 2. Successful completion of the process required preparation, involvement and support for both individual registered nurses/midwives and their line managers. 3. Whittington Health is fully compliant with the implementation, monitoring and reporting requirements of revalidation with regard to staff who work in a substantive, temporary, voluntary and advisory capacity within the organisation.		
Summary of recommendations:	1. To receive the report for information regarding the new process of revalidation for our nurses and midwives 2. Note the work that is being undertaken locally to prepare nurse, midwives and managers, at Whittington Health, for revalidation.		
Fit with WH strategy:	Aligns with clinical and nursing/midwifery strategy		
Reference to related / other documents:	Compliant with CQC registration Trust governance framework		
Date paper completed:	October 2016		

Author name and title:		**Dr. Doug Charlton Deputy Director of Nursing**		**Director name and title:**		**Philippa Davies Director of nursing & Patient Experience**	
Date paper seen by EC		**Equality Impact Assessment completes?**		**Risk assessment undertaken?**		**Legal advice received?**	

1.0 Summary

1.1 This paper provides an update on revalidation with the Nursing and Midwifery Council (NMC) for registered nurses and midwives.

1.2 This paper focuses on National progress with revalidation and how Whittington Health (WH) is preparing its nurses, midwives and managers for revalidation.

2.0 Introduction

2.1 In October 2015 the Nursing and Midwifery Council (NMC) introduced revalidation for all registered nurse and midwives. Revalidation is the new process that all nurses and midwives in the UK will need to follow to renew their registration with the NMC every three years.

2.2 The purpose of revalidation is to strengthen the regulatory framework for nurses and midwives thereby improving public protection by ensuring nurses and midwives continue to be fit to practise safely and effectively throughout their career.

2.3 The first nurses and midwives to revalidate were those with a renewal date of 30 April 2016.

2.4 The NMC's requirements for revalidation are detailed below:

1. To practice a minimum of 450 hours over the three year period of registration
2. Undertake 35 hours of continuing professional development (CPD) of which 20 hours must be participatory
3. Obtain five pieces of practice related feedback
4. Record a minimum of five written reflections on the Code, CPD or practice related feedback
5. Provide a health and character declaration
6. Declare appropriate cover under an indemnity arrangement
7. Gain confirmation from a third party that revalidation requirements have been met.

3.0 National Progress with revalidation

3.1 Following the launch of revalidation in October 2015, the NMC published a range of guidance and education materials to support nurses, midwives, their managers and employers. All nurses and midwives received a direct mailing to help them prepare for revalidation.

3.2 All NHS Trusts were asked to provide quarterly updates to the Trust Development Authority or Monitor regarding their project plan and readiness for revalidation.

3.3 The NMC recently reported the introduction of revalidation had been a major success, with the majority of nurses and midwives due to renew their registration revalidating successfully. A small number of applications have been granted an extension or are subject to additional checks by the NMC.

3.4 For quality assurance purposes, each year, the NMC will select a sample of nurses and midwives to provide further information about their revalidation application. This process is known as 'verification'.

4.0 Local progress with revalidation

4.1 The process for revalidation has been incorporated into the Trust's existing appraisal process. NMC guidance on revalidation has been added to the current Whittington Health appraisal documentation to alert nurses and midwives of the revalidation requirements.

4.2 In preparation for revalidation, nurses and midwives are asked about their revalidation date, and to produce two pieces of reflective evidence and two pieces of practice related feedback to discuss at their appraisal each year.

4.3 Whittington Health, as with many healthcare organisations, has a number of registered nurses in non-nursing roles, (where a nursing registration is not a pre-requisite). Staff wishing to maintain their NMC registration, who work within these roles, have been contacted and offered support with their revalidation.

4.4 The Trust provides a monthly revalidation notification report for Heads of Nursing/Midwifery, which provides details of staff who are due to revalidate in future months and those who have successfully revalidated.

4.5 To ensure revalidation is in the contract with external bank and agency providers the following actions will be undertaken:

- External agency providers have also provided the Trust with information about how they are supporting their staff with revalidation.

5.0 Communication Plan

5.1 Raising staff awareness has been, and continues to be achieved through the following:

- A professional letter is sent via e-mail to every registered nurse and midwife by the Deputy Director of Nursing inviting them to a training seminar at least three months before their identified revalidation date
- Advertisement of revalidation training events via the training calendar and electronic bulletins on the intranet.
- Posters and leaflets distributed to all the wards
- Revalidation section created on the Trust's Nursing and Midwifery webpages

5.2 Staff Engagement has been achieved through the following:

- Staff briefings have been delivered at the following existing forums ; Nursing & Midwifery Executive Meeting, Senior Nurse, Professional Forum, Specialist Nurse Forum, Matron and Ward Manager Meetings

5.3 Guidance has been provided through the following:

- A new revalidation section on the Trust's Nursing and Midwifery web-pages with specific links to all of the resources on the NMC website
- Distribution of NMC training materials advice and guidance to all staff attending the training seminars.

6.0 Training and Education

6.1 Between September 2015 and October 2016 the following education events have been provided:

- monthly revalidation briefings which have been attended by 304 nurses and midwives
- 11 'reflection' workshops for nurses and midwives
- 8 revalidation sessions for confirmers and line managers
- 2 training sessions specifically for Matrons

7.0 On-going Support for Staff

7.1 Feedback from Trust staff, who revalidated since April 2016, has been very positive. Overall staff felt well prepared and did not find the process onerous. There appears to have been no increase in the number of nurses or midwives choosing not to renew their registration as a direct result of revalidation.

7.2 Revalidation briefings will continue for the foreseeable future. Ongoing support is provided through resources on the intranet revalidation pages.

8.0 Non Compliance

8.1 To date 4 staff did not revalidate. Two nurses are on long-term sick and potentially will not be returning to nursing. One member of staff is currently on a career break and the last member of staff is registered as a therapist and no longer wishes to maintain their nursing registration.

9.0 Summary

9.1 Whittington Health have developed and delivered a range of mechanisms to prepare its nurses, midwives and managers for the requirements of revalidation

10.0 Recommendations

The Trust Board is asked to:

- Receive the report for information regarding the new revalidation process and national progress with this
- Note the work that is being undertaken locally to prepare nurse, midwives and managers, at Whittington Health, for revalidation.

Whittington Health NHS

The Whittington Hospital NHS Trust
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Trust Board

2 November 2016

Title:	Month 06 (September) 2016/17 - Financial Performance		
Agenda item:	16/149	**Paper**	07
Action requested:	To agree corrective actions to ensure financial targets are achieved and monitor the on-going improvements and trends		
Executive Summary:	The Trust reported a £3.9m surplus in September and a year to date deficit of £2.9m which is in line with the planned year to date (YTD) performance.		
Summary of recommendations:	To note the financial results relating to performance during September 2016.		
Fit with WH strategy:	Delivering efficient, affordable and effective services. Meeting statutory duties.		
Reference to related / other documents:	Previous monthly finance reports to the Trust Board. Trust Operating Plan 2016/17. Board Assurance Framework (Section 3). Finance Report to Finance & Business Development Committee.		
Date paper completed:	17-Oct-16		

Author name and title:		**Ursula Grueger, Deputy Director of Finance**		**Director name and title:**		**Stephen Bloomer, Chief Finance Officer**	
Date paper seen by EC		**Equality Impact Assessment complete?**		**Quality Impact Assessment complete?**		**Financial Impact Assessment complete?**	

Financial Sustainability Risk Rating

Financial Sustainability Risk Ratings	YTD Plan	YTD Actual	YTD Variance
Liquidity Ratio days (metric)	1	1	0
Capital Servicing Capacity (times)	1	2	1
I&E Margin Rating	1	1	0
I&E Margin Variance from Plan	4	4	0
Overall Financial Sustainability Risk Rating	**2**	**2**	**0**

Executive Summary

The Trust reported a £3.9m surplus in September and a year to date deficit of £2.9m which is in line with the planned year to date (YTD) performance.

The key movements in the month were:

- The achievement of STF which increased income by £3m. A further £0.2m relating to failure to achieve the A&E target is subject to appeal
- An improvement in pay of £0.4m against the average run-rate which was due to a lower spend on agency and locums coupled with high level of vacancies.
- A reduction in nom-pay expenditure of £2.6m which was largely due to commercial agreement with suppliers on disputes which created a non-recurring benefit
- An underperformance on activity particularly in outpatients, direct access and elective care which created a £2m pressure in month. Weekly activity targets and plans are being agreed with ICSUs to catch back activity in the coming months

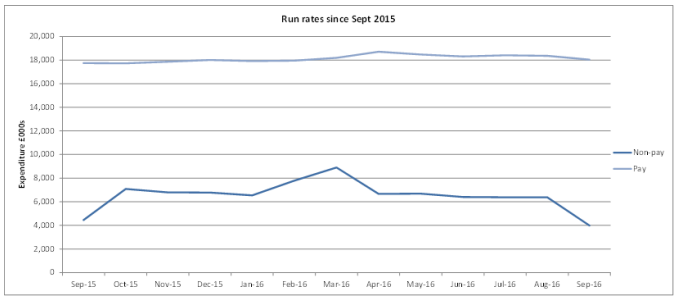
The underlying position at the end of month 6 was a deficit of £8.9m which is £2.5m worse than the planned position. Recovering the recurrent position and creating the the required exit run rate is the key financial target for quarters 3 and 4.

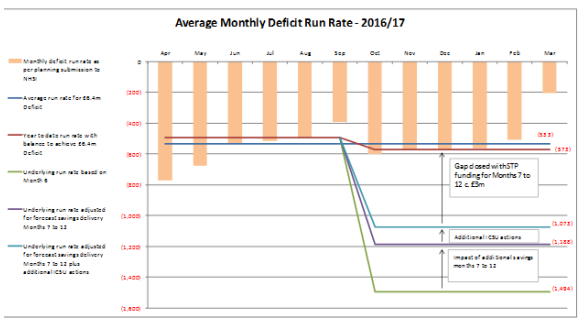
The cash position is approximately £0.5m off plan but this is mainly due to London Borough of Haringey outstanding debtors' invoices that the Trust now expects to be settled in month 7. Capital expenditure is on track but there are delays on major schemes which are being escalated via the Capital management Group.

