University Hospitals of Leicester NHS
NHS Trust

Cover report to the Trust Board meeting to be held on 4 April 2019

	Trust Board paper Q

Report Title:	**Quality and Outcomes Committee – Committee Chair's Report** (formal Minutes will be presented to the next Trust Board meeting)
Author:	Gill Belton – Corporate and Committee Services Officer

Reporting Committee:	**Quality and Outcomes Committee**
Chaired by:	Col (Ret'd) Ian Crowe – Non-Executive Director
Lead Executive Director(s):	Andrew Furlong – Medical Director Carolyn Fox – Chief Nurse
Date of meeting:	28 March 2019

Summary of key public matters considered by the Committee and any related decisions made:

This report provides a summary of the key issues considered at the Quality and Outcomes Committee on 28 March 2019:

- **Matter Arising – Management of the Cross Site Transfer of Patients -** the Medical Director reported verbally to advise that Mr Jameson, Deputy Medical Director, will be leading a multi-disciplinary Task Group specifically established to review the cross site transfer of patients and this work will commence in the following week. Updates on the progression of the work undertaken by this Task Group will be reported through the quarterly Learning from Deaths Reports, with the next such report due to be reported to the Executive Quality Board and Quality and Outcomes Committee in May 2019.

- **Draft Quality Account –** the Director of Clinical Quality presented the draft Quality Account prior to circulation to external partners on 5 April 2019, noting the need for some updated datasets / additional information to be included before circulation to external partners (including the introduction by the Chief Executive Officer), which was currently in progress. The Quality Account would then be externally audited, as per the statutory requirement, and thereafter presented to the public Trust Board in June 2019. In discussion on the content of this draft report, the following matters were discussed (1) it was suggested, and accepted, that the colours of red and green were not utilised throughout this document given that these two colours were frequently used in Trust documents to indicate a RAG rating of actions which had been achieved (marked in green) and those which had not been achieved (marked in red). As this connotation was not applicable to this document, removal of these colours was considered appropriate to prevent any potential misunderstanding (2) that in future such reports (from 2019/20 onwards), the opportunity was taken to consider how the Trust could present this information one year (and beyond) into the Trust's Quality Strategy and accreditation work (albeit noting the largely prescribed nature of the document's contents which would need to be observed). ***The Quality and Outcomes Committee accepted the contents of the draft Quality Account, subject to the addition of the introduction from the Chief Executive Officer and any required updates to the datasets featured, for release to external stakeholders on 5th April 2019 for comment, prior to external auditing and presentation to the public Trust Board on 6 June 2019.***

- **VTE Prevention Task and Finish Group –** the Director of Clinical Quality presented a detailed update regarding the work of the VTE Prevention Task and Finish Group, which had been in place since 11 December 2018. QOC was specifically asked to note the progress made by the various workstreams as detailed within the report and note that recommendations relating to (1) improving the function of the Thrombosis Prevention Committee and (2) improving training for clinicians would be taken to the Executive Quality Board on 2 April 2019. QOC was also requested to note that the NerveCentre VTE risk assessment module was to be implemented in pilot at the LGH site from the beginning of April 2019. In discussion, it was noted that updates on the progress of this workstream were shared with the Coroner. It was also agreed that a further update on progress would be submitted to the June 2019 EQB and QOC meetings.

- **Acting on Results Update –** the Medical Director presented a report detailing an update on work associated with acting upon results and particularly noted the progress made recently through the ICE system, with the requirement placed upon clinicians to 'file' their results in order that acknowledgement could be demonstrated. Group filing had been undertaken of any results over a year old in order to enhance the speed at which the system worked and on the (risk assessed) basis that these were unlikely to be required after such a timeframe. A further step change would now only be possible with the use of NerveCentre, the move to which was estimated to be in approximately one year's time. In discussion, assurance was provided to members that clinicians were able

to access results requested by colleagues if they were covering their workload due to absence and there was recognition of the need to encourage clinicians to utilise the functionality now available to them through ICE. It was agreed that a further update on progress would be submitted to the June 2019 EQB and QOC meetings.