Statement of Comprehensive Income

Statement of Comprehensive Income	In Month Budget (£000s)	In Month Actual (£000s)	Variance (£000s)	YTD Budget (£000s)	Ytd Actuals (£000s)	Varianc (£000s)	Full Year (£000s)
Nhs Clinical Income	21,837	23,424	1,587	129,619	127,741	(1,879)	258,367
Non-Nhs Clinical Income	1,899	1,530	(369)	11,392	11,520	128	22,784
Other Non-Patient Income	2,317	2,240	(77)	12,586	12,289	(298)	26,537
Total Income	**26,053**	**27,194**	**1,141**	**153,597**	**151,550**	**(2,049)**	**307,688**
Non-Pay	6,568	3,990	2,578	39,251	36,480	2,771	79,628
Pay	18,280	18,036	244	109,605	110,329	(724)	217,821
Total Operating Expenditure	**24,848**	**22,026**	**2,822**	**148,856**	**146,809**	**2,047**	**297,449**
EBITDA	**1,205**	**5,168**	**3,963**	**4,741**	**4,741**	**(2)**	**10,239**
Depreciation	690	665	25	4,140	4,091	49	8,280
Dividends Payable	355	354	1	2,122	2,121	1	4,243
Interest Payable	267	258	9	1,578	1,534	44	3,238
Interest Receivable	(3)	0	(3)	(18)	(13)	(5)	(36)
Total	**1,309**	**1,277**	**32**	**7,822**	**7,733**	**89**	**15,725**
Net Surplus / (Deficit) - before IFRIC 12 adjustment	**(104)**	**3,891**	**3,995**	**(3,081)**	**(2,992)**	**87**	**(5,486)**
Add back impairments and adjust for IFRS & Donate	5	5	0	30	30	0	(914)
Adjusted Net Surplus / (Deficit) - including IFRIC 12 adjustments	**(99)**	**3,896**	**3,995**	**(3,051)**	**(2,962)**	**87**	**(6,400)**

The Trust is increasing the use of monthly run rates to enhance monthly monitoring, improve forecasting and better assess trends in performance. Initially this is being undertaken at a high level and based on a monthly average compared to the control total but will be made for use in 2017/18, splitting out Income, Pay and Non Pay for the Trust and ICSUs.





There were in month improvements to run rate with the trus's paybill improving by £0.4m. The underlying run rate is a £1.5m deficit and the target being £1.1m It can be seen from the graph that the improvement is targeted through back-ended CIP delivery, increase in staffing expenditure controls and weekly activity targets with ICSU's.

Cost Improvement Programme

Year to date, £2.4m has been delivered against a target of £3.2m. This equates to a 75% achievement. The Trust CIP profile requires a material increase in the rate of cost improvement during the second half of the financial year to March 2017.

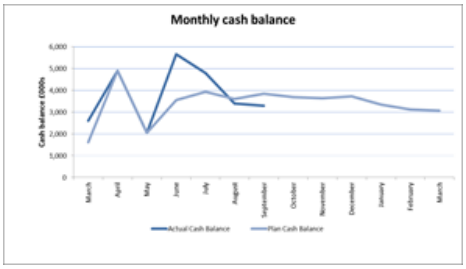
A review of the classifications of the CIP schemes was undertaken and is now reflected in the table below. There are two ICSUs ahead of target Emergency & Urgent Care and Medicine, Frailty & Network Services. The former has achieved income schemes totalling £0.4m resulting in a £0.3m favourable variance against the target. These are principally due to improved coding. The latter is £0.1m favourable, with £0.2m achieved on pay CIP schemes and £0.1m on income plans. The ICSUs that are falling short of their YTD target are principally doing so on pay and non-pay schemes.

The PMO and finance team have continued in assessing progress on scheme milestones and are forecasting PMO related CIP delivery of £6.5-7.1m.

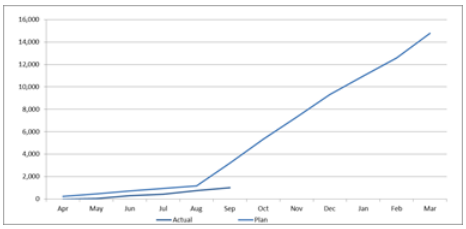
Integrated Clinical Service Units	Annual Plan £'000	YTD Plan £'000	YTD Actual £'000	YTD % achieved	YTD Variance £'000
Children's services	602	107	54	50.3%	-53
Clinical Support Services	1,019	283	136	48.0%	-147
Emergency & Urgent Care	786	121	365	301.0%	244
Medicine, Frailty & Network Services	1,673	347	428	123.2%	81
Outpatients Prevention & LTC	526	136	37	27.2%	-99
Surgery	2,613	716	397	55.4%	-319
Women's Services	1,189	283	166	58.6%	-117
Corporate	2,307	1,185	567	47.8%	-618
Trustwide non-pay	0		250		250
Performance against operating plan	**10,715**	**3,181**	**2,400**	**75.4%**	**-781**

Statement of Financial Position

	As at 1 April £000	Plan 31 March 2017 £000	Year to Date Plan YTD 30 September 2016 £000	Year to Date As at 30 September £000	Year to Date Variance YTD 30 September £000
Property, plant and equipment	194,785	203,023	194,969	192,017	2,952
Intangible assets	4,583	2,831	3,718	4,267	(549)
Trade and other receivables	693	851	821	635	186
Total Non Current Assets	**200,061**	**206,705**	**199,508**	**196,919**	**2,589**
Inventories	1,403	1,500	1,500	1,740	(240)
Trade and other receivables	23,535	25,393	20,447	29,881	(9,434)
Cash and cash equivalents	2,598	3,060	3,845	3,281	564
Total Current Assets	**27,536**	**29,953**	**25,792**	**34,902**	**(9,110)**
Total Assets	**227,597**	**236,658**	**225,300**	**231,821**	**(6,521)**
Trade and other payables	39,112	43,391	34,343	39,840	(5,497)
Borrowings	376	2,455	8,293	8,829	(536)
Provisions	795	756	777	509	268
Total Current Liabilities	**40,283**	**46,602**	**43,413**	**49,178**	**(5,765)**
Net Current Assets (Liabilities)	**(12,747)**	**(16,649)**	**(17,621)**	**(14,276)**	**(3,345)**
Total Assets less Current Liabilities	**187,314**	**190,056**	**181,887**	**182,643**	**(756)**
Borrowings	52,934	61,419	50,749	51,258	(509)
Provisions	1,773	1,513	1,646	1,773	(127)
Total Non Current Liabilities	**54,707**	**62,932**	**52,395**	**53,031**	**(636)**
Total Assets Employed	**132,607**	**127,124**	**129,492**	**129,612**	**(120)**
Public dividend capital	62,404	62,404	62,404	62,404	0
Retained earnings	(7,873)	(13,356)	(10,988)	(10,690)	(298)
Revaluation reserve	78,076	78,076	78,076	77,898	178
Total Taxpayers' Equity	**132,607**	**127,124**	**129,492**	**129,612**	**(120)**
Capital cost absorption rate	**3.5%**	**3.5%**	**3.5%**	**3.5%**	**3.5%**



Capital Programme



Property, Plant & Equipment (inc Intangible Assets): As reported in previous board reports the YTD underspend is a result of on-going negotiations with a managed service provider. It is expected that the plan will be agreed in Q3.

Trade Receivables: Collection of debts is worse than planned and has created an adverse variance of £5.5m. The key are a of concern being the delayed settlement of outstanding activity invoices for 2015/16 and 2016/17. Discussions are on-going with local providers which represent mainly London Borough of Haringey £2.7m, Royal Free Hospital £2.3m, NHS Islington £2.1m, Camden and Islington Foundation Trust £1.1m, London Borough of Islington £0.7m and NHS Haringey £0.6m. The discussions with other local provider organisations are linked to amounts owed by Whittington Health.

Cash: The annual cash plan assumes that the Trust would receive £8.9m cash support. The trust drew down £6.9m as at month 06. The cash position at the close of month 6 was £3.3m. The Trust is managing cash closely to plan and controlling payments.

Payables: Payments to suppliers are made as cash balances allow and as debt collection improves it is anticipated the speed of payment will increase**.** The Trust is negotiating with local providers to clear old invoices and reduce the balances outsanding.

Borrowings: The Trust will borrow, as planned, an additional £8.9m this year to support its financial position. To date the Trust has drawn down £6.9m of this planned facility with a further £2m due in future months.

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The Whittington Hospital NHS Trust
Magdala Avenue, London N19 5NF

Whittington Health Trust Board
2nd November 2016

Title:	Performance Dashboard Report October 2016 (September16 data)		
Agenda item:	**16/150**	**Paper**	**08**
Action requested:	For discussion and decision making		
Executive Summary:	The following is the Performance report for August 2016. **Patient Safety** Whittington Health reported 6 **Serious Incidents** in September 2016. All early learning has been identified and shared with staff. **Theatre Utilisation** Theatre utilisation is still, on average, around 80%. September was a better month regards productivity, and again T&O and General Surgery were 87% and 84% respectively, with Gynaecology at 76%, and Urology and Breast both at 68%. **Hospital Cancellation** Achieved target for first appointment and just above target for follow up appointments. **DNA rate** reduced slightly for first appointments during September 2016 and gone up slightly for follow up appointments at just above the expected target of 10%. **Community Cancellations and DNAs** continue to achieve their target. **Appointments with no outcomes in the community** has gone up to 3.2% in September 2016 due to a large number of appointments not outcomed by the 3rd working day of October 2016 in District Nursing. All appointments however are outcomed by the time the SUS submission is due (2 months arrears). The **MSK service** 6 weeks waiting times target has gone down to 45% of patients seen within 6 weeks from 60% last month. Capacity and Demand study shows that there is a 35% discrepancy. There are ongoing meetings with commissioners looking at specific areas in the recovery action plan for further improvements. The **Podiatry service** has seen an expected further drop in number of patients seen within 6 weeks, due to the focus on backlog reduction. **Islington Intermediate Care REACH** improvement seen in month		

	and compliance expected in December 2016. **The cancer targets** all compliant. **Emergency and Urgent Care** Performance is improved to 93.4% for September 2016 as expected. The improvement plan continues to make the intended impact. Improvement plan work stream is supported by the work Perfect Week on 12th Sept. Perfect week to be repeated in January 2017.
Summary of recommendations:	That the board notes the performance.
Fit with WH strategy:	All five strategic aims
Reference to related / other documents:	N/A
Reference to areas of risk and corporate risks on the Board Assurance Framework:	N/A
Date paper completed:	27th October 2016

Author name and title:		**Hester de Graag, Performance Lead**		**Director name and title:**		**Carol Gillen, Chief Operating Officer**	
Date paper seen by EC		**Equality Impact Assessment complete?**		**Quality Impact Assessment complete?**		**Financial Impact Assessment complete?**	

October 2016 Trust Board Report (Sep data)

Whittington Health NHS

Quality	Threshold	Jul-16	Aug-16	Sep-16
Number of Inpatient Deaths	-	28	26	17
NHS number completion in SUS (OP & IP)	99%	98.9%	98.7%	arrears
NHS number completion in A&E data set	95%	TBC	TBC	arrears

Quality (Mortality index)	Threshold	Oct 14 - Sep 15	Jan 15 - Dec 15	Apr15 - Mar16
SHMI	-	0.65	0.67	0.68

Quality (Mortality index)	Threshold	Apr-16	May-16	Jun-16
Hospital Standardised Mortality Ratio (HSMR)	<100	72	71	66
Hospital Standardised Mortality Ratio (HSMR) - weekend	-	40.0	102.4	48.1
Hospital Standardised Mortality Ratio (HSMR) - weekday	-	81.1	58.0	73.7

Patient Safety	Threshold	Jul-16	Aug-16	Sep-16
Harm Free Care	95%	93.8%	91.9%	90.9%
VTE Risk assessment	95%	98.0%	96.2%	arrears
Medication Errors actually causing Serious/Severe Harm	0	0	0	0
Never Events	0	0	1	0
CAS Alerts (Central Alerting System)	-	0	0	0
Proportion of reported patient safety incidents that are harmful	-	22.5%	21.6%	21.8%
Serious Incident reports	-	3	3	6

Access Standards

Referral to Treatment (in arrears)	Threshold	Jun-16	Jul-16	Aug-16
Diagnostic Waits	99%	99.9%	99.3%	99.5%
Referral to Treatment 18 weeks - 52 Week Waits	0	0	0	0

Efficiency and productivity - Community	Threshold	Jul-16	Aug-16	Sep-16
Service Cancellations - Community	8%	5.7%	5.8%	6.6%
DNA Rates - Community	10%	5.8%	5.7%	5.7%
Community Face to Face Contacts	-	58,740	55,192	58,885
Community Appts with no outcome	0.5%	0.9%	0.9%	3.2%

Community Access Standards	Threshold	Jul-16	Aug-16	Sep-16
MSK Waiting Times - Non-Consultant led patients seen in month (% < 6 weeks)	95%	46.9%	61.0%	45.2%
MSK Waits - Consultant led patients seen in month (% < 18 weeks)	95%	90.5%	90.7%	arrears
IAPT - patients moving to recovery	50%	50.0%	51.7%	arrears
IAPT Waiting Times - patients waiting for treatment (% < 6 weeks)	75%	95.1%	93.8%	arrears
GUM - Appointment within 2 days	98%	97.8%	97.8%	100.0%

Efficiency and Productivity

Efficiency and productivity - acute	Threshold	Jul-16	Aug-16	Sep-16
First:Follow-up ratio - acute	2.31	1.44	1.60	1.50
Theatre Utilisation	95%	78.7%	78.2%	81.8%
Hospital Cancellations - acute - First Appointments	8%	5.9%	6.6%	6.2%
Hospital Cancellations - acute - Follow-up Appointments	8%	8.6%	9.3%	8.8%
DNA rates - acute - First appointments	10%	11.9%	12.7%	12.3%
DNA rates - acute - Follow-up appts	10%	11.5%	11.5%	12.6%
Hospital Cancelled Operations	0	1	6	1
Cancelled ops not rebooked < 28 days	0	0	0	0
Urgent procedures cancelled	0	1	2	0

Meeting threshold

Failed threshold

October 2016 Trust Board Report (Sep data)

Whittington Health NHS

Patient Experience	Threshold	Jul-16	Aug-16	Sep-16
Patient Satisfaction - Inpatient FFT (% recommendation)	-	96%	96%	95%
Patient Satisfaction - ED FFT (% recommendation)	-	89%	92%	96%
Patient Satisfaction - Maternity FFT (% recommendation)	-	92%	93%	91%
Mixed Sex Accommodation breaches	0	0	0	0
Complaints	-	26	38	32
Complaints responded to within 25 working days	80%	95%	85%	86%
Patient admission to adult facilities for under 16 years of age	-	0	0	0

Emergency and Urgent Care	Threshold	Jul-16	Aug-16	Sep-16
Emergency Department waits (4 hrs wait)	95%	87.9%	92.7%	93.4%
ED Indicator - median wait for treatment (minutes)	<60	87	60	62
30 day Emergency readmissions	-	226	201	arrears
12 hour trolley waits in A&E	0	1	0	0
Ambulatory Care (% diverted)	>5%	3.6%	3.1%	3.3%
Ambulance Handover (within 30 minutes)	0	33	13	arrears
Ambulance Handover (within 60 minutes)	0	0	1	arrears

Infection Prevention	Threshold	Jul-16	Aug-16	Sep-16
Hospital acquired MRSA infection	0	0	0	0
Hospital acquired *C difficile* Infections	17 (FY)	1	0	0
Hospital acquired *E. coli* Infections	-	1	0	0
Hospital acquired MSSA Infections	-	0	0	0
Ward Cleanliness	-	98%	-	-

Cancer Access Standards (in arrears)	Threshold	Jun-16	Jul-16	Aug-16
Cancer - 14 days to first seen	93%	96.4%	97.7%	97.9%
Cancer - 14 days to first seen - breast symptomatic	93%	99.2%	100.0%	100.0%
Cancer - 31 days to first treatment	96%	100.0%	100.0%	100.0%
Cancer - 31 days to subsequent treatment - surgery	94%	100.0%	100.0%	100.0%
Cancer - 31 days to subsequent treatment - drugs	98%	-	-	100.0%
Cancer - 62 days from referral to treatment	85%	94.9%	83.3%	93.5%

Access Standards (RTT)

Referral to Treatment (in arrears)	Threshold	Jul-16	Aug-16	Sep-16
Referral to Treatment 18 weeks - Admitted	90%	75.5%	79.1%	arrears
Referral to Treatment 18 weeks - Non-admitted	95%	93.5%	92.0%	arrears
Referral to Treatment 18 weeks - Incomplete	92%	93.9%	92.7%	arrears

Maternity	Threshold	Jul-16	Aug-16	Sep-16
Women seen by HCP or midwife in 10 weeks	-	74%	69%	73%
New Birth Visits - Haringey	95%	93.2%	94.6%	arrears
New Birth Visits - Islington	95%	94.9%	93.7%	arrears
Elective Caesarean Section rate	14.8%	11.5%	11.4%	12.0%
Breastfeeding initiated	90%	93.7%	91.2%	88.6%
Smoking at Delivery	<6%	3.9%	4.4%	4.8%

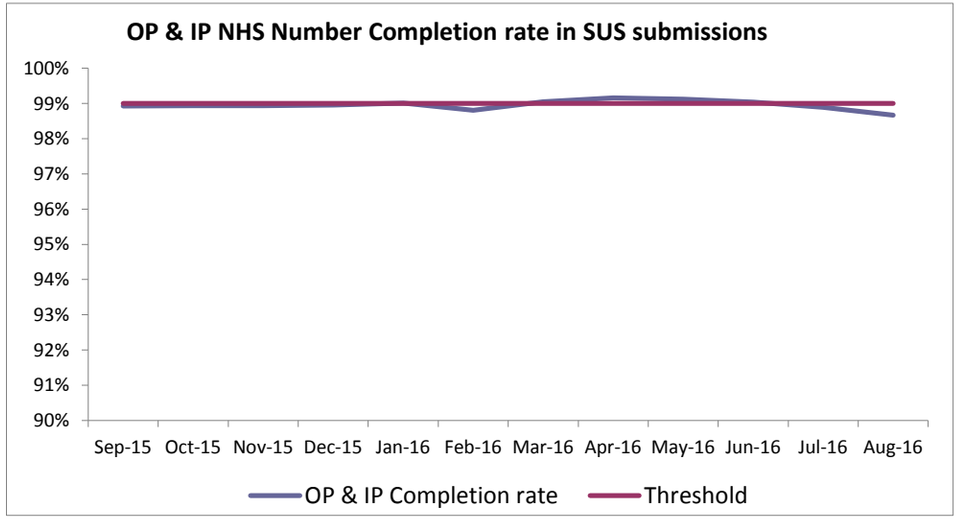
Meeting threshold

Failed threshold

	Threshold	Trust Actual		
		Jul-16	Aug-16	Sep-16
Number of Inpatient Deaths	-	28	26	17
Completion of a valid NHS number in SUS (OP & IP)	99%	98.9%	98.7%	arrears
Completion of a valid NHS number in A&E data sets	95%	TBC	TBC	arrears

	Standardised National Average	Trust		
		Apr-16	May-16	Jun-16
Hospital Standardised Mortality Ratio	<100	71.6	70.7	65.9
Hospital Standardised Mortality Ratio (HSMR) - weekend	-	40.0	102.4	48.1
Hospital Standardised Mortality Ratio (HSMR) - weekday	-	81.1	58.0	73.7

		Lower Limit	Upper Limit	RKE SHMI Indicator
SHMI	Apr 2015 - Mar 2016	0.89	1.13	0.68
	Jan 2015 - Dec 2015	0.89	1.13	0.67
	Oct 2014 - Sep 2015	0.89	1.12	0.65
	Jul 2014 - Jun 2015	0.89	1.12	0.66
	Apr 2015 - Mar 2015	0.89	1.12	0.67
	Jan 2014 - Dec 2014	0.89	1.12	0.66
	Oct 2013 - Sep 2014	0.88	1.13	0.60



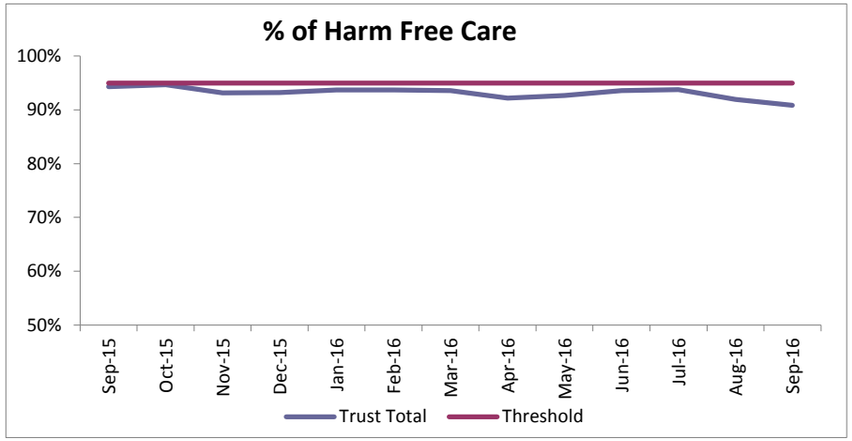
Commentary

Completion of NHS number in SUS
Just below target for Out patients and In patients.
Issue: Missing patient demographics (i.e. NHS numbers and GP unknowns) validated, overseas visitors and un-registered GP patients are not filtered from above data.
Action: All un-registered patients are sent information on 'How to registered with a GP' and asked to confirm this information once they are registered and EPR is updated accordingly.
Timescale: ongoing

Completion of NHS number in A&E data set
An error in the reporting was discovered and is being investigated. Internal reporting is restored and shows over 95% compliance .However, the SUS portal also produces a suite of data quality metrics (including this metric) which seems to be producing slightly different values. To avoid confusion, the trust will not report this measure until it is clear why this discrepancy occurs.
Timescale: Local data used in the monthly Penalty contract meetings which monitor this KPI.