- **Deteriorating Adult Patient Board Quarterly Update –** the Medical Director presented an update on the work of the Deteriorating Adult Patient Board, noting that this report now also encompassed an update relating to Early Warning Scores (EWS) and sepsis. Particular points for noting were: (1) a potential deterioration in performance management of patients with sepsis, albeit noting some potential data issues which could partly account for this, alongside a genuine dip in performance over the Winter period (2) delivery of NEWS2 ahead of the national deadline and (3) continued satisfactory performance against ICNARC metrics. The Trust was performing well in comparison with the national data, albeit wished to continue to improve. Note was made that the Trust's Sepsis Nurses, previously based in the Trust's Emergency Department, now formed part of a Deteriorating Adult Response Team (DART) which had in-reach into the Emergency Department as well as the rest of the Trust. Specific discussion also took place around the increasing availability of and access to real-time data which was being used proactively to manage workflow. It was considered that it would be useful to utilise a future Trust Board Thinking Day to focus on the benefits to be achieved from access to and use of real time data (through the provision of one to two granular examples of this in practice, with focus then on how to apply this further) and it was agreed that the Trust Chairman would discuss the scheduling of this item at a future Trust Board Thinking Day with the Director of Corporate and Legal Affairs.

- **Aseptic Unit Capacity Plan and External Audit Results –** Ms C Ellwood, Chief Pharmacist, attended to present the Aseptic Unit Capacity Plan which had been revised, due to significant changes in workload and staffing, since it was last approved by the Quality Assurance Committee in September 2017, and thereafter by the Trust Board. All activities within the Aseptic Unit, which is responsible for the dispensing of chemotherapy and other aseptically prepared products, must follow the standards laid out in the Quality Assurance of Aseptic Preparation Services (QAAPS) Guide. There was a requirement that the aseptic unit was externally audited, on an annual basis, against the QAAPS standards. This audit was completed on 19 December 2018 and the final report received on 13 February 2019. The external audit had categorised the aseptic unit as low risk, in line with previous audits. A number of actions had been identified as part of the audit and an action plan had been developed to resolve these within the required timescale. The capacity plan indicated that the aseptic unit was safe at current levels of activity, with the short term measures taken to address the 90% capacity level, however additional activity could not be accommodated without increased staffing and there were plans to address this. **QOC received and noted the contents of this report and approved the revised capacity plan (appendix 4 of paper G refers) for onward recommendation onto the Trust Board for formal approval (as now appended to this summary for Trust Board members for this purpose).**

- **Estates and Facilities Update –** in the absence of the Director of Estates and Facilities, Mr Hotson, Head of Business, Commercial and Contracts, presented the quarterly Estates and Facilities performance data report, which provided an update on the provision of key services across UHL. The data presented covered the period of operation to January 2019 and supplemented the data included in the monthly Quality and Performance Report with wider and more detailed narrative. The previously reported plateaued performance standards had continued and remained short of overall target levels across services, with the exception of patient catering. For cleaning standards, the previously noted slight downward trend suggested by the data had resolved and levelled out again. Both financial (revenue and capital) and operational pressures continued to impact upon both the maintenance of standards and the pace of service development required to progress improvement. Particular discussion took place regarding car parking, Estates and Facilities Information Systems and the response to Datix reports made relating to cleaning issues. Note was also made of the opportunities available to gather intelligence from staff members if they felt sufficiently empowered to bring issues to attention, potentially through more informal means than had previously been tried. Particular note was made of the continued satisfaction demonstrated with the patient catering service and note was made of planned discussion on cleaning at a future Joint PPPC / QOC session, as had been agreed during today's Joint Session.