SHMI and HMSR
The above metrics are a ration of observed to expected death.
Whittington Health mortality is, again, below the level that is expected for the hospital.
The two different metric employ slightly different methodologies, so result in different values.

	Threshold	Trust Actual Jun-16	Jul-16	Aug-16	Sep-16	Trend
Harm Free Care	95%	93.6%	93.8%	91.9%	90.9%	
Pressure Ulcers (prevalence)	-	5.85%	5.54%	6.72%	6.23%	
Falls (audit)	-	0.29%	0.38%	1.13%	2.38%	
VTE Risk assessment	95%	96.3%	98.0%	96.2%	arrears	
Medication Errors actually causing **Serious** or **Severe** Harm	0	0	0	0	0	
Medication Errors actually causing **Moderate** Harm	-	0	2	1	1	
Medication Errors actually causing **Low** Harm	-	0	4	5	2	
Never Events	0	0	0	1	0	
Open CAS Alerts (Central Alerting System)	-	0	0	0	0	
Proportion of reported patient safety incidents that are harmful	-	20.7%	22.5%	21.6%	21.8%	
Serious Incidents (Trust Total)	-	3	3	3	6	



Commentary

Harm Free Care and Pressure Ulcer prevalence
Harm Free Care and the figure for prevalence of pressure ulcers include non-avoidable pressure ulcers. which are not attributable to whittington Health. It remains above 90%.

Falls (audit)
Issue: The overall numbers of falls recorded in the Nursing Indicators dashboard remain around 20 per month. It is below the national target of 5 falls per 1000 bed days at 2.73 falls.
Action: Falls awareness and prevention training session continue to be included in new ward training programme (2pm daily). Business case for care of older persons nurse specialist and increased awareness and recognition of delirium has been agreed in principle at the Investment Group and TMG in August 2016, however funding from within the IM ICSU budget is being explored. Funding options will be presented at December TMG.

Medication errors causing harm in September 16
There were 45 medication incidents reported on Datix in September 2016 (monthly average for 2016 is 49).
Thirty one (51%) of medication incidents were reported by E&UC of which 26 (84% of the E&UC total) occurred in patients' homes. The largest reporting group were district nurses (48%), followed by hospital nurses (25%): 13% were reported by medical staff
One incident caused moderate harm: this concerned a patient discharged from Victoria ward with the incorrect drugs: he experienced pain as had not been counselled on the appropriate use of colchicine for acute gout.

Medication errors cont.
The two incidents causing low harm occurred in MF&NS: one involved three days of omitted NG feed on Victoria ward and the other the incorrect dose of IV aciclovir prescribed on Cloudesley ward – patient's renal function deteriorated.

Proportion of reported patient safety incidents that are harmful
Remains around 21%

Serious Incidents
Whittington Health declared 6 SIs in September 2016.

SIs
1. Retained foreign object
2. IG breach in Community RiO list
3. Delayed failure to monitor in community resulting in death
4. 32 wks. in uterine death
5. 38 + 1 weeks in uterine death
6. Active bleed from uterine

All SIs are in the process of being investigated and any early learning from these incidents has been shared with the Services.

Patient Experience

Whittington Health NHS

	Threshold	Trust Actual Jun-16	Jul-16	Aug-16	Sep-16	Trend
Patient Satisfaction - Inpatient FFT (% recommendation) **	-	95%	96%	96%	95%	
Patient Satisfaction - Emergency Department FFT (% recommendation) **	-	88%	89%	92%	96%	
Patient Satisfaction - Maternity FFT (% recommendation) **	-	95%	92%	93%	91%	
Mixed Sex Accommodation (not Clinically justified)	0	0	0	0	0	
Complaints (**incl Corporate**)	-	31	26	38	32	
Complaints responded to within 25 working day	80%	82.1%	95.5%	85.3%	85.7%	
Patient admission to adult facilities for under 16 years of age	-	0	0	0	0	

Commentary

Patient Satisfaction (Local standard 90%)
Please see breakdown of FFT to the left.

ED: Positive response rate above 90%. Response rate below the 15% target

Inpatients: Positive response rate above 90%. Response rate has increased but is below the 25% target

Outpatients: Positive response rate above 90%. Number of responses >200 target.

Community: Positive responses over 90%. Number of responses <750

Maternity
Positive response rate target met; Response rate target met

Complaints
Achieved

Complaints

ICSU	Jul-16	Aug-16	Sep-16
Integrated Medicine	100%	57%	20%
Emergency & UC	100%	100%	100%
Surgery & Cancer	100%	83%	100%
Clinical Support Services	100%	100%	100%
Patient Access, Prevention, etc	100%	100%	100%
Children's Services	50%	100%	100%
Women's Health Services	100%	100%	100%
Estates & Facilities	100%	100%	N/A
Nursing & PE	100%	N/A	N/A
IM&T	N/A	N/A	N/A
Finance	N/A	N/A	N/A
Trust	95%	88%	86%

FFT Maternity

2016/17

Month	Response Rate	% Recommend	% Not Recommend
Apr-16	19.3%	94.6%	0.8%
May-16	16.1%	92.1%	1.0%
Jun-16	18.3%	94.6%	2.2%
Jul-16	10.5%	91.6%	2.8%
Aug-16	18.9%	93.2%	0.0%
Sep-16	24.2%	91.1%	2.5%

Inpatient Friends and Family Test

2016/17

Month	Responses Positive	% Positive	Negative	% Negative	Total	Discharges	Response Rate
April 2016	567	97%	6	1%	587	3033	19%
May 2016	451	94%	16	3%	482	3111	15%
June 2016	491	96%	7	1%	513	3315	15%
July 2016	608	97%	9	1%	629	3253	19%
August 2016	433	96%	2	0%	451	2924	15%
September 2016	600	95%	15	2%	631	3089	20%

Emergency Department Friends and Family Test

2016/17

Month	Responses Positive	% Positive	Negative	% Negative	Total	Discharges	Rate
April 2016	259	90%	19	7%	288	6261	5%
May 2016	298	92%	22	7%	324	6742	5%
June 2016	279	88%	23	7%	318	6244	5%
July 2016	261	89%	22	8%	292	6502	4%
August 2016	194	92%	9	4%	210	6184	3%
September 2016	261	96%	7	3%	273	6579	4%

Outpatient Friends and Family Test

2016/17

Month	Responses Positive	% Positive	Negative	% Negative	Total
April 2016	120	90%	7	5%	133
May 2016	150	88%	9	5%	171
June 2016	144	87%	8	5%	166
July 2016	204	89%	15	7%	229
August 2016	208	91%	12	5%	229
September 2016	272	89%	23	8%	305

Community Services Friends and Family Test

2016/17

Month	Responses Positive	% Positive	Negative	% Negative	Total
April 2016	757	97%	3	0%	778
May 2016	733	97%	5	1%	752
June 2016	612	97%	6	1%	628
July 2016	551	98%	6	1%	563
August 2016	594	98%	5	1%	609
September 2016	611	98%	4	1%	621

Infection Prevention

Whittington Health NHS

	Threshold	Trust Actual Jun-16	Jul-16	Aug-16	Sep-16	Trend
MRSA	0	0	0	0	0	
E. coli Infections*	-	0	1	0	0	
MSSA Infections	-	1	0	0	0	

	Threshold	Jun 16	Jul 16	Aug 16	Sep 16	2016/17 Trust YTD
C difficile Infections	17 (Year)	1	1	0	0	5

* E. coli infections are not specified by ward or division

Ward Cleanliness

Audit period	Trust 01/09/15 to 30/09/15	05/10/15 to 03/11/15	22/12/15 to 31/01/15	16/03/16 to 06/05/16	08/07/16 to 05/08/16	Trend
Trust %	97.7%	97.8%	98.6%	96.9%	97.6%	