- **Nursing and Midwifery Quality and Safe Staffing Report -** the report provided triangulated information relating to nursing and midwifery quality of care and safe staffing, and highlighted those wards triggering a level 3, 2 or 1 concern in the judgement of the Chief Nurse and Corporate Nursing team. In January 2019, 1 ward had triggered a level 3 concern (this was the same as in December 2018), there were 4 wards triggering a level 2 concern (this was 3 less than in December 2018) with 17 wards triggering a level 1 concern (this was 5 less than in December 2018.) A verbal update was provided by the Chief Nurse with regard to the actions being taken in response to the staffing challenges on ward 22 LRI (a CHUGGS ward), as discussed at the previous QOC meeting. Particular discussion took place regarding the deployment of Nursing Associates in Secondary care, following the release of national guidance in January 2019 from the National Quality Board and the circulation of a provider briefing on such from the CQC in the same month. QOC members noted that the wealth of data available in respect of nursing staff was not replicated for Midwifery staff, in response to which the Chief Nurse noted that data was collected and submitted to the Local Maternity System and CCGs. Once the Birthrate Plus report had been

received (the timescale for which was not currently known), the Chief Nurse undertook to submit a separate report to the Committee specifically regarding midwifery staffing. The Chief Nurse undertook to seek notification of the timescale for receipt of the Birthrate Plus report, and report on this verbally at the next QOC meeting.

- **Monthly Highlight Report from the Director of Safety and Risk –** the Director of Safety and Risk presented her monthly highlight report, which specifically featured information this month on the following (1) review of moderate plus harm incidents for quarter 3 (2) progress on the Never Event action plan (3) HSIB maternity investigations for UHL (4) Sign Up to Safety Kitchen Table week and (5) feedback from the visit to UHL of Deputy PHSO. The report also appended the latest available patient safety report and complaints report. QOC were specifically asked to note (1) that HSIB would commence maternity investigations in UHL which met their defined criteria from 18 March 2019 (2) the Kitchen Table events at the three sites and (3) the positive feedback from the Deputy PHSO visit and the planned collaborative work to be undertaken on the development of a good practice framework with regard to complaints and the complaints coding review.

- **Reports for information –** QOC received and noted the following reports for information: (1) Fractured Neck of Femur Update and (2) Ophthalmology GIRFT Report.

- **Minutes for Information –** QOC received and noted the Executive Quality Board (EQB) Minutes from 5 February 2019, EQB actions from 5 March 2019 and Executive Performance Board Minutes from 26 February 2019.

Matters requiring Trust Board consideration and/or approval:

Recommendations for approval:-

- Aseptic Suite Capacity Plan (as appended to this report).

Items for noting:-

- The timetable relating to the Quality Account.

Matters referred to other Committees:

- None.

Date of next meeting:	25 April 2019.

Appendix 4: Aseptic capacity plan

UHL PHARMACY SERVICES

LEICESTER ROYAL INFIRMARY ASEPTIC UNIT CAPACITY PLAN DEC 18

The Pharmacy Aseptic service to UHL is currently provided from the aseptic unit located within the main pharmacy department, Windsor building, Leicester Royal Infirmary. The service mainly provided is the preparation of chemotherapy for adult and paediatric cancer services.

This capacity plan takes into account facilities, staffing and complexity of the items being compounded. Its aim is to provide guidance as to safe and effective compounding limits and trigger points for review of workload, staffing or facilities.

Peaks and troughs in activity are to be expected due to the nature of the work being undertaken, however sustained breaching of the agreed capacity levels may be indicative of potential problems in maintaining quality and should be investigated.

Variable time per item in Clean Room (Cleanroom Operator) (C)

The time taken to manipulate a single aseptically dispensed item will vary according to the number of stages and complexity of the stages to achieve the end product. e.g.

- Simple – Draw up of small volume methotrexate for a pre-filled syringe
- Complex – Reconstitution, draw up and addition of multiple components to an infusion bag e.g. Ifosfamide and Mesna infusion.

In order to place a value on these complexity issues timings have been undertaken for a range of products and a rating assigned.

Time assigned for aseptic manipulation (minutes)	Rating (Workload Units)
0 to 5	1
6 to 10	2
11 to 15	3
16 to 20	4
21 to 25	5
26 to 30	6

Fixed time per item in Preparation Room

In addition to the time taken for physical manipulation of the required product there will also be a time factor attached due to the set-up and checking requirements. These timings have been standardised and are assigned to either a Prep Room Operator (F) or Accredited Product Approver (Pharmacist or Technician) (P). These timings (F) or (P) will remain constant irrespective of the complexity rating to compound the product.