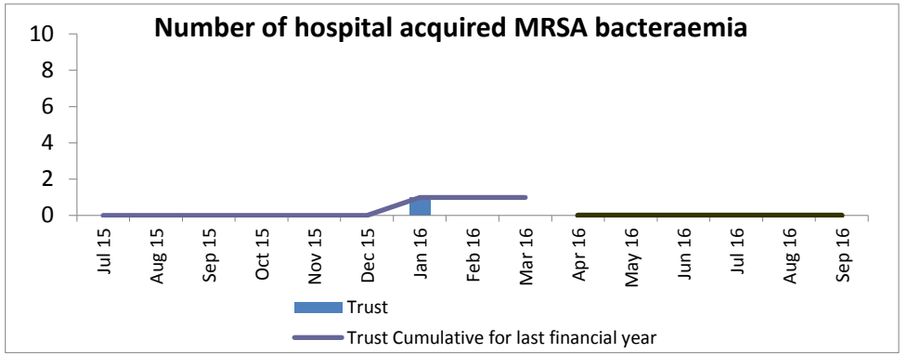
Commentary

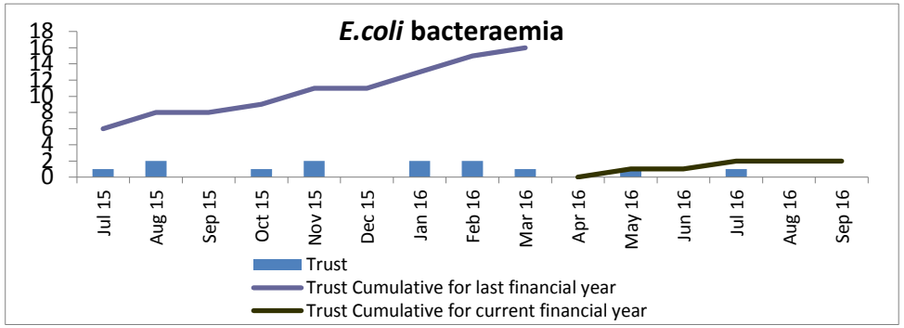
MSRA and E.coli
No new bacteraemia

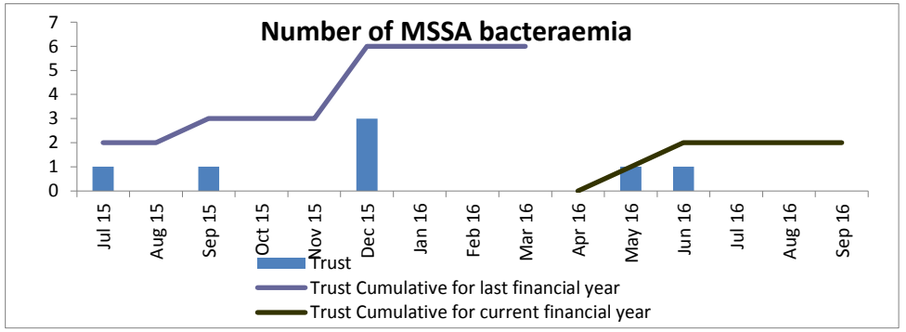
MSSA
No new bacteraemia

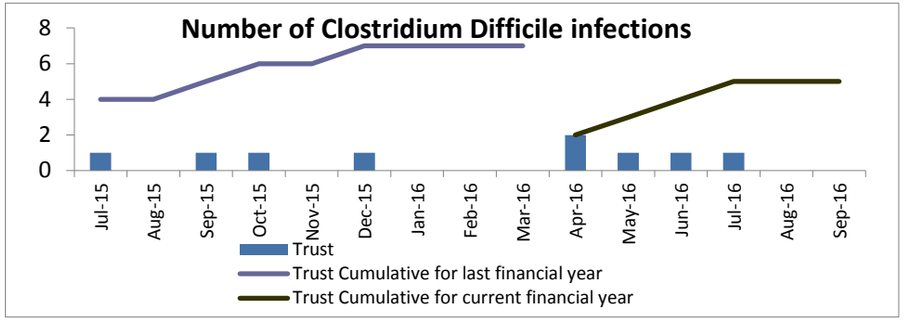
C difficile
No new bacteraemia

Ward Cleanliness
Issue: No new update. Ward Cleanliness improved slightly for the period July to August 16.
Action: A detailed action plan is in place for infection prevention, cleaning standards and audits are being carried by Estates and matrons to ensure standards are maintained.
Timescale: In place.





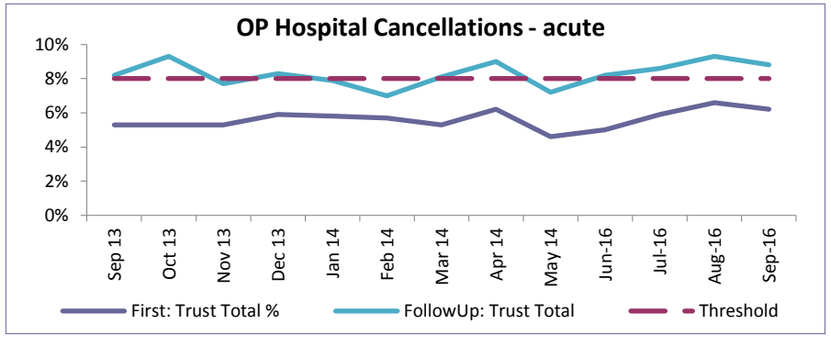




Efficiency and productivity - acute

Whittington Health NHS

	Trust						
	Threshold	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Trend
First:Follow-up ratio - acute	2.31	1.37	1.44	1.44	1.60	1.50	
Theatre Utilisation	95%	81.5%	80.6%	78.7%	78.2%	81.8%	
Hospital Cancellations - acute - First Appointments	<8%	4.6%	5.0%	5.9%	6.6%	6.2%	
Hospital Cancellations - acute - Follow-up Appointments	<8%	7.2%	8.2%	8.6%	9.3%	8.8%	
DNA rates - acute - First appointments	10%	12.3%	11.4%	11.9%	12.7%	12.3%	
DNA rates - acute - Follow-up appointments	10%	11.5%	11.6%	11.5%	11.5%	12.6%	
Hospital Cancelled Operations	0	4	7	1	6	1	
Cancelled ops not rebooked < 28 days	0	0	0	0	0	0	
Urgent Procedures cancelled	0	4	2	1	2	0	
Urgent Procedures cancelled (of these how many cancelled 2nd time)	0	0	0	0	0	0	

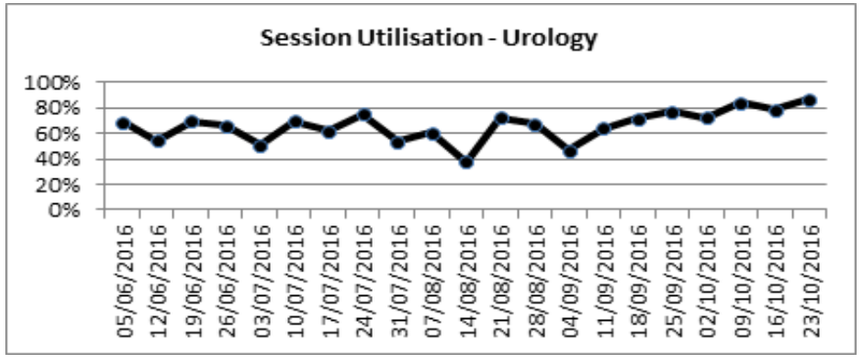


Commentary

Theatre utilisation

Issue: Theatre utilisation is still sitting on average around 80%. An average of 85% is what is expected.
September was a better month regards productivity, and again T&O and General Surgery were 87% and 84% respectively, with Gynaecology at 76%, and Urology and Breast both at 68%.

We are now seeing an improvement in performance for Urology, and the team is well aware of the number of cases needed to make sure that the contracted activity plan is delivered. This is being monitored on a weekly basis, please see trajectory below.



Actions:

1.TCI list meetings are having some impact and are useful to establish numbers booked and best use of theatre staff
2. Daily theatre utilisation report used to challenge each clinician. Triggers red if under 80% utilisation.
3. Pre-operative assessment workshop with Bookings team and Pre-operative assessment team to ensure no patient gets an appointment for surgery unless has been assessed as fit – progressing well number of actions have been completed

Continued Theatre utilisation

and backlog of pre operative assessments is reducing
4. 'Waste' for Urology is predominantly unused time at beginning and end of session, and the turnaround time of patients
Actions : monitor prompt start times and book enough patients for the list available and contracted plan and ensure that turnaround times are swift by surgeons taking lead in organising patient flow through theatre
5. Two lists from Gynae to be removed await detail
6. Theatre utilisation dashboard now implemented, and can be used to monitor the actions above
Timescale: It is anticipated that from late October/early November there will be an impact on utilisation figures to achieve 85% more regularly.

Hospital Cancellations

Within target for first appointments, but above target for follow up appointments, but downward trend as expected.

DNA

Improved for first appointments but slightly higher for follow up appointments.
Action: Further improvement to be expected month on month, using NetCall and continuing drive to update the EPR systems with patient details when attending appointments.
Timescale: expected improve over the next months.

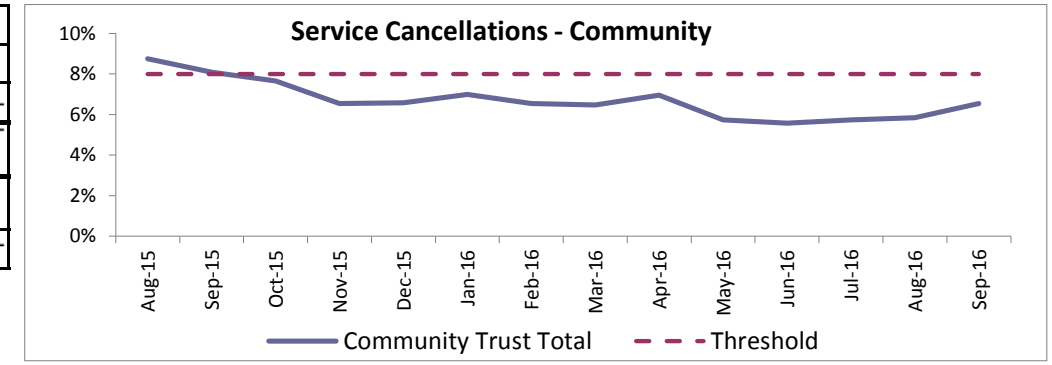
Hospital Cancelled Operations

Issue: There was 1 reportable cancelled operation in gynaecology as the list overran.
The operation was rescheduled within 28 days.

Efficiency and productivity - Community

Whittington Health NHS

	Trust					
	Threshold	Jun-16	Jul-16	Aug-16	Sep-16	Trend
Service Cancellations - Community	8%	5.6%	5.7%	5.8%	6.6%	
DNA Rates - Community	10%	5.7%	5.8%	5.7%	5.7%	
Community Face to Face Contacts*	-	60,875	58,740	55,192	58,885	
Community Appointment with no outcome	0.5%	1.0%	0.9%	0.9%	3.2%	



1866 DN

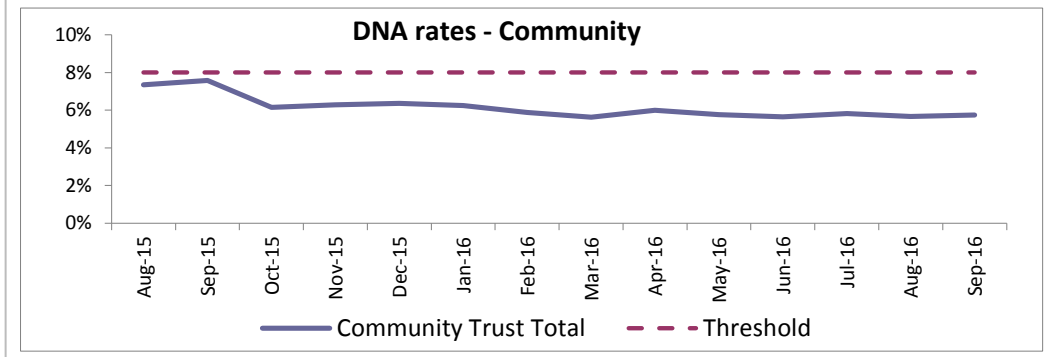
Commentary

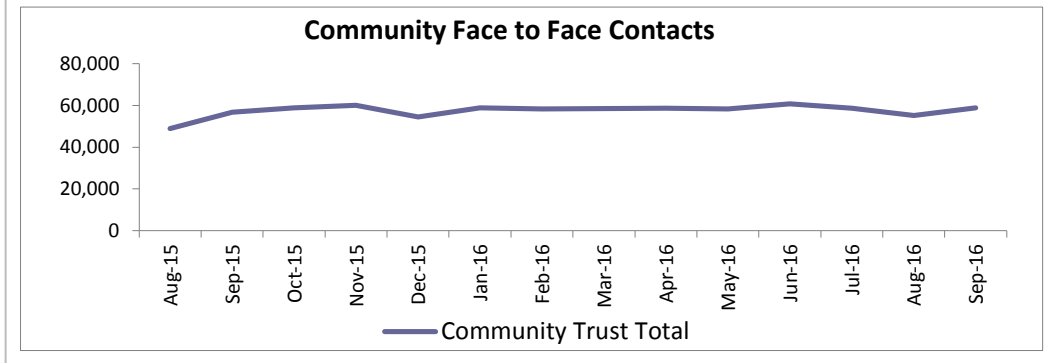
Service Cancellations - Community
Achieved