Process	Accredited Product Approver Time per item (P)	Prep room Operator time per item (F)	Total Time per item (mins)
Professional Check(Clinical Validation) by clinical pharmacy team	(1)		(1)
Preparation of worksheet & labels		2	2
Checking worksheets & labels		1	1
Setting up of ingredients		3	3
Checking setting up of ingredients		2	2
Transfer decontamination (double spray & wipe using sporicide & IMS)		4	4
Labelling & checking		1	1
Final Check & packing	3		3
Final Release	1		1
Total	**4**	**13**	**17**

Therefore production time required for 1 item rated as 1 workload unit

Prep room Operator **(F) = 13 Mins**

Clean room Operator **(C) = 5 Mins**

Accredited Product A… **(P) = 1 Mi…**

Fixed Sessional time

In addition to the time requirements per item produced there are also fixed timings associated with the beginning and end of each production session for quality assurance and monitoring requirements to be undertaken:

Process	Operator Time (mins) (C)	Pharmacist (P)
Change into clean room clothing	10	
Initial clean of workstation	3	
Setting sessional plates	1	
Finger dabs	2	
Final clean of workstation	3	
Change out of clean room clothing	6	
Total per session	**25**	**0**

On average there are 7 sessions per day resulting in 175mins of fixed sessional Operator time per day = 14.6 hours per week **= 0.39wte**

Dispensing of pre-filled Dose Banded Chemotherapy

50% of current demand (items) for chemotherapy is met by pre-made dose banded products supplied by commercial companies.

The dispensing and some checking of these products is done by Aseptic unit operators and carries a workload value of 1 unit (5 minutes) per item dispensed, equivalent to aseptic dispensing of a simple manipulation item (5mins, 1 workload unit)

Also, based on the timings for checking and releasing of aseptically prepared items each dose banded product would produce a requirement of 1 minute of Accredited Product Approver time.

General Running of Unit

In addition to the timings directly associated with the compounding or dispensing process there are additional time pressures linked to maintenance and Quality Assurance (QA) of the unit and equipment including environmental monitoring, processing of cleanroom garments, data collection and filing. These are summarised below and make up an additional requirement

Process	**Time (mins)**	**Pharmacist (P)**	**Operator (T)**	**Weekly Total**	**Monthly Total**
Daily Tasks	532		532	2660	10640
Weekly Tasks	724		724	724	2896
Monthly Tasks	465		465		465
Total				**3384**	**14001min = 1.5wte**

Staff hours establishment

Accredited Product Approver	**wte**	**Production time available (P) (wte)**
Pharmacist band 8b	0.6	0.1
Pharmacist band 6/7/8a	1.1	1.1
Technician band 6	0.2	0.2
Total	**1.9**	**1.4**

Operators	wte	Production time available (T) (wte)
Team leader band 7	1	0.3
Technician band 5	3	2.4
Technician band 4	3	2.4
Assistant band 3	3.5	2.8
Level 3 Apprentice	2	1.4
Level 2 Apprentice	1	0.8
Total	**13.5**	**10.1**

NB. Less 20% for annual leave, sick leave, breaks etc. & less than 100% efficiency; less 70% for band 6 for management time & APA role; and 30% for level 3 apprentices for college days & QCF time.

Staffing Capacity:

Accredited Product Approver Time (P):

With 1.4wte available for production duties this would indicate that a maximum of 788 workload units per week can be maintained.
(1.4wte x 37.5hrs x 60mins) / 4mins
= 40,950 workload units per year

Operator Time (F & C):

Production time (T) available = 10.1wte

Fixed time requirements = Fixed Sessional time = 0.39wte
= General running of unit = 1.5wte
1.89wte

Remaining time = 10.1 – 1.89 = 8.21wte

8.21wte operators available for production (prep room & clean room) would indicate a maximum of 1026 workload units per week can be maintained.
(8.21wte x 37.5hrs x 60mins) / 18mins
= 53,365 workload units per year

Facilities and Equipment

Clean Room Availability (9am to 5pm)

Equipment = 2 x CDC F negative pressure Isolators for chemotherapy
Daily sessions = 8 x 120mins for chemotherapy = 960mins per day = 4,800mins per week

Fixed sessional time for chemotherapy = 8 x 25mins = 200mins per day = 1,000mins per week

Clean room availability = 4,800 – 1,000mins = 3,800mins (63 hours) per week

Dose Banded items

Dose banded items have a workload value of 1 (5 mins)

Prep room Operator time to dispense **(F) = 5 mins**
Accredited Product Approver time to check **(P) = 1 mins**

Additional time is required to release these items from bond following the unlicensed medicines procedure. This task is normally carried out by a pharmacy technician (or pharmacist) from the aseptic unit who has undertaken the necessary competency assessment.

Technician time to release each item from bond **(F) = 2 mins**

Staff hours actual as at December 2018

Accredited Product Approver	wte	Production time available (P) (wte)
Pharmacist band 8b	0.6	0.1
Pharmacist band 6/7/8a	1.1	1.1
Technician band 7	0.2	0.2
Total	**1.9**	**1.4**

Operators	wte	Production time available (T) (wte)
Team leader band 7	1	0.3
Technician band 5	2	1.6
Technician band 4	3	2.4
Assistant band 3	2.5	2.0
Level 3 Apprentice	2	1.4
Level 2 Apprentice	1	0.8
Total	**11.5**	**8.5**

NB. Less 20% for annual leave, sick leave, breaks etc. & less than 100% efficiency; less 70% for band 7 for management time & APA role; and 30% for level 3 apprentices for college days & QCF time.

Operator Capacity Actual

Operator Time (F & C):

Production time available = 8.5wte

Fixed time requirements = Fixed Sessional time = 0.39wte
= General running of unit = 1.5wte
1.89wte

Remaining time = 8.5 – 1.89 = 6.61wte

6.61wte operators available for production (prep room & clean room) would indicate a maximum of 826 workload units per week can be maintained.
(6.61wte x 37.5hrs x 60mins) / 18mins
= 42,965 workload units per year

Dose Banded Item Capacity

Staff Required for Dose Banded Items Jul-Sep 2018 (Q2)

Staff Grade	Items	Required wte	Available wte	Capacity
Accredited Product Approver (1 min/item)	4,431	0.15	0.15	100%
Operator (5 min/item)	4,431	0.76	0.76	100%
Release from bond (2 min/item	4,431	0.30	0.30	100%

Compounding Capacity (workload units – dose banded items)

Staff Establishment vs Workload Jul-Sep 2018 (Q2)

Staff Grade	Available wte	Workload Units	Required wte	Capacity
Accredited Product Approver (4 min/item)	1.4 - 0.15 = 1.25	8,187	1.12	90%
Operator (18 min/item)	8.21 – 1.06 = 7.15	8,187	5.04	71%

Staff Actual vs Workload Jul-Sep 2018 (Q2)

Staff Grade	Available wte	Workload Units	Required wte	Capacity
Accredited Product Approver (4 min/item)	1.4 - 0.15 = 1.25	8,187	1.12	90%
Operator (18 min/item)	6.61 – 1.06 = 5.55	8,187	5.04	91%

Current Capacity Status

Approximately 50% of current demand (items) for chemotherapy is met by pre-made dose banded products supplied by commercial companies.

The unlicensed medicines process, dispensing, checking and releasing of these products is all done by Aseptic unit operators and pharmacists and carries a workload value of 1 per item dispensed. Some checking of dispensed pre-made dose banded products is carried out by pharmacy technicians rather than accredited product approvers, but it is difficult to quantify the proportion that is. Therefore, accredited product approver capacity is less than that stated here in reality, but is reported for ease of calculation in the capacity plan as though all the checking of these items is carried out by accredited product approvers.

The unit is operating at approximately 90% capacity with current staffing levels (but see comment above for checking dose banded products). However, once vacant posts are filled and staff fully trained, then for the same level of workload activity, operator capacity will be at approximately 70%.