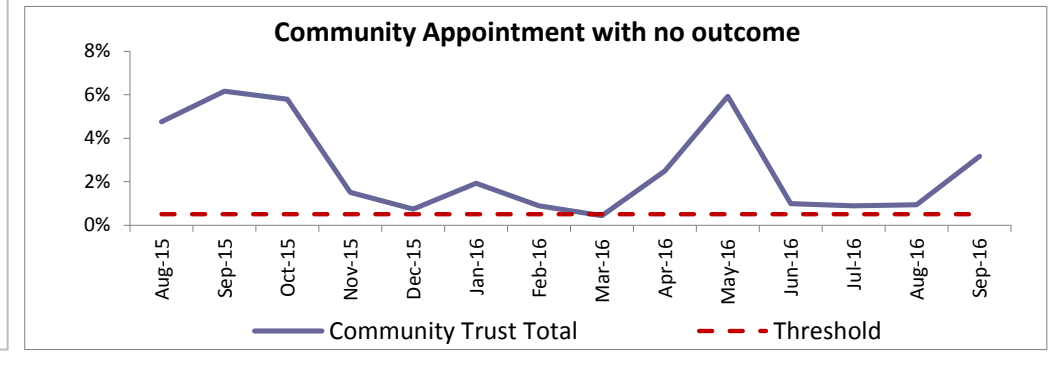
DNA Rates - Community
Achieved.

Community Face to Face Contacts
All services are monitored against activity targets.
Community Dental was not able to submit their number of appointments this month due to annual leave. The continuing Business plan will be amended to reflect continues monthly reporting.

Community Appointment with no outcome
Steep increase in un outcomed appointments on the 3rd working day after months end.
Issue: Appointments are not outcomed in time for services with high volume appointments.
Action: Electronic reports are in place for Services to monitor their unoutcomed appointments, e.g. District Nursing 1866 (as suppose to 250 last month) were not outcomed by the 3rd working day of the following month. All appointments are outcomed retrospectively before submission to SUS 2 month in arrears.
Timescale: in place







	Threshold	Trust Actual Jul-16	Trust Actual Aug-16	Trust Actual Sep-16	Trust YTD
District Nursing Wait Time - 2hrs assess (Islington)	-	-	-		-
District Nursing Wait Time - 2hrs assess (Haringey)	-	-	-		-
District Nursing Wait Time - 48hrs for visit (Islington)	-	-	-	-	-
District Nursing Wait Time - 48hrs for visit (Haringey)	-	-	-	-	-
MSK Waiting Times - Routine MSK (<6 weeks)	95%	46.9%	61.0%	45.2%	46.2%
MSK Waiting Times - Consultant led (<18 weeks)	95%	90.5%	90.7%	arrears	74.4%
IAPT - patients moving to recovery	50%	50.0%	51.7%	arrears	49.7%
GUM - Appointment within 2 days	98%	95.6%	97.8%	100.0%	98.4%
Haringey Adults Community Rehabilitation (<6weeks)	85%	84.2%	82.4%	77.1%	84.7%
Haringey Adults Podiatry (Foot Health) (<6 weeks)	-	44.8%	40.7%	26.6%	43.7%
Islington Community Rehabilitation (<12 weeks)	-	69.9%	78.6%	87.8%	80.0%
Islington Intermediate Care (<6 weeks)	85%	71.3%	65.8%	73.8%	71.1%
Islington Podiatry (Foot Health) (<6 weeks)	-	26.6%	24.3%	28.6%	31.5%
IAPT Waiting Times - patients waiting for treatment (% < 6 weeks)	75%	95.1%	93.8%	arrears	95.0%
Death in place of choice	90%	84.4%	85.7%	72.0%	
Number of DN teams completing a monthly review of Patients of Concern (POC) (eight teams)	8	8	8	-	
Number of DN teams completing a monthly caseload review of timely discharge (eight teams)	8	8	8	-	

District Nursing
Issue: There are no figures for 2 hrs and 48 hrs waiting times. It is not possible to produce these figures electronically.
Action: To mitigate the absence of electronic automated reporting the daily allocations teleconference coordinates the deployment of all nursing capacity to manage the patient demand. The discussion involves a lead district nurse or above reviewing any missed or late visits the previous 24 hours. All exceptions reported are recorded in Datix. There has not been an increase in missed visits. There has also not been a rise in complaints related to urgent wait times. It can be conclude that the quality of care has not been impacted on.
The service will implement a new piece of software which is called E-community platform & store & forward (RiO). This will accurately capture unplanned visits that are added to the workload, the urgency, and when they are actioned by a healthcare professional, recording the time and length of the visit appropriately. From this data, when inputted correctly, it will be possible to capture the 2 and 48hrs waiting times electronically.
Timescale: E community Pilot to launched in November 2016 . Store & Forward (October 2016)

Death in Place of choice:
18 out of 25 palliative care patients died in their place of choice. The district nursing teams and their palliative link nurses have worked hard to sensitively address with service users the preferred place of care.
Issue: Seven patients did not die in their place of choice this month.
Action: Work with teams to consolidate and encourage good practice.

GUM
Achieved this month.

IAPT
Achieved this month.

MSK:
Actions from Sept 16:
Review of other specialist services to show impact on waiting times completed. For discussion next Contract meeting in October 16.
Issue: Waiting times < 6 weeks has gone down to 45.2%. The backlog of patients that built up earlier in the year has been addressed but the number of patients waiting for appointments is still 35% higher as suggested in the demand and capacity study. This shows that Demand and Capacity is still the main issue in keeping wait times improving month on month.
There have also been further resignations since August 16 and recruitment is again ongoing.
Percentage of patients waiting under 18 Weeks (CATS) has improved to 90%. This is the impact of Additional ad-hoc clinics scheduled.
Action: All posts were filled by Sept 16 but there have been further resignations since Aug 16. Recruitment is on-going. Most staff continue to spend 90% of time in face to face clinical contact.
18 Weeks (CATS): Improvement in percentage of patients seen within 18 weeks for past 2 months. 1WTE FTT Extended Scope Practitioner (ESP) recruited to work on waiting list management using GPwSI funds. To start October 16. 1WTE ESP recruited into vacant post to start Jan 17.

Podiatry
Issue: September 6 weeks data has fallen further, particularly in Haringey.
This drop is expected in line with backlog clearing. The % seen indicates the no. of patients seen who waited less than 6 weeks (26.6%) The residual slots were patients from the backlog. Activity in September 16 increased significantly (1,068 patients compared to 658 in August 16), running blitz clinics throughout September 16. Improvement in number of patients seen within 6 weeks should be seen from October 16 onwards; fore cast October 16 shows that 50% of new patients seen have been waiting under 6 weeks.
Action: Work continues to clear back log of long waiters and to improve 6 week target data for new patients; timetable changes are being made, acceptance criteria is being tightened. All vacant posts are now filled although one member of staff is off work which may have an impact on activity in the next month.
Timescales: Demand V Capacity exercise will be carried out shortly to get a definite understanding on the timescales needed to clear the backlog; however improvement should be seen in the percentages from October 16 onwards.

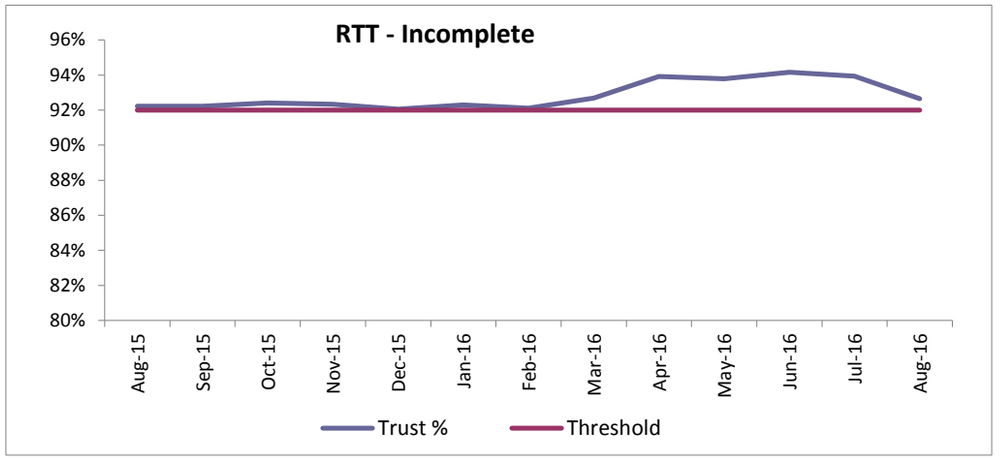
Islington Intermediate Care REACH
Both services showing improvement.
Issue: The performance of the REACH home based team has seen a steady improvement over the last 12 months. At the beginning of the calendar the service was at 50% compliance against the 6 weeks target. Additional locum staff, funded via the CCG for a 3 month period, were appointed in January 2016. The overall performance since March 2016 has on average maintained delivery of 70%.
Action: Newly appointed staff will join the team on a permanent basis; the service will be fully staffed by the end of November 2016.
Timescale: The aim of service to be compliant by December 2016.

Haringey Adults Community Rehabilitation
Decrease in number of patients seen within 6 weeks in the last 3 months due to reduced capacity. Forecast for October shows back on target for 85%.
Action: Recruitment is ongoing.
Timescale: Expected to be back to achieving target in October 2016

Referral to Treatment (RTT) and Diagnostic waits

Whittington Health NHS

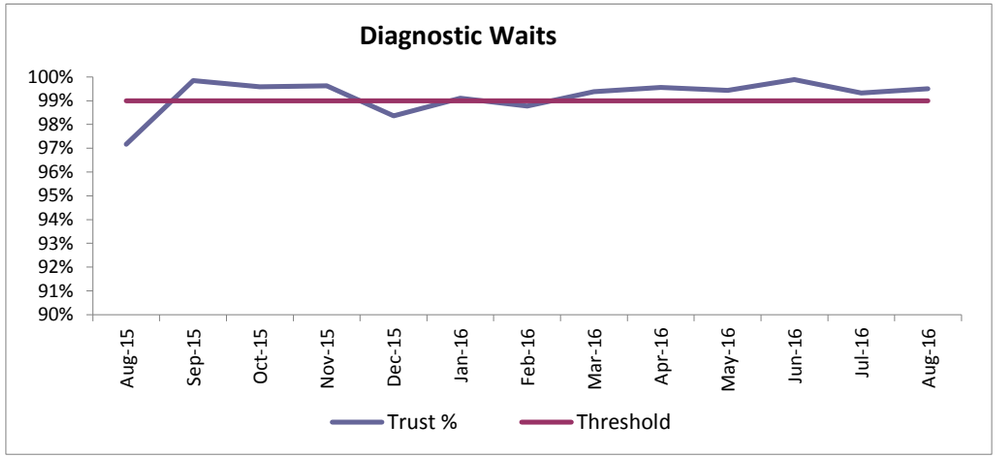
	Trust				
	Threshold	Jun-16	Jul-16	Aug-16	Trend
Referral to Treatment 18 weeks - Admitted	90%	79.3%	75.5%	79.1%	
Referral to Treatment 18 weeks - Non-admitted	95%	90.0%	93.5%	92.0%	
Referral to Treatment 18 weeks - Incomplete	92%	94.2%	93.9%	92.7%	
Referral to Treatment 18 weeks - 52 Week Waits	0	0	0	0	
Diagnostic Waits	99%	99.9%	99.3%	99.5%	



Commentary

RTT
National KPI for 18 weeks incomplete achieved.
Issues: 18 weeks admitted and non-admitted data reported above is un-validated.
These targets are not part of the national reportable standards.

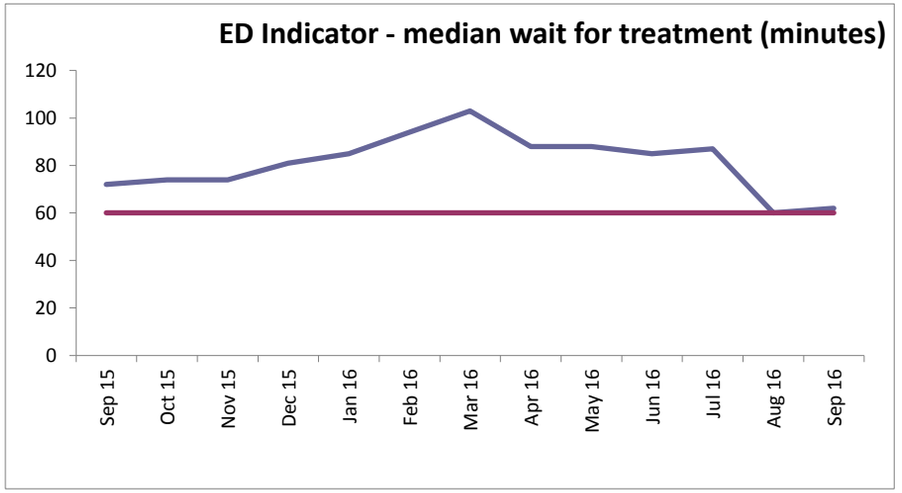
Diagnostic Waits
Target achieved as expected.

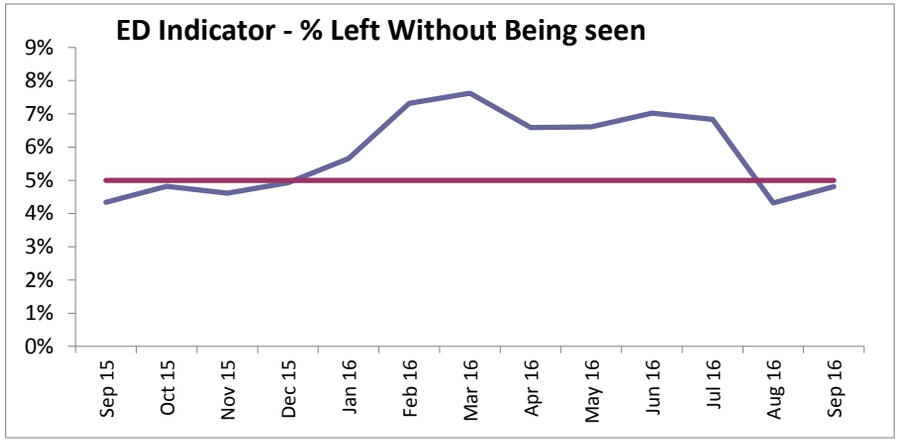


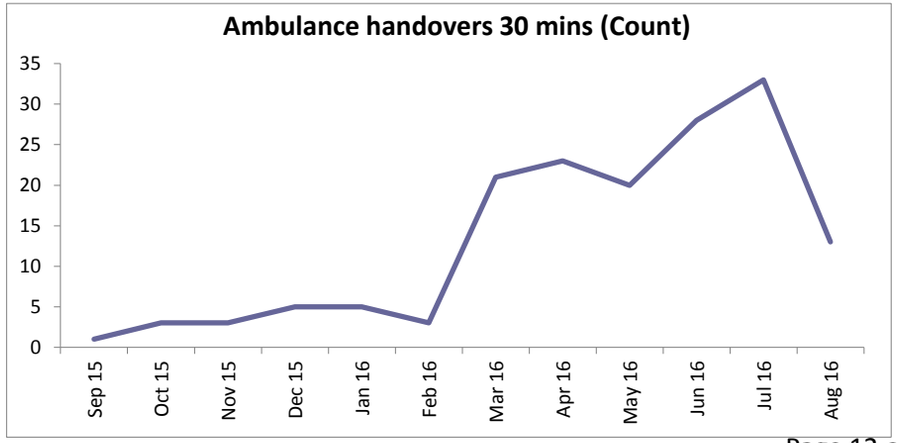
Emergency Care

Whittington Health NHS

	Threshold	Trust Actual Aug-16	Trust Actual Sep-16	2016/17 Trust YTD
Emergency Department waits (4 hrs wait)	95%	92.7%	93.4%	88.6%
Emergency Department waits (4 hrs wait) Paeds only	95%	98.3%	98.0%	96.2%
Wait for assessment (minutes - 95th percentile)	<=15	16	16	18
ED Indicator - median wait for treatment (minutes)	60	60	62	77
Total Time in ED (minutes - 95th percentile)	<=240	360	340	433
ED Indicator - % Left Without Being seen	<=5%	4.3%	4.8%	6.1%
12 hour trolley waits in A&E	0	0	0	4
Ambulance handovers 30 minutes	0	13	arrears	117
Ambulance handovers exceeding 60 minutes	0	1	arrears	12
Ambulatory Care (% diverted)	>5%	3.1%	3.3%	







Commentary

To further support ED in achieving the 4 hour target, the Whittington introduced the perfect week on 12th September which resulted in very successful MDT working not only across the organisation but also with services across the sector with a focus on improving flow and identifying methods for sustaining performance over the winter period and beyond. To build on the success of the first perfect week and to ensure that change is embedded into practice another perfect week will be held in January.

ED four hour wait continued improvement seen in August into September 2016. The median time spend in the ED department decreased and can be attributed to the Improvement plan work stream and supported by the work perfect week on 12th Sept.

Median wait for treatment (minutes) The wait for treatment time remained significantly improved on the YTD average although the performance was marginally below the target.

12 hour trolley waits in A&E there were no 12 hour trolley breaches in September 16.

Ambulance conveyances : Blue light activity diverts from North Middlesex Hospital continue to cause spikes in activity.

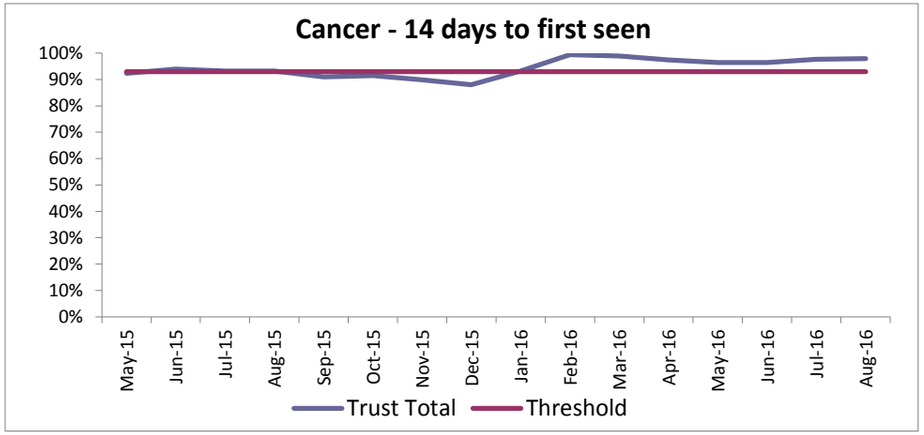
Left without being seen we achieved below the 5% threshold in August which is positive and the number of patients **diverted to Ambulatory Care** saw a slight increase to 3.3% and work between ED and Ambulatory care to further enhance pathways continues.

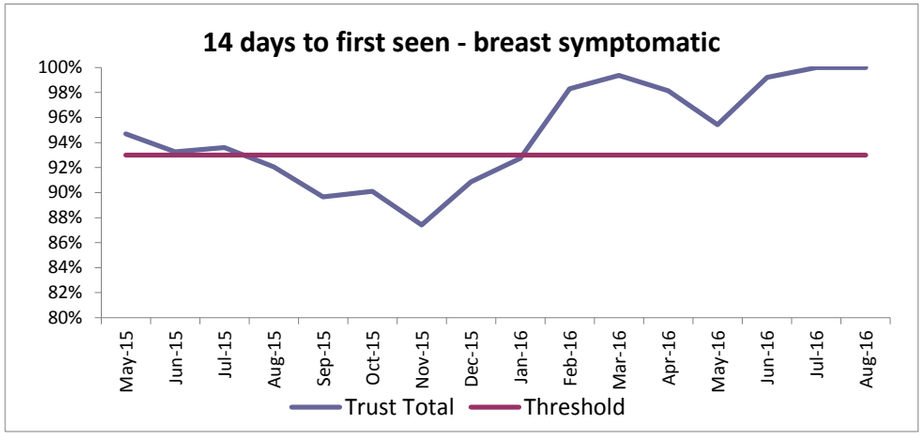
Cancer

Whittington Health NHS

		Trust				2016/17 Trust				
	Threshold	Jun-16	Jul-16	Aug-16	Trend	Q1	Q2	Q3	Q4	YTD
Cancer - 14 days to first seen	93%	96.4%	97.7%	97.9%		96.7%	97.8%	-	-	97.2%
Cancer - 14 days to first seen - breast symptomatic	93%	99.2%	100.0%	100.0%		97.5%	100.0%	-	-	98.4%
Cancer - 31 days to first treatment	96%	100.0%	100.0%	100.0%		100.0%	100.0%	-	-	100.0%
Cancer - 31 days to subsequent treatment - surgery	94%	100.0%	100.0%	100.0%		100.0%	100.0%	-	-	100.0%
Cancer - 31 days to subsequent treatment - drugs	98%	-	-	100.0%		100.0%	100.0%	-	-	100.0%
Cancer - 62 days from referral to treatment	85%	94.9%	83.3%	93.5%		87.4%	89.8%	-	-	88.4%
Cancer - 62 days from consultant upgrade	-	100%	0%	-		100.0%	0.0%	-	-	60.0%

All achieved.





	Threshold	Trust Actual Jul-16	Aug-16	Sep-16	2016/17 Trust YTD
Women seen by HCP or midwife in 10 weeks	-	74.5%	69.1%	72.8%	60.1%
New Birth Visits - Haringey	95%	93.2%	94.6%	Arrears	90.8%
New Birth Visits - Islington	95%	94.9%	93.7%	Arrears	94.8%
Elective Caesarean Section rate	14.8%	11.5%	11.4%	11.3%	11.9%
Emergency Caesarean Section rate	-	17.1%	17.7%	21.4%	17.9%
Breastfeeding initiated	90%	93.7%	91.2%	88.6%	90.6%
Smoking at Delivery	<6%	3.9%	4.4%	4.8%	5.0%

Commentary

Woman see by HCP or midwife in 10 weeks

Improved for September 16

Action: Improvement to be seen over the next months.

Timescale: Staff continue to focus on the 10+0 target.

New Birth Visits August 2016

Haringey continue on upward trajectory due to close monitoring at team level and increase in HV FTE.

Islington fall due to increase in number of new births together with increase in HV vacancies

Islington: 23 (6.3%) late

10x in hospital; 4x late notifications; 4x parental choice; 3x living/staying elsewhere; 1x team error; 1x new birth completed in Chelsea

Haringey: 19 (5.4%) late (Tynemouth Road highest performer - only 3x late)

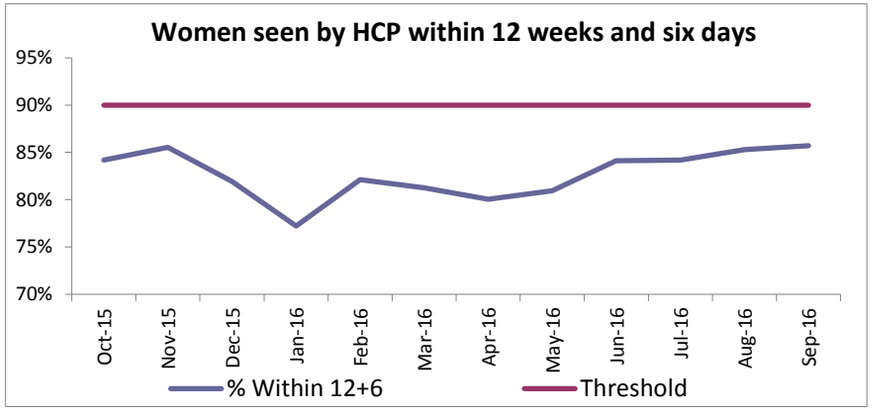
7x in hospital; 3x sent to wrong team (to discuss with CHIS); 3x late notifications; 2x family away; 1x interpreter required; 3x unable to contact/declined

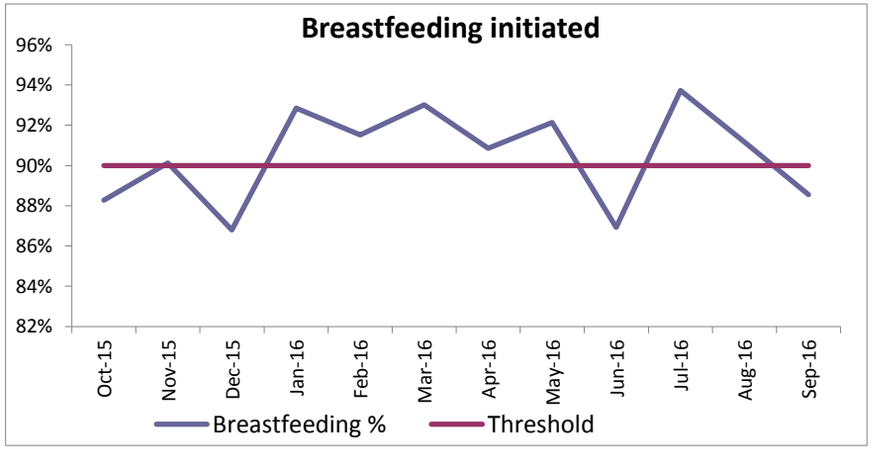
Breast feeding initiated

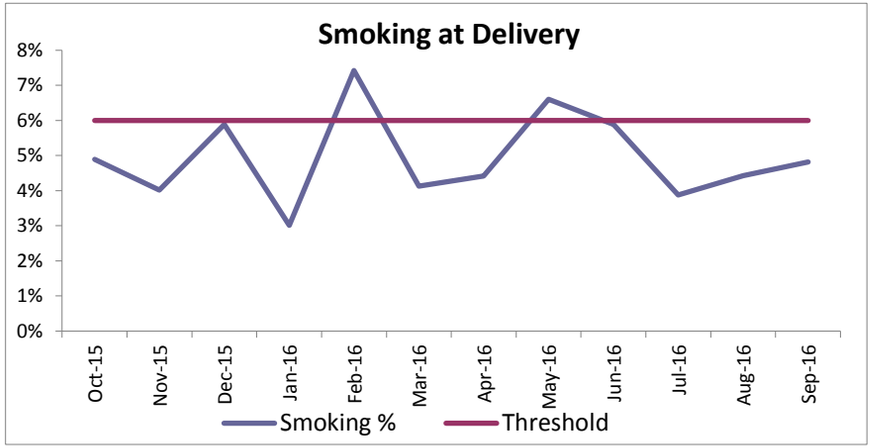
Dip for September 16, expected to be within target for October 2016

Smoking at Delivery

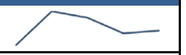
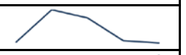
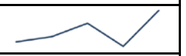
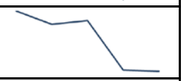
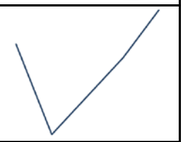
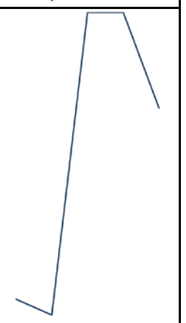
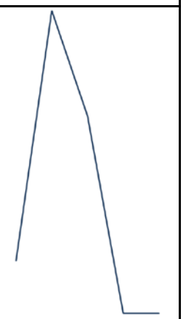
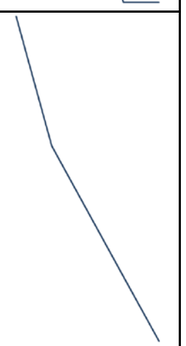
Targets achieved







High Level Workforce Data

Metric	Target or Benchmark	Source	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Notes and Definitions	Trend
Staff Headcount	Trust Annual Plan	ESR	**4,212**	**4,238**	**4,233**	**4,221**	**4,223**	**4,240**	No. of staff employed at the end of the month	
Staff in Post (FTE)	Trust Annual Plan	ESR	**3,837.16**	**3,857.06**	**3,852.00**	**3,838.04**	**3,836.70**	**3,858.33**	No. of staff FTE (full time equivalent) employed at the end of the month	
Establishment (FTE)	Trust Annual Plan	Finance Ledger	**4,401.71**	**4,403.13**	**4,406.87**	**4,400.44**	**4,410.47**	**4,426.19**	Budgeted FTE figures as at the end of the month	
Bank and Agency Use(hrs)		Bank Staff System	**107585.60**	**104955.97**	**105692.53**	**95822.72**	**95574.7**	**90809.1**	Data extracted from Bank Staff on 20/10/2016	
Vacancy Rate %	10%	Calculation	**12.9%**	**12.4%**	**12.6%**	**12.8%**	**13.1%**	**12.8%**	There is continued recruitment activity on hard to recruit roles (nursing and HCAs) . Qualified nursing vacancy rate in Sep was 16.1%, practically no change from August rate (16.2%). HCA vacancy rate has decreased from 18.4% in August to 15.3% in September.	
Annual Turnover %	>13% - red 10-12% - amber <10% - green	ESR	**14.9%**	**14.9%**	**15.8%**	**15.8%**	**15.5%**	**15.9%**	Turnover has slightly increased from last month. At ICSU level Patient Access, Prevention & Planned Care continues to have the highest turnover (22%), Women's Health has the lowest (7.1%), and the remaining ICSUs are above the 13% turnover threshold. In Corporate Finance turnover levels are the highest (33%). Analysis of the 'reasons for leaving' data recorded on ESR in Q2 reflect that the majority of voluntary leavers did not disclose a reason for leaving (45%) and that relocation and promotion were the most common reason for leaving.	
Sickness %	> 3.5% - red 2.5-3.5% - amber <2.5% - green	ESR	**2.9%**	**3.3%**	**3.1%**	**2.8%**	**2.8%**	**2.8%**	Sickness % remain as last month. Medical Director and Facilities had the highest sickness rate in Sep. Sickness rates in Facilities remain at 5.9%, the areas with the highest levels of sickness are in Islington Community Services. PA,Prev&PC had the highest rate (3.7%) within the ICSUs, with Outpatient Nursing and Health Records having the highest levels. Surgery had the second highest with 3.4% (up from 2.8% in Q1), The remaining ICSUs/Directorates remained below or slightly above the threshold of 3%.	
Appraisal Completion	90%	ESR/OLM	**71%**	**69%**	**68%**	**67%**	**66%**	**63%**	As at the end of September 2016 none of the sixteen ICSUs / Directorates were above the 90% threshold, with four areas below 50%. Concern about the drop in appraisal rate has been raised as a matter of urgency with ICSUs and Directorates. Each Director has been asked to prepare an action plan to rectify. In addition the new Trust Pay Progression Policy will be implemented from September 2016 whereby there will no longer be automatic increment progression and a satisfactory appraisal will be required before progressing. This should assist with overall compliance	
Mandatory Training %	90%	ESR/OLM	**81%**	**81%**	**81%**	**81%**	**80%**	**80%**	Percentage of staff compliant for mandatory training. Requirements vary by staff group and roles.