The role of non-pharmacist Accredited Product Approvers has been introduced for checking and releasing aseptic products. At peaks of activity additional support is required from pharmacist or non-pharmacist accredited product approvers to manage the workload currently.

There is currently 1 wte band 5 vacancy (0.5 wte maternity leave & 0.5 wte awaiting approval to advertise), plus 1 wte band 3 post out to advert. The introduction of a sporicidal wipe stage into the transfer decontamination process has increased the time taken for this step, thereby reducing operator capacity. Nevertheless there is sufficient operator staff resource available to maintain the current service, albeit higher than the 80% of capacity required by MHRA to retain sufficient headroom for variable peaks in activity and occasional staff shortages.

The 71% establishment operator capacity reflects the need to retain sufficient training resource for, and oversight of, rotational staff, trainees and apprentices.

The 90% accredited product approver capacity reflects the day to day staffing resource allocated to the aseptic unit for this activity. However, additional authorised pharmacists are available at peaks of activity from the wider pool of oncology pharmacists.

Hours of Service: 09:00-17:30 Hours Monday to Friday

Outside of these hours an On-Call Aseptically trained member of staff is available to undertake aseptic preparation when treatment is considered clinically urgent.

A pilot is underway to extend the finishing time to 18:30 and assess the benefit of this on managing the workload, capacity and staff morale.

Standards for Service Provision to Wards and Clinics

Chemotherapy Day Case Suite: The Day Case Suite operates a 2 stop treatment system and therefore the majority of prescriptions should be received by the Aseptic Unit by 4pm (5pm if the pilot is successful) the day prior to treatment. Completed treatments are transported back to the day case suite by pharmacy personnel on the evening prior to the treatment day. Treatments that cannot be made in advance due to e.g. short expiry dates are scheduled for production on the day and the clinic contacted when ready for collection. There is a two hour turnaround time agreed for 1 stop chemotherapy, however peaks of activity on some days of the week mean that turnaround times are extended beyond two hours at these times. This has been raised as an issue with the Cancer Services chemotherapy group.

Oncology/Haematology Wards
Inpatient chemotherapy is treated as per 1 stop treatment. There is a two hour turnaround time agreed for inpatient chemotherapy unless treatment is scheduled to commence at a later time and the ward contacted when ready for collection prior to this. However peaks of activity on some days of the week mean that turnaround times are extended beyond two

hours at these times. This has been raised as an issue with the Cancer Services chemotherapy group.

Haematology Day Case
Osborne Day Care operate a 1 stop treatment system. There is a two hour turnaround time agreed for 1 stop chemotherapy, and the clinic contacted when ready for collection, however peaks of activity on some days of the week mean that turnaround times are extended beyond two hours at these times. This has been raised as an issue with the Cancer Services chemotherapy group.

HOPE Clinical Trial Unit
The HOPE unit operate a 2 stop treatment system as far as possible within the constraints of trial protocols. The majority of prescriptions should be received by the Aseptic Unit by 4pm (5pm if the pilot is successful) the day prior to treatment. Treatments that cannot be made in advance due to e.g. short expiry dates or protocol restrictions are scheduled for production on the day and the clinic contacted when ready for collection. There is a two hour turnaround time agreed for 1 stop chemotherapy, however peaks of activity on some days of the week mean that turnaround times are extended beyond two hours at these times. This has been raised as an issue with the Cancer Services chemotherapy group.

Paediatric Chemotherapy: Prescriptions for chemotherapy should be received by 4pm (5pm if the pilot is successful) on the day prior to treatment. Chemotherapy is released to the ward following receipt of a treatment confirmation list for that day. Treatments that cannot be made in advance due to e.g. short expiry dates are scheduled for production on the day and the ward contacted when ready for collection. There is a two hour turnaround time agreed for 1 stop chemotherapy.

Updated by David Lovett (Principal Pharmacist for Aseptic Services): 18.12.18

Approved by Claire Ellwood (Chief Pharmacist): 18.12.18

Approved by the Trust Board: