

COUNCIL OF GOVERNORS

**Meeting to be held on Thursday, 23 November 2023 at 9.30 – 12.30 in
 E5 Bristol, 3-15 Jamaica Street, Bristol, BS2 8JP**

AGENDA

NO.	AGENDA ITEM	PURPOSE	SPONSOR	TIMINGS
1.	Welcome and Apologies	Information	Chair	9.30
2.	Declarations of Interest	Information	Chair	
3.	Foundation Trust Members' Questions	Information	Chair	
4.	Minutes of Previous Meeting: <ul style="list-style-type: none"> 29 June 2023 11 September 2023 (AMM) 	Approval Information	Chair	
5.	Matters Arising and Action Log	Approval	Chair	
6.	Chair's Report	Information	Chair	9.35
7.	Chief Executive's Report (Verbal Update)	Information	Chief Executive	9.45
8.	Theme for this month: Finance, Capital and Estates	Discussion	Chief Finance Officer	10.00
9.	Operational Report (Verbal Update)	Information	Chief Operating Officer	10.30
10.	Governor Questions	Discussion	Chair	10.40
11.	Pharmacy Technical Services Outline Business Case	Approval	Director of Pharmacy	11.00
12.	Nominations and Appointments Committee Update	Information	Director of Corporate Governance	11.10
13.	Governor and Membership Forward Look	Information	Director of Corporate Governance	11.15
14.	Governors Log of Communications	Information	Chair	11.20
15.	Any Other Urgent Business <ul style="list-style-type: none"> Quarterly Patient Experience and Complaints Reports (<i>circulated for information</i>) 	Information	Chair	11.25
16.	Date and time of next meeting: <ul style="list-style-type: none"> Tuesday, 16 January 2024 Lecture Theatre, The Academy Weston General Hospital	Information	Chair	



**University Hospitals
Bristol and Weston**
NHS Foundation Trust

**Minutes of the Council of Governors Meeting on Thursday 29th June 2023, held in
Conference Room, Trust Headquarters, Marlborough Street, Bristol.**

Present

Name	Job Title/Position
Jayne Mee	Chair of the Board and Chair of the Council of Governors
Ben Argo	Public Governor
Sofia Castillo	Staff Governor
John Chablo	Public Governor
Mary Conn	Public Governor
Carole Dacombe	Public Governor
Robert Edwards	Public Governor
Tom Frewin	Public Governor
Sarah George	Appointed Governor, University of Bristol
Fi Hance	Appointed Governor, Bristol City Council
Suzanne Harford	Public Governor
Mike Hockett	Appointed Governor, Joint Union Committee
Jude Opogah	Staff Governor
Mo Phillips	Public Governor
Annabel Plaister	Public Governor
Richard Posner	Public Governor
Janis Purdy	Public Governor
Martin Rose	Public Governor
John Sibley	Public Governor

Others in attendance:

Arabel Bailey	Associate Non-executive Director
Sam Chapman	Associate Director of Organisational Development and Wellbeing (item 8)
Guy Dickson	Associate Director of HR Operations (item 8)
Jane Farrell	Interim Chief Operating Officer (item 9)
Bernard Galton	Non-executive Director (item 8)
Rachel Hartles	Membership and Governance Officer (Minutes)
Emily Judd	Corporate Governance Manager
Alex Nestor	Deputy Chief People Officer (item 8)
Mark Pender	Head of Corporate Governance
Eric Sanders	Director of Corporate Governance
Jean Scrase	Associate Director of Education (item 8)
Roy Shubhabrata	Non-executive Director
Daisy Westbrook	Corporate Governance Officer
Emma Wood	Chief People Officer (item 8)
Eugene Yafele	Chief Executive

Jayne Mee, Trust Chair, opened the meeting at 10.00.

Minute Ref:	Item	Actions
COG:01/06/23	Chair's Introduction and Apologies	
	The Chair, Jayne Mee, welcomed everyone to the meeting and in particular Jayne welcomed newly elected and appointed Governors: Janis Purdy; Suzanne Harford; Sofia Castillo; Jude Opogah; Richard Posner; Mary Conn; Tony Tanner and Mike Hockett.	

	<p>Apologies had been received from Aishah Farooq, Karen Low, Mark Patteson, and John Rose.</p> <p>Jayne outlined the new vision for Council of Governors meetings, which would include discussions around key themes which related to the core pillars from the Trust's priorities key risks.</p>	
COG:02/06/23	Declarations of Interest	
	There were no new declarations of interest from Governors relevant to items on the agenda.	
COG:03/06/23	Foundation Trust Member Questions	
	No questions had been received by members of the public.	
COG:04/06/23	Minutes from Previous Meeting	
	<p>Governors considered the minutes of the meeting of the Council of Governors held on 18 April 2023.</p> <p>Annabel Plaister, Public Governor, asked whether the response to a question relating to occupied beds from a Foundation Trust Member that was received in April's meeting had been circulated to the Council of Governors. It was agreed that this would be circulated again.</p> <p>ACTION: Corporate Governance Team to circulate to the Governors the written response to the question raised by a Foundation Trust member received at April's Council of Governors.</p> <p>Members RESOLVED to approve the minutes of the Council of Governors meeting held on 18 April 2023 as a true and accurate record of the proceedings.</p>	Corporate Governance Team
COG:05/06/23	Matters Arising and Action Log	
	There were no outstanding actions on the action log.	
	Members RESOLVED to approve the action log.	
COG:06/06/23	Chair's Report	
	<p>Jayne Mee updated the Governors on her Chair's Report, which included all activity she had undertaken in the previous six months until May 2023. Key points included:</p> <ul style="list-style-type: none"> • A new Joint Clinical Strategy had been given the go-ahead to progress from the Integrated Care Board (ICB) The strategy would need approval from the Acute Provider Collaboration Board, by the Trust Board, and by North Bristol NHS Trust (NBT) Board. Once the approval process had taken place, the strategy would be shared with Governors. • Jayne had participated in the Non-executive Director (NED) recruitment that had been circulated for approval at this meeting, • Jayne had attended the Trust's Staff Network Day Conference in May 2023 and she commended the work undertaken by networks and the Equality, Diversity and Inclusion team. • Visited the Bristol Haematology and Oncology Centre (BHOC). • Jayne advised that a new Integrated Care System (ICS) Strategy had recently been approved and would be published shortly. 	

	<p>Mo Phillips, Public Governor, commended Jayne on the amount of work she had been doing.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Receive the Chair's Report for information. 	
COG:07/04/23	<p>Chief Executive's Report</p> <p>Eugine Yafele, Chief Executive, provided an update on the main issues facing the Trust. Highlights from the update included:</p> <ul style="list-style-type: none"> • A re-ballot was being undertaken by Junior Doctors which was yet to be confirmed. Consultants had also been balloted for industrial action and there was a possibility that these strikes could happen in succession, which would provide some very significant risks to the Trust. • A recruitment centre in Nigeria had been fraudulently providing information on qualifications and sending nurses to work in the United Kingdom. Although in our Trust only one nurse was affected, the Nursing and Midwifery Council was investigating the issue and would provide actions and feedback to the Trust on next steps once their investigation was concluded. • A new discharge hub was to be set up in the Bristol and Weston sites as well as in NBT to help the number of patients with no criteria to reside. More details would follow in due course; however, it was confirmed that this new hub would include members of staff from various partners as well as current discharge hub staff from UHBW. • NHS England had announced that Bristol would be one of several new sites to house a Gender Identity Service, due to launch in 2024. There was already a long waiting list for this service and the Trust would be working hard to have the service up and running as soon as possible. • All NHS Trusts were subjected to being added to 'tiers' by NHS England depending on whether the Trust hit a variety of performance targets. UHBW had been put in tier 2 which demanded additional reporting and oversight functions but due to exceptional progress the organisation was recently released from the tiering programme which was a tremendous achievement. • The Trust had produced the Annual Report and Accounts for 2022-2023 which showed no loss of finances once more and it was noted the Trust had not ended a financial year in deficit for 20 years. • Agency usage for 'level 4' agency nurses in the Trust had decreased significantly due to a new type of pay offered to nursing staff at certain bands. <p>Ben Argo, Public Governor, asked what representations the Trust had made to the Government along with system partners in relation to the ongoing industrial action. Eugene advised that NHS Providers and NHS Confederation had taken the views of the Trust into account when discussing the ongoing industrial action with the Government.</p> <p>Fi Hance, Appointed Governor from the Bristol City Council was interested in receiving further details on the discharge hubs that were being set up in the various hospital settings and where the funding was</p>	

	<p>being found. Eugene Yafele informed Fi that the discharge hubs were being funded through the Better Care funding stream, however further details were not yet available while the set up and specifics were agreed between system partners. John Sibley, Public Governor, was interested in what the hub would look like and how the hub would work together. Jane Farrell, Chief Operating Officer, apprised the Governors that although there was not going to be a specific building for the hub, a space was being sought for the group to work together to increase the number of patients being discharged while cutting down on the amount of patients in hospital with no criteria to reside.</p> <p>Jude Opogah, Staff Governor, queried the wellbeing available to staff who were working tough shifts. Eugene advised that the wellbeing hubs were always available for staff and shift managers were being encouraged to ensure their staff had access to the wellbeing resources at any point that they were required.</p> <p>Eric Sanders, Director of Corporate Governance, confirmed to the Governors that the Annual Report and Accounts had been sent to be laid before Parliament and would be presented to the Council of Governors at the Annual Members Meeting on Thursday 21 September 2023.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Receive the Chief Executive's Report for information. 	
COG:08/06/23	Theme for this month: People, including Education and Leadership Programme	
	<p>Bernard Galton, Non-executive Director and Chair of the People Committee, opened the session by explaining what the People Committee did and when they met. He explained that the Committee would focus on the four objectives of the People Strategy (Growing for the Future, New ways of Working, Inclusion & Belonging, Looking after our People).</p> <p>Bernard introduced Emma Wood, Chief People Officer who would talk about one of the recent successes of the Committee which was the approval of the Education Strategy. Emma thanked Bernard and explained how the People team was split into different focus areas. She introduced Jean Scrase, Associate Director of Education to provide an overview of the Education Strategy and how it would fit into the theme of Growing for the Future.</p> <p>Jean explained that it was a subset of the People Strategy and that it covered system-working now and in the future. She said the strategy covered both internal education and external education options which were aligned to the Leadership Framework. She finished her presentation by explaining that all training information was in the process of being added to Kallidus Learn, the learning portal for staff, and was expected to be available for managers in October 2023.</p> <p>Carole Dacombe, Public Governor, commended the strategy but noted a potential backlog of managers who had not received the mandatory training for leaders. She then asked whether the Trust was confident in the feedback from exit interviews that the leadership training provision would be enough to help retain more staff. Emma Wood agreed that the exit interview process had been revamped and was confident that the</p>	

	<p>information was being provided to the relevant teams to ensure learning from staff exiting the Trust is developed to retain future staff.</p> <p>Richard Posner, Public Governor, asked whether reverse mentoring was being used within the Trust. Jean confirmed that it was, and Jayne Mee, Trust Chair, highlighted that she was in a reciprocal mentoring agreement with Jude Opogah, Staff Governor and noted how valuable the process was.</p> <p>Jean explained how the team had mapped out the possible nursing career pathways available and advised the next steps would be to develop the same plans for other areas of the Trust, such as Allied Health Professionals (AHPs) and Admin and Clerical roles.</p> <p>Tom Frewin, Public Governor, queried whether other Trusts were doing a similar mapping exercise. Jean replied that they were and that our mapping project was being done in alignment with NBT to ensure UHBW was offering the same options to staff.</p> <p>Annabel Plaister, Public Governor, queried the retention rate for staff on the nursing career pathways, which Jean confirmed overall it was around 95% but would depend on the pathway they were on for more specific figures.</p> <p>Ben Argo, Public Governor, queried the entry routes for various levels not included on the pathway and how they would be decided. Jean advised that people with different qualifications to the ones on the pathway would be discussed on a case-by-case basis and an agreement reached.</p> <p>Carole Dacombe commended the strategy and asked whether it would be fed into the ICS to be developed in alignment with other system partners. Jean advised that as the senior officer responsible for the learning and Leadership Academy across the ICS, this would be fed through to other ICS partners.</p> <p>Jean ended her presentation with the offers available for staff to develop themselves and their teams.</p> <p>Ben Argo asked how lived experience was used in training programmes. Jean used the example of the Oliver McGowan training that was now mandated in the Trust for training which used lived experiences of people who had autism and she explained how it impacted on their experiences within the hospitals.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Receive the theme of the month discussion for information. 	
COG:09/06/23	Operational update	
	<p>Jane Farrell, Interim Chief Operating Officer, provided the Governors with an Operational Update. She highlighted that there was improvement in planned and emergency care trajectories, although planned industrial action had caused some significant problems. She finished by highlighting that the trajectories for no patients waiting 65+ weeks by the end of March 2024 was still on target.</p>	

	<p>Tom Frewin, Public Governor, asked how the industrial action was impacting on the Trust, as the national view was not positive. Jane Farrell confirmed that although the industrial action was causing significant issues on the waiting lists at the Trust, there was ongoing improvement overall.</p> <p>Rob Edwards, Public Governor, queried whether the sickness of staff was having a large impact on the Trust. Jane Farrell explained that it was a concern for her over the number of staff off sick, although this had decreased slightly. Tom Frewin further suggested that the national picture was a high level of staff absent due to sickness and asked how this was reflected within the Trust. Bernard Galton, Non-executive Director, highlighted that sickness was monitored constantly within the People Committee.</p> <p>Carole Dacombe, Public Governor, questioned the amount of wellbeing available to staff who were cancelling the appointments with patients, which could effectively cause some difficult conversations. Jane Farrell agreed that this was of paramount importance to the Trust and due to learning from previous industrial action, scheduling was paused rather than having to book and cancel appointments to limit the effect on staff who were having to make the phone calls.</p> <p>Mo Phillip, Public Governor, asked about the outsourcing activity that was ongoing in the Trust. Jane Farrell confirmed this was still ongoing, although was done more at regional level than national due to the ability to update the national picture at a suitable rate.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Receive the Operational Update for information. 	
COG:10/06/23	Governor's questions	
	<p>Jayne Mee, Trust Chair, advised that this item had been added as a standing agenda item to provide time for Governors to ask questions which related to the Public Board meeting held earlier in the month.</p> <p>Rob Edwards, Public Governor, asked about the closure of dental surgeries in the region and how much of an impact this had had on the Dental Hospital. Jayne Mee agreed that this was an area of major concern and the Integrated Care Board had been discussing it in a recent meeting she had attended as well. She did highlight, however, that should a patient need a dentist in an emergency, they would be seen in the Dental Hospital. Conversation continued around the work undertaken the Hospital and how confident the Board was with the dental services being provided by the Trust. Jayne Mee finished the conversation by stating that although it was stretched, the Board was confident in the services provided by the Hospital.</p> <p>Mo Phillips, Public Governor, highlighted issues with communication when contacting the hospital by telephone and the perceived lack of knowledge of the staff who were answering the phones on how to get to the correct person to solve questions and queries. Arabel Bailey, Associate Non-executive Director, advised that as a member of the Finance and Digital Committee, reducing call volumes had been</p>	

	<p>discussed often, and how the Trust could achieve this to ensure patients were getting the answers they sought without any frustration. Eugene Yafele, Chief Executive, assured Governors that the Patient First work that was ongoing in the Trust would capture some of the improvement work that was required in this area, although noted work was already underway to address the issue. Eric Sanders, Director of Corporate Governance, advised that a section of the Customer Service training offered to staff included handling telephone calls, but he would confirm that this was still included.</p> <p>ACTION: Eric Sanders to confirm that the Customer Services training available at the Trust still included elements of customer service on the telephone.</p> <p>Sofia Castillo, Staff Governor, highlighted the number of patients who did not know what they wanted, and asked whether there was provision to expand the Patient Advice and Liaison Service or the LIAISE (Listening, Information, Advice, Involving, Support, Experiences) service available in the Adults and Children's Hospitals respectively. Eugene Yafele advised that there was unfortunately no provision to expand the current services, however there were other ways to provide the same support to patients and this was being invested in by the Trust.</p>	Director of Corporate Governance
COG:11/06/23	Appointment of Non-executive Directors	
	<p><i>Arabel Bailey left the meeting.</i></p> <p>Eric Sanders, Director of Corporate Governance, provided a report to the Council of Governors on recent recruitment to Non-executive Director and Associate Non-executive Director roles in the Trust. Eric explained the recruitment was completed with an External Recruitment Agency (ERA) and was overseen by the Nominations and Appointments Committee (NOMCO).</p> <p>Carole Dacombe, Public Governor, confirmed that members of the NOMCO were consulted on all aspects and included in the process, and there was rigorous conversation over the appointments made.</p> <p>Richard Posner, Public Governor, queried whether the Trust was comfortable with the diversity of people on the Board. Jayne Mee, Trust Chair, advised that the Trust was accepting of the diversity of the Board, as it also reflected the high calibre of the people that had been attracted to a position on the Board.</p> <p>Jayne Mee asked the Council of Governors to approve the appointment of</p> <ul style="list-style-type: none"> • Arabel Bailey, Non-Executive Director. • Dr Rosie Benneyworth, Non-Executive Director. • Emma Glynn, Associate Non-Executive Director. • Susan Hamilton, Associate Non-Executive Director. <p>There were no dissenting voices.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Approve the appointment of: <ul style="list-style-type: none"> ○ Arabel Bailey, Non-Executive Director. ○ Dr Rosie Benneyworth, Non-Executive Director. ○ Emma Glynn, Associate Non-Executive Director. ○ Susan Hamilton, Associate Non-Executive Director. 	

	<i>Arabel Bailey re-joined the meeting.</i>	
COG:12/06/23	Re-appointment of Non-executive Director	
	<p>Eric Sanders, Director of Corporate Governance, presented the report on the re-appointment of Non-executive Director, Martin Sykes. Eric explained to the Governors how all Non-executive Directors were subject to re-appointment every 3 years and every year on their last term of office. He explained that the Trust was seeking approval to re-appoint Martin Sykes from August 2023-August 2024.</p> <p>Jayne Mee, Trust Chair, added that Martin was an excellent Vice Chair and Chair of the Finance and Digital Committee. She asked the Council of Governors to approve the re-appointment and the Council of Governors confirmed re-appointment.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Approve the re-appointment of Martin Sykes for his 7th term of office. 	
COG:13/06/23	Lead Governor Election 2023-2024	
	<p><i>Mo Phillips left the meeting.</i></p> <p>Eric Sanders, Director of Corporate Governance, presented the paper on the Lead Governor election for 2023-2024. He confirmed the role of the Lead Governor was introduced by NHS England to ensure an independent relationship between Trust and the Regulator, should this ever be required. The role had changed over time and had now become the main point of contact between Governors and the Chair. He explained that Mo Phillips was the only person to receive any nominations with seven nominations in total. Mo had agreed to continue in the role for one final year and succession planning was underway to elect for a Deputy Lead Governor within the year.</p> <p>The Council of Governors approved the appointment.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Approve the appointment of Mo Phillips to Lead Governor from 1 July 2023 – 31 May 2024. <p><i>Mo Phillips re-joined the meeting.</i></p>	
COG:14/06/23	Annual Cycle of Business for COG/Focus Groups	
	<p>Emily Judd, Corporate Governance Manager, provided an update to Governors on the Annual Cycle of Business for the Council of Governors and Governor Focus Groups and Nominations and Appointments Committee (NOMCO) Terms of Reference.</p> <p>She advised that changes to the Focus Group Terms of Reference included changes to reflect the merged team into the Corporate Governance team and to include a specific update on Quality Objectives and Patient First. She also confirmed the NOMCO Terms of Reference had been ratified in the recent NOMCO meeting.</p> <p>Emily also advised that there were four members of the Council of Governors who had nominated themselves to be part of the NOMCO membership and the Council of Governors approved these new members.</p>	

	<p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Approve: <ul style="list-style-type: none"> ○ The Governor Focus Groups Terms of Reference, ○ The Nominations and Appointments Terms of Reference, ○ The Council of Governors Annual Business Cycle, ○ Four new members of the Nominations and Appointments Committee: <ul style="list-style-type: none"> ▪ Ben Argo, Public – South Gloucestershire ▪ Libby Thompson, Appointed – UWE ▪ Jude Opogah, Staff – Non-clinical ▪ Sofia Castillo, Staff – Non-clinical 	
COG:15/04/23	Governor and Membership Forward Look and Election Update	
	<p>Emily Judd, Corporate Governance Manager, provided an update to the Council of Governors. She advised of the activity Governors had undertaken since April 2023, which included focus groups, elections and development seminars. Looking forward, Emily highlighted the focus on the Membership Strategy, a Divisional Update Day and the Annual Members Meeting. She also highlighted the team were looking into holding informal drop-in sessions for constituents and would provide details once these were set up.</p> <p>Annabel Plaister, Public Governors, commented on the spacing of Council of Governors meetings and it was agreed to take the conversation offline and discuss in more detail.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Receive the Governor and Membership Forward look for information. 	
COG:16/06/23	Election and Appointment of Governors	
	<p>Emily Judd, Corporate Governance Manager, provided an update on the Election and Appointment of Governors after the Election to the Council of Governors concluded on 21 May 2023. She confirmed that all but one seat was filled in Medical and Dental Staff, and there would be a need to conduct another election later in the year for this seat. She also confirmed that there was only one uncontested seat in the Public (South Gloucestershire) category.</p> <p>Eric Sanders, Director of Corporate Governance added that the team would be working with the Medical Directors office to help with trying to fill the seat that remained unfilled in the Medical and Dental Staff Governor Constituency.</p> <p>There were no comments from the Council of Governors.</p> <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Receive the Election and Appointment of Governors Report for information. 	
COG:17/06/23	Governor's Log of Communications	
	Emily Judd, Corporate Governance Manager, noted the updates in the Governor's Log of Communications.	

	<p>Since the last meeting on 18 April 2023:</p> <ul style="list-style-type: none"> • Six questions had been added to the Governors log relating to Cancer Support, Apprenticeship Support, Discharge, ED processes after Hours, Minor Injuries Units and Internet Perceptions. • Three questions had been answered by Executive Directors relating to Cancer Support, Apprenticeship Support and Discharge. • Three questions were unanswered but were not overdue. • A new system had been found and was being used to log the Governors Log questions and provided a better level of reporting than the previous system. <p>Members RESOLVED to:</p> <ul style="list-style-type: none"> • Receive the Governors Log of Communications for information. 	
COG:18/06/23	Any Other Business	
	There was no other business discussed.	
COG:19/06/23	Meeting close and date of next meeting	
	<p>The Chair declared the meeting closed at 12.20. The date of the next meetings would be:</p> <ul style="list-style-type: none"> • Annual Members Meeting – Thursday 21st September 2023, 17.00 – 19.00 • Council Of Governors; Thursday, 23 November 2023 	

Minutes of the Annual Members' Meeting of University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) held on Tuesday 12 September 2023 at 17:15-19:15

This meeting was held in Lecture Theatre 1, Education and Research Centre, Upper Maudlin Street, Bristol.

Present

Members of the Trust Board of Directors

Jayne Mee – Trust Chair
Sue Balcombe – Non-executive Director
Paula Clarke – Executive Managing Director Weston General Hospital
Neil Darvill – Joint Chief Digital Information Officer
Jane Farrell – Chief Operating Officer
Deirdre Fowler – Chief Nurse and Midwife
Bernard Galton – Non-executive Director
Marc Griffiths – Non-executive Director
Neil Kemsley – Chief Financial Officer
Martin Sykes – Non-executive Director
Stuart Walker – Chief Medical Officer
Eugene Yafele – Chief Executive

Members of the Council of Governors

Ben Argo – Public Governor
John Chablo – Public Governor
Mary Conn – Public Governor
Robert Edwards – Public Governor
Tom Frewin – Public Governor
Lisa Gardiner – Staff Governor
Sarah George – Appointed Governor
Fi Hance – Appointed Governor
Suzanne Harford – Public Governor
Mike Hockett – Appointed Governor
Jude Opogah – Staff Governor
Annabel Plaister – Public Governor
Richard Posner – Public Governor
Janis Purdy – Public Governor
John Rose – Public Governor
Martin Rose – Public Governor
Tony Tanner – Public Governor

Guest Speakers

Duncan Laird, Senior Manager, KPMG – External Auditor
Cathy Caple, Associate Director of Improvement and Innovation, UHBW

In Attendance

Rachel Hartles – Membership Manager
Emily Judd – Corporate Governance Manager
Mark Pender – Head of Corporate Governance
Eric Sanders – Director of Corporate Governance

Approximately 15 members of the public, patients and staff members of University Hospitals Bristol and Weston NHS Foundation Trust were also in attendance.

<p>1. Chair's Introduction and Apologies</p> <p>Jayne Mee, Trust Chair, welcomed everyone to the Annual Members' Meeting (AMM) for University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) and explained that the meeting was being held in person and recorded for posting online at a later date.</p> <p>Apologies had been received from:</p> <ul style="list-style-type: none"> • Carole Dacombe, Public Governor • Jocelyn Hopkins, Staff Governor – Other Clinical • Karen Low, Staff Governor – Nursing and Midwifery • Karen Marshall, Staff Governor – Nursing and Midwifery • Mark Patteson, Public Governor • John Sibley, Public Governor • Libby Thompson, Appointed Governor – University of the West of England • Arabel Bailey, Non-executive Director • Roy Shubhabrata, Non-executive Director • Emma Wood, Chief People Officer
<p>2. Minutes of the previous Annual Members Meeting/Annual General Meeting</p> <p>The minutes of the last meeting were noted by the Board and Governors. The minutes were approved as an accurate record of the meeting.</p>
<p>3. Independent Auditors' Report</p> <p>Duncan Laird, Senior Manager at KPMG, provided an update regarding the Independent Auditors' Report as below:</p> <ul style="list-style-type: none"> • All deadlines had been met to audit the Trust. • KPMG issued an unqualified opinion in 2022/23 for the Trust. This meant that the accounts gave a true and fair view of the Trust's performance during the year and of its year-end financial position. • The key findings from the financial statements and governance review concluded that there were no significant internal control weaknesses identified. • The Trust was not selected as a sampled body for 2022/23, which meant that only limited procedures were required. KPMG did not identify any inconsistencies between the financial statements and the information included in the consolidation schedules. <p>Jayne Mee, Trust Chair, thanked Duncan Laird for the audit work undertaken.</p>
<p>4. Presentation of Annual Report and Accounts for 2022/23</p> <p>Jayne Mee, Trust Chair, introduced Eugene Yafele, Chief Executive, Neil Kemsley, Chief Financial Officer, and Deirdre Fowler, Chief Nurse and Midwife and invited them to present the review of the Trust from 2022-2023.</p> <p><u>Review of the Year 2022/23</u></p> <p>Eugene Yafele, Chief Executive, provided a summary of the highlights from the Annual Report and Accounts as below:</p> <ul style="list-style-type: none"> • The year had seen an increase in attendance in Emergency Departments (EDs) in the Trust – there were 193,471 attendances in ED in 2022-2023. • The Trust had worked hard to arrange discharges for patients and received funding from the Integrated Care System to invest in the Every Minute Matters scheme and an expansion of the Same Day Emergency Care (SDEC) Unit.

- Waiting times had decreased; the Trust had eliminated 104 week waits, seen an 82% reduction in number of patients waiting 78 weeks, only 178 patients waiting 62+ days on GP suspected cancer pathways, improved diagnostic waiting times and made a £3.7m investment in two surgical robots.
- During the year:
 - Weston General Hospital improved their CQC rating with three out of five areas assessed rated Good.
 - The main ED was ranked ninth in the National Urgent and Emergency Care Survey for 2022.
 - The Trust launched an Extra Corporeal Membrane Oxygenation (ECMO) service.
 - The Trust also launched AccessAble guides on its websites.
- The Trust also provided wellbeing support to a large number of staff and increased the variety of support available.

Annual Accounts 2020/21

Neil Kemsley, Chief Financial Officer, highlighted the Trust's financial statements from the Annual Report and Accounts 2022/23 as below:

- For the 20th year in a row, the Trust achieved breakeven or better (before technical items) year-end accounts.
- The Trust also achieved the system capital allocation (CDEL) of £54m.
- The largest amount of income (88%) was generated from treating patients.
- The largest amount of expenditure (61%) was spent on staff costs.
- The Trust spent £60.3m of capital expenditure on strategic investment, medical equipment, IT, general estate maintenance and operational capital.
- There was a further £54m planned capital expenditure in 2023-2024.
- Looking forward there was an ambitious Trust and system plan with stretching financial, activity and performance targets. There would be a renewed focus on elective recovery, productivity improvement and recurrent savings delivery.

Presentation of Quality Achievements 2022/23

Deirdre Fowler, Chief Nurse and Midwife, presented the Quality Achievements as below:

- The Trust had chosen five objectives for 2022/2023:
 - Delivering the NHS Patient Safety Strategy (Year 2).
 - Improving patient experience of discharge from hospital (Year 2).
 - Developing and delivering a new vision for post-pandemic volunteering.
 - Developing a new Trust strategy for Healthcare Inequalities, with a focus on Equality, Diversity & Inclusion for patients and communities.
 - 'Waiting Well'.
- All objectives had been achieved during the financial year.
- A new accreditation scheme had been launched around the monitoring, assessing and improvement of quality of care given at ward or department level. All 66 areas assessed achieved at least silver accreditation, with seven achieving gold accreditation.
- For 2023/2024, three objectives were to be carried forward from 2022/2023 and two new Patient First objectives were created:
 - Delivering the NHS Patient Safety Strategy (Year 3).
 - Improving patient experience of discharge from hospital (Year 3).
 - Waiting well (Year 2).
 - Improving experience of care through better communication.
 - Effective and timely recognition, escalation and response to improve the care of patients whose condition is at risk of deteriorating.

5. Governor/Membership Report

Unfortunately the Governor and Membership Report was not presented at the AMM due to illness. It was advised that the activity of the Governors and Members would be added to the Council of Governors website and any questions on the presentation could be directed to an email address that would be provided when posted.

Guest Speaker Slot – Patient First

Jayne Mee, Trust Chair, introduced Paula Clarke, lead Executive Director for the Patient First Operating model, who provided an overview of the service to the meeting. The following points were highlighted:

- This new operating model would provide the Trust with many benefits such as more involvement, better focus, a culture of improvement, provide a structure, build on strengths and support leadership.
- There were six objectives that would be focussed on in the Trust:
 - Exceptional patient experience (We will be in the top 10% of NHS organisations for providing an outstanding experience for all our patients as reported by them and as recognised by our staff).
 - Excellent care, every time (Building on the many things we do well to keep our patients safe, we will reduce avoidable patient harm events - aspiring for zero avoidable harm, and further developing a “no blame” and “just culture”).
 - Proud to be #TeamUHBW (We will improve the employment experience of all our colleagues to retain our valuable people).
 - Timely access to care for all (By streamlining flow & reducing variation we will eliminate avoidable delays across access pathways).
 - Unlocking our potential (We will be in the top 10% of NHS organisations for our staff stating they can easily make improvements in their area of work).
 - Using our resources wisely (To achieve a 1% income and expenditure surplus from 2025/26 onwards, creating a recurrent source of funding for strategic investment).
- Each objective had an end goal (in brackets above).
- There was a variety of problem solving methods used which depended on the scale of the problem.
- Communication of improvements were seen as the key to achieving the support required for staff.
- The most common form of problem solving was known as A3 thinking. This was a nine step problem solving approach on one A3 page which looked for solutions to the root cause of the problem.

Jayne Mee, Trust Chair, thanked the team on behalf of the Trust for the work they had done to date.

6. Question and Answer Session

Eric Sanders, Director of Corporate Governance, stated that two questions had been submitted in advance of the meeting:

- “Staff costs are always high on expenditures for any company, but how much impact did the industrial action have last year on the bottom line?”
 - Neil Kemsley, Chief Financial Officer, explained that the financial year 2022-2023 saw a £2.5-3m impact on income and expenditure due to paying for shifts to be covered for striking colleagues. There was no secondary impact on the Trust in terms of loss of income due to reduced activity.

- “How many legal settlements have been paid by the Trust to patients in the last financial year as a result of claims for clinical negligence and what is the total sum paid in those settlements?”
 - Eric Sanders, Director of Corporate Governance, confirmed that this question would be answered outside of the meeting as there was no information available at the time.
- “Throughout the evening, reference has been made to productivity. Please can you advise where productivity has most improved in the last financial year?”
 - Neil Kemsley advised that the highest level of improvement had been made in length of stay of around c.30%. This was due to the improvement programmes such as Every Minute Matters and earlier discharges.
- “Could you please update us on the possibility of a merger with North Bristol NHS Trust (NBT)?”
 - Eugene Yafele, Chief Executive, explained that there were no immediate plans to merge with NBT but the two Trusts had committed to collaborating together and becoming more productive in delivering care.
- There was a special thank you to the Corporate Governance team for all their hard work on behalf of the Governors.
- “There have been several news reports about members of staff not feeling safe to come forward with allegations of racism in the hospital and I wondered what the Trust was doing about this?”
 - Eugene Yafele explained that there were a number of schemes launched in the Trust, including the “It stops with me” scheme to highlight things that are difficult to talk about. The conversation within the Trust, however, was increasing and was starting at the top of the organisation with the Board to think and act differently. Eugene highlighted that the Trust was working towards being an anti-racist organisation and said that the Trust was actively engaged in becoming an entirely anti-racist organisation.
- “In light of the recent media coverage on abuse in operating theatres, did the Trust take part in the survey and what will the Trust be doing about it?”
 - Eugene Yafele acknowledged that this was an unacceptable behaviour although admitted that the Trust had not taken part in the survey. He highlighted that NHS England had released a new sexual safety charter that the Trust was working through to ensure the Trust responds appropriately.
- “You have spoken about the activities Trust is engaged in, but what will the Trust be doing to support the staff who report the issues?”
 - Eugene Yafele agreed that it was important for staff to feel safe when reporting incidents, and that Freedom to Speak Up was one of a number of routes for staff to speak out. Eugene warned about being too complacent and advised that the Trust was using a combination of ways for staff to speak up to ensure that the Trust did not assume there was no issue in one area over another.
- “Maternity services are much in the news these days and the comments are that the costs of the maternity services is a lot less than the costs of claims made against it. What are the figures within this Trust?”
 - Neil Kemsley assured the meeting that the costs of the maternity service was considerably more than the insurance premiums paid for the Trust. Within the Clinical Negligence Standards for Trusts, this Trust was one of only 50% of the country that achieved all benchmarking targets for the country.
 - Stuart Walker, Chief Medical Officer, further commented on the Trust’s ambition that they will provide a very high quality, safe and effective service for patients and their families.

Close of meeting

Jayne Mee, Trust Chair, thanked everyone for attending the meeting and reminded members they were welcome to attend the regular Board of Directors and Council of Governors meetings. Thanks were given to the presenters at the meeting, and to all the staff and governors, members and charitable partners that supported the Trust in the wider community.

DRAFT

Council of Governors meeting – 23 November 2023
Action Log

Actions following Council of Governors meeting held on 29 June 2023					
No.	Minute reference	Detail of action required	Responsible Officer	Completion date	Additional comments
1.	COG: 04/06/23	Minutes from previous meeting Corporate Governance Team to circulate to the Governors the written response to the question raised by a Foundation Trust member received at April's Council of Governors.	Corporate Governance Team	November 2023	Suggest action closed Governors now receive all questions raised and answers received updated weekly on Convene.
2.	COG:10/06/23	Governors Questions Eric Sanders to confirm that the Customer Services training available at the Trust still included elements of customer service on the telephone.	Director of Corporate Governance	November 2023	Suggest Action Closed There are three programmes available to staff relating to customer services and all include telephone training. The Leadership and Management Training Team would be happy to reach out to any departments Governors have experienced issues with and offer the training to them if department names are provided.



Meeting of the Council of Governors on Thursday 23rd November 2023

Report Title	Chair's Report
Report Author	Jayne Mee, Trust Chair

For Information

Introduction

It has been another busy few months against the backdrop of elective recovery and multiple episodes of industrial action. Our wonderful staff have continued to go above and beyond over this difficult time to keep our patients safe. We now enter winter, where once again we shall be calling on all their resilience to support our patients through the next few months. The whole Board recognises the challenges and are very grateful to our staff as always.

Board Meetings

I have chaired the usual round of Board and Governor Meetings and attended Board Committees.

Trust Departmental Visits

I have continued my visits in key areas of the Trust with senior clinical colleagues and NEDs, albeit that some visits were postponed or curtailed due to Industrial Action:

- Weston General Hospital on two occasions with Paula Clarke, Exec Managing Director, Judith Hernandez, Hospital Director and Jo Poole, Head of Nursing
- BHOC with Rachel Protheroe, Clinical Chair, Owen Ainsley, Divisional Director and Jamie Cargill, Divisional Director of Nursing
- BRHC with Martin Gargan, Clinical Chair and Fiona Jones, Divisional Director
- Dermatology with Emma Kate Reed, Clinical Chair Medicine
- Diagnostics and Therapies with Rachel Bennett, Clinical Chair
- Accreditation Assessment on Penguin Ward with Juliet Neilson, Assistant Chief Nurse

Board Development

We continued our Board Development and the EDI agenda with Dr Eden Charles from People Opportunities. Eden is now working with the Senior Leadership Team across the Trust to begin embedding a cultural journey to improve the way we think and feel about diversity and inclusion.

The Board has begun working with rhr consultant David Cumberbatch to identify and develop how we can continue to work as a unitary board.



Integrated Care System (ICS)/Partnership Working/NHS Providers/NHS England

I continue to attend the Integrated Care Partnership Board where we finalised the ICB strategy for delivery during the last 6 months. We are now integrating this with our very own strategy refresh at UHBW to ensure that the two fit well together.

I have continued to co-chair the Acute Provider Collaborative Board with Michele Romaine, Chair at North Bristol NHS Trust (NBT). The Governors will be aware there has been much progress as we work more closely with our colleagues at NBT.

We had a pivotal Board to Board with NBT in August which paved the way for our Joint Clinical Strategy.

NHS England Nationally and Regionally have held several meetings for Chairs, one in particular focusing on Winter Resilience. As always it will be challenging, but I think we are in good shape at UHBW with a detailed operational plan.

Governance and Governors

We are required by NHS England to conduct a Well Led review every three-five years. We have been working with DCO Partners to support us in this review. I have had subsequent conversations with DCO and they have observed a number of our Board and Committee meetings.

I was delighted to meet our new Governors at their induction day in the summer. It's always nice to see new faces and have new perspectives on board.

We have continued with our regular Governor/NED engagements sessions which are incredibly helpful in understanding the public and staff perceptions of our patient services.

Staff Networks

I had the pleasure to meet two cohorts of our International Nurses who have joined the Trust. I met some wonderful people who were so pleased to have arrived to start work with us. I have the greatest of understanding and respect for these nurses who have given up their home and family to move to Bristol, that's quite an undertaking.

I have also chaired the two Menopause Conferences we have run this year. I feel so proud that this is something our staff are feeling much more comfortable in talking about. We have certainly moved a long way in the last couple of years with this sponsored by me.

**Reciprocal Mentoring**

What a pleasure it has been to mentor Jude Opogah through the Bridges Talent Management Programme. We have shared stories and learning together, and I am even more delighted that he has become one of our staff Governors. I was so proud to support Jude and to see all the other members of the programme at their graduation afternoon – truly inspirational!

NED Recruitment

I was pleased we were able to appoint one NED and two Associate NEDs from a very strong field when we recruited in late Spring. Rosie Bennyworth (NED), Susan Hamilton (ANED) and Emma Glynn (ANED) joined the Board in July and have settled in very well. I was delighted to confirm Arabel Bailey into role as a NED following her year as an Associate.

Key Decisions and Actions

Looking forward, much of my focus remains consistent over the coming weeks and months:

- Supporting the team through the challenges of Winter
- Keeping Workforce, Estates and Digital high on our agenda.
- Chairing the recruitment of two new NEDs to replace Jane Norman, Audit Committee Chair and Bernard Galton, People Committee Chair
- Continuing to build a unitary high performing Board
- Acute Provider Collaborative implementation of the Joint Clinical Strategy
- Leaving UHBW in good order for a new Chair to pick up next Spring.

Meeting of the Council of Governors on Thursday 23 November 2023

Report Title	Pharmacy Technical Services Outline Business Case
Report Author	Michael Compton c/o Akeso co. LTD
Executive Lead	Stuart Walker, Medical Director UHBW

1. Purpose

The paper details the requirement to transform pharmacy technical services across the BNSSG region and presents the preferred option which has been derived from a full options appraisal undertaken by a specialist external consultancy firm.

The intention is to develop the case into a full business case to bid for capital funding from NHSE Specialist Commissioning with a Capital Departmental Expenditure Limit (CDEL) uplift for the region.

2. Key points to note *(Including any previous decisions taken)*

In 2020, Lord Carter of Coles conducted a review of NHS Pharmacy Aseptic Services in England, which recognised nationally that aseptic services are experiencing significant challenges based on increasing growth in demand, a lack of capacity to meet the demand and aging aseptic units requiring investment to maintain.

These challenges are also reflected locally at University Hospital Bristol and Weston (UHBW), and North Bristol NHS Trust (NBT) where the rising demand in aseptic services has been highlighted along with the aging estate:

- NBT is approaching maximum production output with limited ability to expand their current site of operations.
- UHBW Bristol sites are approaching maximum capacity with significant reinvestment required in the coming years. The additional requirements because of Annex 1 of the Good Manufacturing Practice (GMP) regulations are expected to accelerate and increase the cost of necessary reinvestment required.

This business case is predicated on the assumption of capital funding from outside of the BNSSG ICS CDEL from nationally available funding as part of the national NHSE Infusions and Special Medicines Programme following on from Lord Carter of Coles' Transforming Aseptic Care in England Report.

This paper represents an application for a portion of the £275m national funding from NHSE. Following successful allocation of £75m to phase 1 pathfinder initiatives, this project would be funded through the remaining allocation £200m, which is expected to be made available in FY 2025/26.

UHBW and NBT have come together to initiate a project to assess the opportunities available to transform their pharmacy aseptic and technical services.

The project team have assessed a variety of options to develop Pharmacy Aseptic and Technical Services (PATs) in the region and have worked closely with all service leads across the two trusts to ensure operational and regulatory requirements are fully understood in the development of a future service option.

UHBW and NBT are seeking to establish and operate a new, fully MHRA licensed off-site regional aseptics and technical services hub, supported by existing on-site spokes at both Trusts to deliver the required capacity – Option 4c of the Outline Business Case Options Appraisal.

The proposal capitalises on existing MHRA licensing, and provides futureproofing of pharmacy technical services in terms of growth, service developments (e.g. Hospital at Home) and technical advances in medicine.

The transformation aims to deliver service efficiencies, and ultimately enhance patient safety, patient care, and the patient experience through fulfilling the unmet need and releasing nursing time to care, consistent with the recommendations in the Transforming NHS Pharmacy Aseptic Services in England Report, Lord Carter 2020.

The proposed operating model will also aim to provide services to NHS organisations within other integrated care systems across the country, helping to bridge the demand gap between external suppliers and NHS requirements, as well as creating commercial opportunities in collaboration with the existing market.

This business case has been developed in line with the HMT Blue Book Guidance in accordance with the five case methodology.

3. Strategic Alignment

The case aligns with the Trust strategy ***‘Embracing Change, Proud to Care: Our 2025 strategy’*** through enabling significant update to the old hospital estate, and going some of the way to address one of the areas for improvement identified within the strategy:

‘Although we have made major improvements to our hospital estate, the physical capacity and environment in some of our buildings is still inadequate and there is more work to do.’

Implementation of the preferred option would enable us to ***‘continue to develop our estate and provide a modern, nurturing environment for staff and patients’***, as well as realise the ambitions related to our specialist and regional services:

‘1. Consolidate and grow our specialist portfolio. We offer specialist services in all our hospitals and we have assessed that our core areas of excellence are where we expect demand to continue to rise, from both demographic growth, our reputation and national service designations. We are planning to target growth primarily in the following services:

- Haematology and oncology services including the introduction of new immune effector cell treatments and increased clinical research trials through a further development of the Bristol Haematology and Oncology Centre’***

Implementation of the preferred option aligns with the ambition within the strategy to ***‘Invest in our hospital estate and a healing environment creating the physical capacity required to support our specialist and tertiary care demand, upgrade our core infrastructure’*** and ***‘ensure that adequate estate options are available for future clinical or non-clinical developments.’***

The recommendations in the report also align to all elements in the UHBW Trust vision:

‘grow our specialist hospital services and our position as a leading provider in south west England and beyond’

‘work more closely with our health and care partners to provide more joined up local healthcare services and support the improvement of the health and wellbeing of our communities’

‘become a beacon for outstanding education and research and our culture of innovation.’

The paper recommends developing a hub and spoke model for the provision of pharmacy technical services, to manufacture products for multiple integrated care systems across the country, futureproofing the service regarding capacity and growth. It lays the foundations for innovative technologies in terms of both automation and new medicines.

Development of the paper has been collaborative between key stakeholders in the acute hospitals within the BNSSG ICS. The recommendations have been derived from qualitative and quantitative information provided by pharmacy technical service leads, with shared decision making at the core in order to deliver care to our patients in a more joined up approach across the ICS. Furthermore, key stakeholders from national teams have been engaged in the project to ensure a substantiated approach to aligning the recommendations with national strategy.

The concept of the project aligns to the BNSSG Strategic Framework for Integrated Care through enhancing productivity and value for money in the acute sector by leveraging economies of scale, and by following an innovative and asset-based approach. If realised, the space to be brave and innovative relating to emerging fields such as genomics and new medicines will be created, further reflecting system level and national priorities.

4. Risks and Opportunities

Risks

Risk of requiring significant local financial resource would be presented in not proceeding with the case. Service delivery through the current technical services estates is not sustainable in the long term, and would require renovation and maintenance in line with legislation to ensure adherence to the regulations of the MHRA and new standards such as Annex 1 of GMP. This would place a substantial financial burden on the Trust/ system, along with a risk of down time where refurbishment/ renovation is required, impacting integrated care systems beyond BNSSG for whom UHBW are a current supplier.

There would be an increasing over-reliance on the commercial sector/ third party suppliers in line with demand growth, meaning potential unavoidable cost pressures and decreased resilience in an already fragile supply chain.

Opportunities for innovation may be restricted due to finite capacity and limited room for growth.

Key delivery risks:

The requirement to re-evaluate options for delivery of pharmacy technical services in the region would be mandated if national funding was not allocated to the project. Considerable efforts have been made to liaise with NHSE colleagues and align to expectations; these efforts will continue to further minimise this risk.

The necessary workforce may not be available to support the preferred model. This would be mitigated through exploration of new approaches to skill mix, early initiation of recruitment and phased waves to reduce recruitment burden and impact of risk.

Delays to the project’s transitional timelines may cause a reduction in aseptic services across the region which cannot be covered elsewhere, particularly regarding radiopharmacy services

where UHBW are the key supplier in the region. Services and facilities would transition on a scaling basis and where necessary, would dual-run facilities to cover any potential down-time of services in order to mitigate the risk.

A fully detailed Risk Log can be found in the Management Case of this Business Case with impact and severity scoring.

Opportunities

Supporting development of the case into a full business case would mean the Trust and region would have the opportunity to develop an exemplar pharmacy manufacturing unit, improving and futureproofing service delivery in terms of capacity, growth and innovation. The unit would service other integrated care systems in the country, fulfilling unmet needs in the market and creating commercial viability and income to re-invest into further growth and innovation. The supply of ready to administer (RTA) products would also see nursing time released, which could be redirected towards caring for our patients.

Furthermore, the stature of the facility could positively impact the reputation of UHBW, and increase the appeal of UHBW as an employer, attracting more talent into the organisation and region.

5. Recommendation

This report is for Approval

The Council of Governors is asked to approve the development of this outline business case into a full business case to present to NHSE Specialist Commissioning in order to bid for national funding and regional CDEL uplift for the transformation of pharmacy aseptic services in line with the preferred option.

The Capital Investment policy sets out the governance arrangements for capital investments undertaken by the University Hospitals Bristol and Weston NHS Foundation Trust (UHBW).

Capital Investment refers to funds invested in the Trust with the understanding it will be used to purchase or create assets, rather than used to cover operating expenses.

The policy takes into account NHS Improvement's Single Oversight Framework (SOF) published 30th September 2016 and most recently the introduction of the Fundamental Criteria which is a key change in the way that business cases are reviewed by NHSE/I.

The policy applies to capital investments by UHBW regardless of the source of funding.

Particular consideration is given to capital investments which impact on the Trust's liquidity as measured by the Use of Resources Rating per the SOF and are classed as major and/or high-risk accordingly.

A proposal will be classed as a major investment if its estimated capital cost including VAT exceeds £12 million.

Within the policy, Governors have responsibility to:

Assure that Trust governance has been correctly followed and adhered to for any applications for significant, strategic, and high-risk transactions as outlined in section 7 of the policy.

Detailed in section 7 of the policy, Table 4 shows the thresholds used to determine the internal approval route for all capital investment business cases.

These approval routes are in the context of the Trust having a Long-term financial plan (LTFP) and a capital programme agreed by the Board, so there has already been a formal prioritisation process to get to the scheme into the wider programme before the detail is tested in the development of the business cases.

It is also assumed that all business cases have the formal support of the relevant Divisional Board(s) prior to submission through the wider Trust approval route.

Table 4 – Internal Approval Route for ALL capital investment business cases

Threshold Capital expenditure including VAT £m	Business Case format	Div Board	Trust Capital Group	SEDP B	CPSG	SLT	F&D Comm tee	Trust Board	CoG
<£50k	Short form bus case	Yes							
>£50k <= £1m (Operational Capital)	As determined by OPP	Yes	Yes		Yes				
>£50k <= £3m (Major Medical)	As determined by OPP	Yes	Yes		Yes				
>£1m <= £3m	BJC or SOC+ OBC+ FBC	Yes		Yes	Yes				
>£3m <= £5m	SOC+ OBC+ FBC	Yes		Yes	Yes	Yes			
>£5m <= £12m	SOC+ OBC+ FBC	Yes		Yes	Yes	Yes	Yes		
>£12m	SOC+ OBC+ FBC	Yes		Yes	Yes	Yes	Yes	Yes	Yes

Owing to the level of capital spend (>£12m), the Council of Governors are required to assure that Trust governance has been correctly followed and adhered to for any applications for significant, strategic, and high-risk transactions. The pharmacy business case is classed as a Strategic Investment, as it enables the Trusts strategy as set out in the 'Embracing Change, Proud to Care – Our 2025 strategy.'

6. History of the paper

Please include details of where paper has previously been received.

UHBW Diagnostics and Therapies Divisional Board	26 th April 2023
UHBW Clinical Strategy Delivery Group	15 th May 2023
NBT CCS Divisional Group	16 th May 2023

UHBW Strategic Estates Development Programme Board	18 th May 2023
UHBW Capital Programme Steering Group	23 rd May 2023
NBT Business Case Review Group	5 th July 2023
UHBW Finance, Estates and Digital Committee	25 th July 2023
UHBW Governors Strategy Group	7 th September 2023
UHBW Trust Public Board Meeting	12 th September 2023



UHBW & NBT Pharmacy Aseptic and Technical Services Short Form Business Case Template £5m - £25m Schemes

SECTION 1: SCHEME OVERVIEW		
SCHEME DETAILS		
PROJECT DESCRIPTION	Region:	South West
	STP / ICS Name:	Bristol, North Somerset, and South Gloucestershire
	Lead Organisation for the Scheme:	University Hospital Bristol and Weston NHS Foundation Trust (UHBW), North Bristol NHS Trust (NBT)
	Title of the Scheme:	Pharmacy Aseptic and Technical Services
	One Line Description of the Scheme:	UHBW and NBT are seeking national capital funding to establish a pharmacy technical services hub model to increase production and capacity of these services to better meet current and future patient requirements and support national supply constraints.
	Specific Sites for Investment:	<ul style="list-style-type: none"> UHBW – Bristol Hospital Sites NBT – Southmead Hospital Site UHBW - Weston General Hospital (WGH) Site
	Other Organisations Impacted by this Scheme:	<ul style="list-style-type: none"> BNSSG ICB NHS Hospitals in the South West Region Wider NHS Organisations serving as potential customers to the proposed scheme
BRIEF SCHEME OVERVIEW Summarise the key dimensions of the scheme in terms of the outputs that will be enabled in service terms as a consequence of the investment.		<p>This business case is predicated on the assumption of capital funding from outside of the BNSSG ICS CDEL from nationally available funding as part of the national NHSE Infusions and Special Medicines Programme following on from Lord Carter of Coles' Transforming Aseptic Care in England Report.</p> <p>This represents an application to a portion of the £275m national funding from NHSE. Following successful allocation £75m to phase 1 pathfinder initiatives, this project be funded through the remaining allocation £200m. As with the phase 1 pathfinder initiative, this business case will also be reliant on an uplift of CDEL limits. While this has not been agreed to or approved yet, NHSE stakeholders have indicated that this will be allowed.</p> <p>University Hospital Bristol and Weston (UHBW), combined with North Bristol NHS Trust (NBT) have come together to initiate a project to assess the opportunities available to transform their pharmacy aseptic and technical services. The project identified in 2019 but was delayed due to COVID-19 and was re-initiated in the middle of 2022 once the pandemic pressures had subsided. Given the proportional split of current production volume output and overall scale of operations, UHBW will act as a lead organisation as part of this project. Both organisations have considered this appropriate in the context of current working operations, expected future demand profiles and the intended working operations of the preferred option.</p>

Since then, the project team have assessed a variety of options to develop Pharmacy Aseptic and Technical Services (PATS) in the region and have worked closely with all department leads across the two trusts to ensure operational and regulatory requirements are fully understood in the development of a future service options.

To ensure PATS across Bristol, North Somerset and South Gloucestershire ICS continue to address growing demand, UHBW and NBT are seeking to establish and operate a new, fully MHRA licensed off-site regional aseptics and technical services hub, supported by existing on site spokes at both Trusts to deliver the required capacity (infrastructure, equipment and crucially, the skilled workforce) and capability (including improved batch production capacity) to develop an NHS-leading pharmacy aseptics and technical service, resilient to future demand and pressures.

The transformation aims to deliver service efficiencies, and ultimately enhance patient safety, patient care, and the patient experience through meeting the unmet need and releasing nursing time for redeployment onto other patient care activities, consistent with the recommendations in the Transforming NHS Pharmacy Aseptic Services in England Report, Lord Carter 2020

The proposed operating model will also aim to provide services to other NHS providers, helping to bridge the demand gap between external suppliers and NHS requirements.

This business case has been developed in line with the HMT Blue Book Guidance in accordance with the five case methodology.

LEAD ORGANISATION DETAILS

SENIOR RESPONSIBLE OFFICER (SRO) DETAILS	Title	Director of Finance and Information Officer
	Name	Neil Kemsley
	Organisation	University Hospital Bristol and Weston NHS Foundation Trust
	Office tel.	0117 3423649
	Mobile tel.	
	e-mail	Neil.kemsley@uhbw.nhs.uk

APPENDICES CHECKLIST

APPENDIX	COMPLETED / ATTACHED (Y/N)
Appendix 1 – Additional Programme Detail	Y
Appendix 2 – Schedule of Works	TBC
Appendix 3 – OB Forms	TBC
Appendix 4 – Key Estates Information	TBC

SECTION 2: PROGRAMME SPECIFIC INFORMATION REQUESTS

PROGRAMME TO REQUEST SPECIFIC REQUIREMENTS FROM PROVIDERS

PROPOSED BENEFITS AS A RESULT OF CAPITAL INJECTION

Please provide a description of the anticipated benefit of the scheme on:

- production and supply of ready to administer aseptic infusions.
- anticipated patient safety benefits
- resilience against increases in demand
- release in WTE nursing capacity onto other patient care activities.
- Contribution to the NHS Net Zero aspirations

- **Production & Supply of ready-to-administer aseptic infusions:** Based on the key benefits of, batch scale production, releasing nursing time to other patient care activities and meeting future growth in demand, it was decided that the initial product scope for the off-site hub would focus on products ranging from chemotherapy, immunotherapy, central intravenous additive services (CIVAS), parenteral nutrition and radiopharmacy aseptic products, as well as pre-packs and non-sterile products. The product portfolio will remain under review to ensure the benefits continue to be realised and the overall demand for aseptic products is considered. However, for the purposes of this business case, we have not included costs or benefits related to pre-packs or non-sterile manufactured items. For the purposes of this business case, all numbers presented allow for separation of radiopharmacy from the other in scope aseptic products as defined by NHSE (which we have considered as chemotherapy, immunotherapy, parenteral nutrition and CIVAS). While the authors recognise that the allocated NHSE funding pot is not currently intended for radiopharmacy, there is recognition of the sense that it makes to include radiopharmacy. This is for several reasons.
 - In the context of pharmacy aseptic and technical services, it is important to note that radiopharmacy does not act in total isolation, independent of other service areas.
 - One of the stated goals within the critical success factors working session, during the development of this business case, was to improve internal collaboration capabilities and provide a greater level of contingency in terms of both staffing and facilities. Similarly, in the context of ICSs and the business case requirements of improving external collaboration, we have recognised that we can best support this by improving internal PATS collaborative ability. By providing a single facility from which all core operations will work, this will help to support this aim.
 - Radiopharmacy, along with NHSE in-scope aseptic areas, aligns closely with the NHS Long Term goals regarding improved cancer diagnosis and treatment.
 - The current UHBW radiopharmacy facility supplies to multiple external organisations, including NBT. Given this, and the fact that these services have limited external regional resilience, it makes logical sense to improve this service line in looking to build resilience and improve patient outcomes.
 - Radiopharmacy services is included in the context of the wider South West aseptic services strategic approach.
 - Lastly, in the context of the preferred option (involving a new hub off site), and the current UHBW radiopharmacy site conditions, it makes financial and strategic sense to include these services.
- **Production & Supply of ready-to-administer aseptic infusions (continued):** If needed, the structure of the model design allows for separation of the radiopharmacy elements. Total output for the Off-site hub and the local hospital satellite services will increase from approximately 46.5k doses per annum to 339k doses per annum across UHBW and NBT, with radiopharmacy excluded. Conversely, total dose output rises from 58.5k to 381k dose per annum when radiopharmacy is included. C.25% of the total need of high-cost products (c. 14k dose units, with the majority being chemotherapy products) are purchased from third-party commercial suppliers which are also facing capacity constraint with extended lead times (from 3 to 40+ days). Establishment of the new hub, however, will increase in-house capacity to levels which will remove the high dependency on the third-party sector and significant cost elements. For example, the Weston General Hospital site, which has no pharmacy aseptic production capacity, had an outsourcing cost of £4.9m for 2021/2022 alone. When considered in the context of demand growth, this will represent significant cost avoidance and medication budget efficiency resulting in better use of public resources. One of the stated goals of NHSE's Infusions and Special Medicines

Programme is to scale aseptic volume production from 4 million doses per annum to 40 million doses per annum. The proposed volumetric production scale increases will support this ambition.

Baseline Volume (2021/22)				
Medication Category	Made	Purchased	Total Volume	Relative Contribution
Chemotherapy	26,326	13,449	39,775	55%
CIVAs	8,037	-	8,037	11%
Immunotherapy	4,144	16	4,160	6%
PN	8,062	-	8,062	11%
Radiopharmacy	11,892	-	11,892	11%
Total	58,461	13,465	71,926	100%

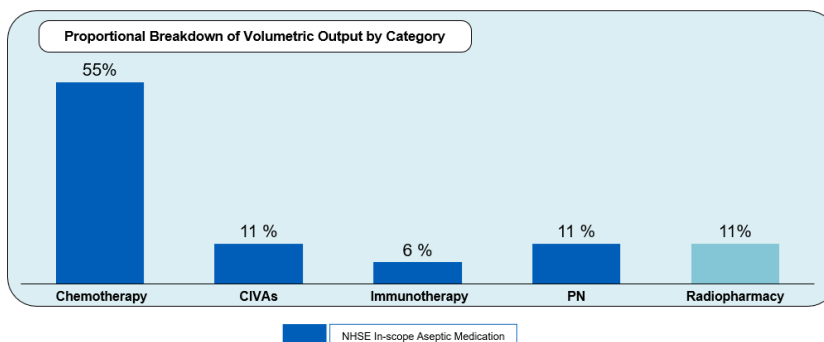


Figure 1: Proportional Breakdown of Baseline Volume

- Anticipated patient safety benefits:** NHS sources have estimated that in 2006, there were approximately 800 patient safety reports per month (nationally) relating to injectable medications. As off 2021, this had risen to a national average of 3750 reports per month, representing a nearly 5-fold increase. While we cannot comment on the causal nature of this increase, the increase in demand for these products will be a significant contributing factor. With the stated goals of the NHS Long Term plan and the expected associated demand in aseptic products, investment in this area is a must. Decreased prescribing and administration errors, by further adoption of standardised or dose banded administration and increase in supply of ready to administer products, as well as reducing infection risk associated with licensed manufacturing. Indeed, this has been stated as a key goal of the NHSE Infusions and Special Medicines Programme. Large scale batch manufacture in a licensed hub will facilitate the movement of 'could-do' and 'should-do' product lines into pharmacy aseptic units which will result in a more optimal skill-mix for preparation and reduce the risks associated with preparation in clinical areas, particularly regarding contamination risk and errors resulting from disruption. A decrease in missed doses is also anticipated due to the availability of ready to administer products. The retention of production capacity in small on-site facilities will further ensure that short shelf life, clinical trials or urgent request items are still available when required. In arriving at the preferred option, retaining on site production capability was recognised by all clinical leads and stakeholders as essential in maintaining the highest standards of patient care.
- Increased ability to contribute toward inpatient reductions:** As outpatient parenteral antibiotic therapy (OPAT) schemes and comparable prioritised care in the community schemes (such as virtual wards) develop, it is envisioned that through effective utilisation and management of the offsite hub facility, it will be possible to contribute to these ambitions. This will have direct care benefits for patients but will also help to manage demand profiles for acute NHS facilities. Furthermore, it should reduce the number and risk of hospital acquired infections (compounding bed pressure reduction benefits) and should support antimicrobial stewardship goals. Already, there is a growing body of evidence of the benefits of utilisation of OPAT services for patients who are otherwise well enough to avoid hospital admissions or facilitate early discharge. Since November 2021 to February 2023 over 4000 bed days have been saved. A Bristol Area OPAT review from 2022 has listed that one of the key decisions for multi-disciplinary teams (MDTs) in reviewing patient eligibility for OPAT services is the direct capacity available. Furthermore, the same retrospective review highlighted the diversity in patients eligible for this service. By ensuring broad access and

improving patient access, this new facility should act to support reduction of health inequalities.

- **Resilience against increases in demand:** The project will deliver improved resilience particularly with respect to availability of workforce and continuity of supply and output as the products are prepared in-house. In line with the Health Building Note (HBN) 00-07 Planning for a resilient healthcare estate, multiple factors have been identified that can negatively impact facility and system resilience that represent current risks to existing facilities. These include facility downtime because of fire or flood, problems related to transport infrastructure that impact delivery availability, security and staffing wellbeing risks, loss of critical support in the wider supply chain (especially in the context of third-party reliance). The new hub model will therefore ensure improved resilience as demand mapping has first ensured that internal demand is satisfied even in the context of increasing demand. Similarly, to the above, the proposed model reduces the reliance on third-party providers who are already struggling to meet NHS demand at current levels. Increasing capacity in the market provides a safety net for BNSSG and the South West to support their demand and capacity planning across the network. As the hub will be a fully licensed facility it will be positioned to be able to support and act as contingency for other SW NHS Trusts who may require aseptic products.
- **Release in WTE nursing capacity onto other patient-facing tasks:** Baseline product volume of high use and stable CIVAS products currently produced at ward level by nurses was provided by UHBW sources. Following the Lord Carter of Coles method (of 12.5 minutes per dose and 1950 hours per WTE), a maximum potential of 31 WTE nursing time to other patient care release per annum was calculated. Based on the modelling conducted by the project team, up to 130,000 nursing hours per annum (approximately 66 whole time equivalents (WTEs)) could be released back to patient care activities by removing some of the requirement for nurses to make the injectable medicines on the wards. This has only been considered from a UHBW and NBT (direct) nursing time to care standpoint, but it is also expected that indirect nursing time could be released through supply of products to other NHS partners.
- **Release in hospital beds:** At a national level, availability of ready to use medicines could free up to 1 million bed days a year. This benefit has not been quantified at a regional level due to its complexities, but it is anticipated that this benefit will be realised across the organisations through the preparation of Outpatient Parenteral Antimicrobial Therapy (OPAT) products, and through reductions in adverse incidents and time to first dose. Although the national project is still in the initial stages, the project team have every confidence that this project will release these benefits across BNSSG and surrounding region.
- **Support the four ICS strategic priorities outlined in the BNSSG Strategic Framework V3:** Through investment and funding in this area, positive contributions can be made to all priorities -
 - Improve outcomes in population health and healthcare – as noted, aseptic ready to administer medication plays an integral role in a variety of patient care pathways and outcomes. Through effective investment, there should be a reduction in treatment delays (through a reduction in reliance in third party providers and associated delays), patient safety incidents (through improved facilities and standardisation of care) and overall patient experience and outcomes. Associated wider benefits such as reduction in bed days etc, should also benefit patients not directly treated by aseptic means.
 - Tackle inequalities in outcomes, experience, and access – through enhanced network demand resilience, external supply capability and overall product output flexibility, this will greatly improve the reactivity of services to patients and enhance access for patients. For example, incidence and mortality rates from respiratory disease and associated infections are significantly higher from disadvantaged groups and individuals from areas of social deprivation. There is already evidence of positive outcomes from respiratory infections treated through OPAT care in the BNSSG area. Enhanced support for such services through

	<p>improved aseptic contributions will therefore help to reduce health inequalities.</p> <ul style="list-style-type: none"> ○ Enhance productivity and value for money – through utilisation of a new hub facility, the direct productivity and value for money benefits will be twofold. Firstly, there will be a direct financial saving through a reduction in reliance on third-party vendors. Secondly, there will be greater leverage of economies of scale in the production of aseptic products through workforce efficiencies. More broadly, there will be productivity gains through the release of nursing time to other patient care activities and value for money benefits by support of NHS-to-NHS product supply. ○ Help the NHS support broader social and economic development – The preferred option will require a significant investment into a new facility. In bringing this facility online, there will be a requirement to recruit relatively large numbers of staff. These jobs will be specialist positions in a niche area of science and healthcare resulting in numerous employment benefits derived from direct (taxation) and indirect (local spending investment) benefits to the local area. Furthermore, there will be a requirement for non-technical roles such as specialist cleaners and transport couriers, further supporting the employment benefits. More broadly, through healthcare improvements and reductions in health inequalities, this will have economic benefits through improved productivity and reduction on public sector service demand (most notably related to healthcare provision). <ul style="list-style-type: none"> ▪ Contribution to the NHS Net Zero Aspirations: The design and implementation of the Preferred Option (Option 4c, see Economic Case) will be in accordance with the NBT's Green Plan and UHBW's, outlining the commitment to improving sustainability throughout the organisations with support for the NHS in the pursuit of becoming the world's first net zero health service. The NHS Green Plan is focused on nine core areas, aligned to the key drivers for change and key sources of carbon emissions, within the NHS. ▪ Increase Investigational Medicinal Products (IMPs) capacity: The current IMP license as held by UHBW is deemed to be broadly underutilised. Accordingly, one of the aims of the new facility will be to enhance the ability to utilise this license facility. This is intended to generate direct financial benefits, and will further support UHBW and NBT reputationally by enhancing their clinical research profile.
<p>TYPE OF SCHEME</p> <p>Please detail the intended output that this scheme intends to deliver. I.e. reconfiguration of an existing site / addition to an existing site, enhancement to existing facilities, etc</p>	<p>The Preferred Option (Option 4c, see Economic Case) will involve establishing a single off-site facility for pharmacy aseptic and technical services. Products produced at the new hub will be distributed to UHBW sites and NBT with excess production capacity prioritised for demand growth, followed by commercial income and finally, release of local nursing time onto other patient care activities. Local sites (excluding Weston General Hospital will maintain a small satellite facility that will be utilised for extremely short shelf-life, clinical trials, and urgent aseptic preparation requests.</p> <p>This prioritisation has been deemed necessary to ensure stability in the network by ensuring internal patient needs are met first. Excess production will be flexible depending commercial income by supplying products to surrounding Trusts within and beyond the ICS while ensuring the flexibility to address short term internal demand spikes. The project envisions that as the likes of community diagnostic hubs and NHS@Home virtual wards (including OPAT) services mature and develop, there will be greater opportunity for alignment with such strategies to support patient care in the community, and reductions of inpatient services and reduce pressure on acute NHS resources.</p>
<p>CAPACITY CREATED</p> <p>Please set out the additional capacity created by the scheme.</p> <p>Provide figures in the table below.</p>	<p>Product Capacity: The scheme can generate increased capacity in production of Chemotherapy, Immunotherapy, CIVAs, Parenteral Nutrition and Radiopharmacy products, as well as to pre-pack activity and non-sterile products from 46.5k doses per annum to 339k (excluding radiopharmacy, pre-pack and other non-aseptic activities). Capacity will also be available to meet the national or regional level requirements for a limited number of strategic high volume activity batch produced lines. This represents an approximate seven-fold increase in doses per annum across UHBW and NBT.</p> <p>As noted, when radiopharmacy is included the baseline number of 58.5k doses per annum rises to 381k, representing a six and half fold increase. These volumetric</p>

output increases have been conservatively estimated during this preliminary phase. As design elements are refined, it is possible that these estimates will increase further. This increased capacity is expected to meet growth and deliver the unmet need, releasing nursing time to other patient care activities.

Product volume and scope will continue to be assessed by the project group as the project continues and periodic assessments of the baseline will be made to ensure the project delivers the required benefits.

Nursing Capacity: The scheme will also generate additional capacity in the form of freeing up nursing staff allowing this time to be utilised for patient care activities. Based on the detailed and conservative modelling conducted by the project team a up to, of 130,000 nursing hours per annum (approximately 66 whole time equivalents (WTEs)) can be released for other patient care.

CAPACITY PROFILE – Additional capacity delivered as a result of this investment.

EXPECTED INCREMENTAL CAPACITY																
	Equipment in place	Production capacity *	Fully trained and operational staff *	Estimated Hospital Beds Released & Released Nursing Time to Other Patient Care Activities												
Y1 H1	Kick off procurement process and define delivery schedule for Isolators and ports	N/A	<p>Preliminary modelling indicates that senior production, QA, QC, and training staff will need to be in post and fully operational during Y1.</p> <p>Consideration for low levels of over recruitment in to UHBW (as lead organisation) operational staff to be assessed by workforce workstream to grow experience workforce in preparation for mid-level positions in both production and QA/QC. At this stage, it will be essential to ensure that over recruitment is at an adequate level that will provide sufficient capacity needed to carry the additional workload associated with validating a new facility.</p> <p>Clinical Leadership Fellows to assist with establishing a recruitment “blueprint” to identify strategy and timelines for recruitment of operational staff, to include training timelines.</p>	N/A												
Y1 H2	Equipment, including isolators and ports to be delivered to hub in staged process as determined in schedule above. Installation and validation to commence on a rolling basis with go live in Q4 following MHRA inspection.	<p>Workforce modelling indicates potential output achievable for go live of Q3 of Y1. However, in looking to achieve this, significant investment into staffing will be required to ensure that they can meet validation and training requirements in line with anticipated go live times.</p> <table><tr><td>Chemotherapy</td><td>116k</td></tr><tr><td>CIVAS</td><td>44k</td></tr><tr><td>Immunotherapy</td><td>16k</td></tr><tr><td>PN</td><td>36k</td></tr><tr><td>Radiopharmacy</td><td>26k</td></tr><tr><td>Total</td><td>238k</td></tr></table>	Chemotherapy	116k	CIVAS	44k	Immunotherapy	16k	PN	36k	Radiopharmacy	26k	Total	238k	<p>Once an achievable go-live date is identified, workforce blueprint will be utilised to establish recruitment focus and training team will be in place to implement this strategy.</p> <p>Over the course of Y1 a phased increase to the existing workforce will be implemented to facilitate a safe transition from the existing facility to the new hub. This will increase exponentially towards Q3-4 in anticipation of go live.</p> <p>During Y1, strong focus on recruitment, in line with the blueprint will be undertaken with the aim to increase the workforce up to a minimum of 60-65% of total required workforce. Given the training and validation activities required before staff can contribute to</p>	<p>Bed release not calculated at this point.</p> <p>Limited excess production capacity means that initial nursing time released for other patient care activities will not be released until Y2. However, depending on management strategy at the time or product demand profile, it may be possible to start releasing WTE nursing time to other patient care activities during this year.</p>
Chemotherapy	116k															
CIVAS	44k															
Immunotherapy	16k															
PN	36k															
Radiopharmacy	26k															
Total	238k															

				production capacity volume will diminish over time.
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SECTION 3: PROJECT DELIVERY OVERVIEW

DELIVERABILITY ASSESSMENT

DELIVERY AND TIMETABLE

Please set out the anticipated commercial and procurement route, and provide a simple timeline with key milestones for the procurement and delivery of the scheme

To achieve the objectives in establishing a new off-site pharmacy technical services hub, particular goods and services that need to be procured include:

- Professional services
- Refurbishment and associated works
- Equipment
- Systems

The UHBW and NBT programme have considered potential routes to markets and frameworks, including NHS Supply chain framework and Procure23, but assessment of procurement routes and implementation of the process is to be conducted as upcoming programme activities. Based on success criteria for the project, UHBW and NBT will evaluate the available procurement routes to identify which procurement offers closest fit to project-specific requirements and drivers.

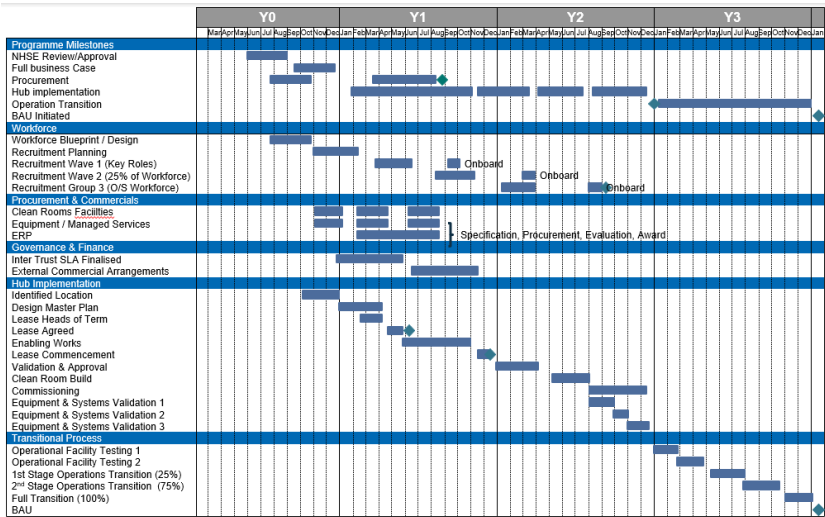


Figure 2: Outline Implementation Timeline

RISKS TO DELIVERY

Please set out the potential risks to delivery and mitigating actions to address these.

A Risk Log is in place for the UHBW and NBT project team and is maintained by the Project Manager. Risks are to be continually monitored and managed by the Project Team, with escalation to the group's Executive Boards when appropriate and will continue to do so throughout the project lifecycle.

Key risks have been classified into four types: financial, transformational change, operations, and workforce. Example risks across these types and supporting mitigation strategies have been captured below:

Financial:

- Necessary capital funding may not be available to support construction of a new pharmacy aseptic and technical services hub. This has been mitigated through review of financial case to align with the national capital funding allocation. Pending approval of NHSE on Business Case, it will also be possible to amend and refine (as needed) given that the capital funding is not expected until 2025 / 26. Considerable efforts have been made to liaise and align with NHSE colleague expectations; these efforts will continue to further minimise this risk. While it is recognised that radiopharmacy is excluded from the current national funding pot, the required capital has been calculated in a method which allows for simple exclusion of these funding elements.
- Significant lead times for procurement of equipment due to high numbers of specialist equipment required. Mitigated by initiation of procurement process at earliest opportunity and scope potential to take delivery of equipment in a staggered process. Additionally, the project team has worked closely with key workstream leads across all aseptic disciplines to understand the key equipment requirements from the outset. As the design matures, personnel will establish relationships with key suppliers to understand lead times and availability of products so that any purchasing requirements can be handled with these lead times in mind.

Transformational Change:

- Timelines and availability of space do not allow for an initial fully automated technology solution where possible; this will be mitigated by design of the hub unit to incorporate ability to replace equipment in future to introduce automated technology if available and supported by the MHRA.
- Delays to the projects transitional timelines may cause a reduction in aseptic services across the region which cannot be covered elsewhere, particularly regarding radiopharmacy services as UHBW are the key supplier in the region. The project will transition services and facilities on a scaling basis and where necessary, will dual-run facilities to cover any potential down-time of services.

Operations:

- Delay to project implementation awaiting MHRA site inspections, especially in the context of the MHRA itself facing staffing challenges, and therefore delaying commissioning. Mitigated through regular liaison with MHRA at regular intervals throughout project and work closely with them to avoid potential delays. The project team have considerable experience in dealing with the MHRA, so effective leveraging of this experience will further help to mitigate this risk.

Workforce:

- The necessary workforce may not be available to support the preferred model or delayed recruitment due to availability. Mitigated through exploration of new approaches to skill mix, early initiation of recruitment and through phased waves to reduce burden of recruitment requirement and impact of risk. This will be further mitigated through consideration of inhouse training and development programmes to augment staffing recruitment drives should significant external recruitment challenges be met. Benefits calculations have factored in gradual phase increases of staffing levels to mitigate this risk and provide a level of achievability reassurance.
- Potential concerns for wellbeing of workforce due to unfavourable shift patterns. The new facility will support staff by providing on-site parking and facilitating public transport, ensuring that the workforce feel comfortable travelling to and from the off-site location. Furthermore, the People Plan will be adhered to, to further mitigate staff welfare related risks.

A fully detailed Risk Log can be found in the Management Case of this Business Case with impact and severity scoring.

Score	Impact	Likelihood
1	None	Rare
2	Low	Unlikely
3	Moderate	Possible
4	Severe	Likely
5	Catastrophic	Certain

Each risk has been allocated an 'impact' score. Each risk has been allocated a 'likelihood' score for each option. Risk rating scores have been individually calculated by multiplying impact and likelihood. These scores have been aggregated to show the total for each option.

Risk Title and Impact Score	Option 4c Major Off-Site Hub	Mitigation Strategy
National funding unavailable (5)	Possible (3)	Business Plan Drafting to align with national strategy.
Procurement related delays (4)	Possible (3)	Planning at the earliest outset to prevent likelihood of delays.
Inability to recruit required staff in relation to preferred option (4)	Possible (3)	Collaboration with workforce strategy team to inform recruitment.
Negative impact on workforce wellbeing owing preferred option working patterns (3)	Possible (3)	Appropriate planning to reduce likelihood and impact.
Patient Care Risk (5)	Unlikely (2)	Full operational mapping to mitigate operational risk and match demand
Reputational Risks (4)	Unlikely (2)	Alignment with national strategy in business case.
Failure to translate design (4)	Possible (3)	Collaboration with estates and facilities and design specialists.
Incorrect cost estimates (3)	Possible (3)	Procurement strategy to maximise competitive advantage and VIM
Contractor default (4)	Unlikely (2)	Procurement strategy to minimise this risk.
Failure to meet performance standards (4)	Unlikely (2)	Collaboration with respective clinical leads.
Incorrect estimated cost of providing clinical services (2)	Possible (3)	Pessimistic cost modelling; iterative reviews.
Changes in the volume of demand for patient services (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities
Estimated income from income generating schemes is incorrect (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities; SCMD demand mapping.
Incorrect time estimates (3)	Possible (3)	Procurement strategy to minimise this risk.
Incorrect cost and time estimates for decanting from existing buildings (2)	Possible (3)	Procurement strategy to minimise this risk.
Regulatory licenses / accreditations cannot be achieved option (5)	Unlikely (2)	Collaboration with respective clinical leads and regulatory stakeholders.
Changes in national agenda shift focus for pharmacy technical services (4)	Unlikely (2)	Collaboration with NHSE colleagues
Model does not sufficiently allow for future changes in infrastructure (3)	Unlikely (2)	Pessimistic output modelling; flexible design capabilities
Local configurations are varied and complex driving additional complexity and cost (3)	Possible (3)	Early collaboration with design specialists.
TOTAL	169	

Figure 3: Risk Log Summary of Preferred option with mitigation strategies

PLANNING ASSUMPTIONS

Please set out the current planning position, and the steps that will be taken to ensure appropriate planning permission is in place.

It is not envisaged that there will be any significant procurement-related commercial or legal issues arising for the design, refurbishment, or associated works of any potential new facility. Once the new hub site has been identified, the need for landlord permission or planning permission to complete the required construction will be assessed, but there is no reason to expect that planning permission or Building Research Establishment Environmental Assessment Method (BREEAM) assessment will be required for the hub.

The project does not anticipate any acquisitions or wider impact on other clinical service designs and provisions.

PROVIDER CAPACITY AND CAPABILITY

Please provide a brief overview of the experience of the SRO and Exec Team accountable for the project.

Across the two Trusts, there are several experienced and knowledgeable personnel with assigned roles within the programme delivery. Key personnel of note include:

Neil Kemsley. UHBW Director of Finance and Information - Project Senior Responsible Officer (To be added)

Jon Standing. UHBW Director of Pharmacy

Jon Standing has 26 years of Hospital Pharmacy service and has built up a significant degree of experience having worked in all key areas. He has been a Chief Pharmacist for nearly 10 years, initially in at Yeovil District Hospital and more recently in a University Hospitals Bristol and Weston NHS FT since October 2017. This has given him experience of the varied spectrums of Acute Trusts and an appreciation of the different challenges set before each.

He currently sits on a wide range of groups, committees and boards (listed below) that has given him a broad understanding of the current areas of focus and strategic NHS delivery;

- National Pharmacy Supply Group
- Specialised Pharmacy Service National Medicines Board
- Medicines Optimisation Clinical Reference Group

- National High-Cost Medicines Steering Group
- SW Regional Medicines Optimisation Committee
- SW Regional Pharmacy Workforce Strategy Group
- SW Regional Pharmacy Education and Training Group
- Chair Regional Pharmacy Procurement Group
- Regional Clinical Senate Assembly member
- Chair UHBW Medicines Advisory Group
- Chair UHBW Medicines Governance Group
- UHBW Antimicrobial Steering Group
- UHBW Advanced Therapy Molecular Products Group
- UHBW Clinical Quality Group
- UHBW Intrathecal Medicines Group
- UHBW Medical Gas Group

Matthew Kaye. NBT Director of Pharmacy

Matt has 22 years of NHS hospital pharmacy experience including 18 months in his current role as Director of Pharmacy for NBT.

Prior to this role, he was the Chief Pharmacist at Northern Devon Healthcare NHS Trust for 6 years. As part of this role, he had 2 secondments into operational management during the pandemic. These secondments included involvement in the North Devon District Hospital (NDDH) “Our Future Hospital” programme as NDDH was one of 40 hospitals included in the Government’s New Hospital Programme (NHP) and was confirmed as a priority for investment in 2020, plus involvement in building a new majors unit for the Emergency Department to develop COVID-19 and non-COVID-19 pathways.

In addition to this experience, Matt is the Chair of the SW Pharmacy Aseptic Group and hosts the Regional QA Service in NBT. Matt is a member of the SW Genomics Steering Group with UHBW and NBT acting as leads for the SW Genomics Medicines Service Alliance (GMSA). Matt is also the SW GMSA Chief Pharmacist (which lies as part of his role as NBT Director of Pharmacy)

Helen Kingston. UHBW Associate Director of Pharmacy – Adult Cancer and Aseptic Services

Helen has been working in NHS Hospital Pharmacy for more than 25 years, with over 20 years been spent working in aseptic technical services. Helen has been employed in the Parenteral Services Unit at UHBW since November 2001 initially as the Lead Clinical Trials and Aseptic Services Pharmacist and then the Senior Aseptic Lead for Chemotherapy.

Helen was promoted to the position as the Associate Director of Pharmacy - Adult Cancer and Aseptic Services back in September 2021. In this position she is the named Accountable Pharmacist for PSU. Helen has extensive knowledge and experience of working and managing an aseptic unit that supplies Chemotherapy and Parenteral Nutrition under section 10 exemption.

Helen has also been involved in several in house improvement projects with UHBW. Most notably, she is currently involved in the UHBW Intrathecal Group, MHRA Inspections Oversight Group and the Weekend Working Group.

Sean Fradgley. UHBW Associate Director of Pharmacy – QA/QC

Sean’s qualifications include a BSc(Hons) in Pharmaceutical Sciences (Aston University, 1987), registration as a professional pharmacist (RPharmS/GPhC, since 1988) and a PhD in breast cancer/medicinal chemistry (Cardiff University, 1992). Subsequently, his career has included 9 years in academic research followed by 25 years in NHS hospital pharmacy as a Quality Assurance specialist. He has been in his present post as UHBW Associate Director of Pharmacy, Quality Assurance since October 2018. Within UHBW, he is Chair of the Pharmacy Technical Services/Stores quality review meetings and the UHBW Medical Gas Group, in addition to attending a variety of other local and regional meetings. During his career, he has been directly involved in the design and commissioning of three new pharmaceutical aseptic cleanroom facilities (University Hospitals of North Midlands/PFI, North Bristol NHS Trust/PFI - temporary and permanent).

Kevin Griffiths. UHBW Associate Director of Pharmacy – Production

Kevin has been qualified as a pharmacist for 29 years, the last 26 of which have been spent working as a Technical Services pharmacist in the NHS. He has been in post at UHBW as Associate Director of Pharmacy – Production for the last 4 years. Prior to that he spent 20 years working at the Royal Free Hospital in London during which time he was named as Production Manager on the MIA(IMP) licence, was deputy to the Head of Production and spent a short period

of time acting up as the Head of Production. He also spent 2 years working at Kings College Hospital in London as a Senior Aseptic Services Pharmacist.

Kevin has held several positions on national NHS Technical Services groups and committees, including 4 years as a London representative on the NHS Pharmaceutical Aseptic Services Group (PASG) during which time he led a project to review and update the high-risk injectable drugs list on behalf of PASG.

He is the Lead Station Writer and Assessor for the Health Education England (HEE) National School of Healthcare Science (NSHCS) Scientist Training Programme (STP) for Clinical Pharmaceutical Scientists (CPS), a position held since the start of 2015. He is a member of the NHS Pharmaceutical Production Committee and acts as the NPPC representative to the NHS Technical Specialist Education and Training (TSET) group.

Whilst working at the Royal Free he was the Technical Lead for the successful preparation of a business case for over £2million to carry out a major refurbishment of the Production department and then contributed to the technical assessment of the tender bids to carry out the building works.

Kathy Beard. UHBW Cancer Lead Pharmacist (Weston General Hospital)

Kathy has worked in cancer services for over 15 years. She has held her current post for 3 years. Kathy has worked as aseptic services pharmacist from about 2003 to 2016 when the Weston pharmacy prepared cytotoxic chemotherapy products and total parenteral nutrition for its patients until the unit closed. Since then, Kathy has managed and overseen all outsourcing of aseptic operations and accompanying clinical oversight.

Annika Boloz. UHBW Associate Director of Pharmacy - Radiopharmacy

Annika is a Pharmacist and Clinical Scientist. Since joining the NHS as a hospital pharmacist, Annika completed MSc Clinical Pharmaceutical Science, then PGDip Pharmaceutical Quality and Regulation and is in her final weeks of completing Masters in Business Administration, MBA. Annika is currently undertaking Qualified Person training, aiming to be a named QP on the MIA (IMP) license at UHBW in early 2024.

Annika completed her Scientist Training Programme (STP) in Manchester University Hospitals NHS Foundation Trust, subsequently held roles as Production Manager and Quality Lead. During pandemic Annika was deployed to Nightingale Hospital to work as the Pharmacy CIVAS Lead, and then was involved in setting up the COVID vaccination centre at UHBW.

Annika actively engages in staff development

- National, presenting at conferences (BNMS, UKRG)
- National, Station writer, Assessor at the National School of Healthcare Science
- National, Specialty Writer for Pharmaceutical Science STP Curriculum Review, where Annika introduced leadership training into revised STP curriculum for Clinical Scientist Trainees
- National, co-wrote a UKRG Guidance for Radiopharmacies during the Covid-19 Pandemic
- National, Royal Pharmaceutical Society Mentor
- Associate Lecturer at the UCL, UWE and University of Bath
- UHBW Training Officer for Clinical Pharmaceutical Science trainees

Annika sits on a wide range of groups/committees

- National Infusions & Special Medicines Workforce Working Group
- National NHS England Radiopharmacy Review
- National UK Radiopharmacy Group Committee
- National Quality Assurance Committee
- Regional Short-life Cytotoxic Residue Group
- UHBW Advanced Therapy Molecular Products Group
- UHBW MHRA Inspections Oversight Group

Kate North. NBT Principal Pharmacist - Technical Services and Haematology

Kate North has 11 years of post-qualification pharmacy experience. She has previously worked for Cardiff and Vale University Hospital Board, Royal Surrey County Hospital before specialising in oncology, haematology and aseptic services with Guys and St Thomas' NHS Trust. She has held her current post with NBT for 4 years which includes Accountable Pharmacist role.

In addition to leading the Technical Services and Haematology services with NBT, she is the chair of the NBT Technical Services and Quality Assurance Pharmaceutical Quality System Group, a member

of the NBT Chemotherapy Multi-professional Team Group and a member of the NBT Nutrition Steering Group.

Matthew Smith. NBT Lead Pharmacy Technician - Aseptic Services

Matt has been qualified for over 30 years, with 27 in Technical Services. While working in Reading 1998-2001, he supported the commissioning of new isolators.

Matt has worked at NBT for 22 years, with most time spent as Senior or Lead Technician in Aseptics. Additionally, Matt was named on the MS License for Frenchay Hospital. Following a failure of facility, he facilitated a period of design and installation while having also managed a temporary facility and commissioning of the new department.

In 2010 Southmead and Frenchay merged departments (with Frenchay surrendering their License). Again, Matt supported the design qualification of the new Brunel facility including the installation, qualification, and commissioning of the temporary unit during the building of the current unit.

Matt is currently responsible for maintaining the MHRA and NHSE expectations regarding the facility and work closely with the estates department to ensure that the unit meets their HTM03 planned maintenance schedule without compromising ISO14644 GMP.

Akeso and Co

UHBW and NBT have also commissioned Akeso & Co, an experienced Healthcare and Life Science Consulting firm, to support in the Business Case development and Healthcare planning.

SECTION 4: FINANCIAL OVERVIEW

These Tables can be provided in Excel Form. If a proposal involves multiple Providers, these Tables will need to be completed for each individual Provider.

FUNDING SOURCES

PLEASE SET OUT ALL FUNDING SOURCES FOR THE PROJECT	DHSC CDEL cover £	£24.6 million (inclusive of radiopharmacy) £20.2 million (exclusive of radiopharmacy)
	Other e.g. ICB (please specify) £	£0.0 million (inclusive and exclusive of radio pharmacy)
	Total £	£24.6 million (inclusive of radiopharmacy) £20.2 million (exclusive of radiopharmacy)

CAPITAL EXPENDITURE PROFILE (inclusive of radiopharmacy, Optimism Bias, Planning Contingency and VAT)

FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
DHSC CDEL cover funded capital expenditure	0	(2,412)	(22,093)	0	0	0	0	(24,549)
Other (<i>specify</i>)	0	0	0	0	0	0	0	0
Total	0	(2,454)	(22,093)	0	0	0	0	(24,549)

CAPITAL EXPENDITURE PROFILE (exclusive of radiopharmacy, inclusive of Optimism Bias, Planning Contingency and VAT)

FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
DHSC CDEL cover funded capital expenditure	0	(2,019)	(18,172)	0	0	0	0	(20,192)
Other (<i>specify</i>)	0	0	0	0	0	0	0	0
Total	0	(2,019)	(18,172)	0	0	0	0	(20,192)

BREAKDOWN OF SCHEME CAPITAL COST (inclusive of radiopharmacy)								
FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
Works Costs	0	(394)	(3547)	0	0	0	0	(3,941)
Fees	0	(140)	(1259)	0	0	0	0	(1,399)
Non-Works Costs	0	(1006)	(9058)	0	0	0	0	(10,064)
Equipment Costs	0	(239)	(2,146)	0	0	0	0	(2,385)
Optimism bias	0	(89)	(801)	0	0	0	0	(889)
Planning contingency	0	(89)	(801)	0	0	0	0	(889)
Inflation Adjustment	0	(89)	(801)	0	0	0	0	(889)
VAT	0	(356)	(3682)	0	0	0	0	(4,091)
Total	0	(2,455)	(22,094)	0	0	0	0	(24,549)
Please provide a narrative on the basis of the costs e.g. tendered costs, PUBSEC indices, cost advisor reports. Please STATE the following:								
1) PUBSEC Indices used:				Previous project estimates validated by independent clinical and clean room advisors.				
2) Basis of the costs: HPCG / benchmark rates from cost advisor / tendered costs / schedules of rates / previously tendered rates.				Previously tendered rates with inflationary uplifts applied.				
3) Cost advisor Review of the VfM / procurement process.				N/A				

BREAKDOWN OF SCHEME CAPITAL COST (exclusive of radiopharmacy)								
FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
Works Costs	0	(337)	(3,036)	0	0	0	0	(3,373)
Fees	0	(120)	(1,077)	0	0	0	0	(1,197)
Non-Works Costs	0	(796)	(7,164)	0	0	0	0	(7,960)
Equipment Costs	0	(210)	(1,892)	0	0	0	0	(2,102)
Optimism bias	0	(73)	(658)	0	0	0	0	(732)
Planning contingency	0	(73)	(658)	0	0	0	0	(732)
Inflation Adjustment	0	(73)	(658)	0	0	0	0	(732)
VAT	0	(337)	(3,028)	0	0	0	0	(3,365)
Total	0	(2,096)	(18,072)	0	0	0	0	(20,192)
Please provide a narrative on the basis of the costs e.g. tendered costs, PUBSEC indices, cost advisor reports. Please STATE the following:								
1) PUBSEC Indices used:				Previous project estimates validated by independent clinical and clean room advisors.				
2) Basis of the costs: HPCG / benchmark rates from cost advisor / tendered costs / schedules of rates / previously tendered rates.				Previously tendered rates with inflationary uplifts applied.				
3) Cost advisor Review of the VfM / procurement process.				N/A				

Total	Option 2 - Do Minimum				Option 4c				Differential			
Council of Governors Part 1 and Public	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0	0	0	23,855,760	16,925,210	0	0	23,855,760	16,925,210
Capital Investment	0	0	0	0	0	0	0	0	0	0	0	0
Depreciation	0	0	0	0	0	0	(346,528)	(346,528)	0	0	(346,528)	(346,528)
TOTAL ASSETS EMPLOYED	0	0	0	0	0	0	23,509,233	16,578,682	0	0	23,509,233	16,578,682
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0	0	0	0	0	0	0	0	0
Operating Income	0	0	19,106,784	589,428,865	0	0	17,645,241	447,748,451	0	0	(1,461,543)	(141,680,414)
Operating Expenditure	0	0	(19,106,784)	(589,428,865)	0	0	(17,645,241)	(447,748,451)	0	0	1,461,543	141,680,414
C/F Before Financing	0	0	0	0	0	0	0	0	0	0	0	0
Financing (PDC Funding)	0	0	0	0	0	0	0	0	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0	0	0	0	0	0	0	0	0
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	19,106,784	589,428,865	0	0	17,645,241	447,748,451	0	0	(1,461,543)	(141,680,414)
Commercial Income	0	0	1,303,719	34,208,181	0	0	2,346,693	61,574,725	0	0	1,042,975	27,366,544
Cost Avoidance	0	0	0	0	0	0	0	0	0	0	0	0
Baseline Trust Funding	0	0	17,803,065	555,220,685	0	0	15,298,547	386,173,726	0	0	(2,504,518)	(169,046,959)
Expenses												
Pay	0	0	(3,933,888)	(103,221,004)	0	0	(5,424,913)	(140,910,799)	0	0	(1,491,026)	(37,689,795)
Non-Pay: Clinical Services	0	0	(14,933,229)	(479,919,248)	0	0	(10,965,302)	(279,901,055)	0	0	3,967,927	200,018,193
Non-Pay: Other	0	0	(239,667)	(6,288,613)	0	0	(592,350)	(15,203,651)	0	0	(352,683)	(8,915,038)
TOTAL COSTS	0	0	(19,106,784)	(589,428,865)	0	0	(16,982,565)	(436,015,505)	0	0	2,124,219	153,413,360
EBITDA	0	0	(580,397)	(15,228,993)	0	0	(20,976)	(3,181,588)	0	0	559,421	12,047,406
Interest	0	0	0	0	0	0	(69,766)	(936,425)	0	0	(69,766)	(936,425)
Depreciation	0	0	0	0	0	0	(346,528)	(7,623,606)	0	0	(346,528)	(7,623,606)
PDC & Finance Charges	0	0	0	0	0	0	(246,382)	(3,172,916)	0	0	(246,382)	(3,172,916)
SUB-TOTAL	0	0	0	0	0	0	(662,675)	(11,732,946)	0	0	(662,675)	(11,732,946)
NET SURPLUS/(DEFICIT)	0	0	0	0	0	0	0	0	0	0	0	0
CUMULATIVE	0	0	0	0	0	0	0	0	0	0	0	0

Figure 4: Combined Financial Position Summary (inclusive of radio pharmacy)

UHBW Option 2 - DO Minimum					Option 4c					Differential				
	Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48		FY 22/23	FY 23/24	FY 27/28	FY 47/48		FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0		0	0	23,855,760	16,925,210		0	0	23,855,760	16,925,210
Capital Investment	0	0	0	0		0	0	0	0		0	0	0	0
Depreciation	0	0	0	0		0	0	(346,528)	(346,528)		0	0	(346,528)	(346,528)
TOTAL ASSETS EMPLOYED	0	0	0	0		0	0	23,509,233	16,578,682		0	0	23,509,233	16,578,682

	Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total		FY 22/23	FY 23/24	FY 27/28	Y25 Total		FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0		0	0	0	0		0	0	0	0
Operating Income	0	0	18,526,387	574,199,872		0	0	16,961,590	432,833,917		0	0	(1,564,798)	(141,365,955)
Operating Expenditure	0	0	(18,526,387)	(574,199,872)		0	0	(16,961,590)	(432,833,917)		0	0	1,564,798	141,365,955
C/F Before Financing	0	0	0	0		0	0	0	0		0	0	0	0
Financing (PDC Funding)	0	0	0	0		0	0	0	0		0	0	0	0
NET CASH (OUT) / IN	0	0	0	0		0	0	0	0		0	0	0	0

	Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total		FY 22/23	FY 23/24	FY 27/28	Y25 Total		FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	18,526,387	574,199,872		0	0	16,961,590	432,833,917		0	0	(1,564,798)	(141,365,955)
Commercial Income	0	0	1,303,719	34,208,181		0	0	2,229,359	58,495,989		0	0	925,640	24,287,808
Cost Avoidance	0	0	0	0		0	0	0	0					
Baseline Trust Funding	0	0	17,222,669	539,991,692		0	0	14,732,231	374,337,928		0	0	(2,490,438)	(165,653,763)
Expenses														
Pay	0	0	(3,462,771)	(90,859,405)		0	0	(4,869,984)	(128,804,451)		0	0	(1,407,213)	(37,945,046)
Non-Pay: Clinical Services	0	0	(14,843,367)	(477,561,365)		0	0	(10,859,453)	(277,591,859)		0	0	3,983,914	199,969,506
Non-Pay: Other	0	0	(220,249)	(5,779,103)		0	0	(569,478)	(14,704,661)		0	0	(349,228)	(8,925,558)
TOTAL COSTS	0	0	(18,526,387)	(574,199,872)		0	0	(16,298,914)	(421,100,971)		0	0	2,227,473	153,098,901
EBITDA	0	0	0	0		0	0	662,675	11,732,946		0	0	662,675	11,732,946
Interest	0	0	0	0		0	0	(69,766)	(936,425)		0	0	(69,766)	(936,425)
Depreciation	0	0	0	0		0	0	(346,528)	(7,623,606)		0	0	(346,528)	(7,623,606)
PDC & Finance Charges	0	0	0	0		0	0	(246,382)	(3,172,916)		0	0	(246,382)	(3,172,916)
SUB-TOTAL	0	0	0	0		0	0	(662,675)	(11,732,946)		0	0	(662,675)	(11,732,946)
NET SURPLUS/(DEFICIT)	0	0	0	0		0	0	0	0		0	0	0	0
CUMULATIVE	0	0	0	0		0	0	0	0		0	0	0	0

Figure 5: UHBW Financial Position Summary (inclusive of radio pharmacy)

	Option 2 - DO Minimum			
	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	Total
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Option 4c			
	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	Total
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	Total
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	580,397	15,228,993
Operating Expenditure	0	0	(580,397)	(15,228,993)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	683,651	14,914,534
Operating Expenditure	0	0	(683,651)	(14,914,534)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	103,254	(314,459)
Operating Expenditure	0	0	(103,254)	314,459
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	580,397	15,228,993
Commercial Income	0	0	0	0
Cost Avoidance	0	0	0	0
Baseline Trust Funding	0	0	580,397	15,228,993
Expenses				
Pay	0	0	(471,117)	(12,361,599)
Non-Pay: Clinical Services	0	0	(89,862)	(2,357,884)
Non-Pay: Other	0	0	(19,418)	(509,510)
TOTAL COSTS	0	0	(580,397)	(15,228,993)
EBITDA	0	0	(580,397)	(15,228,993)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	683,651	14,914,534
Commercial Income	0	0	117,335	3,078,736
Cost Avoidance	0	0	0	0
Baseline Trust Funding	0	0	566,316	11,835,798
Expenses				
Pay	0	0	(554,930)	(12,106,348)
Non-Pay: Clinical Services	0	0	(105,849)	(2,309,196)
Non-Pay: Other	0	0	(22,873)	(498,989)
TOTAL COSTS	0	0	(683,651)	(14,914,534)
EBITDA	0	0	(683,651)	(14,914,534)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	103,254	(314,459)
Commercial Income	0	0	117,335	3,078,736
Cost Avoidance	0	0	0	0
Baseline Trust Funding	0	0	(14,080)	(3,393,196)
Expenses				
Pay	0	0	(83,813)	255,251
Non-Pay: Clinical Services	0	0	(15,987)	48,687
Non-Pay: Other	0	0	(3,455)	10,521
TOTAL COSTS	0	0	(103,254)	314,459
EBITDA	0	0	(103,254)	314,459
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

Figure 6: NBT Financial Position Summary (inclusive of radio pharmacy)

Total	Option 2 - DO Minimum			
	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0
	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	17,974,812	557,226,007
Operating Expenditure	0	0	(17,974,812)	(557,226,007)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0
	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	17,974,812	557,226,007
Commercial Income Potential	0	0	291,823	7,657,116
CRB (Cost Avoidance)	0	0	0	0
Baseline Trust Funding	0	0	17,682,989	549,568,891
Expenses				
Pay	0	0	(3,465,731)	(90,937,065)
Non-Pay: Clinical Services	0	0	(14,382,711)	(462,973,132)
Non-Pay: Other	0	0	(126,370)	(3,315,811)
TOTAL COSTS	0	0	(17,974,812)	(557,226,007)
EBITDA	0	0	0	0
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

Option 4c			
Y0	Y1	Y5	Y25
FY 22/23	FY 23/24	FY 27/28	FY 47/48
0	0	19,598,463	13,667,254
0	0	0	0
0	0	(296,560)	(296,560)
0	0	19,301,902	13,370,693
Y0	Y1	Y5	Y25
FY 22/23	FY 23/24	FY 27/28	Y25 Total
0	0	0	0
0	0	15,425,530	391,077,677
0	0	(15,425,530)	(391,077,677)
0	0	0	0
0	0	0	0
0	0	0	0
0	0	0	0
Y0	Y1	Y5	Y25
FY 22/23	FY 23/24	FY 27/28	Y25 Total
0	0	16,028,178	401,576,321
0	0	535,261	14,044,682
0	0	0	0
0	0	15,492,917	387,531,639
0	0	(4,596,424)	(119,585,076)
0	0	(9,955,860)	(254,029,965)
0	0	(270,598)	(6,963,992)
0	0	(14,822,881)	(380,579,033)
0	0	602,648	10,498,644
0	0	(59,706)	(801,398)
0	0	(296,560)	(6,524,330)
0	0	(246,382)	(3,172,916)
0	0	(602,648)	(10,498,644)
0	0	0	0
0	0	0	0

Differential			
Y0	Y1	Y5	Y25
FY 22/23	FY 23/24	FY 27/28	FY 47/48
0	0	19,598,463	13,667,254
0	0	0	0
0	0	(296,560)	(296,560)
0	0	19,301,902	13,370,693
Y0	Y1	Y5	Y25
FY 22/23	FY 23/24	FY 27/28	Y25 Total
0	0	0	0
0	0	(3,274,778)	(184,319,611)
0	0	3,877,426	194,818,255
0	0	0	0
0	0	0	0
0	0	(46,651,397)	(46,651,397)
Y0	Y1	Y5	Y25
FY 22/23	FY 23/24	FY 27/28	Y25 Total
0	0	(2,549,282)	(166,148,330)
0	0	243,439	6,387,566
0	0	0	0
0	0	(2,792,720)	(172,535,897)
0	0	(1,130,693)	(28,648,012)
0	0	4,426,851	208,943,167
0	0	(144,228)	(3,648,181)
0	0	3,151,930	176,646,974
0	0	602,648	10,498,644
0	0	(59,706)	(801,398)
0	0	(296,560)	(6,524,330)
0	0	(246,382)	(3,172,916)
0	0	(602,648)	(10,498,644)
0	0	0	0
0	0	0	0

Figure 7: Combined Financial Position Summary (exclusive of radio pharmacy)

UHBW	Option 2 - DO Minimum				Option 4c				Differential			
	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0	0	0	19,598,463	13,667,254	0	0	19,598,463	13,667,254
Capital Investment	0	0	0	0	0	0	0	0	0	0	0	0
Depreciation	0	0	0	0	0	0	(296,560)	(296,560)	0	0	(296,560)	(296,560)
TOTAL ASSETS EMPLOYED	0	0	0	0	0	0	19,301,902	13,370,693	0	0	19,301,902	13,370,693

MCFlow Summary	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total								
Starting Position	0	0	0	0	0	0	0	0	0	0	0	0
Operating Income	0	0	17,394,415	541,997,014	0	0	14,700,034	372,180,900	0	0	(2,694,381)	(169,816,114)
Operating Expenditure	0	0	(17,394,415)	(541,997,014)	0	0	(14,700,034)	(372,180,900)	0	0	3,297,030	180,314,758
C/F Before Financing	0	0	0	0	0	0	0	0	0	0	0	0
Financing (PDC Funding)	0	0	0	0	0	0	0	0	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0	0	0	0	0	0	0	602,648	10,498,644

I&E Summary	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total								
TOTAL INCOME	0	0	17,394,415	541,997,014	0	0	14,700,034	372,180,900	0	0	(2,694,381)	(169,816,114)
Commercial Income Potential	0	0	291,823	7,657,116	0	0	508,997	13,355,542	0	0	217,174	5,698,426
CRB (Cost Avoidance)	0	0	0	0	0	0	0	0	0	0	0	0
Baseline Trust Funding	0	0	17,102,592	534,339,898	0	0	14,191,037	358,825,358	0	0	(2,911,556)	(175,514,540)
Expenses												
Pay	0	0	(2,994,614)	(78,575,465)	0	0	(4,007,528)	(104,246,283)	0	0	(1,012,914)	(25,670,818)
Non-Pay: Clinical Services	0	0	(14,292,849)	(460,615,248)	0	0	(9,843,533)	(251,104,203)	0	0	4,449,317	209,511,045
Non-Pay: Other	0	0	(106,952)	(2,806,301)	0	0	(246,325)	(6,331,770)	0	0	(139,373)	(3,525,470)
TOTAL COSTS	0	0	(17,394,415)	(541,997,014)	0	0	(14,097,385)	(361,682,256)	0	0	3,297,030	180,314,758
EBITDA	0	0	0	0	0	0	602,648	10,498,644	0	0	602,648	10,498,644
Interest	0	0			0	0	(59,706)	(801,398)	0	0	(59,706)	(801,398)
Depreciation	0	0			0	0	(296,560)	(6,524,330)	0	0	(296,560)	(6,524,330)
PDC & Finance Charges	0	0			0	0	(246,382)	(3,172,916)	0	0	(246,382)	(3,172,916)
SUB-TOTAL	0	0	0	0	0	0	(602,648)	(10,498,644)	0	0	(602,648)	(10,498,644)
NET SURPLUS/(DEFICIT)	0	0	0	0	0	0	0	0	0	0	0	0
CUMULATIVE	0	0	0	0	0	0	0	0	0	0	0	0

Figure 8: UHBW Financial Position Summary (exclusive of radio pharmacy)

	Option 2 - DO Minimum			
	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Option 4c			
	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	580,397	15,228,993
Operating Expenditure	0	0	(580,397)	(15,228,993)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	725,496	18,896,777
Operating Expenditure	0	0	(725,496)	(18,896,777)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	(580,397)	(14,503,497)
Operating Expenditure	0	0	580,397	14,503,497
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	580,397	15,228,993
Commercial Income Potential	0	0	0	0
CRB (Cost Avoidance)	0	0	0	0
Baseline Trust Funding	0	0	580,397	15,228,993
Expenses				
Pay	0	0	(471,117)	(12,361,599)
Non-Pay: Clinical Services	0	0	(89,862)	(2,357,884)
Non-Pay: Other	0	0	(19,418)	(509,510)
TOTAL COSTS	0	0	(580,397)	(15,228,993)
EBITDA	0	0	(580,397)	(15,228,993)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	725,496	18,896,777
Commercial Income Potential	0	0	26,264	689,140
CRB (Cost Avoidance)	0	0	0	0
Baseline Trust Funding	0	0	699,232	18,207,636
Expenses				
Pay	0	0	(588,896)	(15,338,793)
Non-Pay: Clinical Services	0	0	(112,328)	(2,925,761)
Non-Pay: Other	0	0	(24,273)	(632,222)
TOTAL COSTS	0	0	(725,496)	(18,896,777)
EBITDA	0	0	(725,496)	(18,896,777)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	145,099	3,667,783
Commercial Income Potential	0	0	26,264	689,140
CRB (Cost Avoidance)	0	0	0	0
Baseline Trust Funding	0	0	118,835	2,978,643
Expenses				
Pay	0	0	(117,779)	(2,977,194)
Non-Pay: Clinical Services	0	0	(22,466)	(567,878)
Non-Pay: Other	0	0	(4,855)	(122,712)
TOTAL COSTS	0	0	(145,099)	(3,667,783)
EBITDA	0	0	(145,099)	(3,667,783)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

Figure 9: NBT Financial Position Summary (exclusive of radio pharmacy)

Current Position (based on current position)					Option 4c Differential Impact				Updated Total			
I&E Summary £000s	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Income from Patient Care Activities	1,021,126	1,041,548	1,127,405	32,706,957	0	0	14,732	374,338	1,021,126	1,041,548	1,142,137	33,081,295
Other Operating Income	116,076	118,397	128,157	3,717,942	0	0	2,229	58,496	0	0	0	0
Total Operating Income	1,137,201	1,159,945	1,255,562	1,280,673	0	0	16,962	432,834	1,021,126	1,041,548	1,142,137	33,081,295
Pay Costs	(692,991)	(706,851)	(765,119)	(22,196,725)	0	0	(4,870)	(128,804)	(692,991)	(706,851)	(769,989)	(22,325,529)
Non Pay Costs	(395,064)	(402,965)	(436,182)	(12,654,014)	0	0	(11,429)	(292,297)	(395,064)	(402,965)	(447,611)	(12,946,311)
Depreciation	(38,284)	(39,050)	(42,269)	(1,226,248)	0	0	(347)	(7,624)	(38,284)	(39,050)	(42,615)	(1,233,872)
Impairment	(16,876)	(17,214)	(18,632)	(540,543)	0	0	0	0	(16,876)	(17,214)	(18,632)	(540,543)
Total Operating Expense	(1,143,215)	(1,166,080)	(1,262,202)	(36,617,530)	0	0	(16,645)	(428,725)	(1,143,215)	(1,166,080)	(1,278,848)	(37,046,255)
Total operating surplus/(deficit)	(6,014)	(6,134)	(6,640)	(192,632)	0	0	0	0	(6,014)	(6,134)	(6,640)	(192,632)
PDC dividend charge	(12,863)	(13,120)	(14,202)	(412,006)	0	0	(246)	(3,173)	(12,863)	(13,120)	(14,448)	(415,179)
Other net financing costs	(754)	(769)	(832)	(24,151)	0	0	(70)	(936)	(754)	(769)	(902)	(25,087)
Impact on I&E surplus/(deficit)	(19,631)	(20,024)	(21,674)	(628,788)	0	0	0	0	(19,631)	(20,024)	(21,990)	(632,897)
Less: I&E impairments	16,876	17,214	18,632	540,543	0	0	0	0	16,876	17,214	18,632	540,543
Less: Other technical items	2,776	2,832	3,065	88,916	0	0	0	0	2,776	2,832	3,065	88,916
Impact on I&E surplus/(deficit) - Adjusted Financial Performance	21	21	22	671	0	0	0	0	21	21	22	671

**Figure 10: UHBW Whole Trust Financial Position Impact of Option 4c implementation
(inclusive of radio pharmacy)**

Current Position (based on current position)					Option 4c Differential Impact				Updated Total			
I&E Summary - £000s	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Income from Patient Care Activities	1,021,126	1,041,548	1,127,405	32,706,957	0	0	14,191	358,825	1,021,126	1,041,548	1,141,596	33,065,782
Other Operating Income	116,076	118,397	128,157	3,717,942	0	0	509	13,356	0	0	0	0
Total Operating Income	1,137,201	1,159,945	1,255,562	36,424,899	0	0	14,700	372,181	1,021,126	1,041,548	1,141,596	33,065,782
Pay Costs	(692,991)	(706,851)	(765,119)	(22,196,725)	0	0	(4,008)	(104,246)	(692,991)	(706,851)	(769,126)	(22,300,971)
Non Pay Costs	(395,064)	(402,965)	(436,182)	(12,654,014)	0	0	(10,090)	(257,436)	(395,064)	(402,965)	(446,272)	(12,911,450)
Depreciation	(38,284)	(39,050)	(42,269)	(1,226,248)	0	0	(297)	(6,524)	(38,284)	(39,050)	(42,565)	(1,232,772)
Impairment	(16,876)	(17,214)	(18,632)	(540,543)	0	0	0	0	(16,876)	(17,214)	(18,632)	(540,543)
Total Operating Expense	(1,143,215)	(1,166,080)	(1,262,202)	(36,617,530)	0	0	(14,394)	(368,207)	(1,143,215)	(1,166,080)	(1,276,596)	(36,985,737)
Total operating surplus/(deficit)	(6,014)	(6,134)	(6,640)	(192,632)	0	0	0	0	(6,014)	(6,134)	(6,640)	(192,632)
PDC dividend charge	(12,863)	(13,120)	(14,202)	(412,006)	0	0	(246)	(3,173)	(12,863)	(13,120)	(14,448)	(415,179)
Other net financing costs	(754)	(769)	(832)	(24,151)	0	0	(60)	(801)	(754)	(769)	(892)	(24,952)
Impact on I&E surplus/(deficit)	(19,631)	(20,024)	(21,674)	(628,788)	0	0	0	0	(19,631)	(20,024)	(21,980)	(632,762)
Less: I&E impairments	16,876	17,214	18,632	540,543	0	0	0	0	16,876	17,214	18,632	540,543
Less: Other technical items	2,776	2,832	3,065	88,916	0	0	0	0	2,776	2,832	3,065	88,916
Impact on I&E surplus/(deficit) - Adjusted Financial Performance	21	21	23	671	0	0	0	0	21	21	23	671

Figure 11: UHBW Whole Trust Financial Position Impact of Option 4c implementation (inclusive of radio pharmacy)

SECTION 5: FIVE CASE MODEL PROJECT DETAIL

STRATEGIC CASE

a) Please set out the strategic rationale and case for change.

Please cite Lord Carter's 2020 review and recommendations along with local need

Aseptic preparation can broadly be defined as the reconstitution of an injectable medication or any other aseptic manipulation when undertaken within NHS aseptic facilities to produce a labelled ready-to-administer presentation of a medicine, in accordance with a prescription provided by a practitioner, for a specific patient. It is linked to, but distinct from dispensing which is the supply of a finished product to a specific patient, or to the person responsible for its administration, in accordance with a prescription.

NHS hospital pharmacy aseptic services provide sterile, controlled environments in which highly qualified staff prepare or manufacture injectable medicines for intravenous (IV) antibiotics, chemotherapy, and immunotherapy treatments (such as monoclonal antibodies), as well as parenteral nutrition and cutting-edge medicines for cell therapy and clinical trials. Aseptically produced injectable medicines have an annual cost of £3.8 billion representing 3.1% of the total annual budget of NHS England. While perhaps representing a low-profile aspect of the treatment landscape within the NHS, their importance crucial in terms of treatment outcomes.

Given that the types of products align closely with treatment goals as outlined in the NHS Long Term Plan, there is clear indication that demand for these pharmacy aseptic and technical services will continue to grow.

In 2020, Lord Carter of Coles conducted a review of NHS Pharmacy Aseptic Services in England, which recognised nationally that aseptic services are experiencing significant challenges based on increasing growth in demand, a lack of capacity to meet the demand and aging aseptic units requiring investment to maintain.

On a local level, similar challenges are experienced by the UHBW and NBT where the rising demand in aseptic services can be highlighted by the following:

- Combined product volume growth between FY19/20 – FY22/23 shows a y-o-y growth of 6.85%. At this rate, overall demand doubles after approximately 11 years. This is in line with the national average growth rate of 6% as outlined by NHSE's Infusions and Special Medicines Programme.
- Following shift away from aseptically prepared products where possible to minimise COVID-19 related disruption, there has been significant rebound demand. This is seen most clearly in product growth rate as outlined below.
- UHBW-WGH Cancer Satellite has had non-operational aseptic facilities since 2015, with entire reliance on third-party suppliers. In the context of demand growth, this is not sustainable from a patient care, supply risk or financial standpoint. For example, their 2021/2022 spend on third-party medication supply was c.£4.9m, greater than the entire staffing budget UHBW and NBT pharmacy technical services staffing budget for the same period.
- NBT is approaching maximum production output with limited ability to expand their current site of operations.
- UHBW-Bristol sites are approaching maximum capacity with significant reinvestment required in the coming years. The additional requirement because of Annex 1 of the GMP regulations are expected to accelerate and increase the cost of necessary reinvestment required.

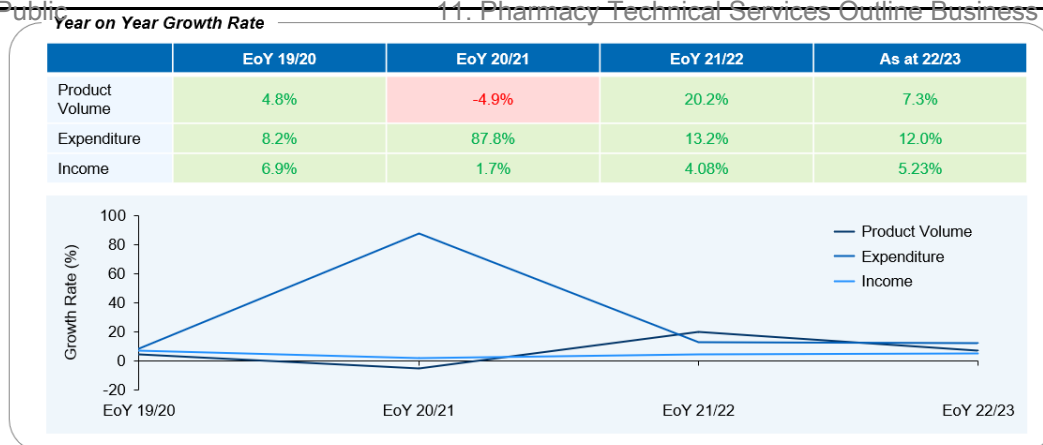


Figure 12: Product volume, expenditure, and income growth rates. Please note, owing to the relatively minor differential influence of Radiopharmacy, these values have been retained within figure 4. Please note the expenditure increase seen in EoY 20/21 is largely derived from supply chain disruption and resulting price increases seen in the initial phases of the COVID-19 Pandemic outbreak.

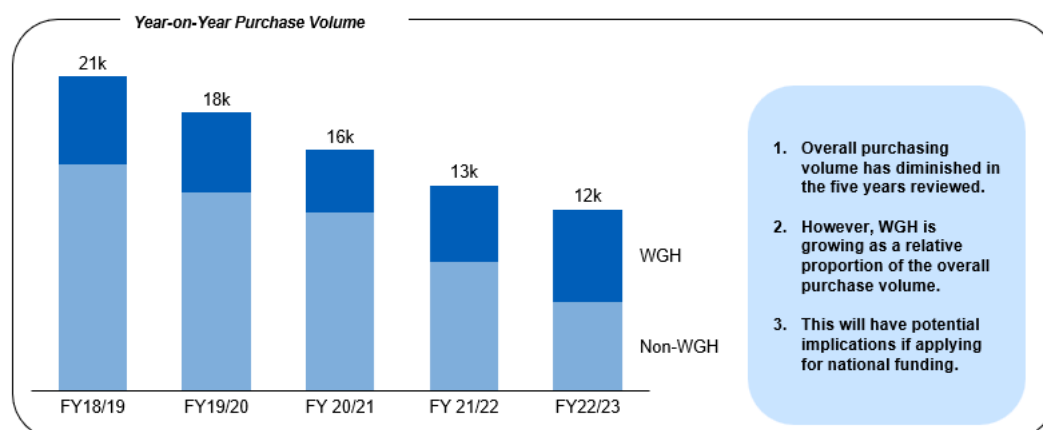


Figure 13: Diminishing, but unsustainable purchase volume. Please note, there is no purchased radiopharmacy volume within these totals.

There is limited available pharmacy technical services capacity across UHBW and NBT to be able to meet these demands sustainably and resiliently and therefore these organisations are faced with the need to invest in new local facilities.



With a lack of transformation, UHBW and NBT have identified significant implications such as increased waiting times for patients to receive specialist services, particular cancer and increase in patient safety incidents due to the increasing demand for ward-based preparation of injectable medicines (as aseptic units are saturated) combined with the increasing complexity of nursing shortages. Furthermore, it is expected to pose a significant reputational and safety risk should they not act to update and modernise their PATS. In the context of the NHS' Long-Term Plan, it is recognised that without significant transformation, there will be limited to no ability to support aims such as improving cancer diagnosis rates and treatment outcomes.

The findings of Lord Carter's review, supported by a series of recommendations, were documented in a report which set out the Case for Change for transformation of these services. The report highlighted that the creation of a network of collaborative regional hub aseptic facilities responsible for preparing large scale volumes of injectable medicines, supported by local Trust-level spoke facilities services will help to deliver the following outcomes:

1. Improved patient experience by enabling care closer to home.

	<ol style="list-style-type: none"> 2. Increased patient safety by reducing errors in the manipulation and administration of these medicines. 3. Free up the time of 4,000 nursing staff for other patient care activities. 4. Increase productivity from the medicines budget. 5. Increase the resilience of the sector. <p>This has led to the Infusions and Specials Medicines workstream within NHSE to press for the development of hub and spoke facilities to modernise practise while scaling up to meet anticipated demand growth. Recommendations of this work are varied and numerous. They include the desire to:</p> <ul style="list-style-type: none"> ▪ Create a network of collaborative regional aseptic hub facilities to scale up production capacity while supporting existing relations with commercial providers. ▪ Agree standard dose bandings for chemotherapy, parenteral nutrition, and antimicrobial products. ▪ Develop an NHS manufacturing network and transform NHS medicines manufacturing into a strategic asset that meets otherwise unmet need of patients. ▪ Assess the potential for new role and skill mixes in aseptic services, while also developing a new pharmacy technical services workforce to enable greater patient facing activities. <p>Already pathfinder projects such as those seen at West Yorkshire Association of Acute Trusts (WYAAT), Manchester University NHS Foundation Trust (through the Greater Manchester Health and Social Care Partnership) and University Hospital Southampton NHS Foundation Trust (through the Hampshire and Isle of White ICS) have evidenced the potential benefit of national investment into aseptic services. By extrapolating the potential benefits as outlined within the Lord Carter of Coles report, there is significant evidence of these benefits extending to UHBW and NBT, and beyond. For example, it is expected that through investment into this aseptic service area, this will help both UHBW and NBT to support the BNSSG strategic aims of improving outcomes in population health and healthcare, tackling inequalities in outcomes, experience, and access, enhancing productivity and value for money, and helping the NHS support broader social and economic development.</p> <p>By extension, the intended benefits of the new hub facility should extend to support Lord Carter's efficiency goals as outlined in the Operational Productivity and Performance in English NHS Acute Hospitals Report. For example, through centralisation of current ward based CIVAS preparation, this will not only release nurse time into other patient care activities, but reduce unwarranted variation in medication preparation practice. This will therefore provide direct and indirect efficiency benefits. Through enhanced collaboration and a greater shift from external to internal supply reliance, this will also have procurement benefits, most notably by reducing the amount paid per medication, reducing staff time spent sourcing medication and reducing the number and duration of patient treatment delays relating to medication delays. Again, this should help to aid efficiency of operations within the hospital, for example, by enabling quicker treatment and discharge pathways to be realised. These will all have further benefits relating to the sustainability and risk factors of the current service.</p>
<p>b) Please explain how this scheme will contribute to the delivery of the programme aims.</p>	<p>In line with the national operating model which identifies the establishment of centralised, regional hubs supported by Trust-located spokes as the gold-standard service transformation, UHBW and NBT are looking to implement a collaborative, region-wide programme that will:</p> <ul style="list-style-type: none"> ▪ Improve the productivity from the medicines budget by reducing the cost and reliance on third-party vendors. This will not only have direct financial benefits given the productivity and efficiency savings but is expected to improve patient experience outcomes and result in significant time savings owing to the relative unsustainability of the private aseptic commercial sector. ▪ Improve safety aspects through improved standardisation of practice at a single hub facility. ▪ Establish the pharmacy capacity and capability to produce central intravenous additives (CIVAs) products that release nursing time to other patient care activities. CIVAS are injectable medicines made in a ready-to-administer format, saving nursing drug preparation time on wards. ▪ Establish production capacity and capability that not only delivers for NBT and UHBW demand but caters to support beyond the ICS to regional strategy (and beyond). This will

	<p>support the wider aim of enhancing system resilience which has been recognised as a significant risk in the context of current demand.</p> <ul style="list-style-type: none"> Establish the capacity to deliver high quality cancer treatment to a steadily increasing proportion of patients diagnosed at Stages 1 and 2 in line with the NHS Long Term Plan ambition. <p>This short-form business case seeks the approval of national capital funding which will allow implementation of this regional hub model and will investigate aspects needed to deliver the long-term vision, for further integration and collaboration to appropriately future proof pharmacy aseptic and technical services in this region.</p>
c) Provide confirmation of stakeholders e.g. support from clinicians, provider collaborative, commissioners and STP / ICS accountable officers (formal letters of support to be appended to this business case template).	<p>The UHBW and NBT Pharmacy Aseptic and Technical Services Options Appraisal Project has been guided and advised by the respective clinical leads throughout development, in addition to the NBT and UHBW Chief Pharmacists and project manager in collaboration with Akeso and Company, a London based management consultancy firm with experience in pharmacy transformation projects. Wider support has been sought from NHS England and NHS Improvement collaborative. Additionally, the project has been considered by the Non-Executive and Financial Directors at UHBW. Both parties have indicated initial support, although formal sign off and approval will be sought at a later stage.</p> <p>Modelled benefits figures have been validated with clinical leads through a series of workshop sessions in addition to individual calls and correspondence. Further validation has been conducted with;</p> <p>NHSE SW Specialised Commissioning Pharmacists SW Regional Chief Pharmacist SW Deputy Regional QA Pharmacist NHSE Infusions & Special Medicines Specialist Pharmacy Advisor BNSSG ICB Deputy Director Medicines Optimisation and ICS Lead Pharmacist</p> <p>BNSSG have been informed regarding the project and indicated high level support. The project is an agreed ICS Medicines Optimisation workstream reporting into the Acute Care Collaborative Group, and part of the Integrated Pharmacy Medicines Optimisation (IPMO) plan/strategy for BNSSG. The preferred option has considered the four strategic priorities as outlined in the BNSSG Strategic Framework v3. These aims are to</p> <ul style="list-style-type: none"> improve outcomes in population health and healthcare; tackle inequalities in outcomes, experience, and access; enhance productivity and value for money; and help the NHS support broader social and economic development. <p>While, formal approval has not been requested and will be sought at a later stage, ICS colleagues have acknowledged how this scheme if effectively executed will contribute to the above list strategic aims.</p> <p>Regional collaboration has also been considered in terms of the long-term preferred option. While this has not formed one of the formal decision criteria, the preferred option selected with consideration for this potential.</p>
d) Please outline the investment objectives for the project.	<p>Investment in designing and implementing an off-site pharmacy aseptic and technical services hub, with retention on site bespoke production, aims to meet the following series of objectives:</p> <ul style="list-style-type: none"> Improve patient experience by reducing time to first dose and enabling greater care in the community potential as wider services such as OPAT. Increase patient safety by reducing medication preparation errors through improved standardisation of preparation practice and a reduction of ward level preparation activity. Leverage economies of scale concerning equipment and workforce, to greatly improve overall volumetric output relative to investment spent. Current combined per annum dose volume output is 58.4k doses per annum. Modelled activity has listed an estimate of 381k, representing a 550% increase. Deliver facilities to support unmet and additional needs for Research and Development/Clinical Trials. Generate additional production capacity to satisfy current demand. At present, approximately 25% of current demand is outsourced representing a significant cost burden.

	<p>Following effective implementation of the preferred option, this will drop to 0% (excluding strategic medication lines chosen for continued outsourcing).</p> <ul style="list-style-type: none"> ▪ Generate additional production capacity to satisfy future demand, with consideration of local, regional, and national strategic lines while also enhancing NHS-to-NHS supply capability. ▪ Satisfy the two above listed aims while also generating additional production capacity to deliver, 'excess', production capacity. <ul style="list-style-type: none"> ○ Excess capacity will be allocated to 'commercial income' with the intention of supplying to parties outside of the UHBW and NBT. ○ Release nursing time to other patient care activities both within the UHBW and NBT and beyond through centralised production at the new facility. ▪ Act as a focal point to reduce unwarranted variation for in-scope products. ▪ Enhance pharmacy technical services resilience, by reducing reliance on private sector vendors and enhancing spend efficiency. <p>Enhance collaborative working, first between NBT and UHBW, but with the potential to expand to pan ICS or pan regional collaboration.</p>
e) Please confirm fit with estate strategy.	<p>The project has support from and is in line with both current UHBW and NBT Estates Strategy. While formal approval from ICS Capital and Infrastructure Board has not been sought at this stage, ICS colleagues have been sighted on the project and formal support is not expected to be a problem.</p> <p>UHBW and NBT have both recognised that neither site would be suitable for an onsite facility, which substantially limits the feasibility of option 3c before considering the economic and value for money aspects. NBT as part of a new PFI build has little to no space for expansion of current facilities. While two potential UHBW on-site options have been considered, neither were deemed suitable from a timescale or feasibility standpoint.</p> <p>The first, Marlborough Hill project would have required significant redesign of current plans which would have required significant internal stakeholder buy in and would have not aligned with planned timelines. The second option would have involved repurposing of an existing building on the UHBW main site. However, it was recognised that this site would have been highly competitive with limited realistic prospect of being able to utilise this space. Furthermore, the ambiguity regarding the actual amount of space available would mean that there would be limited potential to expand for the future, and indeed cast uncertainty regarding the proposed scope of operations.</p> <p>No objection has been raised to the prospect of an offsite facility, although no site has been identified at this stage. To reduce capital requirements of the project, it was decided that it would be more prudent that a leasing strategy was more suitable. While cost and risk elements were raised in relation to pursuing a long-term risk, these were deemed acceptable in the context of the project and alternative options.</p>
ECONOMIC CASE	
a) Please submit a VFM template with this business case template.	<p>CIA Model Template used to support the economic appraisal, including value for money (VfM) analysis, is linked below:</p> <p>Inclusive of radiopharmacy</p> <p> BWPC_CIA_Model_v radio.xlsx</p> <p>Exclusive of radiopharmacy</p> <p> BWPC_CIA_Model_v noradio.xlsx</p>

b) Please provide an incremental VFM analysis that shows the VFM ratio (Net Present Social Value) for Business As Usual and the preferred option and provide an explanatory narrative on the VFM analysis.

Preferred Option Summary

Option	Variation	'Do Nothing' Option 1	'Do Minimum' Option 2	Preferred Option Option 4c
Total Incremental Costs	Exclusive of Radiopharmacy	£297.2m	£327.4m	£302.3m
	Inclusive of Radiopharmacy	£327.6m	£346.4m	£340.5m
Total Incremental Benefits	Exclusive of Radiopharmacy	£34.5m	£102.7m	£606.1m
	Inclusive of Radiopharmacy	£41.5m	£144.5m	£712.7m
Risk-adjusted Net Present Social Value (NPSV)	Exclusive of Radiopharmacy	£262.8m	£224.6m	£303.8m
	Inclusive of Radiopharmacy	£285.7m	£201.9m	£372.3m
Benefit-Cost Ratio	Exclusive of Radiopharmacy	0.12	0.31	2.00
	Inclusive of Radiopharmacy	0.13	0.42	2.09

Figure 14: VFM summary inclusive and exclusive of radiopharmacy

The Preferred Option, Option 4c, offers the highest Value for Money due to the ratio of cost vs output / benefit. This option will involve the lease and refurbishment of an off-site fully licensed hub. Following discussion with the clinical leads from both NBT and UHBW, it was recognised that some degree on site production would have to be retained for acute or products prescribed at short notice. Accordingly, the NBT site would continue to operate to produce bespoke, urgently required, short-shelf life or non-standardised products in line with current operations. However, greater collaboration and utilisation of the hub facility once operational is intended for large volume, standardised products that would be suitable for outsourcing to batch production. The Weston General Hospital Cancer Site would shift its reliance to the new hub facility (except for outsourcing retention for strategically chosen lines, which are yet to be decided). UHBW Bristol site will retain onsite operations in their current Parenteral Services Unit (PSU) as this is expected to match the required bespoke capacity needs while requiring minimal additional investment.

The high-cost elements seen in both do nothing and do minimum derive from the expectation that as demand grows in the context of diminishing or flatlined production capacity, third-party vendor reliance increases. Accordingly, while revenue cost elements such as staffing costs will reduce, this is greatly offset by the expectation of much higher costs because of third-party purchase costs. It should also be noted that the risk elements of these options have not been fully explored, but clinical leads agree that there would be significant supply risks if increasing any reliance on third-party vendors, in addition to the financial risks.

Sensitivity Analysis

Sensitivity analyses were conducted in relation to the nearest VFM option (option 3c which represented a near mirror facility on site). This sensitivity analysis was considered from two perspectives. Firstly, by how much option 3c's production capacity need to increase to shift the preferred option allocation. This rationale was derived from the fact that with increased production capacity, this will increase the benefits generated (relative to modelled costs) thus improving the benefit cost ratio.

Inclusive of radio pharmacy, option 3c must produce an additional 16% dose volume (on top of base assumptions) to match the VFM of option 4c. Exclusive of radio pharmacy, this volumetric increase required to match option 4c's VFM is raised to an additional 18%.

Secondly, sensitivity analysis was considered from the perspective of option 4c costs, i.e., by how much must revenue costs increase to reduce the VFM to below that of option 3c. Again, for both iterations of option 4c (i.e., with and without radiopharmacy), revenue costs must increase

by approximately 18% to reduce option 4c's VfM to below that of option 3c. An increase of 20% to both 3c's volumetric output and 4c's revenue costs are shown in figure 16.

Option	Variation	Option 3c	Option 4c
Total Incremental Costs	Exclusive of Radiopharmacy	-£298.8m	-£302.3m
	Inclusive of Radiopharmacy	-£330.8m	-£340.5m
Total Incremental Benefits	Exclusive of Radiopharmacy	£524.7m	£606.1m
	Inclusive of Radiopharmacy	£618.8m	£712.7m
Risk-adjusted Net Present Social Value (NPSV)	Exclusive of Radiopharmacy	£225.9m	£303.8m
	Inclusive of Radiopharmacy	£288.0m	£372.3m
Benefit-Cost Ratio	Exclusive of Radiopharmacy	<u>1.76</u>	<u>2.00</u>
	Inclusive of Radiopharmacy	<u>1.87</u>	<u>2.09</u>

Figure 15: VfM comparison of option 3c and 4c. Option 3c represents the closest comparison to the preferred option both from an operational and VfM standpoint.

Option	Variation	Option 3c – Additional Volumetric Capacity	Option 4c – Additional Revenue Costs
Total Incremental Costs	Exclusive of Radiopharmacy	-£298.8m	-£358.2m
	Inclusive of Radiopharmacy	-£340.6m	-£403.1m
Total Incremental Benefits	Exclusive of Radiopharmacy	£622.5m	£606.1m
	Inclusive of Radiopharmacy	£730.3m	£712.7m
Risk-adjusted Net Present Social Value (NPSV)	Exclusive of Radiopharmacy	£323.7m	£247.9m
	Inclusive of Radiopharmacy	£389.6m	£309.7m
Benefit-Cost Ratio	Exclusive of Radiopharmacy	<u>2.08</u>	<u>1.69</u>
	Inclusive of Radiopharmacy	<u>2.14</u>	<u>1.77</u>

Figure 16: Sensitivity Analysis of the option 3c and 4c with a volumetric and revenue cost increase of 20% respectively.

In addition to the sensitivity analysis considerations, from a qualitative standpoint, significant doubts were raised regarding the feasibility of implementing option 3c. Given these and the significant changes to operation changes required to make 3c the VfM option, it was agreed that option 4c should proceed as the preferred option.

c) Provide a

narrative on:

- The options considered to achieve the scheme's objectives, including business as usual.
- The process through which the long list of options was narrowed down to the preferred option.
- The main costs, benefits and risks for the Business as Usual and preferred option.
- The appraisal period for the scheme.

The Options Considered

An initial list of four options were provided as the minimum appraisal requirement as part of the Tender Specification. Different permeations of the onsite and offsite facility options were developed following initial discussions and data gathering site visits and calls with respective clinical leads, bringing the total longlist to 8 options. These were assessed and consider in the context of the Critical Success Factors (CSFs) which were discussed during our longlist workshop which took place on 05/12/22.

While a total of ten (CSFs) exceeded the recommended maximum of seven as outlined in the HMT Green Book, it was deemed necessary in the context of the UHBW and NBT project board and wider national aims and guidelines regarding aseptic medication production. The ten CSFs include five defined by Green Book and five defined by UHBW and NBT Strategic Workshop.

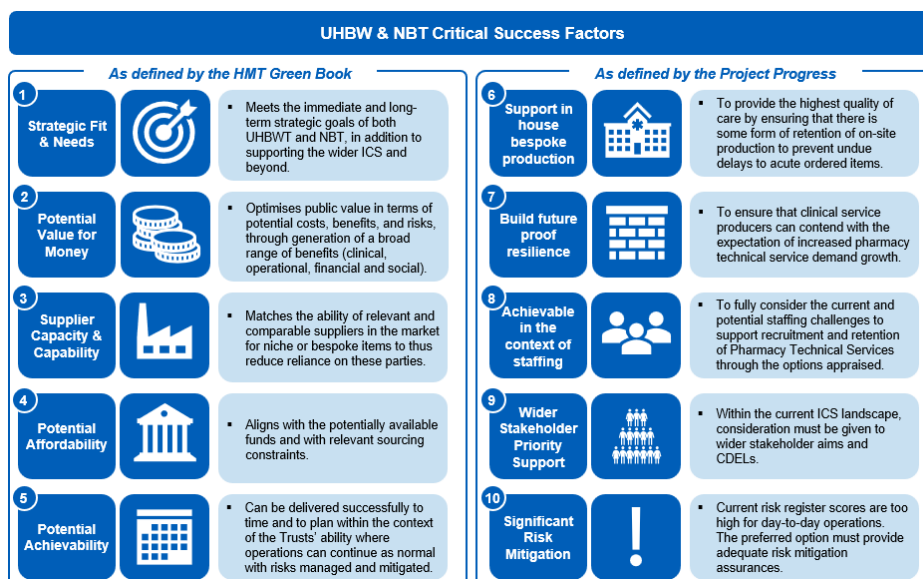


Figure 17: Critical Success Factors as outlined by the HMT Green Book and Project workshop.

The qualitative assessment against the ten CSF's allowed the list to be shortlisted to the following five options, which through more detailed modelling and costing assessment identified Option 4c as the Preferred Option.



AC_UHBTNBT_Workshop1_v4.pdf

- **Option 1 - Business As-Usual (Do Nothing):** This option would involve no refurbishment, reconfiguration or new build works and current state of services would continue As-Is, therefore requiring no capital investment. Accordingly, this option would see diminishing output as equipment falls into disrepair and ceases to function. From a modelling standpoint, volumetric output was matched to diminish proportionally to essential equipment failure in line with listed or expected shelf lives from baseline data provided by clinical leads. In this way, increasing reliance shifts to third-party vendors resulting in significant revenue cost increases with diminishing benefits. While never truly expected to represent a viable long-term solution, this option was carried forward to the short list to evidence the need to act. This option was discounted as it delivered no benefit or value to the Trusts or local health economy and services will continue to operate in an uncoordinated manner through not-fit-for purpose facilities, increasing risk to patient outcomes and safety and anticipated decrease in product output.
- **Option 2 - Do Minimum:** Allocation of capital towards upgrading current Trust-level facilities through major refurbishment and reconfiguration of all in-scope pharmacy technical services. In comparison to Option 1, this would help drive a small increase in output production, however, the option was discounted as it does not represent value for money

from an investment standpoint. Additionally, it does not address the long-term sustainability and demand challenges expected from NHS pharmacy technical services.

- **Option 3c – On-site Hub for Technical Services:** Utilisation of capital to establish a single facility for technical services on-site at UHBW. Products produced at the new hub will be utilised at UHBW (including WGH) and distributed to NBT. Excess production capacity will be prioritised for demand growth, followed by commercial income and nursing time released to other patient care activities. This option was discounted due to additional complications and uncertainty around a viable location for the new hub within the Trust's facilities. Furthermore, during the qualitative assessment following discussions with clinical leads, several potential flaws were recognised. Retrofitting to existing sites would likely be more costly relative to a new site, there would be increased complication and internal governance checks, staffing recruitment would be complicated (relative to options 4a and 4c) based on staff feedback and internal research and there would limit ability to work in an agile or flexible manner to meet evolving demand profiles.
- **Option 4a – Off-Site Hub without WGH Reliance:** Utilisation of capital to establish a single off-site facility for technical services. Products produced at the new hub will be distributed to UHBW and NBT, however WGH will continue to rely on third-party vendors. Excess production at the new hub will be prioritised for commercial output. Despite demonstrating the highest overall monetisable benefits, this option was discounted as the expected growth in expense associated with third-party costs outpace assumed commercial potential. While acknowledging the need to support external demand, it was recognised that the need to prioritise internal demand profiles would have to come first to maintain a financially sustainable and reliable service.
- **Option 4c – Off-Site Hub with WGH Reliance:** Utilisation of capital to establish a single off-site facility for technical services. Products produced at the new hub will be distributed to UHBW (including WGH and NBT with excess production capacity prioritised for demand growth, followed by commercial income and nursing time released to other patient care activities. This option demonstrated the greatest net present social value and benefit cost ratio. Furthermore, it was deemed the preferred option from a qualitative perspective for several reasons. This option owing to the volumetric output potential would support the most thorough future proofed option. While the logistic cost elements have not been fully defined and costed at this stage, it was acknowledged from discussion with experts and based on previous experience that this would not drive a cost element significant enough to diminish the cost benefit ratio below that of 4a (which had the second best from the five options considered).

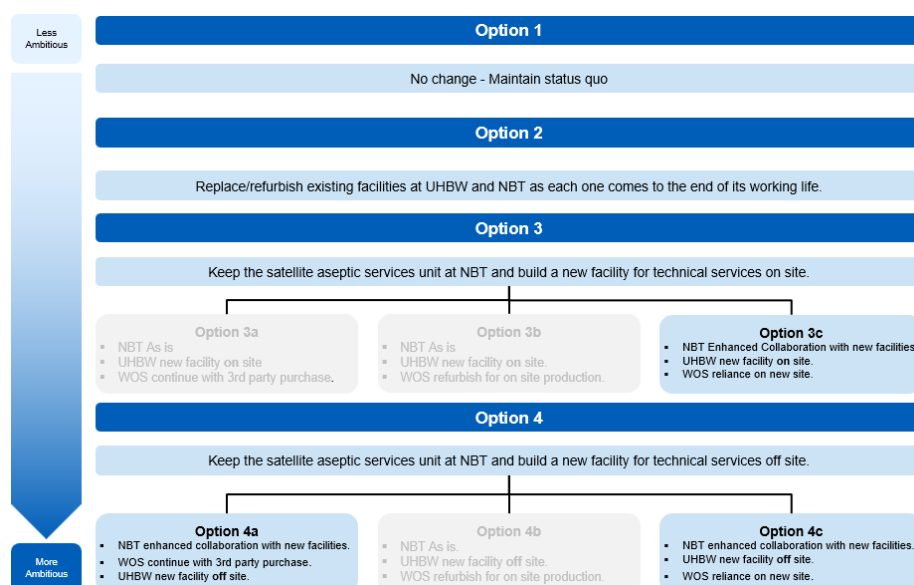
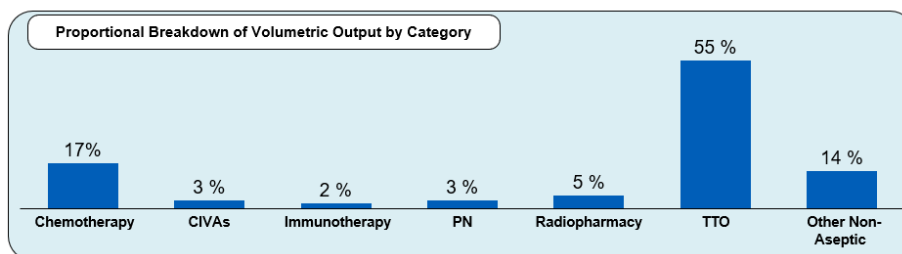


Figure 18: Options Summary confirmation of shortlist following shortlisting workshop**Costs, benefits, and risks for the BAU and Preferred Option**

The quantified benefits of focus were cash-releasing benefits in the form of cost avoidance from a reduction in reliance on purchasing from third-party sources. Medication was categorised with average cost data applied to each medication category (derived from baseline data provided). Y-o-Y growth rates were applied to each category to develop overall demand profiles. These growth rates were applied for 10-year period followed by flatline period afterward owing to the relative unknown of the market after 10 years and the assumption of significant clinical innovation. Baseline production capacity volume data was used to evidence prospect third-party reliance, which when coupled with baseline cost information, showed ongoing cost profile.

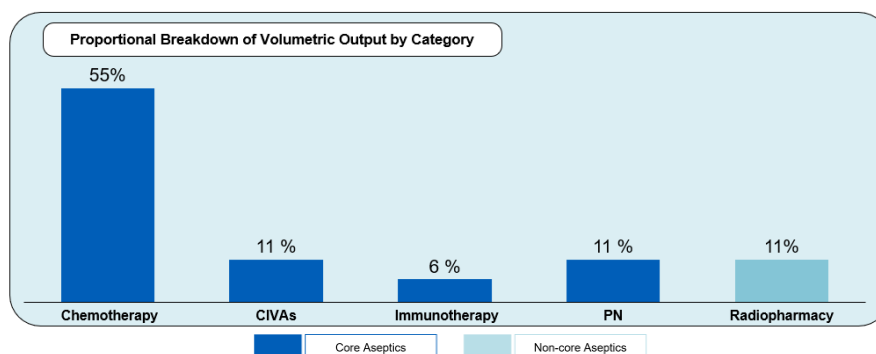
Baseline Volume (2021/22)				
	Made	Purchased	Total Volume	Relative Contribution
Chemotherapy	26,326	13,449	39,775	17%
CIVAs	8,037	-	8,037	3%
Immunotherapy	4,144	16	4,160	2%
PN	8,062	-	8,062	3%
Radiopharmacy	11,892	-	11,892	5%
TTO	127,791	-	127,791	55%
Other Non-Aseptic	33,125	-	33,125	14%
Total	219,377	13,465	232,842	100%

**Figure 19: Overall Baseline Volume Production Proportions**

While to pre-packs and other non-aseptic was included in the categorisation, the associated capital and revenue costs as well as benefits were not considered in terms of the final options appraisal and subsequent VfM calculations.

Rather, this was included in baseline activity review to ensure that by investing in the expansion of aseptic pharmacy technical services, these wider services would not be compromised.

Baseline Volume (2021/22)				
Medication Category	Made	Purchased	Total Volume	Relative Contribution
Chemotherapy	26,326	13,449	39,775	55%
CIVAs	8,037	-	8,037	11%
Immunotherapy	4,144	16	4,160	6%
PN	8,062	-	8,062	11%
Radiopharmacy	11,892	-	11,892	11%
Total	58,461	13,465	71,926	100%

**Figure 20: Proportional Breakdown of Baseline Volume**

Cash releasing benefits focused on the cost avoidance element of no longer requiring purchases from third-party providers. This benefit accounted for the largest single proportion of benefits. Benefit rationale assumed that production capacity would be first prioritised for internal (UHBW and NBT) demand. Excess production capacity was then allocated to either commercial income where production capacity is used to meet demand from third-party NHS partners, or non-cash releasing benefits such as direct CIVAS ward production to release nursing time to other patient care activities (derived from baseline data provided). In this way, it is expected that nursing time released to other patient-facing care will be released directly or indirectly (for example if providing standardised, long shelf life CIVAS products to other trusts thus reducing their requirement for nurse led ward level CIVAS preparation).

Costs:

Option	Variation	'Do Nothing' Option 1	'Do Minimum' Option 2	Preferred Option - Option 4c
Opportunity Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Total Lifecycle Capital Costs + Optimism Bias Uplift	Exclusive of Radiopharmacy	-£9.8k	-£7.7m	-£22.7m
	Inclusive of Radiopharmacy	-£9.8k	-£7.7m	-£27.2m
Revenue Costs	Exclusive of Radiopharmacy	-£297.2m	-£318.1m	-£279.3m
	Inclusive of Radiopharmacy	-£327.2m	-£337.1m	-£313.1m
Transitional Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Externality Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Net Contribution Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Risks	Exclusive of Radiopharmacy	£0	-£1.6m	-£278k
	Inclusive of Radiopharmacy	£0	-£1.6m	-£278k
Total Costs	Inclusive of Radiopharmacy	<u>-£297.2m</u>	<u>-£327.4m</u>	<u>-£302.1m</u>
	Exclusive of Radiopharmacy	<u>-£327.2m</u>	<u>-£346.4m</u>	<u>-£340.2m</u>

Figure 21: Summary of Costs inclusive and exclusive of Radiopharmacy.

Please note risk for the purposes of the Comprehensive Investment Appraisal (CIA), the risks associate with the 'do nothing' option have not been quantified. While this option if pursued will pose the significant financial risks, these will be related to the costs and stability of third-party vendor product supply. For the purposes of the CIA, quantified risks have focused on the costs associated with investment into either a new facility or to bring the current operational facilities up to standard. While the costs calculated shown against option 1, do nothing, are lowest, this has not been considered as a realistic or viable option owing to the assumed unreliability of

relying entirely on third-party vendors. Furthermore, this option delivers no long-term benefits meaning that it produces the lowest benefit cost ratio.

Preferred Option Selection | Quantified Benefits Summary

Benefits have been calculated with focus on three main categories of benefits. While further benefits can be further incorporated to refine the model, these have been deemed as the most relevant in the first instance.

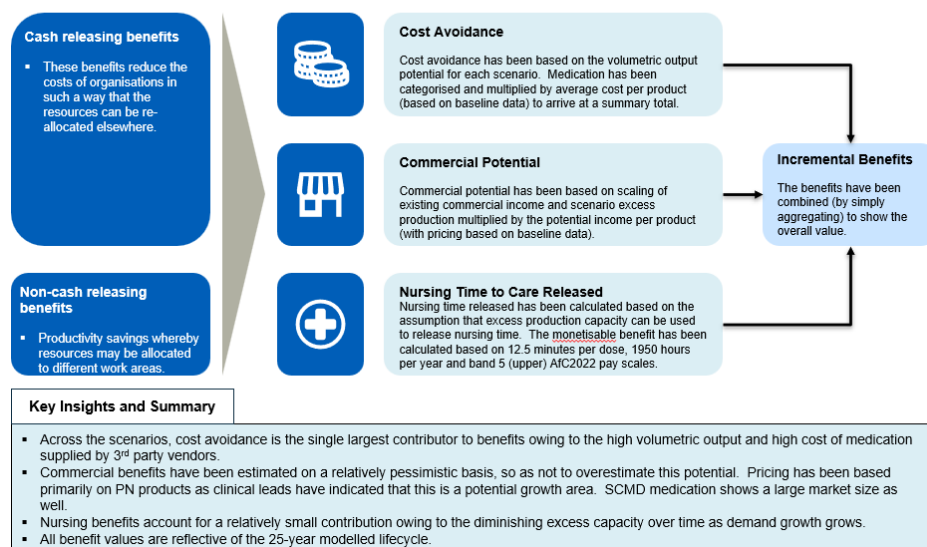


Figure 22: Quantified Benefits Methodology Summary

Benefits:

Option	Variation	'Do Nothing' Option 0	'Do Minimum' Option 1	Preferred Option Option 4c
Cash releasing (cost avoidance)	Exclusive of Radiopharmacy	£33.0m	£98.4m	£563.2m
	Inclusive of Radiopharmacy	£36.9m	£124.8m	£642.2
Non-cash releasing (i.e. nursing time released)	Exclusive of Radiopharmacy	£0	£0	£36.9m
	Inclusive of Radiopharmacy	£0	£0	£6.3m
Cash Releasing (Commercial Income Potential)	Exclusive of Radiopharmacy	£1.4m	£4.4m	£7.5m
	Inclusive of Radiopharmacy	£4.6m	£19.7m	£33.6m
Total Benefits	Exclusive of Radiopharmacy	<u>£34.5m</u>	<u>£102.8m</u>	<u>£606.1m</u>
	Inclusive of Radiopharmacy	<u>£41.5m</u>	<u>£144.5m</u>	<u>£712.8m</u>

Figure 23: Quantitative Benefits of the preferred option inclusive and exclusive of Radiopharmacy

Other Benefits of preferred option 4c:

- Greatest workforce efficiencies.

- Multitude of rooms as specified in the service design will allow for production variation to meet the any demand fluctuations within the network.
- Greatest ability to support wider network.
- Greatest ability to consider future requirements and subsequent refurbishment.
- More effective utilisation of MHRA licenses and greatest potential expansion of clinical trial manufacturing (of IMPs).
- Enhanced ability to support advanced therapy medicinal products (ATMP) and advanced therapy investigational medicinal products (ATIMPs) together with Class 2 Biological handling.
- Improved resilience for UHBW and the wider region and NHS.
- Greatest flexibility to expand production output to meet future demand variations.
- Greatest ability to support OPAT and virtual ward and theoretically improve bed days released.

Please note, these 'other' benefits have not been quantified as part of the economic appraisal through the comprehensive investment appraisal model process. These benefits were deemed to not have sufficient baseline data to consider quantification through extrapolation of each into a workable benefit calculation for considering with each option.

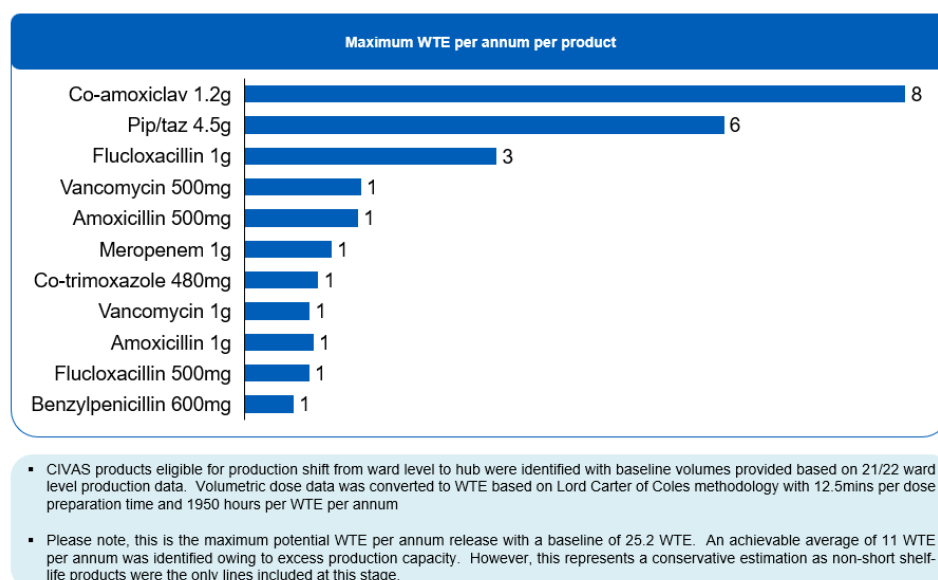


Figure 24: Maximum Nursing Time to Other Patient Care Activities WTE Release Potential

Risks:

Option	'Do Nothing' Option 0	'Do Minimum' Option 1	Preferred Option Option 4c
Identified Risks of each Option	<ul style="list-style-type: none"> ▪ Operating Risk ▪ Revenue Risk ▪ Regulatory Risk ▪ Performance Risk ▪ Technology Risk ▪ Control Risk 	<ul style="list-style-type: none"> ▪ Operating Risk ▪ Revenue Risk ▪ Regulatory Risk ▪ Performance Risk ▪ Technology Risk ▪ Control Risk 	<ul style="list-style-type: none"> ▪ Design Risk ▪ Construction Risk ▪ Performance Risk ▪ Operating Risk ▪ Revenue Risk ▪ Termination Risk ▪ Technology Risk ▪ Control Risk

- Residual Value Risk
- (See CIA model for sub-category risks)

Figure 25: Risk Quantification and summary for preferred option vs do nothing and do minimum.

Appraisal Period:

- The Economic Appraisal has been conducted in accordance with the Treasury Green Book, utilising the DHSC's Comprehensive Investment Appraisal (CIA) Model.
- This reflects the differential costs, benefits, and risks in the different options, appraised against the baseline "Business as Usual" Option.
- The appraisal was conducted over the entire project projected lifecycle of 25 years beginning Year 0 2022/23 and finishing as Year 25 in 2047/48
- UHBW and NBT provided baseline data for analysis in October – December 2022. This was utilised as part of the shortlisting workshops which formed the basis options appraised. The economic appraisal was conducted in December 2022 and January 2023 with a final review with clinical leads and senior stakeholders completed in February 2023.

d) Confirm inflation, VAT, depreciation, CDEL cover are excluded from the economic analysis.

As per DHSC methodology and instructions, inflation, VAT, CDEL, depreciation and PDC have all been excluded from the economic analysis.

COMMERCIAL CASE

a) Please set out the commercial and procurement route, e.g., P22.

To achieve the objectives of the collaboration aseptic project, particular goods and services that need to be procured include:

- Professional services
- Refurbishment and associated works
- Equipment
- Systems
- Logistics

To procure the preferred provider across these functions, the following initial list of procurement routes have been considered:

1. Find-a-Tender (national tender process – replacement to the Official Journal of the European Union since departure from the EU). These could take the form of either an open procedure or a restricted procedure.

Note: there are other routes available, that have not been detailed here as would not be suitable e.g., Competitive Dialogue.
2. Clean Room or Similar Framework Routes: There are no comprehensive national framework routes available for cleanroom design, build and validation. However, the North of England Commercial Procurement Collaborative have a localised pharmacy clean room services framework in place. This covers three specific lots; Pharmacy Clean Room Garments, Provision of mops including processing and pharmacy specific clean room consumables. Suitability of this approach has not been considered, but it is assumed that similar categorisation approach could be mirrored in the development of tender

	<p>specification for UHBW and NBT. Depending on external stakeholder buy in, this could be extended to include the ICS or SW region.</p> <p>3. Construction Frameworks: A construction framework would need to fully verify the credentials of participants to be confident that an appointed provider would have the capability to deliver the complex project. There are numerous construction frameworks available to the project such as the:</p> <ul style="list-style-type: none"> ▪ North of England Commercial Procurement Collaborative – Estates Consultancy ▪ Fusion 21 ▪ NHS ProCure23 Framework (P23) <p>At the next stage of project progression, the UHBW and NBT collaborative in line with the Procurement and Commercial workstream will decide upon the best procurement route which will generate outcomes that deliver best value to the project and UHBW and NBT collaborative. The procurement routes will be assessed based on alignment and fit with project-specific requirements, drivers, and success criteria for the project.</p> <p>When the optimum procurement route for the new regional hub model development has been determined, the procurement framework will align with the following to select the preferred principal partner who will then provide a suitable design to ensure best procurement is secured for cost, time, and quality assurance across the collaborative.</p> <ul style="list-style-type: none"> ▪ Payment Mechanisms ▪ Value for Money ▪ Actual Cost ▪ Incentivisation & Gainshare ▪ Delay Damages
<p>b) Set out the basis of the negotiated position, including the final price for the works.</p>	<p>Professional services</p> <p>Professional services will be acquired in line with the delivery timetable outlined above. Core professional services such as architectural contracting etc will be managed by the procurement and commercial workstream. Wider professional services such as facilities maintenance will also be managed by the workforce workstream. As the exact specification of the facility becomes defined more clearly as the project design matures, exact pricing can be considered regarding the wider professional services. Regardless of overall need, value for money, experience and quality aspects will be considered as the most important aspects.</p> <p>Refurbishment and Fit Out</p> <p>This will be undertaken through a procurement process as outlined above. Outline costs have been established in the business case work up to ensure costs listed have merit, however, further refinement will be added during the procurement process.</p> <p>Construction and associated works will utilise Procure23 and will be led by the Procurement & Commercial workstream, with input from clinical leads to ensure that facilities are suitable, fit for purpose and have the correct level of flexibility to allow for subsequent improvements or expansions as technological improvements or regulatory requirements allow or dictate.</p> <p>Equipment</p> <p>This work will be led by the Procurement & Commercial workstream with detailed input from the hub implementation workstream. The equipment procurement will make use of relevant frameworks where possible with tenders undertaken where necessary.</p> <p>Logistics</p> <p>With the preferred option for an offsite facility, and the longer-term aim to increase commercial income through increased collaboration with NHS parties within the ICS and beyond, there will be further logistics and supply chain management requirement.</p> <p>While price has not been defined at this stage, consideration of storage requirements during transport will influence pricing aspects. This in turn will largely be defined by demand profile including destinations and product mix. Again, as the project matures toward implementation a clearer idea of logistics requirements will be defined which will inform pricing structure. It is expected that NHS Supply Chain will manage this aspect.</p> <p>Systems</p>

	<p>During 2023, a “detailed “design” workstream will establish a subgroup to undertake market scanning for potential systems required to operate a large aseptic hub. Multiple potential suppliers, all available on existing frameworks, will be engaged regarding the requirements of the hub and associated systems. Whilst work is still underway to establish whether a new full Enterprise Resource Planning (ERP) system is required, the costings used in the business case are based on extensive work with previous providers. Other system requirements are based on updates to current systems in place within the production units at UHBW and NBT and therefore minimum input is required to implement updates and expansion as necessary.</p> <p>The use of single tender waivers is appropriate where costs exceed the threshold for competitive tendering or quotation will be applied where appropriate and costings of these systems are well understood.</p> <p>Once the procurement for the works have been conducted and contracted for, the final price for the works can be confirmed.</p> <p>Social Value</p> <p>Underpinning all elements of the procurement strands and strategy will be the need to consider social value in all contracts awarded and partnerships developed. In considering social value benefits, factors such local employment effects, skill improvements for young people, staff welfare factors and sustainable procurement aspects will be assessed. While no social value measurement methodology has been defined yet as part of the procurement and commercial strategy, the National TOMs Framework 2019 for social value measurement should act as a sufficient guide in this matter.</p>
c) Confirm status of any legal documentation or processes required for the scheme to be delivered in full and what (if anything) remains to be agreed.	<p>In accordance with section 12ZB of the Health and Care 2022, all elements of the project will fully comply with all required procurement legislation as well as the SFIs of both UHBW and NBT in terms of the new funding requirements.</p> <p>Furthermore, the following employment legislation has been identified as applicable to the project and will be adhered to:</p> <ul style="list-style-type: none"> ▪ Employment Rights Act 1996 ▪ National Minimum Wage Act 1998 ▪ Employment Relations Act 1999 ▪ The Maternity and Parental Leave etc. Regulations 1999 ▪ Part-Time Workers (Prevention of Less Favourable Treatment) Regulations 2000 ▪ Transfer of Undertakings (Protection of Employment) Regulations 2006 ▪ The Equality Act 2010 ▪ Agency Workers Regulations 2010 <p>Full regulatory requirements have been considered in the context of the MHRA Orange Book. Additionally, the project has been considered in the context of MHRA requirements including Annex 1 of GMP in relation to the manufacture of sterile products.</p> <p>Lastly, in addition to regulatory requirements, the new facility will aim to adhere to NHS best practice requirements such as those outlined in the NHS Agency Rules June 2019.</p>
d) We assume that Modern Methods of Construction (MMC) will be used for new builds. Please provide details of how MMC will be utilised.	<p>The preferred option will identify lease of a facility in place of construction of a new regional hub, refurbishment requirements will be incorporated in the lease terms and conditions and third-party leases will not be considered.</p> <p>Thus, this project does not anticipate the preferred option requiring construct of a new build and fall under a new build scheme remit and will therefore not require a Building Research Establishment's Environmental Assessment Method (BREEAM) assessment or planning permission. However, a BREEAM assessment will be conducted should NHSE deem it necessary. Furthermore, confirmation of both procurement and design will be followed with the completion of the Health Building Note (HBN) on the extension of the aseptic service and facilities (with any deviations explained).</p> <p>Health Technology Memoranda (HTM) reflect a standardised set of documents that offer comprehensive guidance regarding the design, installation and operation of specialised buildings and engineering technology used in the delivery of healthcare. These have been considered at the outset to ensure that best practice has been considered and align with their stated goals of improved patient outcomes relating to safety, effectiveness, and patient experience.</p>

	<p>As the design phase matures further, these will be further considered to ensure compliance with building requirements and alignment with best practice considerations. While no pre-defined hierarchy of HTMs has been confirmed in relation to the HTMs, early consideration has been focused on HTM 00 Policies and principles of healthcare engineering especially regarding the construction management governance arrangements, utilities consideration, infection prevention and control, electrical services and ventilation and cooling considerations. HTM 03 Specialised ventilation for healthcare premises has also been considered and will continue to be relied upon given the requirement for air handling units, particle monitoring and limits as part of clean room, and aseptic production requirements. Furthermore, HTM07-02 Making energy work in healthcare has also been considered in line with broader NHS sustainability goals.</p> <p>Similarly, health building notes (HBN) give best practice guidance on the design and planning of new healthcare buildings and on the adaptation or extension of existing facilities. While the preferred option will not involve construction of a new facility, the relevant principles can still be considered to ensure best practice is achieved. Again, while no confirmed HBN hierarchy has been defined, core consideration has initially focused on HBN00 General design guidance for healthcare buildings especially regarding the policy and regulatory overview elements such as CQC or MHRA requirements, NHS Constitution consideration which sets out the rights to which patient, public and staff are entitled to, health and safety considerations, and the code of practice regarding the practice in infection prevention and control Strategic and master planning elements as outlined in HBN 00 have also been considered. Given that improving resilience has been outlined as one of the key aims of the project, HBN 00-07 Planning for a resilient healthcare estate has also been considered. Key elements of focus from this guidance has centred around robustness of facility design, especially in relation to varying product demand profiles, and aspects that can impact facility robustness. These include, but are not limited to, unavailability of premises due to fire or flood etc, transport infrastructure challenges, major IT or electronic disruption, loss of access to key resources, loss of critical support services or loss of access to key resources. In considering these aspects, it was accepted by clinical leads that UHBW clinical facilities are currently dealing with many of these aspects that can negatively impact facility resilience. Given that the pharmacy aseptic and technical services will require aseptic clean room working conditions, HBN00-09 Infection control in the built environment will also be considered. Lastly, as this is ultimately a pharmacy project, HBN 14-01 Pharmacy and radiopharmacy facilities have been (and will continue to be) considered. General design principles have such as facility location, aseptic and storage requirements, radiation protection, security and general infection control have been considered. As the design phase matures, the detailed information regarding aseptic preparation facilities, including the requirement of changing rooms, inner and outer support rooms, and clean room requirement as well as the flow of overall design.</p>
e) Confirm contribution to carbon reduction plan (if applicable).	<p>The design and implementation of the Preferred Option (Option 4c, see Economic Case) will be in accordance with the Green Plan 2022, outlining the commitment to improving sustainability throughout the organisation with support for the NHS in the pursuit of becoming the world's first net zero health service. The Green Plan is focused on nine core areas, aligned to the key drivers for change and key sources of carbon emissions, within the NHS.</p> <p>Both NBT and UHBW have published individual documents detailing their commitment to the carbon reduction and sustainable development. Full details can be found in UHBW's Sustainable Development Strategy (SDS) 2020-2025 and NBT's Green Plan 2020-2021. Project leads have already considered the need to align the project with this documentation in relation to sustainability elements including carbon reduction strategies. This will range from scope 1, 2 and 3 emissions. While reporting elements are yet to be defined, UHBW's SDS provides clear aims and potential metrics and reporting mechanisms that could be adapted as part of the project. Wider literature sources are available to further support the development of a carbon evaluation calculation methodology. These include the Magenta Book detailing ventral government guidance on evaluation and the carbon valuation literature as developed by the department for Emergency Security and Net Zero and Department for Business, Energy, and Industrial Strategy.</p>

FINANCIAL CASE

a) Please provide narrative to support the detail provided in Section 4 (above).

As noted in the introduction, this business case will rely on the assumption of capital funding from outside of the BNSSG ICS CDEL from nationally available funding as part of the national NHSE Infusions and Special Medicines Programme following on from Lord Carter of Coles' Transforming Aseptic Care in England Report.

The scope of this Business Case is to deliver a full scale aseptics hub with capacity to meet current demand, including supply to Weston General Hospital Cancer Satellite, absorb future growth, of multiple medication categories as well as address the significant unmet need, releasing nursing time to other patient care activities by producing ready-to-administer CIVAS products for use on wards and support product supply to other NHS partners both within and beyond the scope of the BNSSG ICS.

Capital Expenditure Profile

Two iterations of the capital expenditure profile have been presented. The first is inclusive of radiopharmacy and the second exclusive. The key difference in pricing is derived from the expectation that with the exclusion of radio pharmacy, there will be a reduction in floor space and associated equipment which drive the cost differences. While the exact breakdown of capital expenditure has yet to be finalised, it is expected that most of the funding will be spent during the 2025/26 financial year in line with expected NHSE funding release. An initial outlay of 10% has been suggested for the 2024/25 financial year to enable some of the preliminary works etc to be completed and enable smooth transition into full completion in 2025/26. This 10% would be comprised of preliminary planning costs and associated professional fees. Once again, it must be noted that the breakdown of fees presented is for illustrative purposes and may be subject to further change as the design phase matures.

Breakdown of Scheme Capital Costs

Similarly, two iterations of the breakdown of scheme capital costs have been presented, again to enable differentiation of the costs inclusive and exclusive of radio pharmacy. The work costs, fees, non-work costs, equipment costs have all been derived and extrapolated from baseline data provided and third-party experts. Conservative estimates have been applied to reduce the risk of underestimation of costs. Additionally, optimism bias, planning contingency and inflationary adjustments have been included at 5% each, again to reduce the risk of underestimation of costs. These represents approximately £2.6m inclusive of radiopharmacy and £2.2m exclusive of radiopharmacy. VAT has been applied to all elements at the standard 20%.

There are two versions of three tables (i.e., six tables total from figure 4 – 9). Figure 4 shows the combined financial summary of both UHBW and NBT, with figure 5 and 6 detailing UHBW and NBT independently, with all figures reflecting radio pharmacy inclusion. Conversely, figures 7 – 9 show the same detail but exclusive of radio pharmacy activity, or other financial involvement.

Financial Position Summary

Balance Sheet Summary

The balance sheets presented are indicative of the assets employed after completion of the project. No 'additional' assets will be employed under the do minimum scenario, hence this has not been zeroed. Depreciation has been applied on a flat line basis as per UHBW's (the lead organisation) instructions in accordance with IRFS 16 rules over a 23-year basis (excluding 2 base years until FY 25/26) when the facility will be operational with leasing charges incurred. The asset values represented in years Y25 show the value the assets employed after the life of the project with the diminished value driven by the annual depreciation.

MCFlow Summary

Master cash flow statements have been presented inclusive and exclusive of radiopharmacy. Cashflow will operate on a net neutral basis. However, in both figure 5 and 8 the UHBW operating income is significantly lower in option 4c (inclusive and exclusive) of radiopharmacy. This assumes that through operation of the new hub facility, the increased capacity created will lead an increase in volume available for commercial activity. Based on this rationale, this should reduce the baseline funding from trust input needed to operate pharmacy aseptic and technical services.

	<p>I&E Summary</p> <p>Income and expenditure have been developed based on baseline data provided. Commercial income has is driven by current activity, which in turn is derived mainly from PSU activity relating to parenteral nutrition product supply radio pharmacy and UHBW's production facility. While full market scoping and investigations have not been discussed, preliminary review of activity with discussion of current local facility landscape indicate this will be a significant potential revenue driver. This amount diminishes within option 4c as there is a greater potential for commercial income. Inflation at 2% per annum has been applied to all costs and the commercial income potential.</p> <p>Baseline funding is the amount that each respective trust must provide to enable services to continue to operate year on year. The diminished value seen in both iterations of option 4c is reflective of the assumption that as the facility becomes operational, and commercial income potential increases, trusts must commit a reduced level of baseline funding to maintain an operational pharmacy aseptic and technical service.</p> <p>Pay data is derived from 2021/22 baseline pay figures. Minor amendments have been made to accounting data provided by clinical leads to reflect a more accurate cost of operating the facility (i.e., to reduce potential double counting for staff members with current PATS and Non-PATS roles). All assumptions have been confirmed with respective clinical leads and financial representatives. As seen in all sets of tables, there is an increase in staffing costs in option 4c reflecting the additional staff required to operate the service. Inclusive of radiopharmacy, this is reflected in an additional £38m over the course of 25 years. Exclusive of radiopharmacy this is reflected in an additional £26m over the course of 25 years.</p> <p>Non-Pay clinical services are largely driven by third party expenditure costs. As seen in the differential tables, option 4c offers significant cost savings in this element which in turn reduces the amount of trust commitment funding required for the service to operate and reduced the overall total income required for the service to operate.</p> <p>Interest has been applied at the Treasury standard of 0.95%. Public dividend capital (PDC) charges have been assumed at 3.5% of net relevant assets. With the leasing charge derived from assumed floor space requirements, this ranges from approximately £346k to £296k per annum (inclusive and exclusive of radio pharmacy).</p> <p>These charges have been applied to UHBW's financial position alone as it is acting as the lead financial organisation and so will retain responsibility for the management of these elements. As there is no public capital applicable to the do minimum option, these charges are entirely derived from the assumption of the progression of the leasing of the new facility in line with cost estimates. Leasing has been selected as more appropriate from an ongoing financial management standpoint.</p> <p>UHBW Whole Trust Impact</p> <p>The impact of the project on UHBW is represented in figures 10 and 11 (inclusive and exclusive of radio pharmacy respectively). Regardless of radio pharmacy involvement, the overall operating expense in net neutral on the basis that the PATS operating costs will also be. While option 4c does add significant staffing costs to UHBW's position, these costs are greatly offset by the commercial income potential as evidenced in figures 5 and 8.</p>
<p>b) Please explain any incremental revenue consequences of the investment and how they can be mitigated.</p>	<p>For the purposes of the business case, revenue elements have been structured in three categories, pay revenue, clinical services (including drug cost) and miscellaneous cost elements.</p> <p>Increases seen in pay and miscellaneous costs have been greatly offset by the expected savings seen against clinical services costs. This savings element is derived from the expectation that through greater volumetric production capacity, the hub facility will be able to meet current demand levels and absorb subsequent growth. Accordingly, there will be no need to be entirely reliant on third-party vendors for medication supply. Regardless of the financial element, it has also been noted that third-party production capacity has been shown to be currently struggling to meet demand levels. Therefore, it does not make financial or risk management strategic sense to expect this to be a viable supply source.</p> <p>While additional staffing revenue costs will be incurred through increased staffing numbers to maximise the output potential, the reduction in third-party reliance and associated costs means that this is a much more efficient means of managing pharmacy technical services financially.</p>

	<p>In this way, the successful operation of the preferred option through implementation of a new hub facility will mitigate incremental revenue consequences by reducing the overall long-term revenue burden through a reduction in third-party spend expenditure. As outlined in all sets of the total financial position summaries, successful implementation of the preferred option will lead to a significant drop in non-pay clinical service costs which are primarily driven by costs associated with increased costs of purchasing medication from third party commercial providers.</p>
c) Are there any cash flow issues, such as fees, enabling works, that require early funding?	<p>The cashflow from operations are expected to be net zero. This is on the basis that capital funding is drawn down in a profile to match to investments and that income is received from partner organisations to support revenue costs.</p> <p>Accordingly, we do not expect any cash flow issues that require early funding. As noted in the financial tables, the long-term cash flow requirements are significantly lower in option 4c compared to those in the do nothing or do minimum options. While there are initial cost pressures seen in the first five years as recruitment drives raise the level of staffing (and associated pay costs), this is quickly recouped by the anticipated savings from the avoidance of third-party cost elements.</p>
d) Confirm that the project can be managed within existing funding envelopes.	<p>Following NHSE approval of Business Case, national capital funding of £20.2million or £24.6million (i.e., funding pot allocation inclusive or exclusive of radio pharmacy) will be allocated to the project which covers the proposed service works.</p> <p>While there may be some revisions in cost elements as the design phase matures, conservative cost estimates have been applied to minimise the risk of optimism bias. As such, we can confirm that the project will be managed within the funding envelope stated.</p> <p>The project will be managed in pre-defined management stages with cost tolerances established and approved by the board for each stage.</p> <p>If an exception is forecast, this will be reported to the board and corrective action taken to ensure the delivery of the project within the funding envelopes.</p>
e) Confirm and demonstrate that the recurrent revenue cost of the scheme is affordable.	<p>As noted, the comparable 'do nothing' and 'do minimum' result in significantly higher longer revenue costs with the expectation that increased reliance on third party vendors will incur significant revenue increases. Due to the cost associated with "do-nothing", the incremental revenue cost is minimised and accepted as a system cost pressure as detailed above.</p> <p>To date, opportunities for income generation have not been explored fully beyond basic extrapolation of current commercial income. As such, we expect the commercial income listed to be a representation of the floor minimum, meaning this could offer an additional source of affordability for the project.</p> <p>Consideration of options to include income generation will be overseen by the project board.</p> <p>Additionally, the financial benefits associated with support of and collaboration with OPAT services have not been calculated. While these elements are still relatively immature, it was deemed that it would not have been appropriate to calculate financial values as any assumptions made would be abstract and potentially too far removed from working practice. However, given that these schemes, when properly supported, have the potential to have a substantial positive impact on bed release (which represents one of the most considerable pressures facing the acute NHS care settings at present), this could result in significant financial benefits further aiding the affordability of this scheme.</p>
f) Confirm the trust has assessed and is able to fund lifecycle costs to keep the facility at condition B.	<p>Lifecycle costs have been included in the initial CIA model which has been used to populate the VfM model. We have calculated that the expected lifecycle capital required to replace and maintain necessary equipment as per stated shelf lives provided by clinical leads within the baseline data. This has been estimated in line with expected minimum shelf lives, while considering optimism bias and risk elements. We therefore expect that the lifecycle capital costs stated may be an overestimate. Furthermore, we have considered the broader revenue cost elements as part of the costings.</p> <p>All project parties have been sighted to these cost elements and are comfortable with the minimum requirements to maintain the facility to condition B (sound, operationally safe and exhibiting only minor deterioration).</p>

MANAGEMENT CASE

a) Confirm the arrangements for the management and delivery of the scheme.

The new facility will operate to the highest achievable standards. This will be guided by literature sources such as the NHS' Assurance of aseptic preparation of medicines (<https://www.england.nhs.uk/long-read/assurance-of-aseptic-preparation-of-medicines/>), the Royal Pharmaceutical Society's Quality Assurance of Aseptic Preparation Services: Standards (<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Quality%20Assurance%20of%20Aseptic%20Preparation%20Services%20%28QAAPS%29/rps---qaaps-standards-document.pdf>) and compliance with the current MHRA Good Manufacturing Practice and Good Distribution Practice (<https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice>) and in conjunction with leadership from the project team as outlined in the provider capacity and capability section.

A robust 3-tiered governance structure will be established and deployed to manage, oversee, and enable the delivery of the implementation of the aseptic service transformation:

- **Tier 1- Programme Executive:** Responsible for approving any transformational and / or strategic change and is the final point of escalation.
 - Neil Kemsley UHBW Director of Finance and Information, and Project SRO.
 - UHBW Director of Pharmacy
 - Strategy Officers
 - NHSE Colleagues
 - Debbie Campbell – ICB Deputy Director of Medicines Optimisation
 - ICS Chief Pharmacist
- **Tier 2 - Project Board and Clinical Reference Groups:** The board are responsible for overseeing the project planning and delivery and oversight of adherence to the principles set out in the MoU. The Board monitors progress through the monthly Board meeting, and update teleconferences, as needed. The CRG will be responsible for product catalogue changes from a product perspective and horizon scanning.
 - ICB Deputy Director of Medicines Optimisation
 - UHBW Director of Pharmacy
 - NBT Director of Pharmacy
 - UHBW Associate Director of Pharmacy – Production
 - UHBW Associate Director of Pharmacy – Adult Cancer and Aseptic Services
 - UHBW Associate Director of Pharmacy - Radiopharmacy
 - UHBW Associate Director of Pharmacy – QA/QC
- **Tier 3 - Hub Leadership Team:** Management of service delivery and ensuring quality is in line with licensing.
 - UHBW Associate Director of Pharmacy – Adult Cancer and Aseptic Services
 - NBT Principal Pharmacist - Technical Services and Haematology
 - NBT Lead Pharmacy Technician - Aseptic Services
 - UHBW Associate Director of Pharmacy – QA/QC
 - UHBW Associate Director of Pharmacy – Pharmacy Production
 - UHBW Associate Director of Pharmacy - Radiopharmacy

Clear responsibility across the three-tiered structure have been identified within each of the following critical workstreams:

	<ul style="list-style-type: none"> ▪ Contracting and charging ▪ Catalogue Management ▪ Allocation Management ▪ Managing Capital Funding ▪ Business Continuity ▪ Service Key Performance Indicators and Metrics ▪ Term and Exit Provisions ▪ Procurement and Commercial ▪ Workforce ▪ Audit and Risk <p>As part of the project management process, key areas for leadership will be identified from respective subject matter leads. The management strategy of the new facility will endeavour to support individual accountability while also facilitating an open and transparent working environment that does not promote blame culture but enables mistakes to be openly discussed and learned from.</p> <p>For contracts to deliver successfully, on time and on budget, they must be actively managed from inception to conclusion. A proactive contract management plan will also be implemented to ensure successful contract delivery and better achievement of value for money. This will be managed by the procurement and commercial workstream but in conjunction with the audit and risk workstream to ensure that risks are appropriately quantified, and all stakeholders are aware of the potential impacts of poorly managed contracts. Through effective management of this element, this will further support achievement of financial benefits, for example through regular review of medication and pricing structures.</p>
<p>b) Confirm the key risks to delivery and measures to mitigate and manage these risks.</p>	<p>A Risk Log is in place for the collaboration, maintained by the Project Manager. Risks will be continually monitored and managed by the Project Team, with escalation to the Project Board and the Executive when appropriate and will continue to do so throughout the project lifecycle.</p> <p>The key risks to date have been classified into four types: financial, transformational change, operations, and workforce. Example risks across these types and supporting mitigation strategies have been captured below:</p> <p>Financial:</p> <ul style="list-style-type: none"> ▪ Necessary capital funding may not be available to support construction of a new hub to provide increased production of aseptically prepared medicines via a hub and spoke model. Mitigated through review of financial case to align with the national capital funding allocation. Pending approval of NHSE on Business Case. ▪ Incorrect cost or time estimates leading to increased costs (either directly or indirectly). Continual refinement of cost and timeline elements to ensure accuracy will mitigate this risk. With the required capital not expected for release until FY 2025/2026, effective utilisation of this lead time will further strengthen this mitigation strategy. ▪ Significant lead times for procurement of equipment due to high numbers of specialist equipment required. Mitigated by initiation of procurement process at earliest opportunity and scope potential to take delivery of equipment in a staggered process. <p>Transformational Change:</p> <ul style="list-style-type: none"> ▪ Missed opportunity to implement fully automated technology due to market position and feasibility at point of unit build. Flexibility regarding future demand and service provision has been continually highlighted as a necessity within the project, which has in part driven the decision toward a preferred option that will enable flexibility. This will therefore enable mitigation of this risk by design of the hub unit to incorporate ability to replace equipment in future to introduce automated technology if available and supported by the MHRA. <p>Operations:</p> <ul style="list-style-type: none"> ▪ Delay to project implementation awaiting MHRA site inspections and therefore delaying commissioning. Mitigated through regular liaison with MHRA at regular intervals

throughout project and work closely with them to avoid potential delays and effective utilisation of project team's MHRA experience.

Workforce:

- The necessary workforce may not be available to support the preferred model or delayed recruitment due to availability. Mitigated through exploration of new approaches to skill mix, early initiation of recruitment and through phased waves to reduce burden of recruitment requirement and impact of risk. This can be further mitigated through enhanced in-house training opportunities should significant recruitment challenges be encountered. Training of non-pharmacy staff where possible will also act to further mitigate this risk. Benefits calculations have further mitigated this risk through conservative recruitment estimates that have reduced the modelled benefits realisation. In turn this should ensure that the benefits presented are in line with the minimum expected for realisation.

Risk Title and Impact Score	Option 4c Major Off-Site Hub	Mitigation Strategy
National funding unavailable (5)	Possible (3)	Business Plan Drafting to align with national strategy.
Procurement related delays (4)	Possible (3)	Planning at the earliest outset to prevent likelihood of delays.
Inability to recruit required staff in relation to preferred option (4)	Possible (3)	Collaboration with workforce strategy team to inform recruitment.
Negative impact on workforce wellbeing owing preferred option working patterns (3)	Possible (3)	Appropriate planning to reduce likelihood and impact.
Patient Care Risk (5)	Unlikely (2)	Full operational mapping to mitigate operational risk and match demand
Reputational Risks (4)	Unlikely (2)	Alignment with national strategy in business case.
Failure to translate design (4)	Possible (3)	Collaboration with estates and facilities and design specialists.
Incorrect cost estimates (3)	Possible (3)	Procurement strategy to maximise competitive advantage and VIM
Contractor default (4)	Unlikely (2)	Procurement strategy to minimise this risk.
Failure to meet performance standards (4)	Unlikely (2)	Collaboration with respective clinical leads.
Incorrect estimated cost of providing clinical services (2)	Possible (3)	Pessimistic cost modelling; iterative reviews.
Changes in the volume of demand for patient services (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities
Estimated income from income generating schemes is incorrect (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities; SCMD demand mapping.
Incorrect time estimates (3)	Possible (3)	Procurement strategy to minimise this risk.
Incorrect cost and time estimates for decanting from existing buildings (2)	Possible (3)	Procurement strategy to minimise this risk.
Regulatory licenses / accreditations cannot be achieved option (5)	Unlikely (2)	Collaboration with respective clinical leads and regulatory stakeholders.
Changes in national agenda shift focus for pharmacy technical services (4)	Unlikely (2)	Collaboration with NHSE colleagues
Model does not sufficiently allow for future changes in infrastructure (3)	Unlikely (2)	Pessimistic output modelling; flexible design capabilities
Local configurations are varied and complex driving additional complexity and cost (3)	Possible (3)	Early collaboration with design specialists.
TOTAL	169	

Figure 26: Risk Log Summary of Preferred option with mitigation strategies

c) Set out the benefits realisation strategy and how the Trust intend to monitor and report on benefits.

To measure and track benefits realisation, benefits to monitor have been grouped into the following with examples provided for each:

Direct & Financial Benefits

- Release nursing time to other patient care activities.
 - **Realisation Strategy** – This benefit will be realised as the offsite hub facility becomes operational and approaches maximum capacity output. In doing so, it is expected that the excess production capacity will become available to reallocate ward level production to the hub facility.
 - **Calculation Method** – Released nursing time to care will be calculated through the hub CIVAS production output. In line with Lord Carter of Coles methodology, this benefit will assume 12.5mins per dose and 1950 hours per WTE. Monetisable benefits will be extrapolated from the Agenda for Change (updated yearly).
 - **Reporting method** – Production output will be tracked monthly. While yet to be finalised, this benefit will be reported monthly in line with the drafted Governance arrangements.
- third-party cost avoidance Financial Release
 - **Realisation Strategy** – This benefit will be realised through total volumetric output which will in turn link to a reduction in reliance and need from third-party vendors.

- **Calculation Method** – This will be considered through categorisation of volumetric output which will be multiplied against average cost data to calculate estimates of cost levels avoided.
- **Reporting method** – Production output will be tracked on a monthly basis. While yet to be finalised, this benefit is expected to be reported monthly in line with the drafted Governance arrangements.
- Bulk procurement efficiency savings
 - **Realisation Strategy** – With expansion of collaboration services, there will be increased potential to combine procurement elements to leverage economies of scale benefits more effectively. This benefit will therefore be realised as the new facility becomes operational allowing bulk procurement.
 - **Calculation Method** – This benefit will be monitored by the Procurement and Commercial Workstream. Savings targets and potentials will be identified by subject area leads within this workstream, with exact method of calculating savings calculated as the facility becomes operational.
 - **Reporting method** – Corresponding benefits will be reported in a format and frequency as defined by the Procurement and Commercial Workstream, but this is expected to be monthly.

Indirect & Non-financial Benefits

- Improved production safety and product quality
 - **Realisation Strategy** – Improved production safety and product quality should be realised naturally through improved governance benefits. Standardised practice through development and implementation of SOPs and other training guidelines will support realisation of this strategy.
 - **Calculation Method** – No calculation method has been defined for this aspect. However, quarterly, bi-annual, or annual audits for medication safety incidents would seemingly be a suitable method in combination with ongoing error, safety or near miss logs would be prudent.
 - **Reporting method** – Ongoing incident reports will be reported internally. Depending on the frequency, nature and risk of errors or safety incidents, these may be reported on an ad-hoc basis with corrective and preventative actions reported in conjunction.
- Improved product availability of raw materials
 - **Realisation Strategy** – Through combined procurement and bulk purchasing arrangements, it should be possible for the commercial and procurement workstreams to implement a realisation strategy effectively.
 - **Calculation Method** – This benefit will be monitored by the Procurement and Commercial Workstream. Savings targets and potentials will be identified by subject area leads within this workstream, with exact method of calculating savings defined on a case by case basis and as the facility becomes operational.
 - **Reporting method** – Raw material shortages and frequency may be tracked and reported internally. Depending on the nature, risk, and frequency on any

unavailable products, this will be reported on an ad-hoc basis with suggested alternative sourcing strategies.

- Reduced impact of unplanned downtime of equipment / unit
 - **Realisation Strategy** – This benefit will be realised through operations of the new hub facility as it approaches maximum capacity. In ensuring limited downtime, the Service Key Performance Indicators and Metrics Workstream will work to ensure that all equipment is adequately maintained to minimise the risk of any 'knock on' unplanned equipment downtime as a result of unforeseen maintenance or replacement. Furthermore, this benefit should be realised through effective planning and management of demand profiles (both internally and externally) to ensure effective and efficient utilisation of all equipment.
 - **Calculation Method** – Monitoring of planned and unplanned equipment downtime with corresponding reasons or explanation will serve as a suitable calculation method.
 - **Reporting method** – This could potentially serve as a bi-annual audit metric. Unless otherwise specified by the project board, this frequency should be suitable to ensure that this benefit is realised.
- Regulatory and Operation Risk Improvements
 - **Realisation Strategy** – Ongoing review of the relevant risk registers, with recalculation of risks following pre and post the hub becoming operational.
 - **Calculation Method** – Exact method of calculation will be defined by the audit and risk workstream, but it is expected that risks will be scored on an impact x likelihood basis to provide a raw risk score. The TAME framework will further be used to define risk management strategies.
 - **Reporting method** – A risk summary will be reported monthly as part of the appendices. High scoring or risks in need of discussion will be highlighted to the project board on an ad-hoc basis (as defined by the project boards risk appetite score).

Soft Benefits (areas of opportunity)

Soft Benefits represent areas of further potential exploration for the project board to define their feasibility, realisation strategy, calculation, and reporting methods. These include:

- Enforced standardisation.
- Workforce, training, and retention.

A benefits register template has been provided to outline how benefits may be tracked. Again, as the project progresses toward maturity and implementation, this register may need to be refined and update. However, it should serve as an adequate starting point.



BenefitsRegister2.

d) Set out the expectations for Post-Project Evaluation, and

The Project Board once established will meet on a regular monthly basis to provide continuous monitoring of the project. As part of a recurring item on the Project Board meeting agenda, post-project evaluation (PPE) will be regularly conducted, reviewed, and is set as a priority for

the expected timescales for the review of delivery.

all board members to provide feedback on the project throughout the stages of implementation.

This practice will continue post go-live of the aseptics hub. and its partners will undertake PPE, in line with Green Book, NHS England / Improvement, and procurement framework requirements. PPE will enable the following to be reviewed, tracked, and monitored:

- **Business Case Development Review:** Following the completion of both business cases, reviews will be completed between the project delivery team and working group to ensure successful completion of the necessary activities and all lessons learned have been captured.
- **Implementation Review:** Following successful implementation and delivery of the new aseptics facility, an implementation review will be conducted, to assess the specific aspects of implementation and lessons learned for any future implementation programme.
- **Benefits Tracking:** The project's SRO will retain overall responsibility for ensuring benefits' realisation and the PPE will ensure that the project's planned benefits and aims are realised and will measure the extent to which they are realised.
- **Risk Management:** The project's SRO will retain overall responsibility for managing risks and issues which develop over the course of the project and will ensure these are tracked and mitigated successfully in line with PPE requirements.

The project board will define a dedicated PMO function allocated to this project and will commit to ensuring PPE and the activities outlined are completed.

Appendix 1 – Additional Programme Detail

APPENDIX 1: ADDITIONAL PROGRAMME DETAIL	
The approx. population size of your ICS that your hub will cover?	Approximately 1 million
How many hospitals and ICS areas will you be supplying?	Two trusts (multiple sites including the Weston General Hospital) and BNSSG ICS initially with aims to supply to wider parties.
The number of spoke units the hub will support?	Three <ul style="list-style-type: none"> - UHBW - Weston General Hospital will shift its reliance from third-party producers entirely to the new hub facility (unless strategically chosen medication lines retained for third-party outsourcing). - North Bristol Trust to continue on-site bespoke production, but with greater reliance on the new hub facility. - UHBW – Bristol Hospitals (7 sites) to continue on-site bespoke production on site but will shift majority of production operations to the new hub facility.
The range of products, e.g. PN, chemo etc. you will produce?	Core products will consist of parenteral nutrition, chemotherapy, immunotherapy, ATMP/genomic therapy and CIVAS products.
What are your plans for production of standardised products?	<p>The hub would be designed to be able to output a limited number of specifically commissioned high volume activity lines of standardised products as directed by NHSE.</p> <p>All the output from the hub will be standardised in its nature and made under license to allow onward supply to other NHS organisations. Products will be produced in dose bands as recommended by NHSE where this is available; any newer medications produced that do not yet have a national consensus will be manufactured according to an agreed specification as defined by the project board after consultation with other key stakeholders.</p> <p>All CIVAS products will also be standardised, agreed by the overarching clinical reference group which will work closely with National Infusions & Special Medicines Groups and system level antimicrobial stewardship groups. Any changes or amendments to the range of products will require consideration and agreement by the group. Clinical leads will liaise with colleagues in the British Society of Anti-microbial chemotherapy and use connections with other key groups to ensure that the presentations reflect the latest best practice.</p>
What is your workforce plan to support the projected production capacity of the facilities?	<p>Workforce Considerations</p> <p>There is a well understood risk to the existing workforce in establishing a new large workforce for the hub. To mitigate this, the hub would be fully licensed and the use of a novel workforce is being promoted, such as expanded roles SMT apprenticeship graduates and for science graduates to reduce reliance on registered pharmacy staff.</p> <p>Already, project staff have liaised with the staffing working groups to consider the factors that could improve the effectiveness of staff recruitment and retention.</p> <p>Work Planned</p> <p>Consolidation of the learning and themes established is underway and meetings for 2023 have been planned. The workforce group will now look to define the required outputs and implement the required task and finish groups to deliver these.</p>
What are your plans for use of automation, digital and other technology?	<p>Technology considerations have primarily focused on ensuring that the facility is fit from a regulatory standpoint, especially in the context of the upcoming GMP Annex 1 considerations which will be mandatory from August 2023.</p> <p>Market scanning has been undertaken with the adoption of full automation deemed non-viable within the time frames of the project due to regulatory restrictions and technology efficiency. However, as the clean room designs are refined, considerations of future ways of working including integration of new technologies and automations suites with minimal disruption to over</p>

Anticipated operational hours to deliver the projected capacity?	Workforce modelling has been completed based on operational hours of 7am-7pm, Monday-Friday. This model maximises the standard working hours for NHS agenda for change and therefore ensures the best value for money with respect to workforce costs. This also allows for future expansion of capacity by extending the operating hours to include weekends and bank holidays. Any changes to the operating model will be undertaken through consultation and overseen by the board.
Contingency plans to mitigate risk of major site failure?	Extensive work has been done to consider contingency plans in the event of site failure. The first major decision was the retention of onsite minor production facilities to reduce entire reliance on the new hub facility thus mitigating this site failure risk.

Appendix 2 – Schedule of Works (to be attached by Trust)

Appendix 3 – OB Forms (to be attached by Trust)

Appendix 4 – Key Estates Information [to be evaluated and adjusted for each individual programme]

KEY ESTATE METRICS	
Total Area of Building m ²	TBC
New build clinical GIA m ² and % of total GIA	N/A
New build non-clinical GIA m ² and % of total GIA	N/A
Refurbishment clinical GIA m ² and % of total GIA	TBC
Refurbishment non-clinical GIA m ² and % of total GIA	TBC
No. of beds and type	N/A
PFI Estate Implications <ul style="list-style-type: none"> - Is the build on an existing PFI Estate? - Does the build interface with any PFI Estate? - Are there any other implications with the PFI Contract that need to be considered? 	N/A
MMC (Modern Methods of Construction) Status. Percentage to be achieved and brief overview	N/A
Summary of any significant derogations and assurance (derogations template is available)	N/A
£ Reduction in BLM	N/A
Any temporary accommodation required – provide details	TBD
Is a land purchase required – provide details	No.
Is this an owned or leased facility – provide details if leased	Lease (TBC) – Intention to negotiate break clauses for year 10, 15, 20 as part of overall 25 year lease.
Stage of design development and trust approval (please attach design drawings)	TBC
Estimated average lifecycle costs £/m ² over asset life	TBC



UHBW & NBT Pharmacy Aseptic and Technical Services Short Form Business Case Template £5m - £25m Schemes

SECTION 1: SCHEME OVERVIEW		
SCHEME DETAILS		
PROJECT DESCRIPTION	Region:	South West
	STP / ICS Name:	Bristol, North Somerset, and South Gloucestershire
	Lead Organisation for the Scheme:	University Hospital Bristol and Weston NHS Foundation Trust (UHBW), North Bristol NHS Trust (NBT)
	Title of the Scheme:	Pharmacy Aseptic and Technical Services
	One Line Description of the Scheme:	UHBW and NBT are seeking national capital funding to establish a pharmacy technical services hub model to increase production and capacity of these services to better meet current and future patient requirements and support national supply constraints.
	Specific Sites for Investment:	<ul style="list-style-type: none"> ▪ UHBW – Bristol Hospital Sites ▪ NBT – Southmead Hospital Site ▪ UHBW - Weston General Hospital (WGH) Site
	Other Organisations Impacted by this Scheme:	<ul style="list-style-type: none"> ▪ BNSSG ICB ▪ NHS Hospitals in the South West Region ▪ Wider NHS Organisations serving as potential customers to the proposed scheme
BRIEF SCHEME OVERVIEW Summarise the key dimensions of the scheme in terms of the outputs that will be enabled in service terms as a consequence of the investment.	<p>This business case is predicated on the assumption of capital funding from outside of the BNSSG ICS CDEL from nationally available funding as part of the national NHSE Infusions and Special Medicines Programme following on from Lord Carter of Coles' Transforming Aseptic Care in England Report.</p> <p>This represents an application to a portion of the £275m national funding from NHSE. Following successful allocation £75m to phase 1 pathfinder initiatives, this project be funded through the remaining allocation £200m. As with the phase 1 pathfinder initiative, this business case will also be reliant on an uplift of CDEL limits. While this has not been agreed to or approved yet, NHSE stakeholders have indicated that this will be allowed.</p> <p>University Hospital Bristol and Weston (UHBW), combined with North Bristol NHS Trust (NBT) have come together to initiate a project to assess the opportunities available to transform their pharmacy aseptic and technical services. The project identified in 2019 but was delayed due to COVID-19 and was re-initiated in the middle of 2022 once the pandemic pressures had subsided. Given the proportional split of current production volume output and overall scale of operations, UHBW will act as a lead organisation as part of this project. Both organisations have considered this appropriate in the context of current working operations, expected future demand profiles and the intended working operations of the preferred option.</p>	

Since then, the project team have assessed a variety of options to develop Pharmacy Aseptic and Technical Services (PATS) in the region and have worked closely with all department leads across the two trusts to ensure operational and regulatory requirements are fully understood in the development of a future service options.

To ensure PATS across Bristol, North Somerset and South Gloucestershire ICS continue to address growing demand, UHBW and NBT are seeking to establish and operate a new, fully MHRA licensed off-site regional aseptics and technical services hub, supported by existing on site spokes at both Trusts to deliver the required capacity (infrastructure, equipment and crucially, the skilled workforce) and capability (including improved batch production capacity) to develop an NHS-leading pharmacy aseptics and technical service, resilient to future demand and pressures.

The transformation aims to deliver service efficiencies, and ultimately enhance patient safety, patient care, and the patient experience through meeting the unmet need and releasing nursing time for redeployment onto other patient care activities, consistent with the recommendations in the Transforming NHS Pharmacy Aseptic Services in England Report, Lord Carter 2020

The proposed operating model will also aim to provide services to other NHS providers, helping to bridge the demand gap between external suppliers and NHS requirements.

This business case has been developed in line with the HMT Blue Book Guidance in accordance with the five case methodology.

LEAD ORGANISATION DETAILS

SENIOR RESPONSIBLE OFFICER (SRO) DETAILS	Title	Director of Finance and Information Officer
	Name	Neil Kemsley
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APPENDICES CHECKLIST

APPENDIX	COMPLETED / ATTACHED (Y/N)
Appendix 1 – Additional Programme Detail	Y
Appendix 2 – Schedule of Works	TBC
Appendix 3 – OB Forms	TBC
Appendix 4 – Key Estates Information	TBC

SECTION 2: PROGRAMME SPECIFIC INFORMATION REQUESTS

PROGRAMME TO REQUEST SPECIFIC REQUIREMENTS FROM PROVIDERS

PROPOSED BENEFITS AS A RESULT OF CAPITAL INJECTION

Please provide a description of the anticipated benefit of the scheme on:

- production and supply of ready to administer aseptic infusions.
- anticipated patient safety benefits
- resilience against increases in demand
- release in WTE nursing capacity onto other patient care activities.
- Contribution to the NHS Net Zero aspirations

- **Production & Supply of ready-to-administer aseptic infusions:** Based on the key benefits of, batch scale production, releasing nursing time to other patient care activities and meeting future growth in demand, it was decided that the initial product scope for the off-site hub would focus on products ranging from chemotherapy, immunotherapy, central intravenous additive services (CIVAS), parenteral nutrition and radiopharmacy aseptic products, as well as pre-packs and non-sterile products. The product portfolio will remain under review to ensure the benefits continue to be realised and the overall demand for aseptic products is considered. However, for the purposes of this business case, we have not included costs or benefits related to pre-packs or non-sterile manufactured items. For the purposes of this business case, all numbers presented allow for separation of radiopharmacy from the other in scope aseptic products as defined by NHSE (which we have considered as chemotherapy, immunotherapy, parenteral nutrition and CIVAS). While the authors recognise that the allocated NHSE funding pot is not currently intended for radiopharmacy, there is recognition of the sense that it makes to include radiopharmacy. This is for several reasons.

- In the context of pharmacy aseptic and technical services, it is important to note that radiopharmacy does not act in total isolation, independent of other service areas.
- One of the stated goals within the critical success factors working session, during the development of this business case, was to improve internal collaboration capabilities and provide a greater level of contingency in terms of both staffing and facilities. Similarly, in the context of ICSs and the business case requirements of improving external collaboration, we have recognised that we can best support this by improving internal PATS collaborative ability. By providing a single facility from which all core operations will work, this will help to support this aim.
- Radiopharmacy, along with NHSE in-scope aseptic areas, aligns closely with the NHS Long Term goals regarding improved cancer diagnosis and treatment.
- The current UHBW radiopharmacy facility supplies to multiple external organisations, including NBT. Given this, and the fact that these services have limited external regional resilience, it makes logical sense to improve this service line in looking to build resilience and improve patient outcomes.
- Radiopharmacy services is included in the context of the wider South West aseptic services strategic approach.
- Lastly, in the context of the preferred option (involving a new hub off site), and the current UHBW radiopharmacy site conditions, it makes financial and strategic sense to include these services.

- **Production & Supply of ready-to-administer aseptic infusions (continued):** If needed, the structure of the model design allows for separation of the radiopharmacy elements. Total output for the Off-site hub and the local hospital satellite services will increase from approximately 46.5k doses per annum to 339k doses per annum across UHBW and NBT, with radiopharmacy excluded. Conversely, total dose output rises from 58.5k to 381k dose per annum when radiopharmacy is included. C.25% of the total need of high-cost products (c. 14k dose units, with the majority being chemotherapy products) are purchased from third-party commercial suppliers which are also facing capacity constraint with extended lead times (from 3 to 40+ days). Establishment of the new hub, however, will increase in-house capacity to levels which will remove the high dependency on the third-party sector and significant cost elements. For example, the Weston General Hospital site, which has no pharmacy aseptic production capacity, had an outsourcing cost of £4.9m for 2021/2022 alone. When considered in the context of demand growth, this will represent significant cost avoidance and medication budget efficiency resulting in better use of public resources. One of the stated goals of NHSE's Infusions and Special Medicines

Programme is to scale aseptic volume production from 4 million doses per annum to 40 million doses per annum. The proposed volumetric production scale increases will support this ambition.

Baseline Volume (2021/22)				
Medication Category	Made	Purchased	Total Volume	Relative Contribution
Chemotherapy	26,326	13,449	39,775	55%
CIVAs	8,037	-	8,037	11%
Immunotherapy	4,144	16	4,160	6%
PN	8,062	-	8,062	11%
Radiopharmacy	11,892	-	11,892	11%
Total	58,461	13,465	71,926	100%

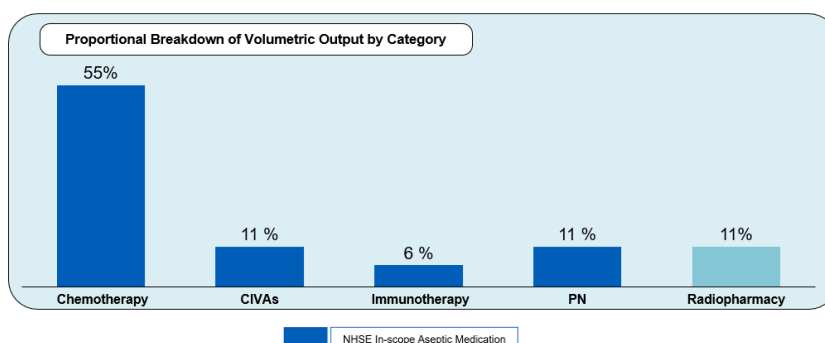


Figure 1: Proportional Breakdown of Baseline Volume

- Anticipated patient safety benefits:** NHS sources have estimated that in 2006, there were approximately 800 patient safety reports per month (nationally) relating to injectable medications. As off 2021, this had risen to a national average of 3750 reports per month, representing a nearly 5-fold increase. While we cannot comment on the causal nature of this increase, the increase in demand for these products will be a significant contributing factor. With the stated goals of the NHS Long Term plan and the expected associated demand in aseptic products, investment in this area is a must. Decreased prescribing and administration errors, by further adoption of standardised or dose banded administration and increase in supply of ready to administer products, as well as reducing infection risk associated with licensed manufacturing. Indeed, this has been stated as a key goal of the NHSE Infusions and Special Medicines Programme. Large scale batch manufacture in a licensed hub will facilitate the movement of 'could-do' and 'should-do' product lines into pharmacy aseptic units which will result in a more optimal skill-mix for preparation and reduce the risks associated with preparation in clinical areas, particularly regarding contamination risk and errors resulting from disruption. A decrease in missed doses is also anticipated due to the availability of ready to administer products. The retention of production capacity in small on-site facilities will further ensure that short shelf life, clinical trials or urgent request items are still available when required. In arriving at the preferred option, retaining on site production capability was recognised by all clinical leads and stakeholders as essential in maintaining the highest standards of patient care.
- Increased ability to contribute toward inpatient reductions:** As outpatient parenteral antibiotic therapy (OPAT) schemes and comparable prioritised care in the community schemes (such as virtual wards) develop, it is envisioned that through effective utilisation and management of the offsite hub facility, it will be possible to contribute to these ambitions. This will have direct care benefits for patients but will also help to manage demand profiles for acute NHS facilities. Furthermore, it should reduce the number and risk of hospital acquired infections (compounding bed pressure reduction benefits) and should support antimicrobial stewardship goals. Already, there is a growing body of evidence of the benefits of utilisation of OPAT services for patients who are otherwise well enough to avoid hospital admissions or facilitate early discharge. Since November 2021 to February 2023 over 4000 bed days have been saved. A Bristol Area OPAT review from 2022 has listed that one of the key decisions for multi-disciplinary teams (MDTs) in reviewing patient eligibility for OPAT services is the direct capacity available. Furthermore, the same retrospective review highlighted the diversity in patients eligible for this service. By ensuring broad access and

improving patient access, this new facility should act to support reduction of health inequalities.

- **Resilience against increases in demand:** The project will deliver improved resilience particularly with respect to availability of workforce and continuity of supply and output as the products are prepared in-house. In line with the Health Building Note (HBN) 00-07 Planning for a resilient healthcare estate, multiple factors have been identified that can negatively impact facility and system resilience that represent current risks to existing facilities. These include facility downtime because of fire or flood, problems related to transport infrastructure that impact delivery availability, security and staffing wellbeing risks, loss of critical support in the wider supply chain (especially in the context of third-party reliance). The new hub model will therefore ensure improved resilience as demand mapping has first ensured that internal demand is satisfied even in the context of increasing demand. Similarly, to the above, the proposed model reduces the reliance on third-party providers who are already struggling to meet NHS demand at current levels. Increasing capacity in the market provides a safety net for BNSSG and the South West to support their demand and capacity planning across the network. As the hub will be a fully licensed facility it will be positioned to be able to support and act as contingency for other SW NHS Trusts who may require aseptic products.
- **Release in WTE nursing capacity onto other patient-facing tasks:** Baseline product volume of high use and stable CIVAS products currently produced at ward level by nurses was provided by UHBW sources. Following the Lord Carter of Coles method (of 12.5 minutes per dose and 1950 hours per WTE), a maximum potential of 31 WTE nursing time to other patient care release per annum was calculated. Based on the modelling conducted by the project team, up to 130,000 nursing hours per annum (approximately 66 whole time equivalents (WTEs)) could be released back to patient care activities by removing some of the requirement for nurses to make the injectable medicines on the wards. This has only been considered from a UHBW and NBT (direct) nursing time to care standpoint, but it is also expected that indirect nursing time could be released through supply of products to other NHS partners.
- **Release in hospital beds:** At a national level, availability of ready to use medicines could free up to 1 million bed days a year. This benefit has not been quantified at a regional level due to its complexities, but it is anticipated that this benefit will be realised across the organisations through the preparation of Outpatient Parenteral Antimicrobial Therapy (OPAT) products, and through reductions in adverse incidents and time to first dose. Although the national project is still in the initial stages, the project team have every confidence that this project will release these benefits across BNSSG and surrounding region.
- **Support the four ICS strategic priorities outlined in the BNSSG Strategic Framework V3:** Through investment and funding in this area, positive contributions can be made to all priorities -
 - Improve outcomes in population health and healthcare – as noted, aseptic ready to administer medication plays an integral role in a variety of patient care pathways and outcomes. Through effective investment, there should be a reduction in treatment delays (through a reduction in reliance in third party providers and associated delays), patient safety incidents (through improved facilities and standardisation of care) and overall patient experience and outcomes. Associated wider benefits such as reduction in bed days etc, should also benefit patients not directly treated by aseptic means.
 - Tackle inequalities in outcomes, experience, and access – through enhanced network demand resilience, external supply capability and overall product output flexibility, this will greatly improve the reactivity of services to patients and enhance access for patients. For example, incidence and mortality rates from respiratory disease and associated infections are significantly higher from disadvantaged groups and individuals from areas of social deprivation. There is already evidence of positive outcomes from respiratory infections treated through OPAT care in the BNSSG area. Enhanced support for such services through

	<p>improved aseptic contributions will therefore help to reduce health inequalities.</p> <ul style="list-style-type: none"> Enhance productivity and value for money – through utilisation of a new hub facility, the direct productivity and value for money benefits will be twofold. Firstly, there will be a direct financial saving through a reduction in reliance on third-party vendors. Secondly, there will be greater leverage of economies of scale in the production of aseptic products through workforce efficiencies. More broadly, there will be productivity gains through the release of nursing time to other patient care activities and value for money benefits by support of NHS-to-NHS product supply. Help the NHS support broader social and economic development – The preferred option will require a significant investment into a new facility. In bringing this facility online, there will be a requirement to recruit relatively large numbers of staff. These jobs will be specialist positions in a niche area of science and healthcare resulting in numerous employment benefits derived from direct (taxation) and indirect (local spending investment) benefits to the local area. Furthermore, there will be a requirement for non-technical roles such as specialist cleaners and transport couriers, further supporting the employment benefits. More broadly, through healthcare improvements and reductions in health inequalities, this will have economic benefits through improved productivity and reduction on public sector service demand (most notably related to healthcare provision). <ul style="list-style-type: none"> Contribution to the NHS Net Zero Aspirations: The design and implementation of the Preferred Option (Option 4c, see Economic Case) will be in accordance with the NBT's Green Plan and UHBW's, outlining the commitment to improving sustainability throughout the organisations with support for the NHS in the pursuit of becoming the world's first net zero health service. The NHS Green Plan is focused on nine core areas, aligned to the key drivers for change and key sources of carbon emissions, within the NHS. Increase Investigational Medicinal Products (IMPs) capacity: The current IMP license as held by UHBW is deemed to be broadly underutilised. Accordingly, one of the aims of the new facility will be to enhance the ability to utilise this license facility. This is intended to generate direct financial benefits, and will further support UHBW and NBT reputationally by enhancing their clinical research profile.
<p>TYPE OF SCHEME</p> <p>Please detail the intended output that this scheme intends to deliver. I.e. reconfiguration of an existing site / addition to an existing site, enhancement to existing facilities, etc</p>	<p>The Preferred Option (Option 4c, see Economic Case) will involve establishing a single off-site facility for pharmacy aseptic and technical services. Products produced at the new hub will be distributed to UHBW sites and NBT with excess production capacity prioritised for demand growth, followed by commercial income and finally, release of local nursing time onto other patient care activities. Local sites (excluding Weston General Hospital) will maintain a small satellite facility that will be utilised for extremely short shelf-life, clinical trials, and urgent aseptic preparation requests.</p> <p>This prioritisation has been deemed necessary to ensure stability in the network by ensuring internal patient needs are met first. Excess production will be flexible depending commercial income by supplying products to surrounding Trusts within and beyond the ICS while ensuring the flexibility to address short term internal demand spikes. The project envisions that as the likes of community diagnostic hubs and NHS@Home virtual wards (including OPAT) services mature and develop, there will be greater opportunity for alignment with such strategies to support patient care in the community, and reductions of inpatient services and reduce pressure on acute NHS resources.</p>
<p>CAPACITY CREATED</p> <p>Please set out the additional capacity created by the scheme.</p> <p>Provide figures in the table below.</p>	<p>Product Capacity: The scheme can generate increased capacity in production of Chemotherapy, Immunotherapy, CIVAs, Parenteral Nutrition and Radiopharmacy products, as well as to pre-pack activity and non-sterile products from 46.5k doses per annum to 339k (excluding radiopharmacy, pre-pack and other non-aseptic activities). Capacity will also be available to meet the national or regional level requirements for a limited number of strategic high volume activity batch produced lines. This represents an approximate seven-fold increase in doses per annum across UHBW and NBT.</p> <p>As noted, when radiopharmacy is included the baseline number of 58.5k doses per annum rises to 381k, representing a six and half fold increase. These volumetric</p>

output increases have been conservatively estimated during this preliminary phase. As design elements are refined, it is possible that these estimates will increase further. This increased capacity is expected to meet growth and deliver the unmet need, releasing nursing time to other patient care activities.

Product volume and scope will continue to be assessed by the project group as the project continues and periodic assessments of the baseline will be made to ensure the project delivers the required benefits.

Nursing Capacity: The scheme will also generate additional capacity in the form of freeing up nursing staff allowing this time to be utilised for patient care activities. Based on the detailed and conservative modelling conducted by the project team a up to, of 130,000 nursing hours per annum (approximately 66 whole time equivalents (WTEs)) can be released for other patient care.

CAPACITY PROFILE – Additional capacity delivered as a result of this investment.

EXPECTED INCREMENTAL CAPACITY																
	Equipment in place	Production capacity *	Fully trained and operational staff *	Estimated Hospital Beds Released & Released Nursing Time to Other Patient Care Activities												
Y1 H1	Kick off procurement process and define delivery schedule for Isolators and ports	N/A	<p>Preliminary modelling indicates that senior production, QA, QC, and training staff will need to be in post and fully operational during Y1.</p> <p>Consideration for low levels of over recruitment in to UHBW (as lead organisation) operational staff to be assessed by workforce workstream to grow experience workforce in preparation for mid-level positions in both production and QA/QC. At this stage, it will be essential to ensure that over recruitment is at an adequate level that will provide sufficient capacity needed to carry the additional workload associated with validating a new facility.</p> <p>Clinical Leadership Fellows to assist with establishing a recruitment “blueprint” to identify strategy and timelines for recruitment of operational staff, to include training timelines.</p>	N/A												
Y1 H2	Equipment, including isolators and ports to be delivered to hub in staged process as determined in schedule above. Installation and validation to commence on a rolling basis with go live in Q4 following MHRA inspection.	<p>Workforce modelling indicates potential output achievable for go live of Q3 of Y1. However, in looking to achieve this, significant investment into staffing will be required to ensure that they can meet validation and training requirements in line with anticipated go live times.</p> <table><tr><td>Chemotherapy</td><td>116k</td></tr><tr><td>CIVAS</td><td>44k</td></tr><tr><td>Immunotherapy</td><td>16k</td></tr><tr><td>PN</td><td>36k</td></tr><tr><td>Radiopharmacy</td><td>26k</td></tr><tr><td>Total</td><td>238k</td></tr></table>	Chemotherapy	116k	CIVAS	44k	Immunotherapy	16k	PN	36k	Radiopharmacy	26k	Total	238k	<p>Once an achievable go-live date is identified, workforce blueprint will be utilised to establish recruitment focus and training team will be in place to implement this strategy.</p> <p>Over the course of Y1 a phased increase to the existing workforce will be implemented to facilitate a safe transition from the existing facility to the new hub. This will increase exponentially towards Q3-4 in anticipation of go live.</p> <p>During Y1, strong focus on recruitment, in line with the blueprint will be undertaken with the aim to increase the workforce up to a minimum of 60-65% of total required workforce. Given the training and validation activities required before staff can contribute to</p>	<p>Bed release not calculated at this point.</p> <p>Limited excess production capacity means that initial nursing time released for other patient care activities will not be released until Y2. However, depending on management strategy at the time or product demand profile, it may be possible to start releasing WTE nursing time to other patient care activities during this year.</p>
Chemotherapy	116k															
CIVAS	44k															
Immunotherapy	16k															
PN	36k															
Radiopharmacy	26k															
Total	238k															

11. Pharmacy Technical Services Outline Business Case																
			production activities, it has been deemed necessary to begin this recruitment drive in Y1.													
Y2 H1	Transfer existing equipment to hub and complete outstanding validation, subject to staffing capacity activities to facilitate 100% output	Phase increase in output modelled in line with workforce planning. All operational isolators in use at project capacity over incremental steps. <table><tr><td>Chemotherapy</td><td>139k</td></tr><tr><td>CIVAS</td><td>53k</td></tr><tr><td>Immunotherapy</td><td>20k</td></tr><tr><td>PN</td><td>43k</td></tr><tr><td>Radiopharmacy</td><td>32k</td></tr><tr><td>Total</td><td>286k</td></tr></table>	Chemotherapy	139k	CIVAS	53k	Immunotherapy	20k	PN	43k	Radiopharmacy	32k	Total	286k	Continued efforts will be made regarding the staffing recruitment drive. A target minimum of 70% of the required staff is expected during this phase. Should this target not be achieved or there are significant validation and training disruptions, considerations regarding the revision of the workforce blueprint and go-live date will be completed.	Bed release not calculated at this point. Initial nursing time released to other patient care activities will be 10k hours, equivalent to 5 WTE. Initial estimates have not taken full OPAT demand into account, so it may be possible to release further time depending on the refinement and maturity of these.
Chemotherapy	139k															
CIVAS	53k															
Immunotherapy	20k															
PN	43k															
Radiopharmacy	32k															
Total	286k															
Transitional Year Impact Y3	All equipment should have full operational capacity. Limiting factor will be staffing recruitment. Subsequent calculations have been based on conservative estimates, but possible that 28/29 benefits will be realised in this year.	<table><tr><td>Chemotherapy</td><td>162k</td></tr><tr><td>CIVAS</td><td>62k</td></tr><tr><td>Immunotherapy</td><td>23k</td></tr><tr><td>PN</td><td>50k</td></tr><tr><td>Radiopharmacy</td><td>37k</td></tr><tr><td>Total</td><td>333k</td></tr></table>	Chemotherapy	162k	CIVAS	62k	Immunotherapy	23k	PN	50k	Radiopharmacy	37k	Total	333k	During Y3, further workforce recruitment efforts will be made to ensure that this does not significantly production capacity. Modelled estimates have assumed that the project will achieve 70-85% of total required workforce.	Bed release not calculated at this point. Nursing time released to other patient care activities in this year has been estimated at 21k hours, equivalent to 11 WTE.
Chemotherapy	162k															
CIVAS	62k															
Immunotherapy	23k															
PN	50k															
Radiopharmacy	37k															
Total	333k															
Recurrent Full Year Impact Y4	N/A	<table><tr><td>Chemotherapy</td><td>185k</td></tr><tr><td>CIVAS</td><td>71k</td></tr><tr><td>Immunotherapy</td><td>26k</td></tr><tr><td>PN</td><td>57k</td></tr><tr><td>Radiopharmacy</td><td>42k</td></tr><tr><td>Total</td><td>381k</td></tr></table>	Chemotherapy	185k	CIVAS	71k	Immunotherapy	26k	PN	57k	Radiopharmacy	42k	Total	381k	Workforce to be taken to 100% if not already achieved prior. Focus on retention and maintaining pipeline for recruitment. Ongoing work will be required to ensure safe staffing levels are maintained throughout by the hub	Bed release not calculated at this point. Peak of 31k Nursing Time to Care Hours released to other patient care activities (equivalent to 16 WTE). This benefit has been modelled as diminishing over a 4-year period before staying on a long-term average of 22k hours (11 WTE) owing to demand peaks. The diminishing levels of benefit seen here are in line with the assumption that production capacity will be prioritised to address in house demand growth meaning that excess
Chemotherapy	185k															
CIVAS	71k															
Immunotherapy	26k															
PN	57k															
Radiopharmacy	42k															
Total	381k															

				production capacity volume will diminish over time.
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SECTION 3: PROJECT DELIVERY OVERVIEW

DELIVERABILITY ASSESSMENT

DELIVERY AND TIMETABLE

Please set out the anticipated commercial and procurement route, and provide a simple timeline with key milestones for the procurement and delivery of the scheme

To achieve the objectives in establishing a new off-site pharmacy technical services hub, particular goods and services that need to be procured include:

- Professional services
- Refurbishment and associated works
- Equipment
- Systems

The UHBW and NBT programme have considered potential routes to markets and frameworks, including NHS Supply chain framework and Procure23, but assessment of procurement routes and implementation of the process is to be conducted as upcoming programme activities. Based on success criteria for the project, UHBW and NBT will evaluate the available procurement routes to identify which procurement offers closest fit to project-specific requirements and drivers.

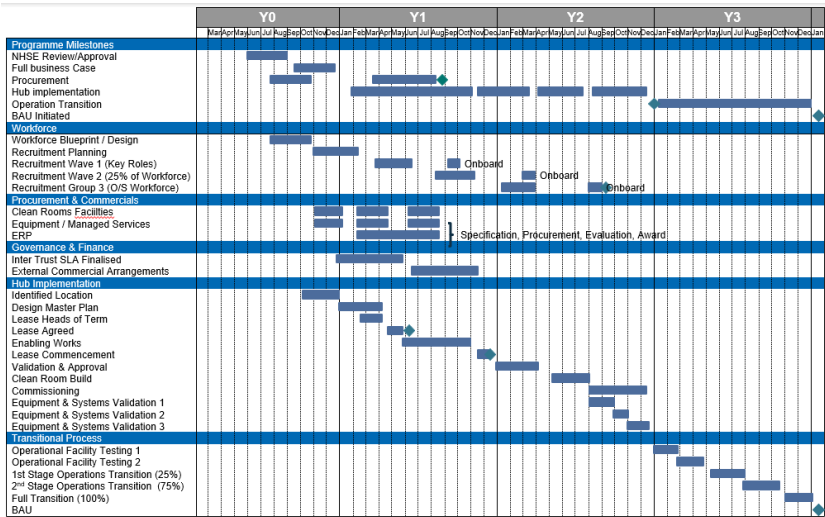


Figure 2: Outline Implementation Timeline

RISKS TO DELIVERY

Please set out the potential risks to delivery and mitigating actions to address these.

A Risk Log is in place for the UHBW and NBT project team and is maintained by the Project Manager. Risks are to be continually monitored and managed by the Project Team, with escalation to the group's Executive Boards when appropriate and will continue to do so throughout the project lifecycle.

Key risks have been classified into four types: financial, transformational change, operations, and workforce. Example risks across these types and supporting mitigation strategies have been captured below:

Financial:

- Necessary capital funding may not be available to support construction of a new pharmacy aseptic and technical services hub. This has been mitigated through review of financial case to align with the national capital funding allocation. Pending approval of NHSE on Business Case, it will also be possible to amend and refine (as needed) given that the capital funding is not expected until 2025 / 26. Considerable efforts have been made to liaise and align with NHSE colleague expectations; these efforts will continue to further minimise this risk. While it is recognised that radiopharmacy is excluded from the current national funding pot, the required capital has been calculated in a method which allows for simple exclusion of these funding elements.
- Significant lead times for procurement of equipment due to high numbers of specialist equipment required. Mitigated by initiation of procurement process at earliest opportunity and scope potential to take delivery of equipment in a staggered process. Additionally, the project team has worked closely with key workstream leads across all aseptic disciplines to understand the key equipment requirements from the outset. As the design matures, personnel will establish relationships with key suppliers to understand lead times and availability of products so that any purchasing requirements can be handled with these lead times in mind.

Transformational Change:

- Timelines and availability of space do not allow for an initial fully automated technology solution where possible; this will be mitigated by design of the hub unit to incorporate ability to replace equipment in future to introduce automated technology if available and supported by the MHRA.
- Delays to the projects transitional timelines may cause a reduction in aseptic services across the region which cannot be covered elsewhere, particularly regarding radiopharmacy services as UHBW are the key supplier in the region. The project will transition services and facilities on a scaling basis and where necessary, will dual-run facilities to cover any potential down-time of services.

Operations:

- Delay to project implementation awaiting MHRA site inspections, especially in the context of the MHRA itself facing staffing challenges, and therefore delaying commissioning. Mitigated through regular liaison with MHRA at regular intervals throughout project and work closely with them to avoid potential delays. The project team have considerable experience in dealing with the MHRA, so effective leveraging of this experience will further help to mitigate this risk.

Workforce:

- The necessary workforce may not be available to support the preferred model or delayed recruitment due to availability. Mitigated through exploration of new approaches to skill mix, early initiation of recruitment and through phased waves to reduce burden of recruitment requirement and impact of risk. This will be further mitigated through consideration of inhouse training and development programmes to augment staffing recruitment drives should significant external recruitment challenges be met. Benefits calculations have factored in gradual phase increases of staffing levels to mitigate this risk and provide a level of achievability reassurance.
- Potential concerns for wellbeing of workforce due to unfavourable shift patterns. The new facility will support staff by providing on-site parking and facilitating public transport, ensuring that the workforce feel comfortable travelling to and from the off-site location. Furthermore, the People Plan will be adhered to, to further mitigate staff welfare related risks.

A fully detailed Risk Log can be found in the Management Case of this Business Case with impact and severity scoring.

Score	Impact	Likelihood
1	None	Rare
2	Low	Unlikely
3	Moderate	Possible
4	Severe	Likely
5	Catastrophic	Certain

Each risk has been allocated an 'impact' score. Each risk has been allocated a 'likelihood' score for each option. Risk rating scores have been individually calculated by multiplying impact and likelihood. These scores have been aggregated to show the total for each option.

Risk Title and Impact Score	Option 4c Major Off-Site Hub	Mitigation Strategy
National funding unavailable (5)	Possible (3)	Business Plan Drafting to align with national strategy.
Procurement related delays (4)	Possible (3)	Planning at the earliest outset to prevent likelihood of delays.
Inability to recruit required staff in relation to preferred option (4)	Possible (3)	Collaboration with workforce strategy team to inform recruitment.
Negative impact on workforce wellbeing owing preferred option working patterns (3)	Possible (3)	Appropriate planning to reduce likelihood and impact.
Patient Care Risk (5)	Unlikely (2)	Full operational mapping to mitigate operational risk and match demand
Reputational Risks (4)	Unlikely (2)	Alignment with national strategy in business case.
Failure to translate design (4)	Possible (3)	Collaboration with estates and facilities and design specialists.
Incorrect cost estimates (3)	Possible (3)	Procurement strategy to maximise competitive advantage and VIM
Contractor default (4)	Unlikely (2)	Procurement strategy to minimise this risk.
Failure to meet performance standards (4)	Unlikely (2)	Collaboration with respective clinical leads.
Incorrect estimated cost of providing clinical services (2)	Possible (3)	Pessimistic cost modelling; iterative reviews.
Changes in the volume of demand for patient services (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities
Estimated income from income generating schemes is incorrect (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities; SCMD demand mapping.
Incorrect time estimates (3)	Possible (3)	Procurement strategy to minimise this risk.
Incorrect cost and time estimates for decanting from existing buildings (2)	Possible (3)	Procurement strategy to minimise this risk.
Regulatory licenses / accreditations cannot be achieved option (5)	Unlikely (2)	Collaboration with respective clinical leads and regulatory stakeholders.
Changes in national agenda shift focus for pharmacy technical services (4)	Unlikely (2)	Collaboration with NHSE colleagues
Model does not sufficiently allow for future changes in infrastructure (3)	Unlikely (2)	Pessimistic output modelling; flexible design capabilities
Local configurations are varied and complex driving additional complexity and cost (3)	Possible (3)	Early collaboration with design specialists.
TOTAL	169	

Figure 3: Risk Log Summary of Preferred option with mitigation strategies

PLANNING ASSUMPTIONS

Please set out the current planning position, and the steps that will be taken to ensure appropriate planning permission is in place.

It is not envisaged that there will be any significant procurement-related commercial or legal issues arising for the design, refurbishment, or associated works of any potential new facility. Once the new hub site has been identified, the need for landlord permission or planning permission to complete the required construction will be assessed, but there is no reason to expect that planning permission or Building Research Establishment Environmental Assessment Method (BREEAM) assessment will be required for the hub.

The project does not anticipate any acquisitions or wider impact on other clinical service designs and provisions.

PROVIDER CAPACITY AND CAPABILITY

Please provide a brief overview of the experience of the SRO and Exec Team accountable for the project.

Across the two Trusts, there are several experienced and knowledgeable personnel with assigned roles within the programme delivery. Key personnel of note include:

Neil Kemsley. UHBW Director of Finance and Information - Project Senior Responsible Officer (To be added)

Jon Standing. UHBW Director of Pharmacy

Jon Standing has 26 years of Hospital Pharmacy service and has built up a significant degree of experience having worked in all key areas. He has been a Chief Pharmacist for nearly 10 years, initially in at Yeovil District Hospital and more recently in a University Hospitals Bristol and Weston NHS FT since October 2017. This has given him experience of the varied spectrums of Acute Trusts and an appreciation of the different challenges set before each.

He currently sits on a wide range of groups, committees and boards (listed below) that has given him a broad understanding of the current areas of focus and strategic NHS delivery;

- National Pharmacy Supply Group
- Specialised Pharmacy Service National Medicines Board
- Medicines Optimisation Clinical Reference Group

- National High-Cost Medicines Steering Group
- SW Regional Medicines Optimisation Committee
- SW Regional Pharmacy Workforce Strategy Group
- SW Regional Pharmacy Education and Training Group
- Chair Regional Pharmacy Procurement Group
- Regional Clinical Senate Assembly member
- Chair UHBW Medicines Advisory Group
- Chair UHBW Medicines Governance Group
- UHBW Antimicrobial Steering Group
- UHBW Advanced Therapy Molecular Products Group
- UHBW Clinical Quality Group
- UHBW Intrathecal Medicines Group
- UHBW Medical Gas Group

Matthew Kaye. NBT Director of Pharmacy

Matt has 22 years of NHS hospital pharmacy experience including 18 months in his current role as Director of Pharmacy for NBT.

Prior to this role, he was the Chief Pharmacist at Northern Devon Healthcare NHS Trust for 6 years. As part of this role, he had 2 secondments into operational management during the pandemic. These secondments included involvement in the North Devon District Hospital (NDDH) “Our Future Hospital” programme as NDDH was one of 40 hospitals included in the Government’s New Hospital Programme (NHP) and was confirmed as a priority for investment in 2020, plus involvement in building a new majors unit for the Emergency Department to develop COVID-19 and non-COVID-19 pathways.

In addition to this experience, Matt is the Chair of the SW Pharmacy Aseptic Group and hosts the Regional QA Service in NBT. Matt is a member of the SW Genomics Steering Group with UHBW and NBT acting as leads for the SW Genomics Medicines Service Alliance (GMSA). Matt is also the SW GMSA Chief Pharmacist (which lies as part of his role as NBT Director of Pharmacy)

Helen Kingston. UHBW Associate Director of Pharmacy – Adult Cancer and Aseptic Services

Helen has been working in NHS Hospital Pharmacy for more than 25 years, with over 20 years been spent working in aseptic technical services. Helen has been employed in the Parenteral Services Unit at UHBW since November 2001 initially as the Lead Clinical Trials and Aseptic Services Pharmacist and then the Senior Aseptic Lead for Chemotherapy.

Helen was promoted to the position as the Associate Director of Pharmacy - Adult Cancer and Aseptic Services back in September 2021. In this position she is the named Accountable Pharmacist for PSU. Helen has extensive knowledge and experience of working and managing an aseptic unit that supplies Chemotherapy and Parenteral Nutrition under section 10 exemption.

Helen has also been involved in several in house improvement projects with UHBW. Most notably, she is currently involved in the UHBW Intrathecal Group, MHRA Inspections Oversight Group and the Weekend Working Group.

Sean Fradgley. UHBW Associate Director of Pharmacy – QA/QC

Sean’s qualifications include a BSc(Hons) in Pharmaceutical Sciences (Aston University, 1987), registration as a professional pharmacist (RPharmS/GPhC, since 1988) and a PhD in breast cancer/medicinal chemistry (Cardiff University, 1992). Subsequently, his career has included 9 years in academic research followed by 25 years in NHS hospital pharmacy as a Quality Assurance specialist. He has been in his present post as UHBW Associate Director of Pharmacy, Quality Assurance since October 2018. Within UHBW, he is Chair of the Pharmacy Technical Services/Stores quality review meetings and the UHBW Medical Gas Group, in addition to attending a variety of other local and regional meetings. During his career, he has been directly involved in the design and commissioning of three new pharmaceutical aseptic cleanroom facilities (University Hospitals of North Midlands/PFI, North Bristol NHS Trust/PFI - temporary and permanent).

Kevin Griffiths. UHBW Associate Director of Pharmacy – Production

Kevin has been qualified as a pharmacist for 29 years, the last 26 of which have been spent working as a Technical Services pharmacist in the NHS. He has been in post at UHBW as Associate Director of Pharmacy – Production for the last 4 years. Prior to that he spent 20 years working at the Royal Free Hospital in London during which time he was named as Production Manager on the MIA(IMP) licence, was deputy to the Head of Production and spent a short period

of time acting up as the Head of Production. He also spent 2 years working at Kings College Hospital in London as a Senior Aseptic Services Pharmacist.

Kevin has held several positions on national NHS Technical Services groups and committees, including 4 years as a London representative on the NHS Pharmaceutical Aseptic Services Group (PASG) during which time he led a project to review and update the high-risk injectable drugs list on behalf of PASG.

He is the Lead Station Writer and Assessor for the Health Education England (HEE) National School of Healthcare Science (NSHCS) Scientist Training Programme (STP) for Clinical Pharmaceutical Scientists (CPS), a position held since the start of 2015. He is a member of the NHS Pharmaceutical Production Committee and acts as the NPPC representative to the NHS Technical Specialist Education and Training (TSET) group.

Whilst working at the Royal Free he was the Technical Lead for the successful preparation of a business case for over £2million to carry out a major refurbishment of the Production department and then contributed to the technical assessment of the tender bids to carry out the building works.

Kathy Beard. UHBW Cancer Lead Pharmacist (Weston General Hospital)

Kathy has worked in cancer services for over 15 years. She has held her current post for 3 years. Kathy has worked as aseptic services pharmacist from about 2003 to 2016 when the Weston pharmacy prepared cytotoxic chemotherapy products and total parenteral nutrition for its patients until the unit closed. Since then, Kathy has managed and overseen all outsourcing of aseptic operations and accompanying clinical oversight.

Annika Boloz. UHBW Associate Director of Pharmacy - Radiopharmacy

Annika is a Pharmacist and Clinical Scientist. Since joining the NHS as a hospital pharmacist, Annika completed MSc Clinical Pharmaceutical Science, then PGDip Pharmaceutical Quality and Regulation and is in her final weeks of completing Masters in Business Administration, MBA. Annika is currently undertaking Qualified Person training, aiming to be a named QP on the MIA (IMP) license at UHBW in early 2024.

Annika completed her Scientist Training Programme (STP) in Manchester University Hospitals NHS Foundation Trust, subsequently held roles as Production Manager and Quality Lead. During pandemic Annika was deployed to Nightingale Hospital to work as the Pharmacy CIVAS Lead, and then was involved in setting up the COVID vaccination centre at UHBW.

Annika actively engages in staff development

- National, presenting at conferences (BNMS, UKRG)
- National, Station writer, Assessor at the National School of Healthcare Science
- National, Specialty Writer for Pharmaceutical Science STP Curriculum Review, where Annika introduced leadership training into revised STP curriculum for Clinical Scientist Trainees
- National, co-wrote a UKRG Guidance for Radiopharmacies during the Covid-19 Pandemic
- National, Royal Pharmaceutical Society Mentor
- Associate Lecturer at the UCL, UWE and University of Bath
- UHBW Training Officer for Clinical Pharmaceutical Science trainees

Annika sits on a wide range of groups/committees

- National Infusions & Special Medicines Workforce Working Group
- National NHS England Radiopharmacy Review
- National UK Radiopharmacy Group Committee
- National Quality Assurance Committee
- Regional Short-life Cytotoxic Residue Group
- UHBW Advanced Therapy Molecular Products Group
- UHBW MHRA Inspections Oversight Group

Kate North. NBT Principal Pharmacist - Technical Services and Haematology

Kate North has 11 years of post-qualification pharmacy experience. She has previously worked for Cardiff and Vale University Hospital Board, Royal Surrey County Hospital before specialising in oncology, haematology and aseptic services with Guys and St Thomas' NHS Trust. She has held her current post with NBT for 4 years which includes Accountable Pharmacist role.

In addition to leading the Technical Services and Haematology services with NBT, she is the chair of the NBT Technical Services and Quality Assurance Pharmaceutical Quality System Group, a member

of the NBT Chemotherapy Multi-professional Team Group and a member of the NBT Nutrition Steering Group.

Matthew Smith. NBT Lead Pharmacy Technician - Aseptic Services

Matt has been qualified for over 30 years, with 27 in Technical Services. While working in Reading 1998-2001, he supported the commissioning of new isolators.

Matt has worked at NBT for 22 years, with most time spent as Senior or Lead Technician in Aseptics. Additionally, Matt was named on the MS License for Frenchay Hospital. Following a failure of facility, he facilitated a period of design and installation while having also managed a temporary facility and commissioning of the new department.

In 2010 Southmead and Frenchay merged departments (with Frenchay surrendering their License). Again, Matt supported the design qualification of the new Brunel facility including the installation, qualification, and commissioning of the temporary unit during the building of the current unit.

Matt is currently responsible for maintaining the MHRA and NHSE expectations regarding the facility and work closely with the estates department to ensure that the unit meets their HTM03 planned maintenance schedule without compromising ISO14644 GMP.

Akeso and Co

UHBW and NBT have also commissioned Akeso & Co, an experienced Healthcare and Life Science Consulting firm, to support in the Business Case development and Healthcare planning.

SECTION 4: FINANCIAL OVERVIEW

These Tables can be provided in Excel Form. If a proposal involves multiple Providers, these Tables will need to be completed for each individual Provider.

FUNDING SOURCES

PLEASE SET OUT ALL FUNDING SOURCES FOR THE PROJECT	DHSC CDEL cover £	£24.6 million (inclusive of radiopharmacy) £20.2 million (exclusive of radiopharmacy)
	Other e.g. ICB (please specify) £	£0.0 million (inclusive and exclusive of radio pharmacy)
	Total £	£24.6 million (inclusive of radiopharmacy) £20.2 million (exclusive of radiopharmacy)

CAPITAL EXPENDITURE PROFILE (inclusive of radiopharmacy, Optimism Bias, Planning Contingency and VAT)

FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
DHSC CDEL cover funded capital expenditure	0	(2,412)	(22,093)	0	0	0	0	(24,549)
Other (<i>specify</i>)	0	0	0	0	0	0	0	0
Total	0	(2,454)	(22,093)	0	0	0	0	(24,549)

CAPITAL EXPENDITURE PROFILE (exclusive of radiopharmacy, inclusive of Optimism Bias, Planning Contingency and VAT)

FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
DHSC CDEL cover funded capital expenditure	0	(2,019)	(18,172)	0	0	0	0	(20,192)
Other (<i>specify</i>)	0	0	0	0	0	0	0	0
Total	0	(2,019)	(18,172)	0	0	0	0	(20,192)

BREAKDOWN OF SCHEME CAPITAL COST (inclusive of radiopharmacy)								
FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
Works Costs	0	(394)	(3547)	0	0	0	0	(3,941)
Fees	0	(140)	(1259)	0	0	0	0	(1,399)
Non-Works Costs	0	(1006)	(9058)	0	0	0	0	(10,064)
Equipment Costs	0	(239)	(2,146)	0	0	0	0	(2,385)
Optimism bias	0	(89)	(801)	0	0	0	0	(889)
Planning contingency	0	(89)	(801)	0	0	0	0	(889)
Inflation Adjustment	0	(89)	(801)	0	0	0	0	(889)
VAT	0	(356)	(3682)	0	0	0	0	(4,091)
Total	0	(2,455)	(22,094)	0	0	0	0	(24,549)
Please provide a narrative on the basis of the costs e.g. tendered costs, PUBSEC indices, cost advisor reports. Please STATE the following:								
1) PUBSEC Indices used:				Previous project estimates validated by independent clinical and clean room advisors.				
2) Basis of the costs: HPCG / benchmark rates from cost advisor / tendered costs / schedules of rates / previously tendered rates.				Previously tendered rates with inflationary uplifts applied.				
3) Cost advisor Review of the VfM / procurement process.				N/A				

BREAKDOWN OF SCHEME CAPITAL COST (exclusive of radiopharmacy)								
FUNDING SOURCE	2023/24 £'000	2024/25 £'000	2025/26 £'000	2026/27 £'000	2027/28 £'000	2028/29 £'000	2029/ 2030 - 2047/48 £'000	TOTAL £'000
Works Costs	0	(337)	(3,036)	0	0	0	0	(3,373)
Fees	0	(120)	(1,077)	0	0	0	0	(1,197)
Non-Works Costs	0	(796)	(7,164)	0	0	0	0	(7,960)
Equipment Costs	0	(210)	(1,892)	0	0	0	0	(2,102)
Optimism bias	0	(73)	(658)	0	0	0	0	(732)
Planning contingency	0	(73)	(658)	0	0	0	0	(732)
Inflation Adjustment	0	(73)	(658)	0	0	0	0	(732)
VAT	0	(337)	(3,028)	0	0	0	0	(3,365)
Total	0	(2,096)	(18,072)	0	0	0	0	(20,192)
Please provide a narrative on the basis of the costs e.g. tendered costs, PUBSEC indices, cost advisor reports. Please STATE the following:								
1) PUBSEC Indices used:				Previous project estimates validated by independent clinical and clean room advisors.				
2) Basis of the costs: HPCG / benchmark rates from cost advisor / tendered costs / schedules of rates / previously tendered rates.				Previously tendered rates with inflationary uplifts applied.				
3) Cost advisor Review of the VfM / procurement process.				N/A				

Total	Option 2 - Do Minimum				Option 4c				Differential			
Council of Governors Part 1 and Public	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0	0	0	23,855,760	16,925,210	0	0	23,855,760	16,925,210
Capital Investment	0	0	0	0	0	0	0	0	0	0	0	0
Depreciation	0	0	0	0	0	0	(346,528)	(346,528)	0	0	(346,528)	(346,528)
TOTAL ASSETS EMPLOYED	0	0	0	0	0	0	23,509,233	16,578,682	0	0	23,509,233	16,578,682
	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0	0	0	0	0	0	0	0	0
Operating Income	0	0	19,106,784	589,428,865	0	0	17,645,241	447,748,451	0	0	(1,461,543)	(141,680,414)
Operating Expenditure	0	0	(19,106,784)	(589,428,865)	0	0	(17,645,241)	(447,748,451)	0	0	1,461,543	141,680,414
C/F Before Financing	0	0	0	0	0	0	0	0	0	0	0	0
Financing (PDC Funding)	0	0	0	0	0	0	0	0	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0	0	0	0	0	0	0	0	0
	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	19,106,784	589,428,865	0	0	17,645,241	447,748,451	0	0	(1,461,543)	(141,680,414)
Commercial Income	0	0	1,303,719	34,208,181	0	0	2,346,693	61,574,725	0	0	1,042,975	27,366,544
Cost Avoidance	0	0	0	0	0	0	0	0	0	0	0	0
Baseline Trust Funding	0	0	17,803,065	555,220,685	0	0	15,298,547	386,173,726	0	0	(2,504,518)	(169,046,959)
Expenses												
Pay	0	0	(3,933,888)	(103,221,004)	0	0	(5,424,913)	(140,910,799)	0	0	(1,491,026)	(37,689,795)
Non-Pay: Clinical Services	0	0	(14,933,229)	(479,919,248)	0	0	(10,965,302)	(279,901,055)	0	0	3,967,927	200,018,193
Non-Pay: Other	0	0	(239,667)	(6,288,613)	0	0	(592,350)	(15,203,651)	0	0	(352,683)	(8,915,038)
TOTAL COSTS	0	0	(19,106,784)	(589,428,865)	0	0	(16,982,565)	(436,015,505)	0	0	2,124,219	153,413,360
EBITDA	0	0	(580,397)	(15,228,993)	0	0	(20,976)	(3,181,588)	0	0	559,421	12,047,406
Interest	0	0	0	0	0	0	(69,766)	(936,425)	0	0	(69,766)	(936,425)
Depreciation	0	0	0	0	0	0	(346,528)	(7,623,606)	0	0	(346,528)	(7,623,606)
PDC & Finance Charges	0	0	0	0	0	0	(246,382)	(3,172,916)	0	0	(246,382)	(3,172,916)
SUB-TOTAL	0	0	0	0	0	0	(662,675)	(11,732,946)	0	0	(662,675)	(11,732,946)
NET SURPLUS/(DEFICIT)	0	0	0	0	0	0	0	0	0	0	0	0
CUMULATIVE	0	0	0	0	0	0	0	0	0	0	0	0

Figure 4: Combined Financial Position Summary (inclusive of radio pharmacy)

UHBW Option 2 - DO Minimum					Option 4c					Differential				
	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25	
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48		FY 22/23	FY 23/24	FY 27/28	FY 47/48	
Opening Balance	0	0	0	0	0	0	23,855,760	16,925,210		0	0	23,855,760	16,925,210	
Capital Investment	0	0	0	0	0	0	0	0		0	0	0	0	
Depreciation	0	0	0	0	0	0	(346,528)	(346,528)		0	0	(346,528)	(346,528)	
TOTAL ASSETS EMPLOYED	0	0	0	0	0	0	23,509,233	16,578,682		0	0	23,509,233	16,578,682	

	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25	
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total		FY 22/23	FY 23/24	FY 27/28	Y25 Total	
Starting Position	0	0	0	0	0	0	0	0		0	0	0	0	
Operating Income	0	0	18,526,387	574,199,872	0	0	16,961,590	432,833,917		0	0	(1,564,798)	(141,365,955)	
Operating Expenditure	0	0	(18,526,387)	(574,199,872)	0	0	(16,961,590)	(432,833,917)		0	0	1,564,798	141,365,955	
C/F Before Financing	0	0	0	0	0	0	0	0		0	0	0	0	
Financing (PDC Funding)	0	0	0	0	0	0	0	0		0	0	0	0	
NET CASH (OUT) / IN	0	0	0	0	0	0	0	0		0	0	0	0	

	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25		Y0	Y1	Y5	Y25	
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total		FY 22/23	FY 23/24	FY 27/28	Y25 Total	
TOTAL INCOME	0	0	18,526,387	574,199,872	0	0	16,961,590	432,833,917		0	0	(1,564,798)	(141,365,955)	
Commercial Income	0	0	1,303,719	34,208,181	0	0	2,229,359	58,495,989		0	0	925,640	24,287,808	
Cost Avoidance	0	0	0	0	0	0	0	0						
Baseline Trust Funding	0	0	17,222,669	539,991,692	0	0	14,732,231	374,337,928		0	0	(2,490,438)	(165,653,763)	
Expenses														
Pay	0	0	(3,462,771)	(90,859,405)	0	0	(4,869,984)	(128,804,451)		0	0	(1,407,213)	(37,945,046)	
Non-Pay: Clinical Services	0	0	(14,843,367)	(477,561,365)	0	0	(10,859,453)	(277,591,859)		0	0	3,983,914	199,969,506	
Non-Pay: Other	0	0	(220,249)	(5,779,103)	0	0	(569,478)	(14,704,661)		0	0	(349,228)	(8,925,558)	
TOTAL COSTS	0	0	(18,526,387)	(574,199,872)	0	0	(16,298,914)	(421,100,971)		0	0	2,227,473	153,098,901	
EBITDA	0	0	0	0	0	0	662,675	11,732,946		0	0	662,675	11,732,946	
Interest	0	0	0	0	0	0	(69,766)	(936,425)		0	0	(69,766)	(936,425)	
Depreciation	0	0	0	0	0	0	(346,528)	(7,623,606)		0	0	(346,528)	(7,623,606)	
PDC & Finance Charges	0	0	0	0	0	0	(246,382)	(3,172,916)		0	0	(246,382)	(3,172,916)	
SUB-TOTAL	0	0	0	0	0	0	(662,675)	(11,732,946)		0	0	(662,675)	(11,732,946)	
NET SURPLUS/(DEFICIT)	0	0	0	0	0	0	0	0		0	0	0	0	
CUMULATIVE	0	0	0	0	0	0	0	0		0	0	0	0	

Figure 5: UHBW Financial Position Summary (inclusive of radio pharmacy)

	Option 2 - DO Minimum			
	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	Total
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Option 4c			
	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	Total
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	Total
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	580,397	15,228,993
Operating Expenditure	0	0	(580,397)	(15,228,993)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	683,651	14,914,534
Operating Expenditure	0	0	(683,651)	(14,914,534)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	103,254	(314,459)
Operating Expenditure	0	0	(103,254)	314,459
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	580,397	15,228,993
Commercial Income	0	0	0	0
Cost Avoidance	0	0	0	0
Baseline Trust Funding	0	0	580,397	15,228,993
Expenses				
Pay	0	0	(471,117)	(12,361,599)
Non-Pay: Clinical Services	0	0	(89,862)	(2,357,884)
Non-Pay: Other	0	0	(19,418)	(509,510)
TOTAL COSTS	0	0	(580,397)	(15,228,993)
EBITDA	0	0	(580,397)	(15,228,993)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	683,651	14,914,534
Commercial Income	0	0	117,335	3,078,736
Cost Avoidance	0	0	0	0
Baseline Trust Funding	0	0	566,316	11,835,798
Expenses				
Pay	0	0	(554,930)	(12,106,348)
Non-Pay: Clinical Services	0	0	(105,849)	(2,309,196)
Non-Pay: Other	0	0	(22,873)	(498,989)
TOTAL COSTS	0	0	(683,651)	(14,914,534)
EBITDA	0	0	(683,651)	(14,914,534)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	103,254	(314,459)
Commercial Income	0	0	117,335	3,078,736
Cost Avoidance	0	0	0	0
Baseline Trust Funding	0	0	(14,080)	(3,393,196)
Expenses				
Pay	0	0	(83,813)	255,251
Non-Pay: Clinical Services	0	0	(15,987)	48,687
Non-Pay: Other	0	0	(3,455)	10,521
TOTAL COSTS	0	0	(103,254)	314,459
EBITDA	0	0	(103,254)	314,459
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

Figure 6: NBT Financial Position Summary (inclusive of radio pharmacy)

Total	Option 2 - DO Minimum				Option 4c				Differential			
	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0	0	0	19,598,463	13,667,254	0	0	19,598,463	13,667,254
Capital Investment	0	0	0	0	0	0	0	0	0	0	0	0
Depreciation	0	0	0	0	0	0	(296,560)	(296,560)	0	0	(296,560)	(296,560)
TOTAL ASSETS EMPLOYED	0	0	0	0	0	0	19,301,902	13,370,693	0	0	19,301,902	13,370,693
MCFlow Summary	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0	0	0	0	0	0	0	0	0
Operating Income	0	0	17,974,812	557,226,007	0	0	15,425,530	391,077,677	0	0	(3,274,778)	(184,319,611)
Operating Expenditure	0	0	(17,974,812)	(557,226,007)	0	0	(15,425,530)	(391,077,677)	0	0	3,877,426	194,818,255
C/F Before Financing	0	0	0	0	0	0	0	0	0	0	0	0
Financing (PDC Funding)	0	0	0	0	0	0	0	0	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0	0	0	0	0	0	0	(46,651,397)	(46,651,397)
I&E Summary	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	17,974,812	557,226,007	0	0	16,028,178	401,576,321	0	0	(2,549,282)	(166,148,330)
Commercial Income Potential	0	0	291,823	7,657,116	0	0	535,261	14,044,682	0	0	243,439	6,387,566
CRB (Cost Avoidance)	0	0	0	0	0	0	0	0	0	0	0	0
Baseline Trust Funding	0	0	17,682,989	549,568,891	0	0	15,492,917	387,531,639	0	0	(2,792,720)	(172,535,897)
Expenses												
Pay	0	0	(3,465,731)	(90,937,065)	0	0	(4,596,424)	(119,585,076)	0	0	(1,130,693)	(28,648,012)
Non-Pay: Clinical Services	0	0	(14,382,711)	(462,973,132)	0	0	(9,955,860)	(254,029,965)	0	0	4,426,851	208,943,167
Non-Pay: Other	0	0	(126,370)	(3,315,811)	0	0	(270,598)	(6,963,992)	0	0	(144,228)	(3,648,181)
TOTAL COSTS	0	0	(17,974,812)	(557,226,007)	0	0	(14,822,881)	(380,579,033)	0	0	3,151,930	176,646,974
EBITDA	0	0	0	0	0	0	602,648	10,498,644	0	0	602,648	10,498,644
Interest	0	0	0	0	0	0	(59,706)	(801,398)	0	0	(59,706)	(801,398)
Depreciation	0	0	0	0	0	0	(296,560)	(6,524,330)	0	0	(296,560)	(6,524,330)
PDC & Finance Charges	0	0	0	0	0	0	(246,382)	(3,172,916)	0	0	(246,382)	(3,172,916)
SUB-TOTAL	0	0	0	0	0	0	(602,648)	(10,498,644)	0	0	(602,648)	(10,498,644)
NET SURPLUS/(DEFICIT)	0	0	0	0	0	0	0	0	0	0	0	0
CUMULATIVE	0	0	0	0	0	0	0	0	0	0	0	0

Figure 7: Combined Financial Position Summary (exclusive of radio pharmacy)

UHBW	Option 2 - DO Minimum				Option 4c				Differential			
	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0	0	0	19,598,463	13,667,254	0	0	19,598,463	13,667,254
Capital Investment	0	0	0	0	0	0	0	0	0	0	0	0
Depreciation	0	0	0	0	0	0	(296,560)	(296,560)	0	0	(296,560)	(296,560)
TOTAL ASSETS EMPLOYED	0	0	0	0	0	0	19,301,902	13,370,693	0	0	19,301,902	13,370,693

MCFlow Summary	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total								
Starting Position	0	0	0	0	0	0	0	0	0	0	0	0
Operating Income	0	0	17,394,415	541,997,014	0	0	14,700,034	372,180,900	0	0	(2,694,381)	(169,816,114)
Operating Expenditure	0	0	(17,394,415)	(541,997,014)	0	0	(14,700,034)	(372,180,900)	0	0	3,297,030	180,314,758
C/F Before Financing	0	0	0	0	0	0	0	0	0	0	0	0
Financing (PDC Funding)	0	0	0	0	0	0	0	0	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0	0	0	0	0	0	0	602,648	10,498,644

I&E Summary	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total								
TOTAL INCOME	0	0	17,394,415	541,997,014	0	0	14,700,034	372,180,900	0	0	(2,694,381)	(169,816,114)
Commercial Income Potential	0	0	291,823	7,657,116	0	0	508,997	13,355,542	0	0	217,174	5,698,426
CRB (Cost Avoidance)	0	0	0	0	0	0	0	0	0	0	0	0
Baseline Trust Funding	0	0	17,102,592	534,339,898	0	0	14,191,037	358,825,358	0	0	(2,911,556)	(175,514,540)
Expenses												
Pay	0	0	(2,994,614)	(78,575,465)	0	0	(4,007,528)	(104,246,283)	0	0	(1,012,914)	(25,670,818)
Non-Pay: Clinical Services	0	0	(14,292,849)	(460,615,248)	0	0	(9,843,533)	(251,104,203)	0	0	4,449,317	209,511,045
Non-Pay: Other	0	0	(106,952)	(2,806,301)	0	0	(246,325)	(6,331,770)	0	0	(139,373)	(3,525,470)
TOTAL COSTS	0	0	(17,394,415)	(541,997,014)	0	0	(14,097,385)	(361,682,256)	0	0	3,297,030	180,314,758
EBITDA	0	0	0	0	0	0	602,648	10,498,644	0	0	602,648	10,498,644
Interest	0	0			0	0	(59,706)	(801,398)	0	0	(59,706)	(801,398)
Depreciation	0	0			0	0	(296,560)	(6,524,330)	0	0	(296,560)	(6,524,330)
PDC & Finance Charges	0	0			0	0	(246,382)	(3,172,916)	0	0	(246,382)	(3,172,916)
SUB-TOTAL	0	0	0	0	0	0	(602,648)	(10,498,644)	0	0	(602,648)	(10,498,644)
NET SURPLUS/(DEFICIT)	0	0	0	0	0	0	0	0	0	0	0	0
CUMULATIVE	0	0	0	0	0	0	0	0	0	0	0	0

Figure 8: UHBW Financial Position Summary (exclusive of radio pharmacy)

	Option 2 - DO Minimum			
	Y0	Y1	Y5	Y25
Balance Sheet Summary	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Option 4c			
	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	FY 47/48
Opening Balance	0	0	0	0
Capital Investment	0	0	0	0
Depreciation	0	0	0	0
TOTAL ASSETS EMPLOYED	0	0	0	0

	Y0	Y1	Y5	Y25
MCFlow Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	580,397	15,228,993
Operating Expenditure	0	0	(580,397)	(15,228,993)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	725,496	18,896,777
Operating Expenditure	0	0	(725,496)	(18,896,777)
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
TOTAL CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Starting Position	0	0	0	0
Operating Income	0	0	(580,397)	(14,503,497)
Operating Expenditure	0	0	580,397	14,503,497
C/F Before Financing	0	0	0	0
Financing (PDC Funding)	0	0	0	0
NET CASH (OUT) / IN	0	0	0	0

	Y0	Y1	Y5	Y25
I&E Summary	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	580,397	15,228,993
Commercial Income Potential	0	0	0	0
CRB (Cost Avoidance)	0	0	0	0
Baseline Trust Funding	0	0	580,397	15,228,993
Expenses				
Pay	0	0	(471,117)	(12,361,599)
Non-Pay: Clinical Services	0	0	(89,862)	(2,357,884)
Non-Pay: Other	0	0	(19,418)	(509,510)
TOTAL COSTS	0	0	(580,397)	(15,228,993)
EBITDA	0	0	(580,397)	(15,228,993)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	725,496	18,896,777
Commercial Income Potential	0	0	26,264	689,140
CRB (Cost Avoidance)	0	0	0	0
Baseline Trust Funding	0	0	699,232	18,207,636
Expenses				
Pay	0	0	(588,896)	(15,338,793)
Non-Pay: Clinical Services	0	0	(112,328)	(2,925,761)
Non-Pay: Other	0	0	(24,273)	(632,222)
TOTAL COSTS	0	0	(725,496)	(18,896,777)
EBITDA	0	0	(725,496)	(18,896,777)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

	Y0	Y1	Y5	Y25
	FY 22/23	FY 23/24	FY 27/28	Y25 Total
TOTAL INCOME	0	0	145,099	3,667,783
Commercial Income Potential	0	0	26,264	689,140
CRB (Cost Avoidance)	0	0	0	0
Baseline Trust Funding	0	0	118,835	2,978,643
Expenses				
Pay	0	0	(117,779)	(2,977,194)
Non-Pay: Clinical Services	0	0	(22,466)	(567,878)
Non-Pay: Other	0	0	(4,855)	(122,712)
TOTAL COSTS	0	0	(145,099)	(3,667,783)
EBITDA	0	0	(145,099)	(3,667,783)
Interest	0	0	0	0
Depreciation	0	0	0	0
PDC & Finance Charges	0	0	0	0
SUB-TOTAL	0	0	0	0
NET SURPLUS/(DEFICIT)	0	0	0	0
CUMULATIVE	0	0	0	0

Figure 9: NBT Financial Position Summary (exclusive of radio pharmacy)

Current Position (based on current position)					Option 4c Differential Impact				Updated Total			
I&E Summary £000s	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Income from Patient Care Activities	1,021,126	1,041,548	1,127,405	32,706,957	0	0	14,732	374,338	1,021,126	1,041,548	1,142,137	33,081,295
Other Operating Income	116,076	118,397	128,157	3,717,942	0	0	2,229	58,496	0	0	0	0
Total Operating Income	1,137,201	1,159,945	1,255,562	1,280,673	0	0	16,962	432,834	1,021,126	1,041,548	1,142,137	33,081,295
Pay Costs	(692,991)	(706,851)	(765,119)	(22,196,725)	0	0	(4,870)	(128,804)	(692,991)	(706,851)	(769,989)	(22,325,529)
Non Pay Costs	(395,064)	(402,965)	(436,182)	(12,654,014)	0	0	(11,429)	(292,297)	(395,064)	(402,965)	(447,611)	(12,946,311)
Depreciation	(38,284)	(39,050)	(42,269)	(1,226,248)	0	0	(347)	(7,624)	(38,284)	(39,050)	(42,615)	(1,233,872)
Impairment	(16,876)	(17,214)	(18,632)	(540,543)	0	0	0	0	(16,876)	(17,214)	(18,632)	(540,543)
Total Operating Expense	(1,143,215)	(1,166,080)	(1,262,202)	(36,617,530)	0	0	(16,645)	(428,725)	(1,143,215)	(1,166,080)	(1,278,848)	(37,046,255)
Total operating surplus/(deficit)	(6,014)	(6,134)	(6,640)	(192,632)	0	0	0	0	(6,014)	(6,134)	(6,640)	(192,632)
PDC dividend charge	(12,863)	(13,120)	(14,202)	(412,006)	0	0	(246)	(3,173)	(12,863)	(13,120)	(14,448)	(415,179)
Other net financing costs	(754)	(769)	(832)	(24,151)	0	0	(70)	(936)	(754)	(769)	(902)	(25,087)
Impact on I&E surplus/(deficit)	(19,631)	(20,024)	(21,674)	(628,788)	0	0	0	0	(19,631)	(20,024)	(21,990)	(632,897)
Less: I&E impairments	16,876	17,214	18,632	540,543	0	0	0	0	16,876	17,214	18,632	540,543
Less: Other technical items	2,776	2,832	3,065	88,916	0	0	0	0	2,776	2,832	3,065	88,916
Impact on I&E surplus/(deficit) - Adjusted Financial Performance	21	21	22	671	0	0	0	0	21	21	22	671

**Figure 10: UHBW Whole Trust Financial Position Impact of Option 4c implementation
(inclusive of radio pharmacy)**

Current Position (based on current position)					Option 4c Differential Impact				Updated Total			
I&E Summary - £000s	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total	FY 22/23	FY 23/24	FY 27/28	Y25 Total
Income from Patient Care Activities	1,021,126	1,041,548	1,127,405	32,706,957	0	0	14,191	358,825	1,021,126	1,041,548	1,141,596	33,065,782
Other Operating Income	116,076	118,397	128,157	3,717,942	0	0	509	13,356	0	0	0	0
Total Operating Income	1,137,201	1,159,945	1,255,562	36,424,899	0	0	14,700	372,181	1,021,126	1,041,548	1,141,596	33,065,782
Pay Costs	(692,991)	(706,851)	(765,119)	(22,196,725)	0	0	(4,008)	(104,246)	(692,991)	(706,851)	(769,126)	(22,300,971)
Non Pay Costs	(395,064)	(402,965)	(436,182)	(12,654,014)	0	0	(10,090)	(257,436)	(395,064)	(402,965)	(446,272)	(12,911,450)
Depreciation	(38,284)	(39,050)	(42,269)	(1,226,248)	0	0	(297)	(6,524)	(38,284)	(39,050)	(42,565)	(1,232,772)
Impairment	(16,876)	(17,214)	(18,632)	(540,543)	0	0	0	0	(16,876)	(17,214)	(18,632)	(540,543)
Total Operating Expense	(1,143,215)	(1,166,080)	(1,262,202)	(36,617,530)	0	0	(14,394)	(368,207)	(1,143,215)	(1,166,080)	(1,276,596)	(36,985,737)
Total operating surplus/(deficit)	(6,014)	(6,134)	(6,640)	(192,632)	0	0	0	0	(6,014)	(6,134)	(6,640)	(192,632)
PDC dividend charge	(12,863)	(13,120)	(14,202)	(412,006)	0	0	(246)	(3,173)	(12,863)	(13,120)	(14,448)	(415,179)
Other net financing costs	(754)	(769)	(832)	(24,151)	0	0	(60)	(801)	(754)	(769)	(892)	(24,952)
Impact on I&E surplus/(deficit)	(19,631)	(20,024)	(21,674)	(628,788)	0	0	0	0	(19,631)	(20,024)	(21,980)	(632,762)
Less: I&E impairments	16,876	17,214	18,632	540,543	0	0	0	0	16,876	17,214	18,632	540,543
Less: Other technical items	2,776	2,832	3,065	88,916	0	0	0	0	2,776	2,832	3,065	88,916
Impact on I&E surplus/(deficit) - Adjusted Financial Performance	21	21	23	671	0	0	0	0	21	21	23	671

Figure 11: UHBW Whole Trust Financial Position Impact of Option 4c implementation (inclusive of radio pharmacy)

SECTION 5: FIVE CASE MODEL PROJECT DETAIL

STRATEGIC CASE

a) Please set out the strategic rationale and case for change.

Please cite Lord Carter's 2020 review and recommendations along with local need

Aseptic preparation can broadly be defined as the reconstitution of an injectable medication or any other aseptic manipulation when undertaken within NHS aseptic facilities to produce a labelled ready-to-administer presentation of a medicine, in accordance with a prescription provided by a practitioner, for a specific patient. It is linked to, but distinct from dispensing which is the supply of a finished product to a specific patient, or to the person responsible for its administration, in accordance with a prescription.

NHS hospital pharmacy aseptic services provide sterile, controlled environments in which highly qualified staff prepare or manufacture injectable medicines for intravenous (IV) antibiotics, chemotherapy, and immunotherapy treatments (such as monoclonal antibodies), as well as parenteral nutrition and cutting-edge medicines for cell therapy and clinical trials. Aseptically produced injectable medicines have an annual cost of £3.8 billion representing 3.1% of the total annual budget of NHS England. While perhaps representing a low-profile aspect of the treatment landscape within the NHS, their importance crucial in terms of treatment outcomes.

Given that the types of products align closely with treatment goals as outlined in the NHS Long Term Plan, there is clear indication that demand for these pharmacy aseptic and technical services will continue to grow.

In 2020, Lord Carter of Coles conducted a review of NHS Pharmacy Aseptic Services in England, which recognised nationally that aseptic services are experiencing significant challenges based on increasing growth in demand, a lack of capacity to meet the demand and aging aseptic units requiring investment to maintain.

On a local level, similar challenges are experienced by the UHBW and NBT where the rising demand in aseptic services can be highlighted by the following:

- Combined product volume growth between FY19/20 – FY22/23 shows a y-o-y growth of 6.85%. At this rate, overall demand doubles after approximately 11 years. This is in line with the national average growth rate of 6% as outlined by NHSE's Infusions and Special Medicines Programme.
- Following shift away from aseptically prepared products where possible to minimise COVID-19 related disruption, there has been significant rebound demand. This is seen most clearly in product growth rate as outlined below.
- UHBW-WGH Cancer Satellite has had non-operational aseptic facilities since 2015, with entire reliance on third-party suppliers. In the context of demand growth, this is not sustainable from a patient care, supply risk or financial standpoint. For example, their 2021/2022 spend on third-party medication supply was c.£4.9m, greater than the entire staffing budget UHBW and NBT pharmacy technical services staffing budget for the same period.
- NBT is approaching maximum production output with limited ability to expand their current site of operations.
- UHBW-Bristol sites are approaching maximum capacity with significant reinvestment required in the coming years. The additional requirement because of Annex 1 of the GMP regulations are expected to accelerate and increase the cost of necessary reinvestment required.

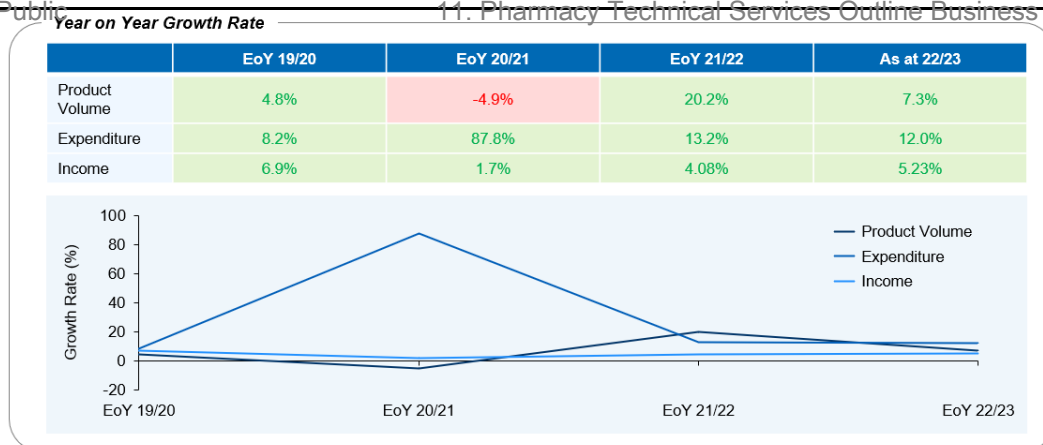


Figure 12: Product volume, expenditure, and income growth rates. Please note, owing to the relatively minor differential influence of Radiopharmacy, these values have been retained within figure 4. Please note the expenditure increase seen in EoY 20/21 is largely derived from supply chain disruption and resulting price increases seen in the initial phases of the COVID-19 Pandemic outbreak.

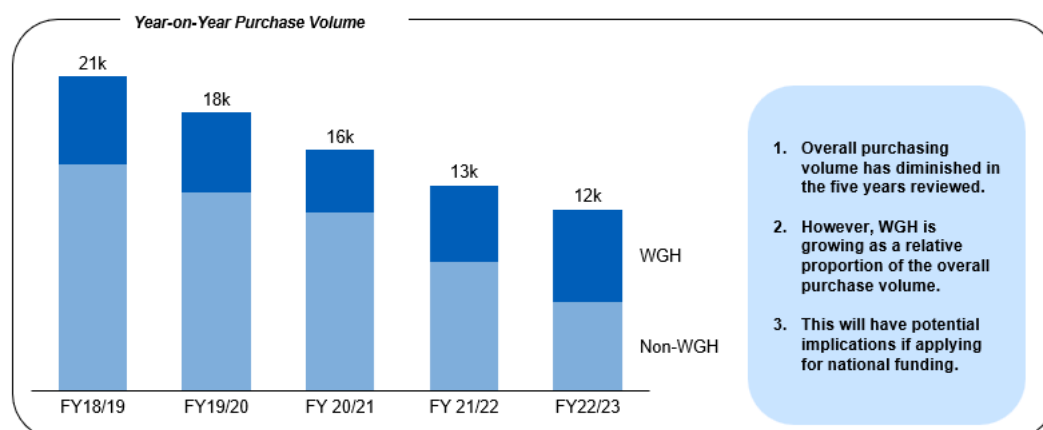


Figure 13: Diminishing, but unsustainable purchase volume. Please note, there is no purchased radiopharmacy volume within these totals.

There is limited available pharmacy technical services capacity across UHBW and NBT to be able to meet these demands sustainably and resiliently and therefore these organisations are faced with the need to invest in new local facilities.

With a lack of transformation, UHBW and NBT have identified significant implications such as increased waiting times for patients to receive specialist services, particular cancer and increase in patient safety incidents due to the increasing demand for ward-based preparation of injectable medicines (as aseptic units are saturated) combined with the increasing complexity of nursing shortages. Furthermore, it is expected to pose a significant reputational and safety risk should they not act to update and modernise their PATS. In the context of the NHS' Long-Term Plan, it is recognised that without significant transformation, there will be limited to no ability to support aims such as improving cancer diagnosis rates and treatment outcomes.

The findings of Lord Carter's review, supported by a series of recommendations, were documented in a report which set out the Case for Change for transformation of these services. The report highlighted that the creation of a network of collaborative regional hub aseptic facilities responsible for preparing large scale volumes of injectable medicines, supported by local Trust-level spoke facilities services will help to deliver the following outcomes:

1. Improved patient experience by enabling care closer to home.

2. Increased patient safety by reducing errors in the manipulation and administration of these medicines.
3. Free up the time of 4,000 nursing staff for other patient care activities.
4. Increase productivity from the medicines budget.
5. Increase the resilience of the sector.

This has led to the Infusions and Specials Medicines workstream within NHSE to press for the development of hub and spoke facilities to modernise practise while scaling up to meet anticipated demand growth. Recommendations of this work are varied and numerous. They include the desire to:

- Create a network of collaborative regional aseptic hub facilities to scale up production capacity while supporting existing relations with commercial providers.
- Agree standard dose bandings for chemotherapy, parenteral nutrition, and antimicrobial products.
- Develop an NHS manufacturing network and transform NHS medicines manufacturing into a strategic asset that meets otherwise unmet need of patients.
- Assess the potential for new role and skill mixes in aseptic services, while also developing a new pharmacy technical services workforce to enable greater patient facing activities.

Already pathfinder projects such as those seen at West Yorkshire Association of Acute Trusts (WYAAT), Manchester University NHS Foundation Trust (through the Greater Manchester Health and Social Care Partnership) and University Hospital Southampton NHS Foundation Trust (through the Hampshire and Isle of White ICS) have evidenced the potential benefit of national investment into aseptic services. By extrapolating the potential benefits as outlined within the Lord Carter of Coles report, there is significant evidence of these benefits extending to UHBW and NBT, and beyond. For example, it is expected that through investment into this aseptic service area, this will help both UHBW and NBT to support the BNSSG strategic aims of improving outcomes in population health and healthcare, tackling inequalities in outcomes, experience, and access, enhancing productivity and value for money, and helping the NHS support broader social and economic development.



By extension, the intended benefits of the new hub facility should extend to support Lord Carter's efficiency goals as outlined in the Operational Productivity and Performance in English NHS Acute Hospitals Report. For example, through centralisation of current ward based CIVAS preparation, this will not only release nurse time into other patient care activities, but reduce unwarranted variation in medication preparation practice. This will therefore provide direct and indirect efficiency benefits. Through enhanced collaboration and a greater shift from external to internal supply reliance, this will also have procurement benefits, most notably by reducing the amount paid per medication, reducing staff time spent sourcing medication and reducing the number and duration of patient treatment delays relating to medication delays. Again, this should help to aid efficiency of operations within the hospital, for example, by enabling quicker treatment and discharge pathways to be realised. These will all have further benefits relating to the sustainability and risk factors of the current service.

b) Please explain how this scheme will contribute to the delivery of the programme aims.

In line with the national operating model which identifies the establishment of centralised, regional hubs supported by Trust-located spokes as the gold-standard service transformation, UHBW and NBT are looking to implement a collaborative, region-wide programme that will:

- Improve the productivity from the medicines budget by reducing the cost and reliance on third-party vendors. This will not only have direct financial benefits given the productivity and efficiency savings but is expected to improve patient experience outcomes and result in significant time savings owing to the relative unsustainability of the private aseptic commercial sector.
- Improve safety aspects through improved standardisation of practice at a single hub facility.
- Establish the pharmacy capacity and capability to produce central intravenous additives (CIVAs) products that release nursing time to other patient care activities. CIVAS are injectable medicines made in a ready-to-administer format, saving nursing drug preparation time on wards.
- Establish production capacity and capability that not only delivers for NBT and UHBW demand but caters to support beyond the ICS to regional strategy (and beyond). This will

	<p>support the wider aim of enhancing system resilience which has been recognised as a significant risk in the context of current demand.</p> <ul style="list-style-type: none"> Establish the capacity to deliver high quality cancer treatment to a steadily increasing proportion of patients diagnosed at Stages 1 and 2 in line with the NHS Long Term Plan ambition. <p>This short-form business case seeks the approval of national capital funding which will allow implementation of this regional hub model and will investigate aspects needed to deliver the long-term vision, for further integration and collaboration to appropriately future proof pharmacy aseptic and technical services in this region.</p>
c) Provide confirmation of stakeholders e.g. support from clinicians, provider collaborative, commissioners and STP / ICS accountable officers (formal letters of support to be appended to this business case template).	<p>The UHBW and NBT Pharmacy Aseptic and Technical Services Options Appraisal Project has been guided and advised by the respective clinical leads throughout development, in addition to the NBT and UHBW Chief Pharmacists and project manager in collaboration with Akeso and Company, a London based management consultancy firm with experience in pharmacy transformation projects. Wider support has been sought from NHS England and NHS Improvement collaborative. Additionally, the project has been considered by the Non-Executive and Financial Directors at UHBW. Both parties have indicated initial support, although formal sign off and approval will be sought at a later stage.</p> <p>Modelled benefits figures have been validated with clinical leads through a series of workshop sessions in addition to individual calls and correspondence. Further validation has been conducted with;</p> <p>NHSE SW Specialised Commissioning Pharmacists SW Regional Chief Pharmacist SW Deputy Regional QA Pharmacist NHSE Infusions & Special Medicines Specialist Pharmacy Advisor BNSSG ICB Deputy Director Medicines Optimisation and ICS Lead Pharmacist</p> <p>BNSSG have been informed regarding the project and indicated high level support. The project is an agreed ICS Medicines Optimisation workstream reporting into the Acute Care Collaborative Group, and part of the Integrated Pharmacy Medicines Optimisation (IPMO) plan/strategy for BNSSG. The preferred option has considered the four strategic priorities as outlined in the BNSSG Strategic Framework v3. These aims are to</p> <ul style="list-style-type: none"> improve outcomes in population health and healthcare; tackle inequalities in outcomes, experience, and access; enhance productivity and value for money; and help the NHS support broader social and economic development. <p>While, formal approval has not been requested and will be sought at a later stage, ICS colleagues have acknowledged how this scheme if effectively executed will contribute to the above list strategic aims.</p> <p>Regional collaboration has also been considered in terms of the long-term preferred option. While this has not formed one of the formal decision criteria, the preferred option selected with consideration for this potential.</p>
d) Please outline the investment objectives for the project.	<p>Investment in designing and implementing an off-site pharmacy aseptic and technical services hub, with retention on site bespoke production, aims to meet the following series of objectives:</p> <ul style="list-style-type: none"> Improve patient experience by reducing time to first dose and enabling greater care in the community potential as wider services such as OPAT. Increase patient safety by reducing medication preparation errors through improved standardisation of preparation practice and a reduction of ward level preparation activity. Leverage economies of scale concerning equipment and workforce, to greatly improve overall volumetric output relative to investment spent. Current combined per annum dose volume output is 58.4k doses per annum. Modelled activity has listed an estimate of 381k, representing a 550% increase. Deliver facilities to support unmet and additional needs for Research and Development/Clinical Trials. Generate additional production capacity to satisfy current demand. At present, approximately 25% of current demand is outsourced representing a significant cost burden.

	<p>Following effective implementation of the preferred option, this will drop to 0% (excluding strategic medication lines chosen for continued outsourcing).</p> <ul style="list-style-type: none"> ▪ Generate additional production capacity to satisfy future demand, with consideration of local, regional, and national strategic lines while also enhancing NHS-to-NHS supply capability. ▪ Satisfy the two above listed aims while also generating additional production capacity to deliver, 'excess', production capacity. <ul style="list-style-type: none"> ○ Excess capacity will be allocated to 'commercial income' with the intention of supplying to parties outside of the UHBW and NBT. ○ Release nursing time to other patient care activities both within the UHBW and NBT and beyond through centralised production at the new facility. ▪ Act as a focal point to reduce unwarranted variation for in-scope products. ▪ Enhance pharmacy technical services resilience, by reducing reliance on private sector vendors and enhancing spend efficiency. <p>Enhance collaborative working, first between NBT and UHBW, but with the potential to expand to pan ICS or pan regional collaboration.</p>
e) Please confirm fit with estate strategy.	<p>The project has support from and is in line with both current UHBW and NBT Estates Strategy. While formal approval from ICS Capital and Infrastructure Board has not been sought at this stage, ICS colleagues have been sighted on the project and formal support is not expected to be a problem.</p> <p>UHBW and NBT have both recognised that neither site would be suitable for an onsite facility, which substantially limits the feasibility of option 3c before considering the economic and value for money aspects. NBT as part of a new PFI build has little to no space for expansion of current facilities. While two potential UHBW on-site options have been considered, neither were deemed suitable from a timescale or feasibility standpoint.</p> <p>The first, Marlborough Hill project would have required significant redesign of current plans which would have required significant internal stakeholder buy in and would have not aligned with planned timelines. The second option would have involved repurposing of an existing building on the UHBW main site. However, it was recognised that this site would have been highly competitive with limited realistic prospect of being able to utilise this space. Furthermore, the ambiguity regarding the actual amount of space available would mean that there would be limited potential to expand for the future, and indeed cast uncertainty regarding the proposed scope of operations.</p> <p>No objection has been raised to the prospect of an offsite facility, although no site has been identified at this stage. To reduce capital requirements of the project, it was decided that it would be more prudent that a leasing strategy was more suitable. While cost and risk elements were raised in relation to pursuing a long-term risk, these were deemed acceptable in the context of the project and alternative options.</p>
ECONOMIC CASE	
a) Please submit a VFM template with this business case template.	<p>CIA Model Template used to support the economic appraisal, including value for money (VfM) analysis, is linked below:</p> <p>Inclusive of radiopharmacy</p> <p> BWPC_CIA_Model_v radio.xlsx</p> <p>Exclusive of radiopharmacy</p> <p> BWPC_CIA_Model_v noradio.xlsx</p>

b) Please provide an incremental VFM analysis that shows the VFM ratio (Net Present Social Value) for Business As Usual and the preferred option and provide an explanatory narrative on the VFM analysis.

Preferred Option Summary

Option	Variation	'Do Nothing' Option 1	'Do Minimum' Option 2	Preferred Option Option 4c
Total Incremental Costs	Exclusive of Radiopharmacy	£297.2m	£327.4m	£302.3m
	Inclusive of Radiopharmacy	£327.6m	£346.4m	£340.5m
Total Incremental Benefits	Exclusive of Radiopharmacy	£34.5m	£102.7m	£606.1m
	Inclusive of Radiopharmacy	£41.5m	£144.5m	£712.7m
Risk-adjusted Net Present Social Value (NPSV)	Exclusive of Radiopharmacy	£262.8m	£224.6m	£303.8m
	Inclusive of Radiopharmacy	£285.7m	£201.9m	£372.3m
Benefit-Cost Ratio	Exclusive of Radiopharmacy	0.12	0.31	2.00
	Inclusive of Radiopharmacy	0.13	0.42	2.09

Figure 14: VFM summary inclusive and exclusive of radiopharmacy

The Preferred Option, Option 4c, offers the highest Value for Money due to the ratio of cost vs output / benefit. This option will involve the lease and refurbishment of an off-site fully licensed hub. Following discussion with the clinical leads from both NBT and UHBW, it was recognised that some degree on site production would have to be retained for acute or products prescribed at short notice. Accordingly, the NBT site would continue to operate to produce bespoke, urgently required, short-shelf life or non-standardised products in line with current operations. However, greater collaboration and utilisation of the hub facility once operational is intended for large volume, standardised products that would be suitable for outsourcing to batch production. The Weston General Hospital Cancer Site would shift its reliance to the new hub facility (except for outsourcing retention for strategically chosen lines, which are yet to be decided). UHBW Bristol site will retain onsite operations in their current Parenteral Services Unit (PSU) as this is expected to match the required bespoke capacity needs while requiring minimal additional investment.

The high-cost elements seen in both do nothing and do minimum derive from the expectation that as demand grows in the context of diminishing or flatlined production capacity, third-party vendor reliance increases. Accordingly, while revenue cost elements such as staffing costs will reduce, this is greatly offset by the expectation of much higher costs because of third-party purchase costs. It should also be noted that the risk elements of these options have not been fully explored, but clinical leads agree that there would be significant supply risks if increasing any reliance on third-party vendors, in addition to the financial risks.

Sensitivity Analysis

Sensitivity analyses were conducted in relation to the nearest VFM option (option 3c which represented a near mirror facility on site). This sensitivity analysis was considered from two perspectives. Firstly, by how much option 3c's production capacity need to increase to shift the preferred option allocation. This rationale was derived from the fact that with increased production capacity, this will increase the benefits generated (relative to modelled costs) thus improving the benefit cost ratio.

Inclusive of radio pharmacy, option 3c must produce an additional 16% dose volume (on top of base assumptions) to match the VFM of option 4c. Exclusive of radio pharmacy, this volumetric increase required to match option 4c's VFM is raised to an additional 18%.

Secondly, sensitivity analysis was considered from the perspective of option 4c costs, i.e., by how much must revenue costs increase to reduce the VFM to below that of option 3c. Again, for both iterations of option 4c (i.e., with and without radiopharmacy), revenue costs must increase

by approximately 18% to reduce option 4c's VfM to below that of option 3c. An increase of 20% to both 3c's volumetric output and 4c's revenue costs are shown in figure 16.

Option	Variation	Option 3c	Option 4c
Total Incremental Costs	Exclusive of Radiopharmacy	-£298.8m	-£302.3m
	Inclusive of Radiopharmacy	-£330.8m	-£340.5m
Total Incremental Benefits	Exclusive of Radiopharmacy	£524.7m	£606.1m
	Inclusive of Radiopharmacy	£618.8m	£712.7m
Risk-adjusted Net Present Social Value (NPSV)	Exclusive of Radiopharmacy	£225.9m	£303.8m
	Inclusive of Radiopharmacy	£288.0m	£372.3m
Benefit-Cost Ratio	Exclusive of Radiopharmacy	<u>1.76</u>	<u>2.00</u>
	Inclusive of Radiopharmacy	<u>1.87</u>	<u>2.09</u>

Figure 15: VfM comparison of option 3c and 4c. Option 3c represents the closest comparison to the preferred option both from an operational and VfM standpoint.

Option	Variation	Option 3c – Additional Volumetric Capacity	Option 4c – Additional Revenue Costs
Total Incremental Costs	Exclusive of Radiopharmacy	-£298.8m	-£358.2m
	Inclusive of Radiopharmacy	-£340.6m	-£403.1m
Total Incremental Benefits	Exclusive of Radiopharmacy	£622.5m	£606.1m
	Inclusive of Radiopharmacy	£730.3m	£712.7m
Risk-adjusted Net Present Social Value (NPSV)	Exclusive of Radiopharmacy	£323.7m	£247.9m
	Inclusive of Radiopharmacy	£389.6m	£309.7m
Benefit-Cost Ratio	Exclusive of Radiopharmacy	<u>2.08</u>	<u>1.69</u>
	Inclusive of Radiopharmacy	<u>2.14</u>	<u>1.77</u>

Figure 16: Sensitivity Analysis of the option 3c and 4c with a volumetric and revenue cost increase of 20% respectively.

In addition to the sensitivity analysis considerations, from a qualitative standpoint, significant doubts were raised regarding the feasibility of implementing option 3c. Given these and the significant changes to operation changes required to make 3c the VfM option, it was agreed that option 4c should proceed as the preferred option.

- c) Provide a narrative on:
- The options considered to achieve the scheme's objectives, including business as usual.
 - The process through which the long list of options was narrowed down to the preferred option.
 - The main costs, benefits and risks for the Business as Usual and preferred option.
 - The appraisal period for the scheme.

The Options Considered

An initial list of four options were provided as the minimum appraisal requirement as part of the Tender Specification. Different permutations of the onsite and offsite facility options were developed following initial discussions and data gathering site visits and calls with respective clinical leads, bringing the total longlist to 8 options. These were assessed and considered in the context of the Critical Success Factors (CSFs) which were discussed during our longlist workshop which took place on 05/12/22.

While a total of ten (CSFs) exceeded the recommended maximum of seven as outlined in the HMT Green Book, it was deemed necessary in the context of the UHBW and NBT project board and wider national aims and guidelines regarding aseptic medication production. The ten CSFs include five defined by Green Book and five defined by UHBW and NBT Strategic Workshop.

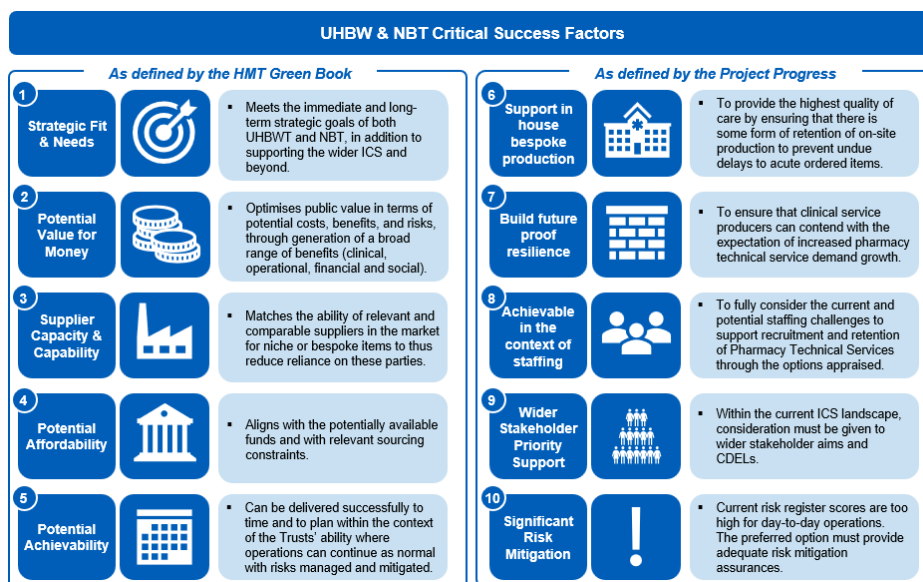


Figure 17: Critical Success Factors as outlined by the HMT Green Book and Project workshop.

The qualitative assessment against the ten CSF's allowed the list to be shortlisted to the following five options, which through more detailed modelling and costing assessment identified Option 4c as the Preferred Option.



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- **Option 1 - Business As-Usual (Do Nothing):** This option would involve no refurbishment, reconfiguration or new build works and current state of services would continue As-Is, therefore requiring no capital investment. Accordingly, this option would see diminishing output as equipment falls into disrepair and ceases to function. From a modelling standpoint, volumetric output was matched to diminish proportionally to essential equipment failure in line with listed or expected shelf lives from baseline data provided by clinical leads. In this way, increasing reliance shifts to third-party vendors resulting in significant revenue cost increases with diminishing benefits. While never truly expected to represent a viable long-term solution, this option was carried forward to the short list to evidence the need to act. This option was discounted as it delivered no benefit or value to the Trusts or local health economy and services will continue to operate in an uncoordinated manner through not-fit-for purpose facilities, increasing risk to patient outcomes and safety and anticipated decrease in product output.
- **Option 2 - Do Minimum:** Allocation of capital towards upgrading current Trust-level facilities through major refurbishment and reconfiguration of all in-scope pharmacy technical services. In comparison to Option 1, this would help drive a small increase in output production, however, the option was discounted as it does not represent value for money

from an investment standpoint. Additionally, it does not address the long-term sustainability and demand challenges expected from NHS pharmacy technical services.

- **Option 3c – On-site Hub for Technical Services:** Utilisation of capital to establish a single facility for technical services on-site at UHBW. Products produced at the new hub will be utilised at UHBW (including WGH) and distributed to NBT. **Excess production capacity will be prioritised for demand growth, followed by commercial income and nursing time released to other patient care activities.** This option was discounted due to additional complications and uncertainty around a viable location for the new hub within the Trust's facilities. Furthermore, during the qualitative assessment following discussions with clinical leads, several potential flaws were recognised. Retrofitting to existing sites would likely be more costly relative to a new site, there would be increased complication and internal governance checks, staffing recruitment would be complicated (relative to options 4a and 4c) based on staff feedback and internal research and there would limit ability to work in an agile or flexible manner to meet evolving demand profiles.
- **Option 4a – Off-Site Hub without WGH Reliance:** Utilisation of capital to establish a single off-site facility for technical services. Products produced at the new hub will be distributed to UHBW and NBT, however WGH will continue to rely on third-party vendors. Excess production at the new hub will be prioritised for commercial output. Despite demonstrating the highest overall monetisable benefits, this option was discounted as the expected growth in expense associated with third-party costs outpace assumed commercial potential. While acknowledging the need to support external demand, it was recognised that the need to prioritise internal demand profiles would have to come first to maintain a financially sustainable and reliable service.
- **Option 4c – Off-Site Hub with WGH Reliance:** Utilisation of capital to establish a single off-site facility for technical services. **Products produced at the new hub will be distributed to UHBW (including WGH and NBT with excess production capacity prioritised for demand growth, followed by commercial income and nursing time released to other patient care activities.** This option demonstrated the greatest net present social value and benefit cost ratio. Furthermore, it was deemed the preferred option from a qualitative perspective for several reasons. This option owing to the volumetric output potential would support the most thorough future proofed option. While the logistic cost elements have not been fully defined and costed at this stage, it was acknowledged from discussion with experts and based on previous experience that this would not drive a cost element significant enough to diminish the cost benefit ratio below that of 4a (which had the second best from the five options considered).

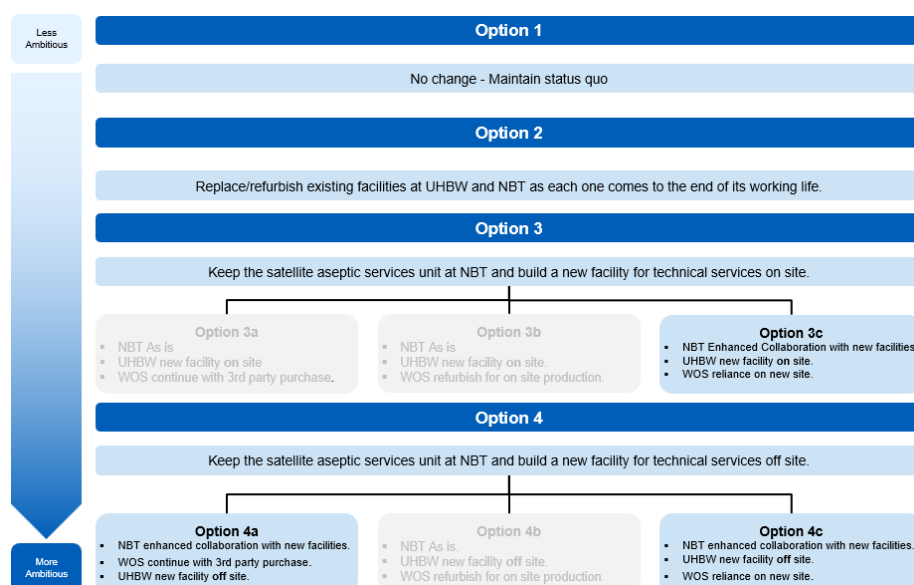
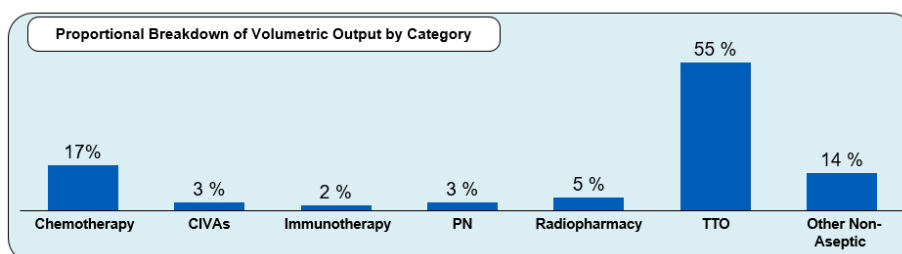


Figure 18: Options Summary confirmation of shortlist following shortlisting workshop**Costs, benefits, and risks for the BAU and Preferred Option**

The quantified benefits of focus were cash-releasing benefits in the form of cost avoidance from a reduction in reliance on purchasing from third-party sources. Medication was categorised with average cost data applied to each medication category (derived from baseline data provided). Y-o-Y growth rates were applied to each category to develop overall demand profiles. These growth rates were applied for 10-year period followed by flatline period afterward owing to the relative unknown of the market after 10 years and the assumption of significant clinical innovation. Baseline production capacity volume data was used to evidence prospect third-party reliance, which when coupled with baseline cost information, showed ongoing cost profile.

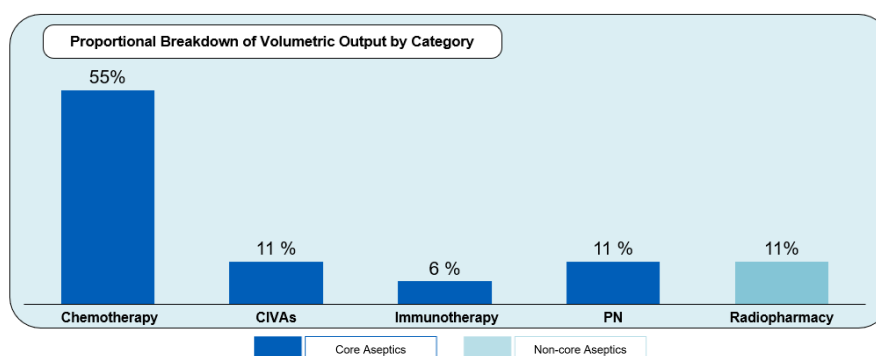
Baseline Volume (2021/22)				
	Made	Purchased	Total Volume	Relative Contribution
Chemotherapy	26,326	13,449	39,775	17%
CIVAs	8,037	-	8,037	3%
Immunotherapy	4,144	16	4,160	2%
PN	8,062	-	8,062	3%
Radiopharmacy	11,892	-	11,892	5%
TTO	127,791	-	127,791	55%
Other Non-Aseptic	33,125	-	33,125	14%
Total	219,377	13,465	232,842	100%

**Figure 19: Overall Baseline Volume Production Proportions**

While to pre-packs and other non-aseptic was included in the categorisation, the associated capital and revenue costs as well as benefits were not considered in terms of the final options appraisal and subsequent VfM calculations.

Rather, this was included in baseline activity review to ensure that by investing in the expansion of aseptic pharmacy technical services, these wider services would not be compromised.

Baseline Volume (2021/22)				
Medication Category	Made	Purchased	Total Volume	Relative Contribution
Chemotherapy	26,326	13,449	39,775	55%
CIVAs	8,037	-	8,037	11%
Immunotherapy	4,144	16	4,160	6%
PN	8,062	-	8,062	11%
Radiopharmacy	11,892	-	11,892	11%
Total	58,461	13,465	71,926	100%

**Figure 20: Proportional Breakdown of Baseline Volume**

Cash releasing benefits focused on the cost avoidance element of no longer requiring purchases from third-party providers. This benefit accounted for the largest single proportion of benefits. Benefit rationale assumed that production capacity would be first prioritised for internal (UHBW and NBT) demand. Excess production capacity was then allocated to either commercial income where production capacity is used to meet demand from third-party NHS partners, or non-cash releasing benefits such as direct CIVAS ward production to release nursing time to other patient care activities (derived from baseline data provided). In this way, it is expected that nursing time released to other patient-facing care will be released directly or indirectly (for example if providing standardised, long shelf life CIVAS products to other trusts thus reducing their requirement for nurse led ward level CIVAS preparation).

Costs:

Option	Variation	'Do Nothing' Option 1	'Do Minimum' Option 2	Preferred Option - Option 4c
Opportunity Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Total Lifecycle Capital Costs + Optimism Bias Uplift	Exclusive of Radiopharmacy	-£9.8k	-£7.7m	-£22.7m
	Inclusive of Radiopharmacy	-£9.8k	-£7.7m	-£27.2m
Revenue Costs	Exclusive of Radiopharmacy	-£297.2m	-£318.1m	-£279.3m
	Inclusive of Radiopharmacy	-£327.2m	-£337.1m	-£313.1m
Transitional Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Externality Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Net Contribution Costs	Exclusive of Radiopharmacy	£0	£0	£0
	Inclusive of Radiopharmacy	£0	£0	£0
Risks	Exclusive of Radiopharmacy	£0	-£1.6m	-£278k
	Inclusive of Radiopharmacy	£0	-£1.6m	-£278k
Total Costs	Inclusive of Radiopharmacy	<u>-£297.2m</u>	<u>-£327.4m</u>	<u>-£302.1m</u>
	Exclusive of Radiopharmacy	<u>-£327.2m</u>	<u>-£346.4m</u>	<u>-£340.2m</u>

Figure 21: Summary of Costs inclusive and exclusive of Radiopharmacy.

Please note risk for the purposes of the Comprehensive Investment Appraisal (CIA), the risks associate with the 'do nothing' option have not been quantified. While this option if pursued will pose the significant financial risks, these will be related to the costs and stability of third-party vendor product supply. For the purposes of the CIA, quantified risks have focused on the costs associated with investment into either a new facility or to bring the current operational facilities up to standard. While the costs calculated shown against option 1, do nothing, are lowest, this has not been considered as a realistic or viable option owing to the assumed unreliability of

relying entirely on third-party vendors. Furthermore, this option delivers no long-term benefits meaning that it produces the lowest benefit cost ratio.

Preferred Option Selection | Quantified Benefits Summary

Benefits have been calculated with focus on three main categories of benefits. While further benefits can be further incorporated to refine the model, these have been deemed as the most relevant in the first instance.

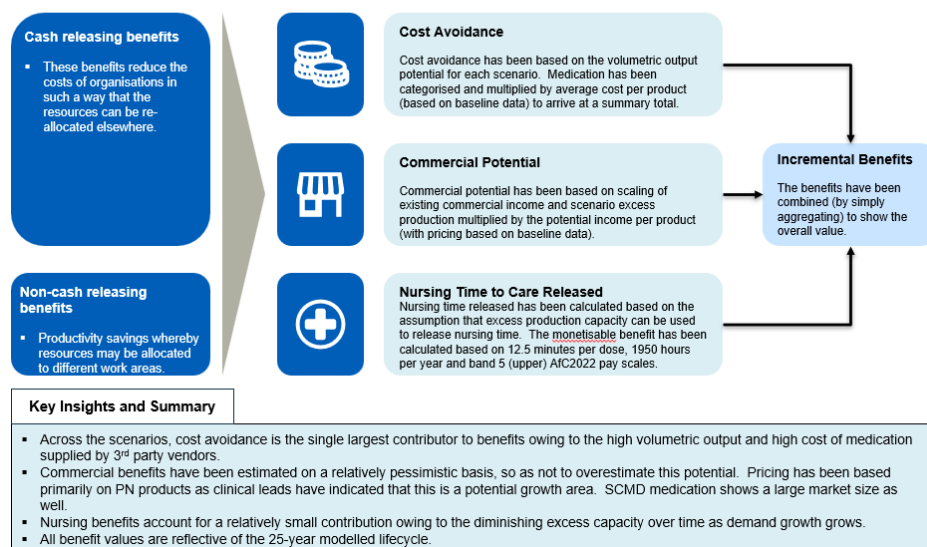


Figure 22: Quantified Benefits Methodology Summary

Benefits:

Option	Variation	'Do Nothing' Option 0	'Do Minimum' Option 1	Preferred Option Option 4c
Cash releasing (cost avoidance)	Exclusive of Radiopharmacy	£33.0m	£98.4m	£563.2m
	Inclusive of Radiopharmacy	£36.9m	£124.8m	£642.2
Non-cash releasing (i.e. nursing time released)	Exclusive of Radiopharmacy	£0	£0	£36.9m
	Inclusive of Radiopharmacy	£0	£0	£6.3m
Cash Releasing (Commercial Income Potential)	Exclusive of Radiopharmacy	£1.4m	£4.4m	£7.5m
	Inclusive of Radiopharmacy	£4.6m	£19.7m	£33.6m
Total Benefits	Exclusive of Radiopharmacy	<u>£34.5m</u>	<u>£102.8m</u>	<u>£606.1m</u>
	Inclusive of Radiopharmacy	<u>£41.5m</u>	<u>£144.5m</u>	<u>£712.8m</u>

Figure 23: Quantitative Benefits of the preferred option inclusive and exclusive of Radiopharmacy

Other Benefits of preferred option 4c:

- Greatest workforce efficiencies.

- Multitude of rooms as specified in the service design will allow for production variation to meet the any demand fluctuations within the network.
- Greatest ability to support wider network.
- Greatest ability to consider future requirements and subsequent refurbishment.
- More effective utilisation of MHRA licenses and greatest potential expansion of clinical trial manufacturing (of IMPs).
- Enhanced ability to support advanced therapy medicinal products (ATMP) and advanced therapy investigational medicinal products (ATIMPs) together with Class 2 Biological handling.
- Improved resilience for UHBW and the wider region and NHS.
- Greatest flexibility to expand production output to meet future demand variations.
- Greatest ability to support OPAT and virtual ward and theoretically improve bed days released.

Please note, these 'other' benefits have not been quantified as part of the economic appraisal through the comprehensive investment appraisal model process. These benefits were deemed to not have sufficient baseline data to consider quantification through extrapolation of each into a workable benefit calculation for considering with each option.

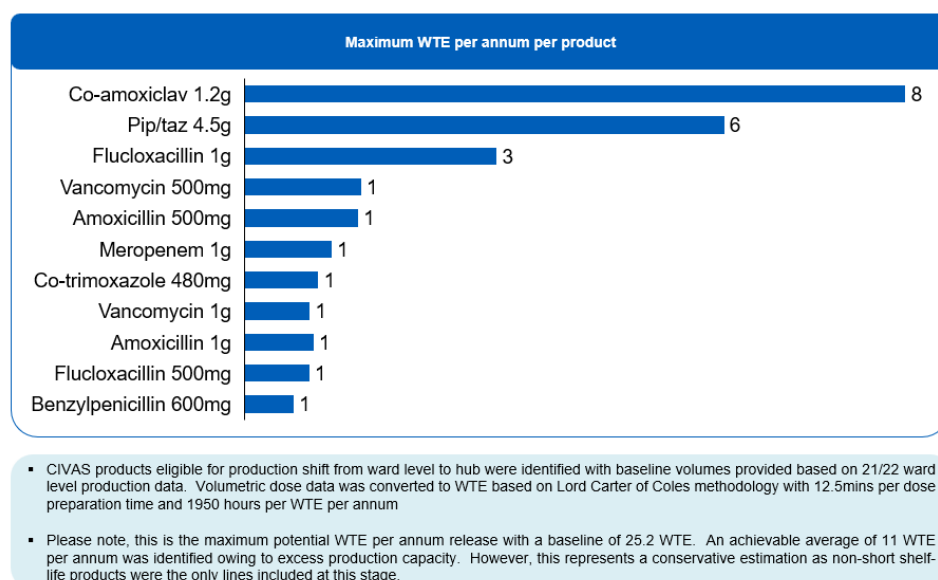


Figure 24: Maximum Nursing Time to Other Patient Care Activities WTE Release Potential

Risks:

Option	'Do Nothing' Option 0	'Do Minimum' Option 1	Preferred Option Option 4c
Identified Risks of each Option	<ul style="list-style-type: none"> ▪ Operating Risk ▪ Revenue Risk ▪ Regulatory Risk ▪ Performance Risk ▪ Technology Risk ▪ Control Risk 	<ul style="list-style-type: none"> ▪ Operating Risk ▪ Revenue Risk ▪ Regulatory Risk ▪ Performance Risk ▪ Technology Risk ▪ Control Risk 	<ul style="list-style-type: none"> ▪ Design Risk ▪ Construction Risk ▪ Performance Risk ▪ Operating Risk ▪ Revenue Risk ▪ Termination Risk ▪ Technology Risk ▪ Control Risk

- Residual Value Risk
- (See CIA model for sub-category risks)

Figure 25: Risk Quantification and summary for preferred option vs do nothing and do minimum.

Appraisal Period:

- The Economic Appraisal has been conducted in accordance with the Treasury Green Book, utilising the DHSC's Comprehensive Investment Appraisal (CIA) Model.
- This reflects the differential costs, benefits, and risks in the different options, appraised against the baseline "Business as Usual" Option.
- The appraisal was conducted over the entire project projected lifecycle of 25 years beginning Year 0 2022/23 and finishing as Year 25 in 2047/48
- UHBW and NBT provided baseline data for analysis in October – December 2022. This was utilised as part of the shortlisting workshops which formed the basis options appraised. The economic appraisal was conducted in December 2022 and January 2023 with a final review with clinical leads and senior stakeholders completed in February 2023.

d) Confirm inflation, VAT, depreciation, CDEL cover are excluded from the economic analysis.

As per DHSC methodology and instructions, inflation, VAT, CDEL, depreciation and PDC have all been excluded from the economic analysis.

COMMERCIAL CASE

a) Please set out the commercial and procurement route, e.g., P22.

To achieve the objectives of the collaboration aseptic project, particular goods and services that need to be procured include:

- Professional services
- Refurbishment and associated works
- Equipment
- Systems
- Logistics

To procure the preferred provider across these functions, the following initial list of procurement routes have been considered:

1. Find-a-Tender (national tender process – replacement to the Official Journal of the European Union since departure from the EU). These could take the form of either an open procedure or a restricted procedure.

Note: there are other routes available, that have not been detailed here as would not be suitable e.g., Competitive Dialogue.
2. Clean Room or Similar Framework Routes: There are no comprehensive national framework routes available for cleanroom design, build and validation. However, the North of England Commercial Procurement Collaborative have a localised pharmacy clean room services framework in place. This covers three specific lots; Pharmacy Clean Room Garments, Provision of mops including processing and pharmacy specific clean room consumables. Suitability of this approach has not been considered, but it is assumed that similar categorisation approach could be mirrored in the development of tender

	<p>specification for UHBW and NBT. Depending on external stakeholder buy in, this could be extended to include the ICS or SW region.</p> <p>3. Construction Frameworks: A construction framework would need to fully verify the credentials of participants to be confident that an appointed provider would have the capability to deliver the complex project. There are numerous construction frameworks available to the project such as the:</p> <ul style="list-style-type: none"> ▪ North of England Commercial Procurement Collaborative – Estates Consultancy ▪ Fusion 21 ▪ NHS ProCure23 Framework (P23) <p>At the next stage of project progression, the UHBW and NBT collaborative in line with the Procurement and Commercial workstream will decide upon the best procurement route which will generate outcomes that deliver best value to the project and UHBW and NBT collaborative. The procurement routes will be assessed based on alignment and fit with project-specific requirements, drivers, and success criteria for the project.</p> <p>When the optimum procurement route for the new regional hub model development has been determined, the procurement framework will align with the following to select the preferred principal partner who will then provide a suitable design to ensure best procurement is secured for cost, time, and quality assurance across the collaborative.</p> <ul style="list-style-type: none"> ▪ Payment Mechanisms ▪ Value for Money ▪ Actual Cost ▪ Incentivisation & Gainshare ▪ Delay Damages
<p>b) Set out the basis of the negotiated position, including the final price for the works.</p>	<p>Professional services</p> <p>Professional services will be acquired in line with the delivery timetable outlined above. Core professional services such as architectural contracting etc will be managed by the procurement and commercial workstream. Wider professional services such as facilities maintenance will also be managed by the workforce workstream. As the exact specification of the facility becomes defined more clearly as the project design matures, exact pricing can be considered regarding the wider professional services. Regardless of overall need, value for money, experience and quality aspects will be considered as the most important aspects.</p> <p>Refurbishment and Fit Out</p> <p>This will be undertaken through a procurement process as outlined above. Outline costs have been established in the business case work up to ensure costs listed have merit, however, further refinement will be added during the procurement process.</p> <p>Construction and associated works will utilise Procure23 and will be led by the Procurement & Commercial workstream, with input from clinical leads to ensure that facilities are suitable, fit for purpose and have the correct level of flexibility to allow for subsequent improvements or expansions as technological improvements or regulatory requirements allow or dictate.</p> <p>Equipment</p> <p>This work will be led by the Procurement & Commercial workstream with detailed input from the hub implementation workstream. The equipment procurement will make use of relevant frameworks where possible with tenders undertaken where necessary.</p> <p>Logistics</p> <p>With the preferred option for an offsite facility, and the longer-term aim to increase commercial income through increased collaboration with NHS parties within the ICS and beyond, there will be further logistics and supply chain management requirement.</p> <p>While price has not been defined at this stage, consideration of storage requirements during transport will influence pricing aspects. This in turn will largely be defined by demand profile including destinations and product mix. Again, as the project matures toward implementation a clearer idea of logistics requirements will be defined which will inform pricing structure. It is expected that NHS Supply Chain will manage this aspect.</p> <p>Systems</p>

	<p>During 2023, a “detailed “design” workstream will establish a subgroup to undertake market scanning for potential systems required to operate a large aseptic hub. Multiple potential suppliers, all available on existing frameworks, will be engaged regarding the requirements of the hub and associated systems. Whilst work is still underway to establish whether a new full Enterprise Resource Planning (ERP) system is required, the costings used in the business case are based on extensive work with previous providers. Other system requirements are based on updates to current systems in place within the production units at UHBW and NBT and therefore minimum input is required to implement updates and expansion as necessary.</p> <p>The use of single tender waivers is appropriate where costs exceed the threshold for competitive tendering or quotation will be applied where appropriate and costings of these systems are well understood.</p> <p>Once the procurement for the works have been conducted and contracted for, the final price for the works can be confirmed.</p> <p>Social Value</p> <p>Underpinning all elements of the procurement strands and strategy will be the need to consider social value in all contracts awarded and partnerships developed. In considering social value benefits, factors such local employment effects, skill improvements for young people, staff welfare factors and sustainable procurement aspects will be assessed. While no social value measurement methodology has been defined yet as part of the procurement and commercial strategy, the National TOMs Framework 2019 for social value measurement should act as a sufficient guide in this matter.</p>
c) Confirm status of any legal documentation or processes required for the scheme to be delivered in full and what (if anything) remains to be agreed.	<p>In accordance with section 12ZB of the Health and Care 2022, all elements of the project will fully comply with all required procurement legislation as well as the SFIs of both UHBW and NBT in terms of the new funding requirements.</p> <p>Furthermore, the following employment legislation has been identified as applicable to the project and will be adhered to:</p> <ul style="list-style-type: none"> ▪ Employment Rights Act 1996 ▪ National Minimum Wage Act 1998 ▪ Employment Relations Act 1999 ▪ The Maternity and Parental Leave etc. Regulations 1999 ▪ Part-Time Workers (Prevention of Less Favourable Treatment) Regulations 2000 ▪ Transfer of Undertakings (Protection of Employment) Regulations 2006 ▪ The Equality Act 2010 ▪ Agency Workers Regulations 2010 <p>Full regulatory requirements have been considered in the context of the MHRA Orange Book. Additionally, the project has been considered in the context of MHRA requirements including Annex 1 of GMP in relation to the manufacture of sterile products.</p> <p>Lastly, in addition to regulatory requirements, the new facility will aim to adhere to NHS best practice requirements such as those outlined in the NHS Agency Rules June 2019.</p>
d) We assume that Modern Methods of Construction (MMC) will be used for new builds. Please provide details of how MMC will be utilised.	<p>The preferred option will identify lease of a facility in place of construction of a new regional hub, refurbishment requirements will be incorporated in the lease terms and conditions and third-party leases will not be considered.</p> <p>Thus, this project does not anticipate the preferred option requiring construct of a new build and fall under a new build scheme remit and will therefore not require a Building Research Establishment's Environmental Assessment Method (BREEAM) assessment or planning permission. However, a BREEAM assessment will be conducted should NHSE deem it necessary. Furthermore, confirmation of both procurement and design will be followed with the completion of the Health Building Note (HBN) on the extension of the aseptic service and facilities (with any deviations explained).</p> <p>Health Technology Memoranda (HTM) reflect a standardised set of documents that offer comprehensive guidance regarding the design, installation and operation of specialised buildings and engineering technology used in the delivery of healthcare. These have been considered at the outset to ensure that best practice has been considered and align with their stated goals of improved patient outcomes relating to safety, effectiveness, and patient experience.</p>

	<p>As the design phase matures further, these will be further considered to ensure compliance with building requirements and alignment with best practice considerations. While no pre-defined hierarchy of HTMs has been confirmed in relation to the HTMs, early consideration has been focused on HTM 00 Policies and principles of healthcare engineering especially regarding the construction management governance arrangements, utilities consideration, infection prevention and control, electrical services and ventilation and cooling considerations. HTM 03 Specialised ventilation for healthcare premises has also been considered and will continue to be relied upon given the requirement for air handling units, particle monitoring and limits as part of clean room, and aseptic production requirements. Furthermore, HTM07-02 Making energy work in healthcare has also been considered in line with broader NHS sustainability goals.</p> <p>Similarly, health building notes (HBN) give best practice guidance on the design and planning of new healthcare buildings and on the adaptation or extension of existing facilities. While the preferred option will not involve construction of a new facility, the relevant principles can still be considered to ensure best practice is achieved. Again, while no confirmed HBN hierarchy has been defined, core consideration has initially focused on HBN00 General design guidance for healthcare buildings especially regarding the policy and regulatory overview elements such as CQC or MHRA requirements, NHS Constitution consideration which sets out the rights to which patient, public and staff are entitled to, health and safety considerations, and the code of practice regarding the practice in infection prevention and control Strategic and master planning elements as outlined in HBN 00 have also been considered. Given that improving resilience has been outlined as one of the key aims of the project, HBN 00-07 Planning for a resilient healthcare estate has also been considered. Key elements of focus from this guidance has centred around robustness of facility design, especially in relation to varying product demand profiles, and aspects that can impact facility robustness. These include, but are not limited to, unavailability of premises due to fire or flood etc, transport infrastructure challenges, major IT or electronic disruption, loss of access to key resources, loss of critical support services or loss of access to key resources. In considering these aspects, it was accepted by clinical leads that UHBW clinical facilities are currently dealing with many of these aspects that can negatively impact facility resilience. Given that the pharmacy aseptic and technical services will require aseptic clean room working conditions, HBN00-09 Infection control in the built environment will also be considered. Lastly, as this is ultimately a pharmacy project, HBN 14-01 Pharmacy and radiopharmacy facilities have been (and will continue to be) considered. General design principles have such as facility location, aseptic and storage requirements, radiation protection, security and general infection control have been considered. As the design phase matures, the detailed information regarding aseptic preparation facilities, including the requirement of changing rooms, inner and outer support rooms, and clean room requirement as well as the flow of overall design.</p>
e) Confirm contribution to carbon reduction plan (if applicable).	<p>The design and implementation of the Preferred Option (Option 4c, see Economic Case) will be in accordance with the Green Plan 2022, outlining the commitment to improving sustainability throughout the organisation with support for the NHS in the pursuit of becoming the world's first net zero health service. The Green Plan is focused on nine core areas, aligned to the key drivers for change and key sources of carbon emissions, within the NHS.</p> <p>Both NBT and UHBW have published individual documents detailing their commitment to the carbon reduction and sustainable development. Full details can be found in UHBW's Sustainable Development Strategy (SDS) 2020-2025 and NBT's Green Plan 2020-2021. Project leads have already considered the need to align the project with this documentation in relation to sustainability elements including carbon reduction strategies. This will range from scope 1, 2 and 3 emissions. While reporting elements are yet to be defined, UHBW's SDS provides clear aims and potential metrics and reporting mechanisms that could be adapted as part of the project. Wider literature sources are available to further support the development of a carbon evaluation calculation methodology. These include the Magenta Book detailing ventral government guidance on evaluation and the carbon valuation literature as developed by the department for Emergency Security and Net Zero and Department for Business, Energy, and Industrial Strategy.</p>

FINANCIAL CASE

a) Please provide narrative to support the detail provided in Section 4 (above).

As noted in the introduction, this business case will rely on the assumption of capital funding from outside of the BNSSG ICS CDEL from nationally available funding as part of the national NHSE Infusions and Special Medicines Programme following on from Lord Carter of Coles' Transforming Aseptic Care in England Report.

The scope of this Business Case is to deliver a full scale aseptics hub with capacity to meet current demand, including supply to Weston General Hospital Cancer Satellite, absorb future growth, of multiple medication categories as well as address the significant unmet need, releasing nursing time to other patient care activities by producing ready-to-administer CIVAS products for use on wards and support product supply to other NHS partners both within and beyond the scope of the BNSSG ICS.

Capital Expenditure Profile

Two iterations of the capital expenditure profile have been presented. The first is inclusive of radiopharmacy and the second exclusive. The key difference in pricing is derived from the expectation that with the exclusion of radio pharmacy, there will be a reduction in floor space and associated equipment which drive the cost differences. While the exact breakdown of capital expenditure has yet to be finalised, it is expected that most of the funding will be spent during the 2025/26 financial year in line with expected NHSE funding release. An initial outlay of 10% has been suggested for the 2024/25 financial year to enable some of the preliminary works etc to be completed and enable smooth transition into full completion in 2025/26. This 10% would be comprised of preliminary planning costs and associated professional fees. Once again, it must be noted that the breakdown of fees presented is for illustrative purposes and may be subject to further change as the design phase matures.

Breakdown of Scheme Capital Costs

Similarly, two iterations of the breakdown of scheme capital costs have been presented, again to enable differentiation of the costs inclusive and exclusive of radio pharmacy. The work costs, fees, non-work costs, equipment costs have all been derived and extrapolated from baseline data provided and third-party experts. Conservative estimates have been applied to reduce the risk of underestimation of costs. Additionally, optimism bias, planning contingency and inflationary adjustments have been included at 5% each, again to reduce the risk of underestimation of costs. These represents approximately £2.6m inclusive of radiopharmacy and £2.2m exclusive of radiopharmacy. VAT has been applied to all elements at the standard 20%.

There are two versions of three tables (i.e., six tables total from figure 4 – 9). Figure 4 shows the combined financial summary of both UHBW and NBT, with figure 5 and 6 detailing UHBW and NBT independently, with all figures reflecting radio pharmacy inclusion. Conversely, figures 7 – 9 show the same detail but exclusive of radio pharmacy activity, or other financial involvement.

Financial Position Summary

Balance Sheet Summary

The balance sheets presented are indicative of the assets employed after completion of the project. No 'additional' assets will be employed under the do minimum scenario, hence this has not been zeroed. Depreciation has been applied on a flat line basis as per UHBW's (the lead organisation) instructions in accordance with IRFS 16 rules over a 23-year basis (excluding 2 base years until FY 25/26) when the facility will be operational with leasing charges incurred. The asset values represented in years Y25 show the value the assets employed after the life of the project with the diminished value driven by the annual depreciation.

MCFlow Summary

Master cash flow statements have been presented inclusive and exclusive of radiopharmacy. Cashflow will operate on a net neutral basis. However, in both figure 5 and 8 the UHBW operating income is significantly lower in option 4c (inclusive and exclusive) of radiopharmacy. This assumes that through operation of the new hub facility, the increased capacity created will lead an increase in volume available for commercial activity. Based on this rationale, this should reduce the baseline funding from trust input needed to operate pharmacy aseptic and technical services.

I&E Summary

Income and expenditure have been developed based on baseline data provided. Commercial income has is driven by current activity, which in turn is derived mainly from PSU activity relating to parenteral nutrition product supply radio pharmacy and UHBW's production facility. While full market scoping and investigations have not been discussed, preliminary review of activity with discussion of current local facility landscape indicate this will be a significant potential revenue driver. This amount diminishes within option 4c as there is a greater potential for commercial income. Inflation at 2% per annum has been applied to all costs and the commercial income potential.

Baseline funding is the amount that each respective trust must provide to enable services to continue to operate year on year. The diminished value seen in both iterations of option 4c is reflective of the assumption that as the facility becomes operational, and commercial income potential increases, trusts must commit a reduced level of baseline funding to maintain an operational pharmacy aseptic and technical service.

Pay data is derived from 2021/22 baseline pay figures. Minor amendments have been made to accounting data provided by clinical leads to reflect a more accurate cost of operating the facility (i.e., to reduce potential double counting for staff members with current PATS and Non-PATS roles). All assumptions have been confirmed with respective clinical leads and financial representatives. As seen in all sets of tables, there is an increase in staffing costs in option 4c reflecting the additional staff required to operate the service. Inclusive of radiopharmacy, this is reflected in an additional £38m over the course of 25 years. Exclusive of radiopharmacy this is reflected in an additional £26m over the course of 25 years.

Non-Pay clinical services are largely driven by third party expenditure costs. As seen in the differential tables, option 4c offers significant cost savings in this element which in turn reduces the amount of trust commitment funding required for the service to operate and reduced the overall total income required for the service to operate.

Interest has been applied at the Treasury standard of 0.95%. Public dividend capital (PDC) charges have been assumed at 3.5% of net relevant assets. With the leasing charge derived from assumed floor space requirements, this ranges from approximately £346k to £296k per annum (inclusive and exclusive of radio pharmacy).

These charges have been applied to UHBW's financial position alone as it is acting as the lead financial organisation and so will retain responsibility for the management of these elements. As there is no public capital applicable to the do minimum option, these charges are entirely derived from the assumption of the progression of the leasing of the new facility in line with cost estimates. Leasing has been selected as more appropriate from an ongoing financial management standpoint.

UHBW Whole Trust Impact

The impact of the project on UHBW is represented in figures 10 and 11 (inclusive and exclusive of radio pharmacy respectively). Regardless of radio pharmacy involvement, the overall operating expense in net neutral on the basis that the PATS operating costs will also be. While option 4c does add significant staffing costs to UHBW's position, these costs are greatly offset by the commercial income potential as evidenced in figures 5 and 8.

b) Please explain any incremental revenue consequences of the investment and how they can be mitigated.

For the purposes of the business case, revenue elements have been structured in three categories, pay revenue, clinical services (including drug cost) and miscellaneous cost elements.

Increases seen in pay and miscellaneous costs have been greatly offset by the expected savings seen against clinical services costs. This savings element is derived from the expectation that through greater volumetric production capacity, the hub facility will be able to meet current demand levels and absorb subsequent growth. Accordingly, there will be no need to be entirely reliant on third-party vendors for medication supply. Regardless of the financial element, it has also been noted that third-party production capacity has been shown to be currently struggling to meet demand levels. Therefore, it does not make financial or risk management strategic sense to expect this to be a viable supply source.

While additional staffing revenue costs will be incurred through increased staffing numbers to maximise the output potential, the reduction in third-party reliance and associated costs means that this is a much more efficient means of managing pharmacy technical services financially.

	<p>In this way, the successful operation of the preferred option through implementation of a new hub facility will mitigate incremental revenue consequences by reducing the overall long-term revenue burden through a reduction in third-party spend expenditure. As outlined in all sets of the total financial position summaries, successful implementation of the preferred option will lead to a significant drop in non-pay clinical service costs which are primarily driven by costs associated with increased costs of purchasing medication from third party commercial providers.</p>
c) Are there any cash flow issues, such as fees, enabling works, that require early funding?	<p>The cashflow from operations are expected to be net zero. This is on the basis that capital funding is drawn down in a profile to match to investments and that income is received from partner organisations to support revenue costs.</p> <p>Accordingly, we do not expect any cash flow issues that require early funding. As noted in the financial tables, the long-term cash flow requirements are significantly lower in option 4c compared to those in the do nothing or do minimum options. While there are initial cost pressures seen in the first five years as recruitment drives raise the level of staffing (and associated pay costs), this is quickly recouped by the anticipated savings from the avoidance of third-party cost elements.</p>
d) Confirm that the project can be managed within existing funding envelopes.	<p>Following NHSE approval of Business Case, national capital funding of £20.2million or £24.6million (i.e., funding pot allocation inclusive or exclusive of radio pharmacy) will be allocated to the project which covers the proposed service works.</p> <p>While there may be some revisions in cost elements as the design phase matures, conservative cost estimates have been applied to minimise the risk of optimism bias. As such, we can confirm that the project will be managed within the funding envelope stated.</p> <p>The project will be managed in pre-defined management stages with cost tolerances established and approved by the board for each stage.</p> <p>If an exception is forecast, this will be reported to the board and corrective action taken to ensure the delivery of the project within the funding envelopes.</p>
e) Confirm and demonstrate that the recurrent revenue cost of the scheme is affordable.	<p>As noted, the comparable 'do nothing' and 'do minimum' result in significantly higher longer revenue costs with the expectation that increased reliance on third party vendors will incur significant revenue increases. Due to the cost associated with "do-nothing", the incremental revenue cost is minimised and accepted as a system cost pressure as detailed above.</p> <p>To date, opportunities for income generation have not been explored fully beyond basic extrapolation of current commercial income. As such, we expect the commercial income listed to be a representation of the floor minimum, meaning this could offer an additional source of affordability for the project.</p> <p>Consideration of options to include income generation will be overseen by the project board.</p> <p>Additionally, the financial benefits associated with support of and collaboration with OPAT services have not been calculated. While these elements are still relatively immature, it was deemed that it would not have been appropriate to calculate financial values as any assumptions made would be abstract and potentially too far removed from working practice. However, given that these schemes, when properly supported, have the potential to have a substantial positive impact on bed release (which represents one of the most considerable pressures facing the acute NHS care settings at present), this could result in significant financial benefits further aiding the affordability of this scheme.</p>
f) Confirm the trust has assessed and is able to fund lifecycle costs to keep the facility at condition B.	<p>Lifecycle costs have been included in the initial CIA model which has been used to populate the VfM model. We have calculated that the expected lifecycle capital required to replace and maintain necessary equipment as per stated shelf lives provided by clinical leads within the baseline data. This has been estimated in line with expected minimum shelf lives, while considering optimism bias and risk elements. We therefore expect that the lifecycle capital costs stated may be an overestimate. Furthermore, we have considered the broader revenue cost elements as part of the costings.</p> <p>All project parties have been sighted to these cost elements and are comfortable with the minimum requirements to maintain the facility to condition B (sound, operationally safe and exhibiting only minor deterioration).</p>

MANAGEMENT CASE

a) Confirm the arrangements for the management and delivery of the scheme.

The new facility will operate to the highest achievable standards. This will be guided by literature sources such as the NHS' Assurance of aseptic preparation of medicines (<https://www.england.nhs.uk/long-read/assurance-of-aseptic-preparation-of-medicines/>), the Royal Pharmaceutical Society's Quality Assurance of Aseptic Preparation Services: Standards (<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Quality%20Assurance%20of%20Aseptic%20Preparation%20Services%20%28QAAPS%29/rps---qaaps-standards-document.pdf>) and compliance with the current MHRA Good Manufacturing Practice and Good Distribution Practice (<https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice>) and in conjunction with leadership from the project team as outlined in the provider capacity and capability section.

A robust 3-tiered governance structure will be established and deployed to manage, oversee, and enable the delivery of the implementation of the aseptic service transformation:

- **Tier 1- Programme Executive:** Responsible for approving any transformational and / or strategic change and is the final point of escalation.
 - Neil Kemsley UHBW Director of Finance and Information, and Project SRO.
 - UHBW Director of Pharmacy
 - Strategy Officers
 - NHSE Colleagues
 - Debbie Campbell – ICB Deputy Director of Medicines Optimisation
 - ICS Chief Pharmacist
- **Tier 2 - Project Board and Clinical Reference Groups:** The board are responsible for overseeing the project planning and delivery and oversight of adherence to the principles set out in the MoU. The Board monitors progress through the monthly Board meeting, and update teleconferences, as needed. The CRG will be responsible for product catalogue changes from a product perspective and horizon scanning.
 - ICB Deputy Director of Medicines Optimisation
 - UHBW Director of Pharmacy
 - NBT Director of Pharmacy
 - UHBW Associate Director of Pharmacy – Production
 - UHBW Associate Director of Pharmacy – Adult Cancer and Aseptic Services
 - UHBW Associate Director of Pharmacy - Radiopharmacy
 - UHBW Associate Director of Pharmacy – QA/QC
- **Tier 3 - Hub Leadership Team:** Management of service delivery and ensuring quality is in line with licensing.
 - UHBW Associate Director of Pharmacy – Adult Cancer and Aseptic Services
 - NBT Principal Pharmacist - Technical Services and Haematology
 - NBT Lead Pharmacy Technician - Aseptic Services
 - UHBW Associate Director of Pharmacy – QA/QC
 - UHBW Associate Director of Pharmacy – Pharmacy Production
 - UHBW Associate Director of Pharmacy - Radiopharmacy

Clear responsibility across the three-tiered structure have been identified within each of the following critical workstreams:

	<ul style="list-style-type: none"> ▪ Contracting and charging ▪ Catalogue Management ▪ Allocation Management ▪ Managing Capital Funding ▪ Business Continuity ▪ Service Key Performance Indicators and Metrics ▪ Term and Exit Provisions ▪ Procurement and Commercial ▪ Workforce ▪ Audit and Risk <p>As part of the project management process, key areas for leadership will be identified from respective subject matter leads. The management strategy of the new facility will endeavour to support individual accountability while also facilitating an open and transparent working environment that does not promote blame culture but enables mistakes to be openly discussed and learned from.</p> <p>For contracts to deliver successfully, on time and on budget, they must be actively managed from inception to conclusion. A proactive contract management plan will also be implemented to ensure successful contract delivery and better achievement of value for money. This will be managed by the procurement and commercial workstream but in conjunction with the audit and risk workstream to ensure that risks are appropriately quantified, and all stakeholders are aware of the potential impacts of poorly managed contracts. Through effective management of this element, this will further support achievement of financial benefits, for example through regular review of medication and pricing structures.</p>
b) Confirm the key risks to delivery and measures to mitigate and manage these risks.	<p>A Risk Log is in place for the collaboration, maintained by the Project Manager. Risks will be continually monitored and managed by the Project Team, with escalation to the Project Board and the Executive when appropriate and will continue to do so throughout the project lifecycle.</p> <p>The key risks to date have been classified into four types: financial, transformational change, operations, and workforce. Example risks across these types and supporting mitigation strategies have been captured below:</p> <p>Financial:</p> <ul style="list-style-type: none"> ▪ Necessary capital funding may not be available to support construction of a new hub to provide increased production of aseptically prepared medicines via a hub and spoke model. Mitigated through review of financial case to align with the national capital funding allocation. Pending approval of NHSE on Business Case. ▪ Incorrect cost or time estimates leading to increased costs (either directly or indirectly). Continual refinement of cost and timeline elements to ensure accuracy will mitigate this risk. With the required capital not expected for release until FY 2025/2026, effective utilisation of this lead time will further strengthen this mitigation strategy. ▪ Significant lead times for procurement of equipment due to high numbers of specialist equipment required. Mitigated by initiation of procurement process at earliest opportunity and scope potential to take delivery of equipment in a staggered process. <p>Transformational Change:</p> <ul style="list-style-type: none"> ▪ Missed opportunity to implement fully automated technology due to market position and feasibility at point of unit build. Flexibility regarding future demand and service provision has been continually highlighted as a necessity within the project, which has in part driven the decision toward a preferred option that will enable flexibility. This will therefore enable mitigation of this risk by design of the hub unit to incorporate ability to replace equipment in future to introduce automated technology if available and supported by the MHRA. <p>Operations:</p> <ul style="list-style-type: none"> ▪ Delay to project implementation awaiting MHRA site inspections and therefore delaying commissioning. Mitigated through regular liaison with MHRA at regular intervals

throughout project and work closely with them to avoid potential delays and effective utilisation of project team's MHRA experience.

Workforce:

- The necessary workforce may not be available to support the preferred model or delayed recruitment due to availability. Mitigated through exploration of new approaches to skill mix, early initiation of recruitment and through phased waves to reduce burden of recruitment requirement and impact of risk. This can be further mitigated through enhanced in-house training opportunities should significant recruitment challenges be encountered. Training of non-pharmacy staff where possible will also act to further mitigate this risk. Benefits calculations have further mitigated this risk through conservative recruitment estimates that have reduced the modelled benefits realisation. In turn this should ensure that the benefits presented are in line with the minimum expected for realisation.

Risk Title and Impact Score	Option 4c Major Off-Site Hub	Mitigation Strategy
National funding unavailable (5)	Possible (3)	Business Plan Drafting to align with national strategy.
Procurement related delays (4)	Possible (3)	Planning at the earliest outset to prevent likelihood of delays.
Inability to recruit required staff in relation to preferred option (4)	Possible (3)	Collaboration with workforce strategy team to inform recruitment.
Negative impact on workforce wellbeing owing preferred option working patterns (3)	Possible (3)	Appropriate planning to reduce likelihood and impact.
Patient Care Risk (5)	Unlikely (2)	Full operational mapping to mitigate operational risk and match demand
Reputational Risks (4)	Unlikely (2)	Alignment with national strategy in business case.
Failure to translate design (4)	Possible (3)	Collaboration with estates and facilities and design specialists.
Incorrect cost estimates (3)	Possible (3)	Procurement strategy to maximise competitive advantage and VIM
Contractor default (4)	Unlikely (2)	Procurement strategy to minimise this risk.
Failure to meet performance standards (4)	Unlikely (2)	Collaboration with respective clinical leads.
Incorrect estimated cost of providing clinical services (2)	Possible (3)	Pessimistic cost modelling; iterative reviews.
Changes in the volume of demand for patient services (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities
Estimated income from income generating schemes is incorrect (2)	Possible (3)	Pessimistic output modelling; flexible design capabilities; SCMD demand mapping.
Incorrect time estimates (3)	Possible (3)	Procurement strategy to minimise this risk.
Incorrect cost and time estimates for decanting from existing buildings (2)	Possible (3)	Procurement strategy to minimise this risk.
Regulatory licenses / accreditations cannot be achieved option (5)	Unlikely (2)	Collaboration with respective clinical leads and regulatory stakeholders.
Changes in national agenda shift focus for pharmacy technical services (4)	Unlikely (2)	Collaboration with NHSE colleagues
Model does not sufficiently allow for future changes in infrastructure (3)	Unlikely (2)	Pessimistic output modelling; flexible design capabilities
Local configurations are varied and complex driving additional complexity and cost (3)	Possible (3)	Early collaboration with design specialists.
TOTAL	169	

Figure 26: Risk Log Summary of Preferred option with mitigation strategies

c) Set out the benefits realisation strategy and how the Trust intend to monitor and report on benefits.

To measure and track benefits realisation, benefits to monitor have been grouped into the following with examples provided for each:

Direct & Financial Benefits

- Release nursing time to other patient care activities.
 - **Realisation Strategy** – This benefit will be realised as the offsite hub facility becomes operational and approaches maximum capacity output. In doing so, it is expected that the excess production capacity will become available to reallocate ward level production to the hub facility.
 - **Calculation Method** – Released nursing time to care will be calculated through the hub CIVAS production output. In line with Lord Carter of Coles methodology, this benefit will assume 12.5mins per dose and 1950 hours per WTE. Monetisable benefits will be extrapolated from the Agenda for Change (updated yearly).
 - **Reporting method** – Production output will be tracked monthly. While yet to be finalised, this benefit will be reported monthly in line with the drafted Governance arrangements.
- third-party cost avoidance Financial Release
 - **Realisation Strategy** – This benefit will be realised through total volumetric output which will in turn link to a reduction in reliance and need from third-party vendors.

- **Calculation Method** – This will be considered through categorisation of volumetric output which will be multiplied against average cost data to calculate estimates of cost levels avoided.
- **Reporting method** – Production output will be tracked on a monthly basis. While yet to be finalised, this benefit is expected to be reported monthly in line with the drafted Governance arrangements.
- Bulk procurement efficiency savings
 - **Realisation Strategy** – With expansion of collaboration services, there will be increased potential to combine procurement elements to leverage economies of scale benefits more effectively. This benefit will therefore be realised as the new facility becomes operational allowing bulk procurement.
 - **Calculation Method** – This benefit will be monitored by the Procurement and Commercial Workstream. Savings targets and potentials will be identified by subject area leads within this workstream, with exact method of calculating savings calculated as the facility becomes operational.
 - **Reporting method** – Corresponding benefits will be reported in a format and frequency as defined by the Procurement and Commercial Workstream, but this is expected to be monthly.

Indirect & Non-financial Benefits

- Improved production safety and product quality
 - **Realisation Strategy** – Improved production safety and product quality should be realised naturally through improved governance benefits. Standardised practice through development and implementation of SOPs and other training guidelines will support realisation of this strategy.
 - **Calculation Method** – No calculation method has been defined for this aspect. However, quarterly, bi-annual, or annual audits for medication safety incidents would seemingly be a suitable method in combination with ongoing error, safety or near miss logs would be prudent.
 - **Reporting method** – Ongoing incident reports will be reported internally. Depending on the frequency, nature and risk of errors or safety incidents, these may be reported on an ad-hoc basis with corrective and preventative actions reported in conjunction.
- Improved product availability of raw materials
 - **Realisation Strategy** – Through combined procurement and bulk purchasing arrangements, it should be possible for the commercial and procurement workstreams to implement a realisation strategy effectively.
 - **Calculation Method** – This benefit will be monitored by the Procurement and Commercial Workstream. Savings targets and potentials will be identified by subject area leads within this workstream, with exact method of calculating savings defined on a case by case basis and as the facility becomes operational.
 - **Reporting method** – Raw material shortages and frequency may be tracked and reported internally. Depending on the nature, risk, and frequency on any

unavailable products, this will be reported on an ad-hoc basis with suggested alternative sourcing strategies.

- Reduced impact of unplanned downtime of equipment / unit
 - **Realisation Strategy** – This benefit will be realised through operations of the new hub facility as it approaches maximum capacity. In ensuring limited downtime, the Service Key Performance Indicators and Metrics Workstream will work to ensure that all equipment is adequately maintained to minimise the risk of any 'knock on' unplanned equipment downtime as a result of unforeseen maintenance or replacement. Furthermore, this benefit should be realised through effective planning and management of demand profiles (both internally and externally) to ensure effective and efficient utilisation of all equipment.
 - **Calculation Method** – Monitoring of planned and unplanned equipment downtime with corresponding reasons or explanation will serve as a suitable calculation method.
 - **Reporting method** – This could potentially serve as a bi-annual audit metric. Unless otherwise specified by the project board, this frequency should be suitable to ensure that this benefit is realised.
- Regulatory and Operation Risk Improvements
 - **Realisation Strategy** – Ongoing review of the relevant risk registers, with recalculation of risks following pre and post the hub becoming operational.
 - **Calculation Method** – Exact method of calculation will be defined by the audit and risk workstream, but it is expected that risks will be scored on an impact x likelihood basis to provide a raw risk score. The TAME framework will further be used to define risk management strategies.
 - **Reporting method** – A risk summary will be reported monthly as part of the appendices. High scoring or risks in need of discussion will be highlighted to the project board on an ad-hoc basis (as defined by the project boards risk appetite score).

Soft Benefits (areas of opportunity)

Soft Benefits represent areas of further potential exploration for the project board to define their feasibility, realisation strategy, calculation, and reporting methods. These include:

- Enforced standardisation.
- Workforce, training, and retention.

A benefits register template has been provided to outline how benefits may be tracked. Again, as the project progresses toward maturity and implementation, this register may need to be refined and update. However, it should serve as an adequate starting point.



BenefitsRegistersv2.

d) Set out the expectations for Post-Project Evaluation, and

The Project Board once established will meet on a regular monthly basis to provide continuous monitoring of the project. As part of a recurring item on the Project Board meeting agenda, post-project evaluation (PPE) will be regularly conducted, reviewed, and is set as a priority for

the expected timescales for the review of delivery.

all board members to provide feedback on the project throughout the stages of implementation.

This practice will continue post go-live of the aseptics hub. and its partners will undertake PPE, in line with Green Book, NHS England / Improvement, and procurement framework requirements. PPE will enable the following to be reviewed, tracked, and monitored:

- **Business Case Development Review:** Following the completion of both business cases, reviews will be completed between the project delivery team and working group to ensure successful completion of the necessary activities and all lessons learned have been captured.
- **Implementation Review:** Following successful implementation and delivery of the new aseptics facility, an implementation review will be conducted, to assess the specific aspects of implementation and lessons learned for any future implementation programme.
- **Benefits Tracking:** The project's SRO will retain overall responsibility for ensuring benefits' realisation and the PPE will ensure that the project's planned benefits and aims are realised and will measure the extent to which they are realised.
- **Risk Management:** The project's SRO will retain overall responsibility for managing risks and issues which develop over the course of the project and will ensure these are tracked and mitigated successfully in line with PPE requirements.

The project board will define a dedicated PMO function allocated to this project and will commit to ensuring PPE and the activities outlined are completed.

Appendix 1 – Additional Programme Detail

APPENDIX 1: ADDITIONAL PROGRAMME DETAIL	
The approx. population size of your ICS that your hub will cover?	Approximately 1 million
How many hospitals and ICS areas will you be supplying?	Two trusts (multiple sites including the Weston General Hospital) and BNSSG ICS initially with aims to supply to wider parties.
The number of spoke units the hub will support?	Three <ul style="list-style-type: none"> - UHBW - Weston General Hospital will shift its reliance from third-party producers entirely to the new hub facility (unless strategically chosen medication lines retained for third-party outsourcing). - North Bristol Trust to continue on-site bespoke production, but with greater reliance on the new hub facility. - UHBW – Bristol Hospitals (7 sites) to continue on-site bespoke production on site but will shift majority of production operations to the new hub facility.
The range of products, e.g. PN, chemo etc. you will produce?	Core products will consist of parenteral nutrition, chemotherapy, immunotherapy, ATMP/genomic therapy and CIVAS products.
What are your plans for production of standardised products?	<p>The hub would be designed to be able to output a limited number of specifically commissioned high volume activity lines of standardised products as directed by NHSE.</p> <p>All the output from the hub will be standardised in its nature and made under license to allow onward supply to other NHS organisations. Products will be produced in dose bands as recommended by NHSE where this is available; any newer medications produced that do not yet have a national consensus will be manufactured according to an agreed specification as defined by the project board after consultation with other key stakeholders.</p> <p>All CIVAS products will also be standardised, agreed by the overarching clinical reference group which will work closely with National Infusions & Special Medicines Groups and system level antimicrobial stewardship groups. Any changes or amendments to the range of products will require consideration and agreement by the group. Clinical leads will liaise with colleagues in the British Society of Anti-microbial chemotherapy and use connections with other key groups to ensure that the presentations reflect the latest best practice.</p>
What is your workforce plan to support the projected production capacity of the facilities	<p>Workforce Considerations</p> <p>There is a well understood risk to the existing workforce in establishing a new large workforce for the hub. To mitigate this, the hub would be fully licensed and the use of a novel workforce is being promoted, such as expanded roles SMT apprenticeship graduates and for science graduates to reduce reliance on registered pharmacy staff.</p> <p>Already, project staff have liaised with the staffing working groups to consider the factors that could improve the effectiveness of staff recruitment and retention.</p> <p>Work Planned</p> <p>Consolidation of the learning and themes established is underway and meetings for 2023 have been planned. The workforce group will now look to define the required outputs and implement the required task and finish groups to deliver these.</p>
What are your plans for use of automation, digital and other technology?	<p>Technology considerations have primarily focused on ensuring that the facility is fit from a regulatory standpoint, especially in the context of the upcoming GMP Annex 1 considerations which will be mandatory from August 2023.</p> <p>Market scanning has been undertaken with the adoption of full automation deemed non-viable within the time frames of the project due to regulatory restrictions and technology efficiency. However, as the clean room designs are refined, considerations of future ways of working including integration of new technologies and automations suites with minimal disruption to over</p>

Anticipated operational hours to deliver the projected capacity?	Workforce modelling has been completed based on operational hours of 7am-7pm, Monday-Friday. This model maximises the standard working hours for NHS agenda for change and therefore ensures the best value for money with respect to workforce costs. This also allows for future expansion of capacity by extending the operating hours to include weekends and bank holidays. Any changes to the operating model will be undertaken through consultation and overseen by the board.
Contingency plans to mitigate risk of major site failure?	Extensive work has been done to consider contingency plans in the event of site failure. The first major decision was the retention of onsite minor production facilities to reduce entire reliance on the new hub facility thus mitigating this site failure risk.

Appendix 2 – Schedule of Works (to be attached by Trust)

Appendix 3 – OB Forms (to be attached by Trust)

Appendix 4 – Key Estates Information [to be evaluated and adjusted for each individual programme]

KEY ESTATE METRICS	
Total Area of Building m ²	TBC
New build clinical GIA m ² and % of total GIA	N/A
New build non-clinical GIA m ² and % of total GIA	N/A
Refurbishment clinical GIA m ² and % of total GIA	TBC
Refurbishment non-clinical GIA m ² and % of total GIA	TBC
No. of beds and type	N/A
PFI Estate Implications <ul style="list-style-type: none"> - Is the build on an existing PFI Estate? - Does the build interface with any PFI Estate? - Are there any other implications with the PFI Contract that need to be considered? 	N/A
MMC (Modern Methods of Construction) Status. Percentage to be achieved and brief overview	N/A
Summary of any significant derogations and assurance (derogations template is available)	N/A
£ Reduction in BLM	N/A
Any temporary accommodation required – provide details	TBD
Is a land purchase required – provide details	No.
Is this an owned or leased facility – provide details if leased	Lease (TBC) – Intention to negotiate break clauses for year 10, 15, 20 as part of overall 25 year lease.
Stage of design development and trust approval (please attach design drawings)	TBC
Estimated average lifecycle costs £/m ² over asset life	TBC

Meeting of the Council of Governors on Thursday 23rd November 2023

Report Title	Nominations and Appointments Committee Report
Report Author	Mark Pender, Head of Corporate Governance
Executive Lead	Eric Sanders, Director of Corporate Governance

1. Report Summary

This report provides a summary of the recent business of the Governors' Nominations and Appointments Committee.

This is a formal Committee of the Council of Governors to enable governors to carry out their duties in relation to the appointment, re-appointment, removal, remuneration and other terms of service of the Chair and Non-executive Directors.

2. Key points to note

A meeting of the Nominations and Appointments Committee was held on Wednesday 8th November 2023. The meeting was attended by seven Committee members and was Chaired by Jayne Mee, Trust Chair. The meeting discussed various items:

1. Non-Executive Director Appraisals

The appraisals of Roy Shubhabrata, Marc Griffiths and Arabel Bailey were discussed, and Jayne Mee provided an outline of the conversations held. Members noted the positive contribution of the Non-Executive Directors and discussed areas for development.

2. Non-Executive Director Activity Reports

All Non-executive Directors provided an activity report detailing their activity in the Trust between May 2023 and November 2023.

3. Review of Non-Executive Director Roles

The membership of Board Sub-Committees and Champions roles were reviewed by the Nominations and Appointments Committee.

4. Non-Executive Director (NED) Recruitment

Following the known end of offices for Jane Norman and Bernard Galton, it was agreed to hold a round of recruitment for two NED positions. The group was provided an outlined timetable and discussed the recruitment process. The skills mix was discussed and Members supported the recruitment of a NED with an HR background and a NED with a financial background who would also Chair the Audit Committee. Members of the Committee resolved to note the proposed role descriptions and proposal for Non-Executive Director recruitment; endorse the approach and the timeline for recruitment and approve use of an External Recruitment Agency for the recruitment process to commence.



**University Hospitals
Bristol and Weston**
NHS Foundation Trust

Next Meeting: 2 May 2024 (although the Committee agreed an Extraordinary Committee will need to be convened once the recruitment process was nearing its end).

3. Advice and Recommendations

- This report is for **Information**.



Meeting of the Council of Governors on Thursday 23rd November 2023

Report Title	Governor Activity Report and Membership Forward Look
Report Author	Emily Judd, Corporate Governance Manager
Executive Lead	Eric Sanders, Director of Corporate Governance

1. Report Summary

This report provides a summary of governor activity since the last Council of Governors meeting, to provide assurance that governors are carrying out their statutory duties, particularly their duty to hold the Chair and Non-Executive Directors to account.

It includes an activity summary for the three main groups through which the governors carry out most of their work (the Governors' Strategy Group, the Quality Focus Group and the Membership and Constitution Group), and any other governor activity in the period.

2. Key points to note (Including decisions taken)

Since the last Council of Governors meeting on 29th June 2023, we have welcomed three new Governors: Lisa Gardiner (Staff, Non-Clinical), Maisy McCollum and Grace Burn (Appointed – Youth Involvement Group). Mary Conn (Public – Bristol), is also due to leave us for a short period from December for maternity leave.

GOVERNOR MEETINGS

Governor Group Reports: Most governor work is carried out through three Governor Groups, the Quality Focus Group, the Governors' Strategy Group, and the Membership and Constitution Group. Each group receives reports from each of the Non-Executive Chairs of the Board Committees to allow governors to stay informed of the Board's main areas of focus and to enable them to carry out their statutory duty to hold Non-Executive Directors to account.

1. Quality Focus Group

There has been three meetings of the Quality Focus Group since the last report. Agenda items included the Wellbeing Biannual Report; the Equality, Diversity and Inclusion Biannual Report; a Patient First Introduction; a welcome to the new Joint Chief Digital Information Officer; the Outpatient Strategy Update; the Experience of Care Quality Objective Update; the National Survey Outcomes and the new Respecting Everyone Framework. Other agenda items included updates from the Quality and Outcomes Committee Chair's Report and the People Committee Chair's Report as well as Governor Lay Representation on the Experience of Care Group, the Health Equity Delivery Group and the Accessible Information Standards Working Group.

2. Governors' Strategy Group

There has been one meeting of the Governor Strategy Group since the last report. Agenda items included updates on the Strategic Initiatives; Working with Health and Care Improvement Groups and a deep dive into the Pharmacy Technical Services Business Case. An update was also received from the Chair of the Finance and Digital Committee.

3. Membership and Constitution Group

There has been one meeting of the Membership and Constitution Group since the last report. Agenda items included a membership report, Membership Strategy Planning, details on the Annual



Members Meeting (held in September 2023), a Media and Health Matters Update and a discussion on Meeting dates.

Other governor meetings and activity in the period included:

Annual Members' Meeting: Our Annual Members' Meeting was held on Tuesday 12th September in the Education and Research Centre. There was a positive turnout, with around 50 Governors, Board members and Members of the public attending to hear the updates on our last 12 months and plans for the next 12 months.

Governor Development Seminars: The Trust has a duty to provide its governors with training for their role, and so holds regular seminar days for governors. The last seminar for the Governors was held on Wednesday 11th October and included updates from each of the Trust Divisions on their successes and challenges.

Public Board Meetings: A number of governors watched the recent meetings of the Board of Directors on 12th September and 14th November, to observe the Board conducting their business.

PLACE Assessments: The Governors have been invited to partake in the yearly Patient Led Assessment of the Care Environment (PLACE) around the Trust, looking at the environment and how this supports the clinical care given to patients. PLACE Assessments have been running through September until the end of November and Governors will receive outcome action plans in March 2024.

MEMBERSHIP TEAM FORWARD LOOK

Over the next quarter, The Governors will have a variety of meetings (Quality Focus Group, Membership and Constitution Group), and Non-executive Director Engagement sessions.

Membership Strategy: The team is looking to refresh the Membership Strategy for the next three years and is consulting with the Communications Team on a fresh look for the strategy. The team hope to be able to launch the strategy in 2024 after engaging with the Governors at the next Membership and Constitution Group.

Governor Community Drop-in Sessions: The team is looking to organise drop-in sessions for our different constituencies to improve and the develop the connection between the community and our governors.

Elections: The team is anticipating a further election in 2024 for the Staff Governor vacancy in Medical and Dental and the Public Rest of England and Wales constituency.

Meeting Dates for 2024-2025: The dates for meetings in 2024-2025 have now been finalised and released to Governors; these are also attached in appendix A.

Advice and Recommendations

- The Council of Governors is asked to **note** this update for information.

Month of Meeting	Bank holidays/ school holidays	Trust PUBLIC Board	Council of Governors	Governors/ NED Engagement Session	Nominations and Appointments Committee	Quality Focus Group	Membership and Constitution Group	Governors Strategy Group	Governor Development Seminar	Staff Governor Meetings
Usual meeting day		Tuesday	Tuesday	Tuesday/Thursday	Various	Various	Various	Various	Various	Various
Time		13.45 - 16.45		Govs- 11.30-13.45* NEDs- 12.45-13.45*	See below	10.00-12.00	13.00- 15.00	13.00-15.00	10.00-16.00	10.00-11.00
Apr-24	29 Mar 1 Apr 28 Mar-15 Apr			Tue 30 Apr Virtual					Wed 17 Apr Conf Rm, THQ	
May-24	6 May 27 May 24 May-3 Jun	Tue 14 May City Hall, Bristol	Thu 23 May 14.00-16.30 Conf Rm, THQ		Thu 2 May 10.00-11.30 Virtual	Wed 8 May Conf Rm, THQ		Wed 8 May Conf Rm, THQ		
Jun-24	24 May-3 Jun			Tue 25 Jun NEDs join 12.45-13.45 Conf Rm, THQ					Tue 18 Jun Conf Rm, THQ	Mon 24 Jun 2.00-3.00 Virtual
Jul-24	23 Jul-2 Sep	Tue 9 Jul City Hall, Bristol	Tue 16 Jul 10.00-12.30 Conf Rm, THQ			Tue 2 Jul Conf Rm, THQ	Tue 2 Jul Conf Rm, THQ		Thu 11 Jul Divisional Update Day Conf Rm, THQ	
Aug-24	23 Jul-2 Sep 26 Aug									
Sep-24	23 Jul-2 Sep	Tue 10 Sep City Hall, Bristol	Tue 10 Sep (AMM) 17.15-19.15	Thu 26 Sep Virtual		Thu 5 Sep Conf Rm, THQ		Thu 5 Sep Conf Rm, THQ		Mon 23 Sep 2.00-3.00 Virtual
Oct-24	25 Oct-4 Nov			Tue 22 Oct NEDs join at 12.30-13.30 Conf Rm, THQ					Wed 16 Oct Conf Rm, THQ	
Nov-24	25 Oct-4 Nov	Tue 12 Nov City Hall, Bristol	Thu 21 Nov 10.00-12.30 Conf Rm, THQ		Tue 19 Nov 13.30-15.00 Virtual	Fri 8 Nov Conf Rm, THQ		Fri 8 Nov Conf Rm, THQ		Mon 25 Nov 2.00-3.00 Virtual
Dec-24	25 Dec 26 Dec 20 Dec-6 Jan			Thu 12 Dec Virtual						
Jan-25	20 Dec-6 Jan 1 Jan	Tue 14 Jan Education Ctr	Fri 24 Jan 10.00-12.30 Conf Rm, THQ			Thu 9 Jan Conf Rm, THQ	Thu 9 Jan Conf Rm, THQ			
Feb-25	14 Feb-24 Feb								Thu 6 Feb Conf Rm, THQ	
Mar-25		Tue 11 Mar Education Ctr		Thu 27 Mar Virtual		Mon 3 Mar Conf Rm, THQ		Mon 3 Mar Conf Rm, THQ		Mon 24 Mar 2.00-3.00 Virtual
Frequency		Bi-monthly	4x per year	6 per year to fall on months without a COG	Twice a Year	Bi-monthly	Twice a Year	4x per year	4x per year plus 1 DUD	4x per year
Venue		Various	Conference Room for COG. Education Centre for AMM	Virtual	Virtual	Hybrid	Hybrid	Hybrid	Hybrid	Virtual
Chair		Jayne Mee	Jayne Mee	Jayne Mee	Jayne Mee	Carole Dacombe	Mo Phillips	Martin Rose	Emily Judd	Eugene Yafele

Face to face session

Meeting of the Council of Governors on Thursday 23rd November 2023

Report Title	Governors' Log of Communications
Report Author	Mark Pender, Head of Corporate Governance
Executive Lead	Eric Sanders, Director of Corporate Governance

1. Purpose	
The purpose of this report is to provide the Council of Governors with an update on all questions on the Governors' Log of Communications and subsequent responses added or modified since the previous meeting. The Governors' Log of Communications is a means of channelling communications between the governors and the officers of the Trust.	
2. Key points to note <i>(Including any previous decisions taken)</i>	
Since the previous Board of Directors meeting held in public on 12 th September:	
<ul style="list-style-type: none"> One question has been added to the Governor's log relating to Oliver McGowan training. This question has also been answered and closed. 	
3. Strategic Alignment	
N/A	
4. Risks and Opportunities	
None	
5. Recommendation	
This report is for Information	
6. History of the paper	
Please include details of where paper has <u>previously</u> been received.	
Trust Public Board	14 th November 2023

Governors Log November 2023

Governors questions reference number	Coverage start date	Governor Name	Governor Constituency	Description	Executive Lead	Coverage end date	Response	Status
285	18/09/2023	Ben Argo		Please could you provide an update on the rollout of Oliver McGowan mandatory training on learning disabilities and autism?	Chief People Officer	16/10/2023	The BNSSG ICB is leading the implementation of the Oliver McGowan mandatory training with an NHSE forecast target of 33% compliance by September 2024. The Trust has implemented the part 1 eLearning package into the Learning Management System, currently 5,640 Trust staff have completed the online programme. An initial pilot audience of clinical staff was identified to attend part 2 of a training programme, offered by the ICB, which commenced at the start of October. Part 2 is face-to-face training and uptake of the training offer has been high across the ICB, to date121 Trust staff booked onto sessions. Attendance to the part 2 sessions will be passported into the learning management system to enable the recording of overall compliance.	Closed



Fast access to reliable
health advice



Effective treatment
delivered by trusted
professionals



Clear information,
communication, and
support for self-care



Involvement in
decisions and respect
for preferences



Continuity of
care and smooth
transitions



Involvement and
support for family
and carers



Emotional support,
empathy and respect



Attention to physical
and environmental
needs

Please use the tabs along the top
to navigate through this report



University Hospitals
Bristol and Weston
NHS Foundation Trust

Experience of Care Quarterly Report

Quarter 1 2023/24
(April 2023 - June 2023)

Report author:
Matthew Areskog, Head of Experience of Care & Inclusion

Successes

UHBW has been shortlisted for four projects at the National Patient Experience Network Awards 2023. The awards ceremony takes place on 28th September in Birmingham.

The Inpatient experience tracker score and kindness and understanding tracker scores were above target during Q1 2023/24. For Specialised Services and Maternity Services, the inpatient experience score and kindness and understanding score in Q1 2023/24 were above their averages from 2022/23.

FFT scores for inpatients, day cases, maternity and outpatients remain positive, all greater than or equal to 95% in Q1 2023/24. FFT scores in the Trust's emergency departments have remained stable from Q4 2022/23 to Q1 2023/24.

BRI ED performed in the top 10% of Trust's nationally for overall experience in the 2022 National Urgent and Emergency Care (UEC) Survey Results.

Priorities

Patient First – Experience of Care deployment.

Patient Experience Hub – commence weekly uploads for FFT and monthly survey programme into the Hub for more timely feedback. Continue to embed use of the Hub within Divisions.

BRI ED to continue to implement their patient experience action plan which has been updated to reflect the results of the 2022 National UEC Survey.

WGH ED to draft a patient experience action plan based on the findings of the local 2022 UEC Survey.

Analysis of the 2022 National Cancer Patient Experience Survey results following their publication at end of July.

Risks & Threats

Although the Outpatient experience tracker score was above target during Quarter 1 2023/24, it has been falling since October 2022 which has been flagged to the Outpatient Services Manager.

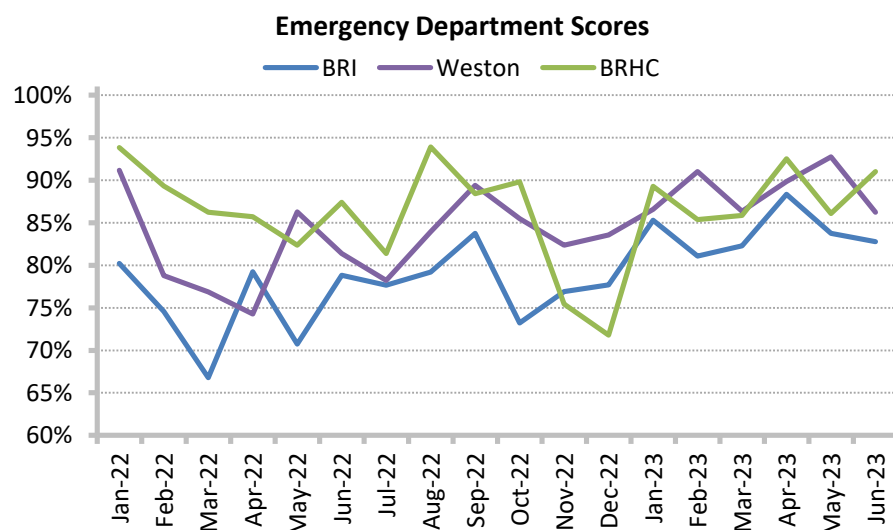
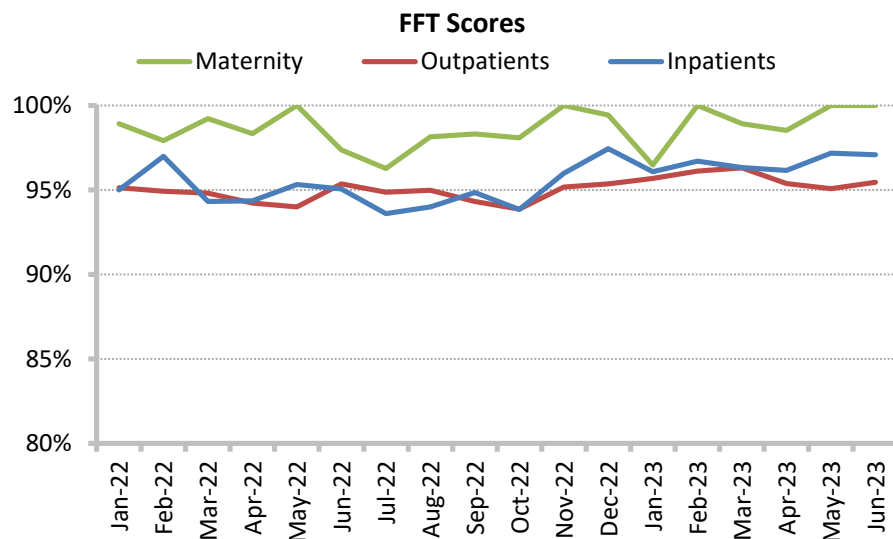
The inpatient experience tracker score and kindness and understanding score were below target for Division of Medicine during Q1 2023/24 and slightly below their average fluctuation from 2022/23.

Opportunities

Phase 2 developments of the Patient Experience Hub planned for Q2 and Q3 2023/24 will allow for more automated functionality, such as alerting teams to declining performance and comments from patients with trigger words included.

The number of Divisions with 'local' Experience of Care groups is growing which provides an opportunity to strengthen governance across UHBW in this domain of quality and share learning and best-practice across teams, departments and specialties across the Trust (carried forward from previous report).

Friends and Family Test



What does this tell us?

FFT scores for inpatients, day cases, maternity and outpatients remain positive, all greater than or equal to 95% in Q1 2023/24.

FFT scores in the Trust's emergency departments have remained stable from Q4 2022/23 to Q1 2023/24. Scores during Q1 were above the ED national average (as below).

Actions planned or taken:

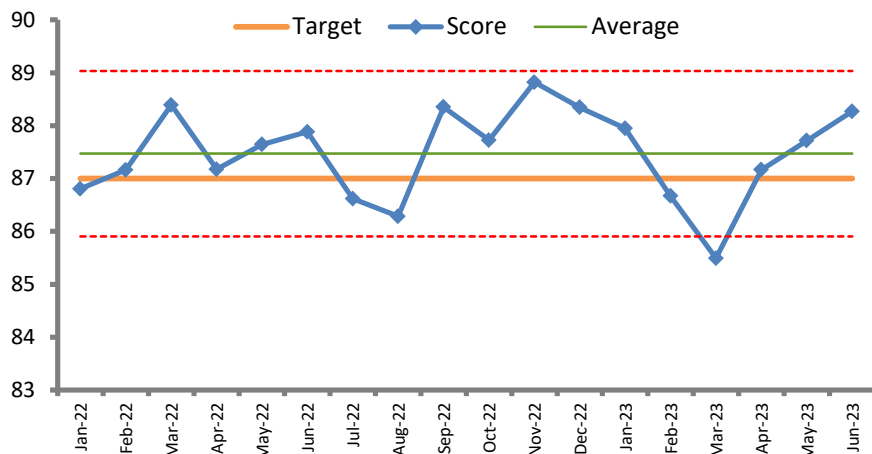
Weekly reports are provided to ED divisional leads with their FFT data for the previous week. This results in the data being reviewed in a more timely manner which supports with identifying opportunities for improvements.

National benchmarking for FFT Scores (NHSE data as at February 2023 – latest available)



Monthly Patient Surveys

Inpatient Tracker Score



What does this tell us?

The Inpatient experience tracker score fell below target during February and March 2023 but has since recovered and was above target during Quarter 1 2023/24.

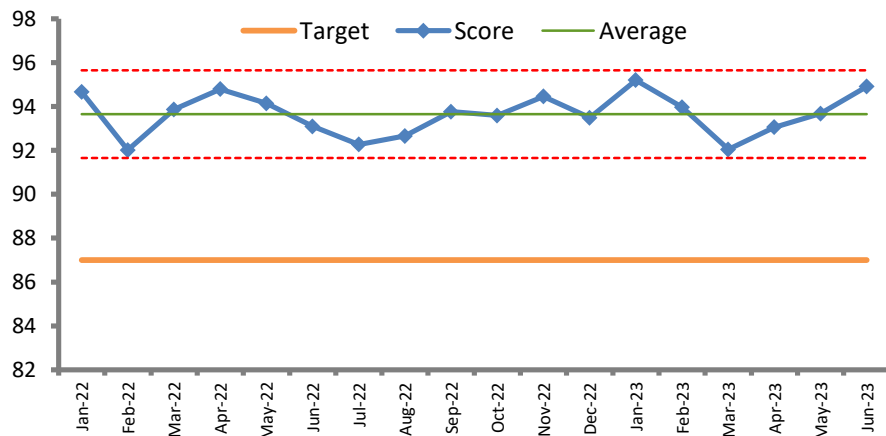
The Kindness and Understanding tracker score was above target during Quarter 1 2023/24 and within the normal expected range.

The Outpatient experience tracker score was above target during Quarter 1 2023/24 although it has been falling since October 2022.

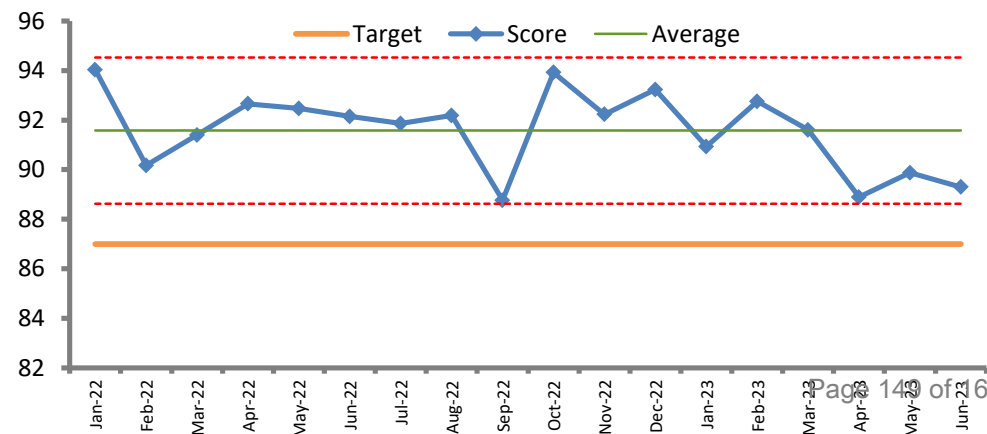
Actions:

Head of Experience of Care & Inclusion has contacted the Trust's Outpatient Services Manager to alert them regarding the declining Outpatient experience tracker score and to identify any drivers / potential remedial actions for this.

Kindness and Understanding Score



Outpatient Tracker Score



National Patient Surveys

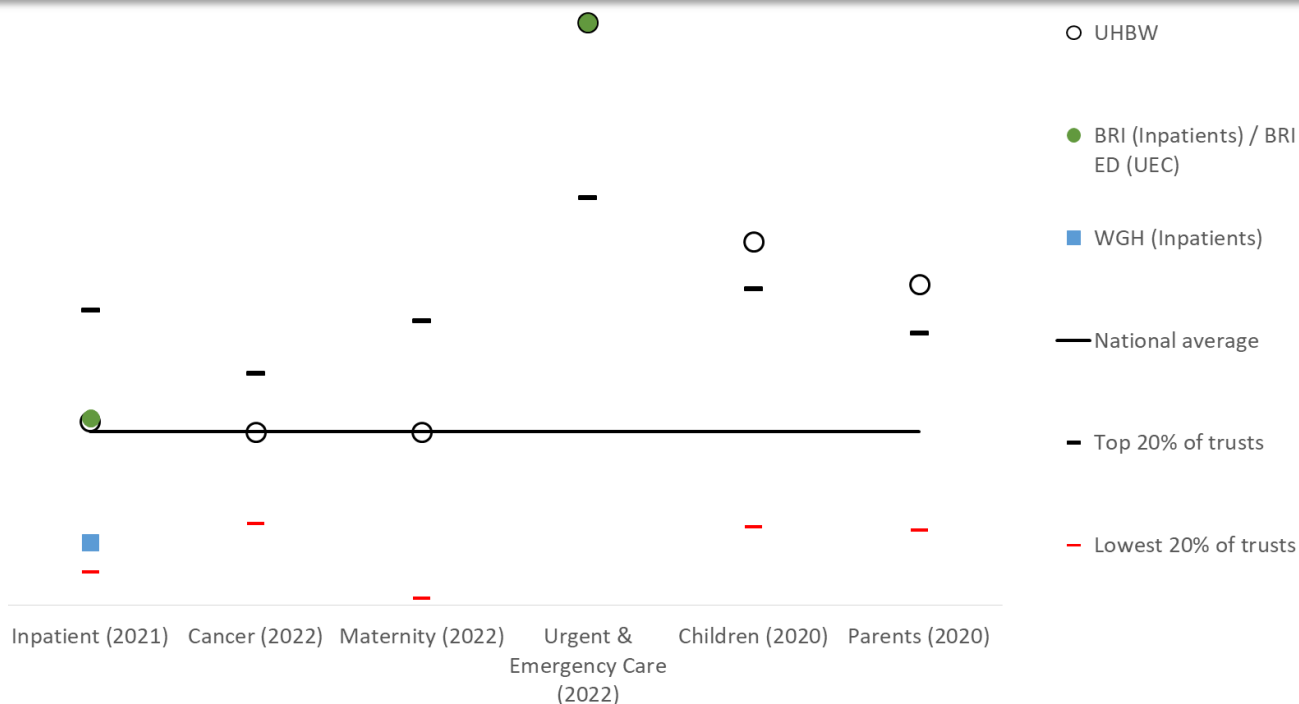
What does this tell us?

UHBW performs in line with the national average in the Inpatient, Maternity and Cancer experience surveys. UHBW performs in the top 10% of Trusts nationally in the National Urgency and Emergency Care Survey (BRI ED), and in the top 20% of Trusts in the Children and Young People survey.

Since the last quarterly report, this chart has been updated with the results of the 2022 National Urgent and Emergency Care Survey (overall experience improved since 2021) and the 2022 National Cancer Patient Experience Survey (remained in a similar position to the results of the 2021 survey).

Actions: The 2022 National Urgent and Emergency Care Survey results were published in July 2023 and have been shared with the BRI ED management team. A local survey was undertaken for WGH ED with the results showing a small decrease in the overall experience question. It is not possible to make comparisons of the results for Weston to the national benchmarking report due to how the results are calculated. A patient experience action plan is in place for BRI ED and WGH ED.

Assurance on the delivery of action plans arising from national patient surveys takes place in the relevant Division (with the exception of the national adult inpatient survey which is Trust-wide) plus a 6-month update to Experience of Care Group.



Thematic Analysis

**The Picker principles were developed based on evidence from across Europe and the USA on what patients and carers tell us matters most in delivering person-centred care in a healthcare context.*

What does this tell us?

The questions in the monthly surveys for inpatients, outpatients and maternity are mapped to the Picker Principles of Person-Centred Care*. The Picker principles provide us a framework for theming patient feedback and for monitoring trends over time. The data shown here is for Quarter 1 2023/24 at Trust-level and includes inpatients, outpatients and maternity services. There is no comparison to previous data at this stage. This is because the monthly surveys were refreshed with new versions in place from April 2023. In addition, the survey methodology was modernised to provide digital / phone options for completion (as well as paper surveys for some older groups). The maximum score is 100 for each theme. The data can be broken down to Division and Speciality and ward/department level.

Actions: A quarterly trend over time will be reported from the Quarter 2 Experience of Care report.

Surveys	Involvement in decisions and respect for preferences	Clear information, communication and support for self-care	Involvement and support for family and carers	Continuity of care and smooth transitions	Effective treatment by trusted professionals	Fast access to reliable healthcare advice	Emotional support, empathy and respect	Attention to physical and environmental needs
→	→	→	→	→	→	→	→	→
1737	71.66	86.80	88.92	74.33	89.80	73.38	91.70	84.69



"The only frustration with my stay was that I wasn't seeing the same doctors so I was having to repeat the same things over and over about my symptoms. I've lived with my illness and I know what does and doesn't work."

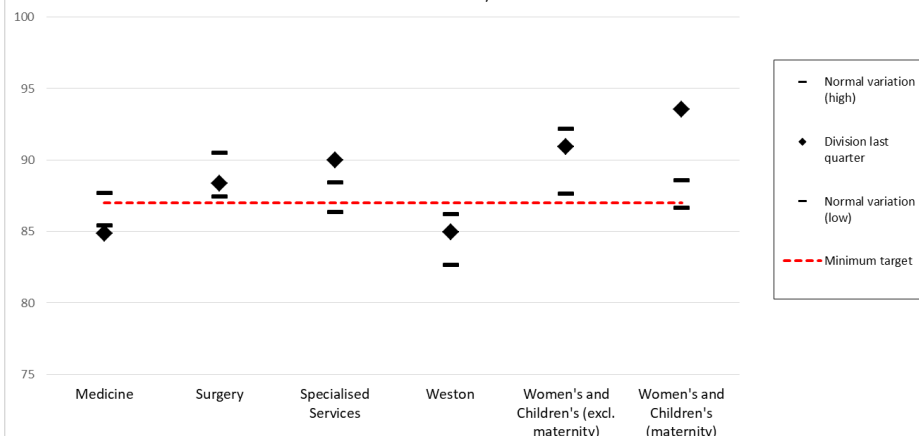
"Sometimes communication didn't seem to happen between colleagues or changes in shifts or documents hadn't been filled out in handover so I had to clarify that I had moved from IV antibiotics to oral."

"I would like to express my sincere thanks to Dr (*name removed*) and her two nurses for their genuine kindness and understanding that they gave me during my appointment. To say I was emotional and anxious before and during my appointment was a huge understatement."

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Divisional experience metrics

Q1 2023/24 Divisional-level inpatient experience "tracker" scores, compared to the average fluctuation from 2022/23



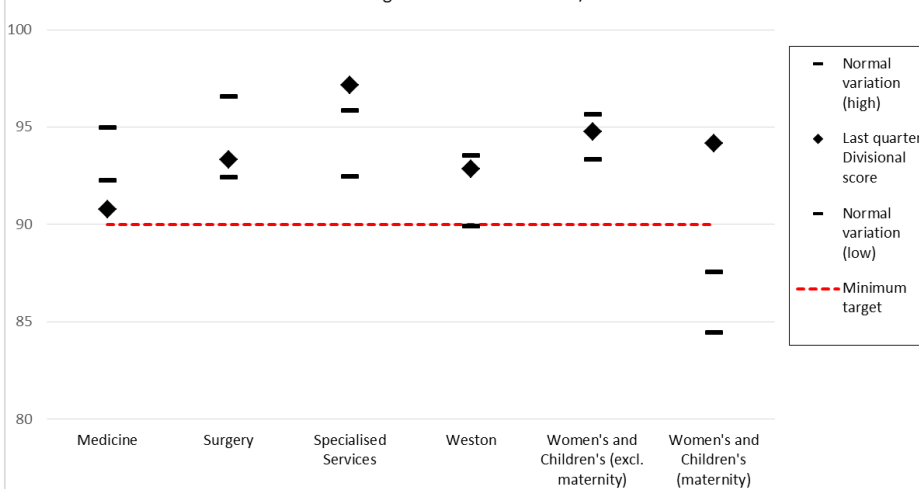
What does this tell us?

The inpatient experience tracker score and kindness and understanding score were below target for Division of Medicine during Q1 2023/24 and slightly below their average fluctuation from 2022/23. Director of Nursing for the Division of Medicine is reviewing this data at a ward level to identify next steps.

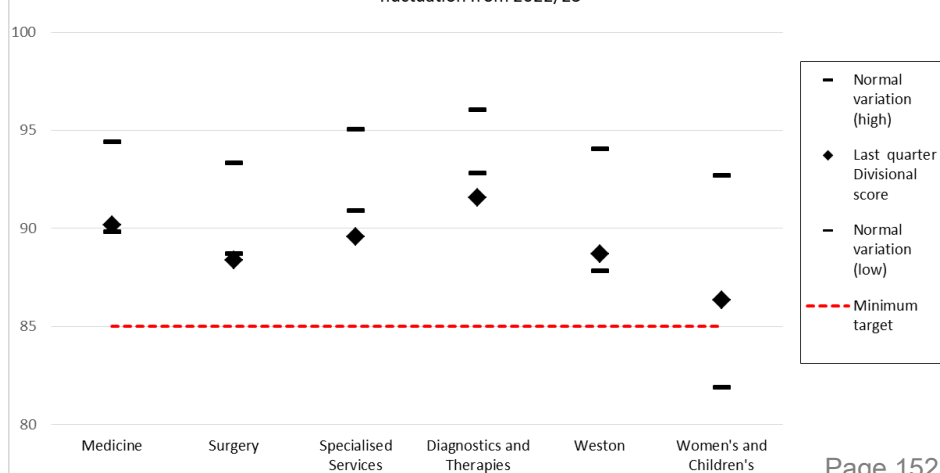
For Specialised Services and Maternity Services, the inpatient experience score and kindness and understanding score in Q1 2023/24 were above their averages from 2022/23.

Outpatient experience tracker scores are above target in all Divisions although scores in all Divisions (with the exceptions of Women's and Children's) are tracking towards the lower end of the average fluctuations seen during 2022/23.

Q1 2023/24 Divisional inpatient "kindness and understanding" scores compared to the average fluctuation from 2022/23



Q1 2023/24 Divisional outpatient experience tracker scores compared to the average fluctuation from 2022/23



"There seemed to be a real lack of communication so I ended up being stuck for another day in hospital which wasn't needed. Nurses let me eat, then doctors said I shouldn't have because of the ultrasound I had. I wasn't offered a gown or anything to clean myself. I was admitted from A&E so had nothing with me." *Patient, Steepholt Ward, May 2023.*



1. Matron has spoken to team to re-iterate that the nurse responsible for each patient must greet the patient on arrival to ensure they know their named nurse.
2. Named nurse will orientate patients to ward offering toiletries / clothing.
3. Ward Manager contacted consultants to liaise with their teams regarding communication between patients and nursing staff, to ensure that when they tell patients that they can be discharged, their expectations are managed.

"I would have found it useful if I was given a leaflet about miscarriage on discharge. I was given my discharge summary and no other useful resources that I could've read." *Patient, Ward 78, April 2023.*



1. Additional leaflet holders stocked with a variety of leaflets are being installed on the ward for patients to access.
2. Staff have been reminded to provide leaflets and other relevant resources to patients for additional support.

"Some Nurses appeared unapproachable and lack empathy. Son could be in room for hours without seeing a nurse. One occasion it took multiple times of asking for faeces to be removed from room (sample in bed pan). There was no introduction as to who was named nurse etc. Nurses didn't take time to talk to my son really other than to ask the questions they had to. Play therapist was excellent." *Parent, Apollo Ward, May 2023*



1. Ward sister used this feedback as a theme for a Ward meeting to ensure staff are aware of this experience in order to reflect and learn.
2. Ward sister created a Ward Welcome Sheet for external staff (bank and agency) in order that they are consistently aware of expectations of them.
3. Ward sister has been actively involved in Health Care Support Worker recruitment with the aim to be fully recruited to for this staff group who support a range of fundamental ward tasks including liaising with patients / parents to meet their needs holistically.

Spotlight on improvement initiatives from Divisions

Specialised Services

A newly qualified staff nurse on D603 has taken on the role of patient experience lead for the ward. The role includes acting as an ambassador for understanding and improving patient experience. Feedback on the Patient Experience Hub is regularly reviewed by the nurse who ensures it is fed back to the ward team routinely and in a timely way. The nurse also ensures patients have the Friends and Family Test card available to complete. As part of their role, the nurse has reinstated a welcome pack to the ward, which includes information on what to expect each day and key information leaflets on reducing risks of falls and pressure sores. As part of the routine review of the Patient Experience Hub, noise at night was identified as a common issue for patients. As a result, a noise at night poster aimed at staff is now displayed across the ward and patients have been provided with eye masks and ear plugs in their welcome pack.

Surgery

The Surgical Day Case Unit (SDCU) has developed an environment improvement programme specifically aimed at improving the experience for patients with a Learning Disability and those with Neurodiversity. SDCU are formally launching this in August. Two other areas in Surgery – GA theatres for paediatrics and our Surgical Trauma and Assessment Unit – are following SDCU's example.

Maternity

As part of the Black Maternity Matters programme, Maternity services have ordered bouffant theatre caps for patients' partners who have afro or braided hair and need to go into theatre for the birth of their child to ensure the service is culturally inclusive.

Spotlight on improvement initiatives from Divisions

Weston

Draycott Ward introduced a patient well-being/experience initiative in June which sees staff taking patients off the ward, helping especially with the patients with dementia where their sleep cycle may be affected. The ward team are aiming to improve sun-downing by giving exposure to sunlight, improving melatonin. The team also play games with patients, paint nails and use equipment bought for the ward with funds to interact with patients. Tea parties with Kewstoke ward commenced in August.

Kewstoke Ward is introducing well-being walks with staff and patients to improve and continue rehabilitation. The ward staff are also part of the wider 'early-risers' group of ward teams who are working hard to ensure patients are getting up and dressed. Kewstoke is introducing activities for patients to keep them motivated. Tea parties with Draycott ward commenced in August.

Uphill Ward has introduced a lunch time co-ordinator to assist with helping patients chose their own meal options by assisting them to the lunch queue and helping them carry their food choices back to their bedside. They are aiming to improve rehabilitation and nutrition, recognising that mealtimes are a very important part of recovery and often an important part of the day when someone is in hospital. This will also help the therapists when planning support on discharge, as they will know what equipment might be recommended if adaptations are required such as wheeled trollies.

Knightstone Ward is aiming to improve the rehabilitation and enhanced recovery of patients by getting them involved with achieving their targets. Each patient will have individualised goals, which will be on a white board on their room door. They will have access to whiteboard markers and will be able to walk to the door and mark of the achieved criteria. In order to achieve improved response rates with the Friends and Family Test this is also being added to each patient's criteria for discharge goal.

Trust-wide Experience of Care Development Priorities

Achievements in Quarter 1 2023/24

- Patient First - Baseline analysis complete for 2022/23 for all Divisions and ward areas. Inpatient care and Maternity services in scope. Project Charter complete. Governance structure forming although yet to be finalised.
- Patient Experience Hub: we have refreshed our monthly surveys for inpatients, outpatients and maternity and have tagged questions to themes using the Picker Principles of Person-Centred Care
- Experience of Care Strategy engagement plan and timeframe agreed with Chief Nurse & Midwife culminating in Board approval in March 2024.
- Five volunteers have been recruited to the My Journey team with an initial focus to gather feedback to support improvements to Enhanced Care Observations in August/September.

Priorities for Quarter 2 2023/24

- Patient First - Experience of Care deployment. Catch-ball conversations between Exec team and Divisions to follow from September onwards.
- Design and launch of new 'You said, we did' poster template for ward areas and outpatient departments.
- Patient Experience Hub: timely feedback – commence weekly uploads for FFT and monthly survey programme into the Patient Experience Hub.
- Embed 'My Journey' volunteers in clinical accreditation programme.



Let's make
complaints
count!

Complaints Quarterly Report

Q1 (April 2023 - June 2023)

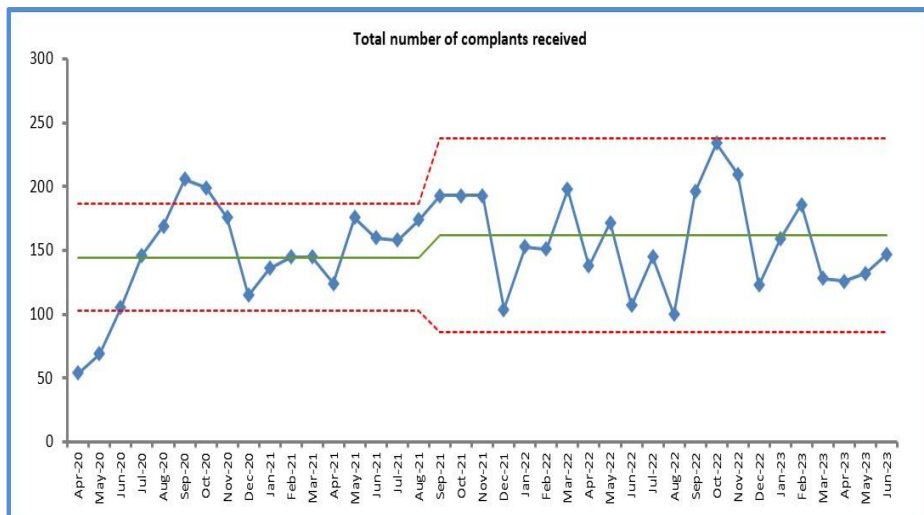
Report author:
Tanya Tofts, Head of Complaints

Please use the tabs along the top
to navigate through this report

Total complaints received	405	↓
Complaints acknowledged within set timescale	86.5%	↓
Complaints responded to within agreed timescale – formal investigation	67.1%	↑
Complaints responded to within agreed timescale – informal investigation	85.6%	↑
Proportion of complainants dissatisfied with our response (formal investigation)	11.4%	↓

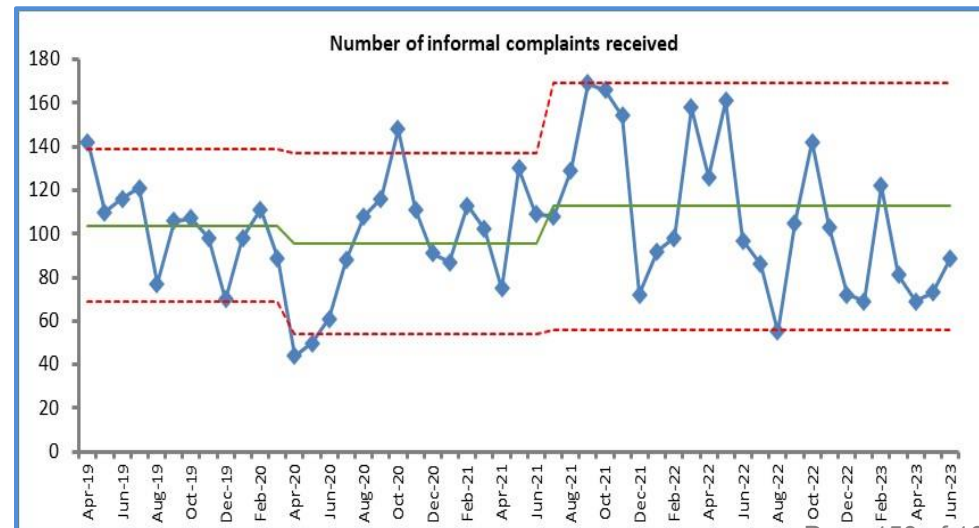
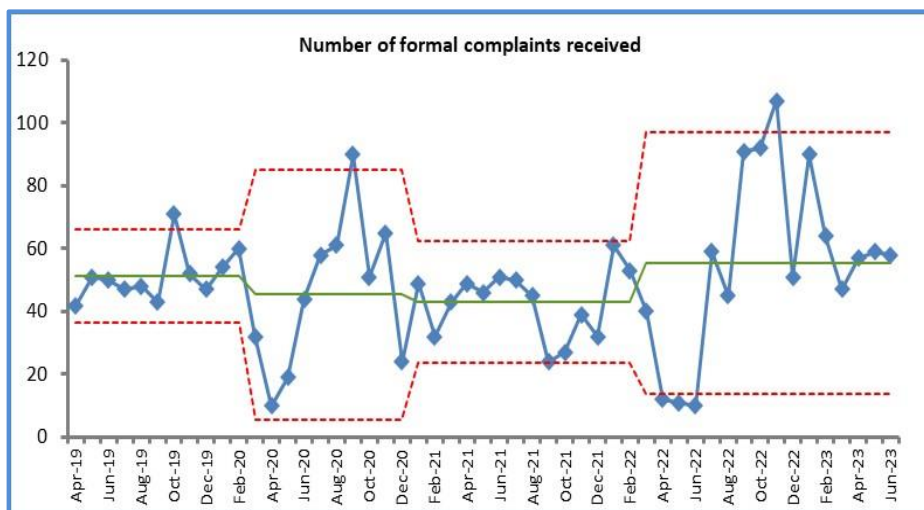
Successes	Priorities
<ul style="list-style-type: none"> The total number of complaints received by the Trust decreased (from 473 in Q4 to 405 in Q1) and the overall number of new enquiries dealt with by the Patient Support & Complaints Team (PSCT) also decreased (from 1,061 in Q4 to 848 in Q1). More than half (57%) of all complaints were dealt with via the informal investigation process, leading to quicker resolution for complainants. Divisional performance against targets for responding to complaints within agreed timescales improved. 	<ul style="list-style-type: none"> To clear the backlog of enquiries and complaints received by PSCT and waiting to be acknowledged and allocated to a complaints officer. To ensure consistent quality of draft complaints responses letters by offering high-quality training for divisional and corporate complaints staff. To continue to improve performance in sending out complaint responses by the deadlines agreed with complainants.
Risks & Threats	Opportunities
<ul style="list-style-type: none"> Throughout Q1, continuing into Q2, the PSCT has continued to operate with significant backlogs in respect of acknowledging new complaints and in cases waiting to be allocated to a caseworker. This has been due to high levels of staff sickness in the PSCT and the volume of new enquiries coming into the service. Data indicates a slow but steady upward trajectory in respect of the numbers of complainants advising us they are unhappy with our response to their complaint. Despite overall reductions in complaints received, complaints about staff attitude and communication increased in Surgery and Specialised Services. 	<ul style="list-style-type: none"> Since the end of Q1, the Trust has appointed a new Complaints Manager to work alongside the Head of Complaints. From 2nd October the PSCT will be re-branded as 'PALS & Complaints' and the drop-in service in the Bristol Royal Infirmary will be re-opened (the drop-in facility has been closed since the pandemic). Divisional complaints review panels will recommence from September 2023. The PHSO (Ombudsman) has developed a comprehensive training offer for NHS Trusts, supporting its 'principles of good complaint handling'

Complaints Received

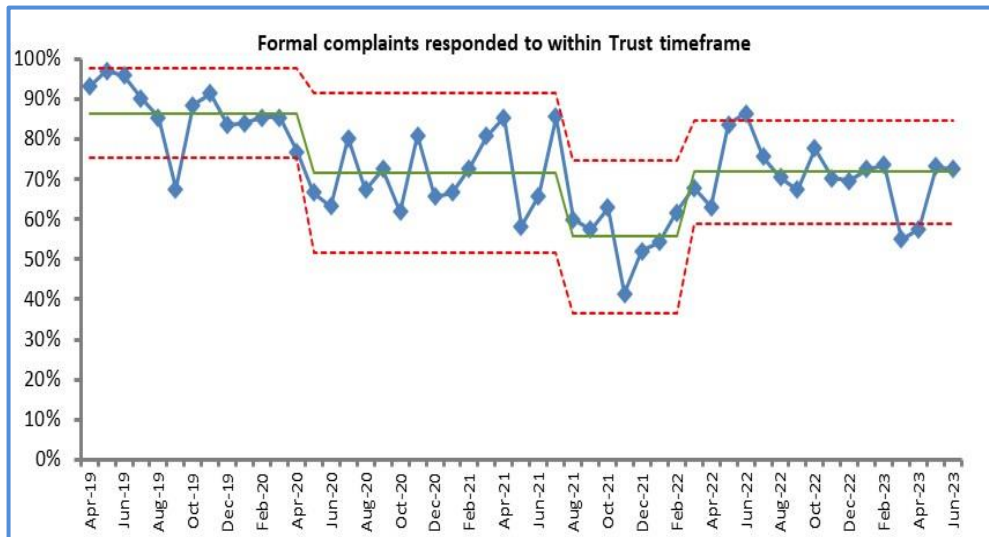


What does this tell us?

The Trust received 405 complaints in Q1 of 2023/24, a reduction on the 473 reported in Q4 of 2022/23. This total includes complaints received and managed via either formal or informal resolution (whichever has been agreed with the complainant) but does not include concerns which may have been raised by patients and dealt with immediately by front line staff. These charts provide assurance that the variation shown in terms of numbers of complaints received is relatively stable and predictable (common cause variation). The graphs also show encouraging signs of more complaints being investigated informally, enabling quicker resolution.



Divisional performance

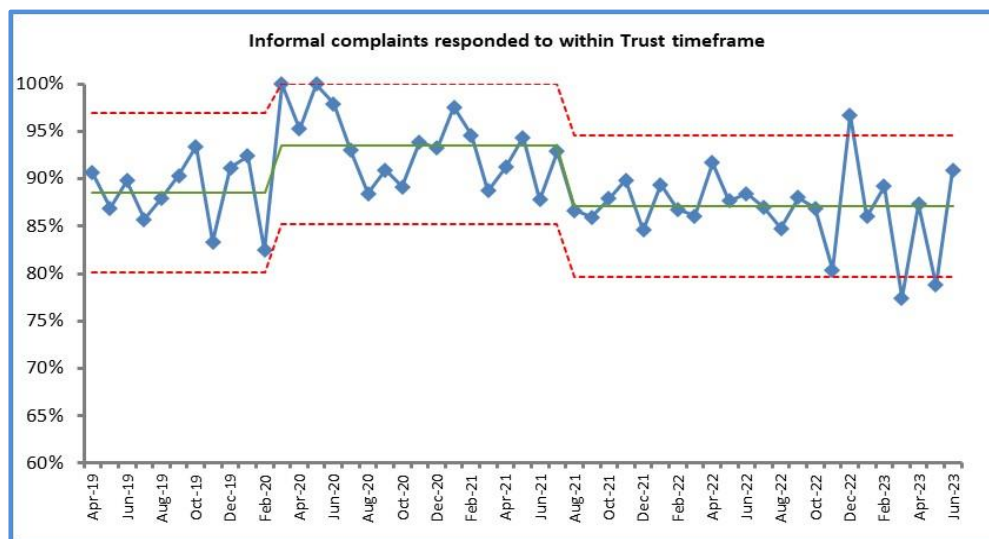


What does this tell us?

The Trust's target is for 95% of complaints to be responded to within the timeframe agreed with the complainant. This is usually 30 working days for formal complaints and 10 working days for informal resolution. However, in Q1, this was temporarily extended to 45 working days and 15 working days respectively, to allow for the additional operational pressures on divisions caused by ongoing industrial action.

In Q1, 67.1% of formal responses were sent out within the agreed timescale, meaning that 51 responses breached the agreed deadline. This compares with 66.7% in Q4 and 75.2% during the same period one year ago.

During the same period, 85.6% of informal complaints were resolved within the agreed timescale, with 28 breaches of the agreed deadline. This is a small improvement on the 83.2% reported in Q4 and compares with 88.8% during the same period one year ago.



Corporate performance – Patient Support & Complaints Team

Acknowledgement of new complaints

The NHS Complaints Procedure (2009) states that complaints must be acknowledged within three working days. This is also a requirement of the NHS Constitution. The Trust's own policy states that complaints made in writing (including emails) will be acknowledged within three working days and that complaints made orally (via the telephone or in person) will be acknowledged within two working days.

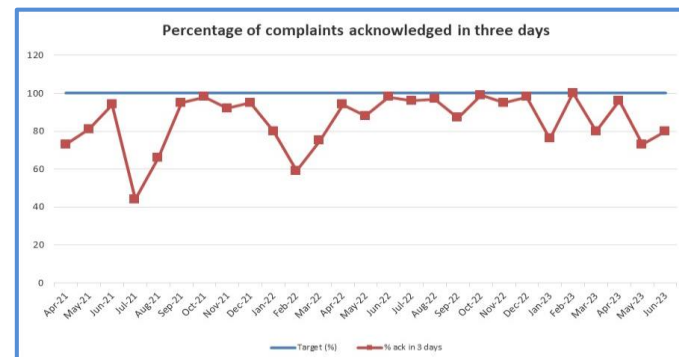
In Q1, the Patient Support & Complaints Team acknowledged 82.7% of all new complaints within the nationally agreed timescale. This is a deterioration on the 86.5% reported in Q4 and reflects the recognised backlog of new complaints waiting to be acknowledged by the team, due to the high volume of new enquiries coming into the service overall.

PSCT Backlogs

For some time, there has been a backlog of new complaints and enquiries waiting to be allocated to complaints officers and forwarded to divisions for investigation. There has been related risk on the Trust's Risk Register since 2018 (risk 2680) – backlogs typically emerge when high volumes of new enquiries coincide with sickness absence within the PSCT.

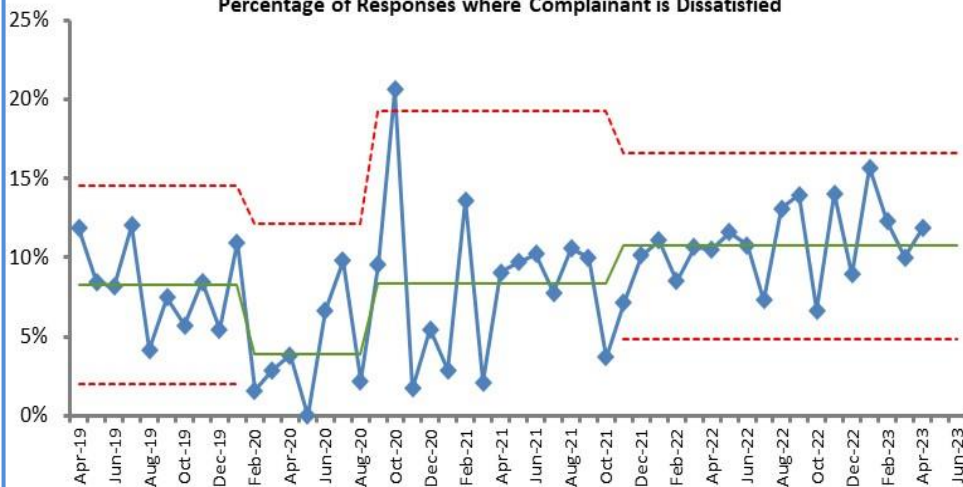
During Q1, a second backlog developed, at the 'front end' of the complaints process. This backlog consisted of new enquiries (some of which will be complaints) waiting to be logged onto Datix and an acknowledgment sent to the enquirer. Again, this backlog arose due to the consistently high number of new enquiries being received by the team, exacerbated by the long-term sickness absence of a key member of staff in this administrative role.

In order to reduce the administrative backlog and ensure that all service users know we have safely received their enquiry, overtime was offered to the team's part time administrators, help has been provided from outside of the team, and other members of the complaints team have focused on logging new enquiries and acknowledging the new complaints amongst them. This plan has proved successful in steadily reducing the backlog of cases awaiting acknowledgement, however as new cases are logged, the backlog of cases awaiting allocation and investigation has inevitably increased. Clearing both backlogs will be the primary focus on the PSCT during the remainder of 2023.



Dissatisfied complainants

Percentage of Responses where Complainant is Dissatisfied



What does this tell us?

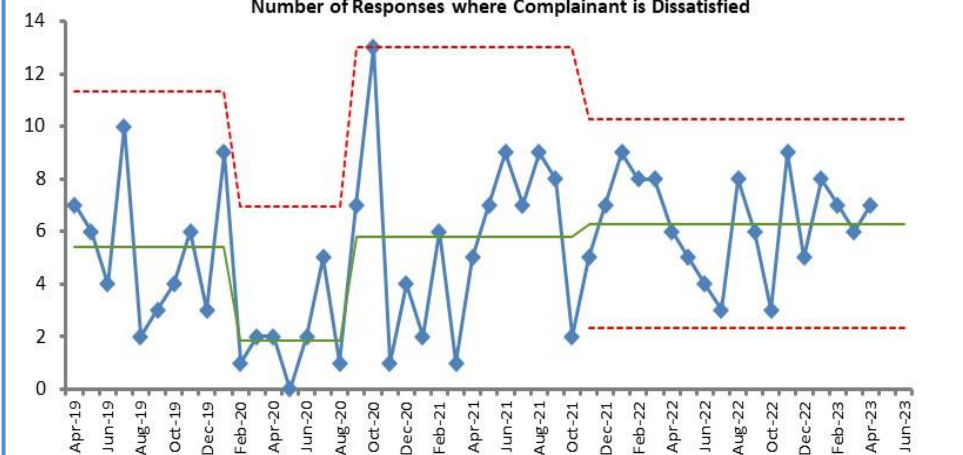
The Trust's current target is that no more than 8% of complaints responses should lead to a dissatisfied response. This target is based on previous analysis of dissatisfied responses received by the Trust. Data is reported two months in arrears to capture the majority of cases where, having considered the findings of our investigations, complainants tell us they are not happy with our response. In Q1, we are therefore reporting dissatisfied data for February, March and April 2023. Of the complainants who received a first response from the Trust during those months, 20 have since contacted us to say they were dissatisfied, representing 11.4% of the 176 first responses sent out during that period, compared with 12.9% in Q4.

Actions planned or taken:

The Head of Complaints or the Associate Director for Quality continue to review all draft responses to dissatisfied complainants and work closely with divisions to identify any learning in terms of whether anything could have been improved in the original response that would have prevented the complainant from having outstanding concerns.

Divisional complaints review panels, which focus on learning from dissatisfied complaints, will recommence from September 2023.

Number of Responses where Complainant is Dissatisfied



Thematic Analysis

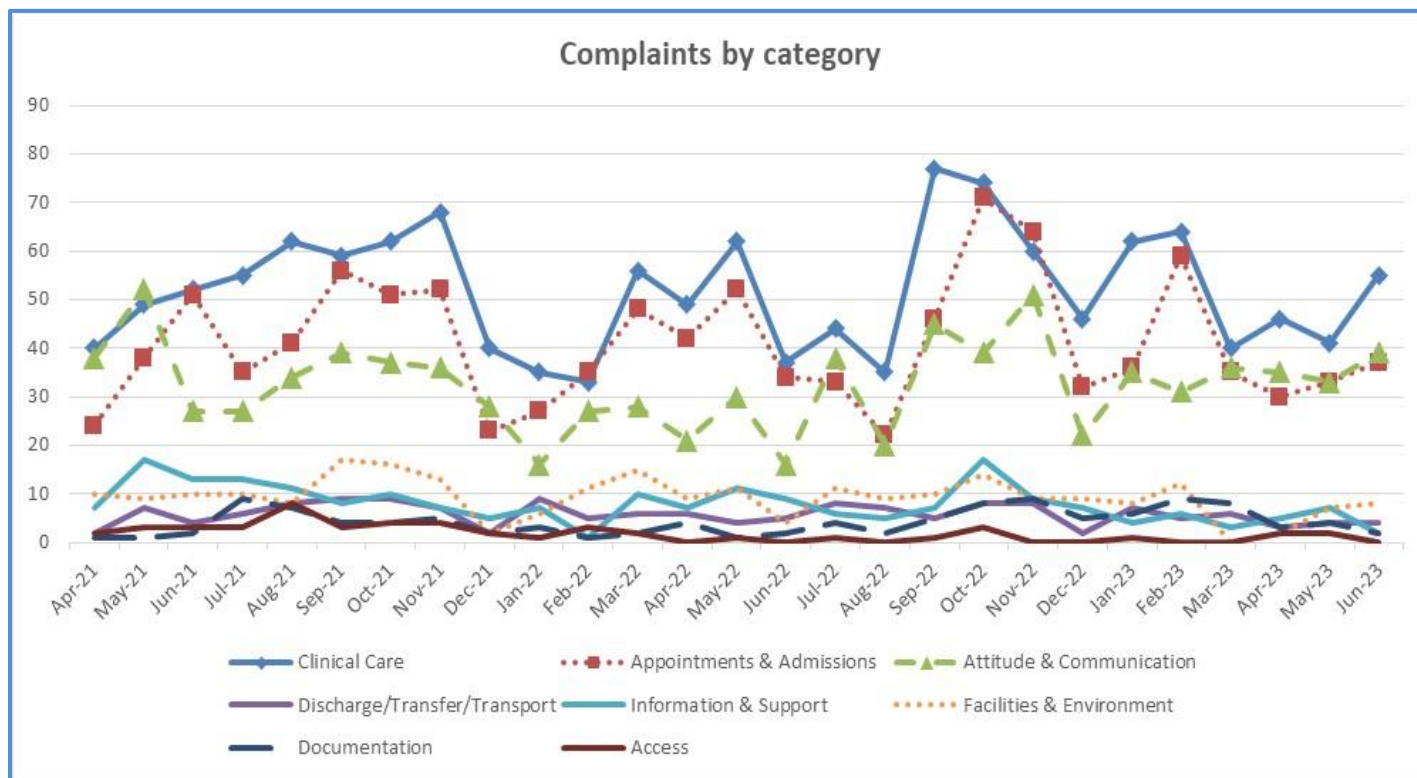
What does this tell us?

The highest numbers of complaints received by the Trust are consistently in three of the eight primary categories, those being 'Clinical Care', 'Appointments and Admissions' and 'Attitude and Communication'. These three categories accounted for 86.2% (349 of 405) of all complaints received in Q1 of 2023/24. In Q1, the highest number of complaints received by sub-category within each of these three primary categories were 'clinical care – medical/surgical' (73 of 142), 'cancelled or delayed appointment/operation' (80 of 100) and 'attitude of medical staff' (35 of 107).

Actions:

A more detailed breakdown of categories and sub-categories of complaints is shared with divisions on a monthly as well as quarterly basis to help identify areas of improvement. Improving communication has been agreed as the year 1 'breakthrough objective' for the forthcoming deployment of Patient First.

Complaints by category



Divisional complaints metrics

Q4 2022/23	Surgery	Medicine	Specialised Services	Women & Children	Diagnostics & Therapies	Weston
Total number of complaints received in Q1	107 (109) ↓	101 (129) ↓	45 (60) ↓	71 (92) ↓	24 (29) ↓	36 (31) ↑
Number of complaints about appointments and admissions	34 (46) ↓	23 (19) ↑	12 (13) ↓	20 (37) ↓	7 (11) ↓	3 (3) =
Number of complaints about staff attitude and communication	24 (19) ↑	30 (35) ↓	17 (9) ↑	16 (15) ↑	9 (9) =	5 (9) ↓
Number of complaints about clinical care	37 (31) ↑	36 (47) ↓	11 (26) ↓	29 (35) ↓	6 (9) ↓	21 (16) ↑
Area where the most complaints have been received in Q4	Bristol Dental Hospital (BDH) – 25 (21) Bristol Eye Hospital (BEH) – 24 (23) BEH Outpatients – 20 (21) ENT Outpatients – 6 (15) Trauma & Orthopaedics – 2 (8) Upper GI – 6 (2)	Emergency Department (BRI) (inc. EMU & Ambulatory Care) – 21 (32) Dermatology – 12 (6) Sleep Unit – 12 (18) Clinic A410 – 5 (9) Ward A900 – 3 (6)	BHI (all) – 32 (34) BHOC (all) – 10 (21) (Plus one each for Clinical Genetics, WGH Oncology and WGH Cardiology) BHI Outpatients (inc. Outpatient Echo) – 14 (22) BHOC Outpatients & Chemo Day Unit – 7 (10) Ward D603 – Oncology – 0 (5)	BRHC (all) – 35 (62) (Plus two for WGH Seashore Centre) Children's ED – 6 (3) Carrousel Outpatients – 9 (9) StMH (all) – 33 (27) (Plus one for WGH EPC) Central Delivery Suite – 2 (7) Gynae Outpatients – 8 (8)	Radiology – 9 (9) Audiology – 7 (12) Physiotherapy – 4 (1)	Accident & Emergency (inc. AMU and Ambulatory Care) – 12 (15)
Notable deteriorations compared with Q4	Upper GI – 6 (2)	Dermatology – 12 (6)		No notable deteriorations	No notable deterioration	No notable deteriorations
Notable improvements compared with Q4	ENT Outpatients – 6 (15)	Clinic A410 – 5 (9) Ward A900 – 3 (6)	Ward D603 – Oncology – 0 (5) BHI Outpatients – 14 (22) BHOC (all) – 10 (21)	BRHC (all) – 35 (62)	Audiology – 7 (12)	No notable improvements

"I had an outpatient appointment at Bristol Eye Hospital and my complaint is about the lack of interest, awareness and administrative systems to deal with visually impaired patients' access requirements. I want my complaint to result in demonstrable change, compliance with the Equality Act (2010) and the NHS Accessible Information Standard (AIS)."

Patient of Bristol Eye Hospital



1. Development, with the Sight Loss Council, of an e-learning package for all patient-facing administrative staff at BEH, including a module on AIS.
2. Outcome of complaints investigation shared with Trust's AIS communications group to support sharing of learning.
3. Exploration of potential external accreditation called Disability Confident.

"A doctor called me to say my mother had had a fall whilst in the ED and as a result sustained a brain haemorrhage and they could not stop the bleeding as she is on blood thinners. When I saw her, the injuries she had sustained were horrific and she was understandably terrified."

Daughter of patient admitted to medical ward via BRI ED



1. New training and education package developed to raise awareness of the risk of falls with staff in the ED.
2. Practice Education Facilitator now required to liaise with Palliative Care Team to ensure competencies completed regarding PRN medication.
3. Patient's story shared with Trust's End of Life steering group.

"I received excellent care, but one nurse was rude and unprofessional. She was supposed to be showing me how to use an epi-pen but completely ignored my fear of needles and repeatedly pushed the epi-pen against my leg (with the lid on) and then injected me with the contents of the pen which I was not supposed to have as this was an extra dose."

BRI ED patient



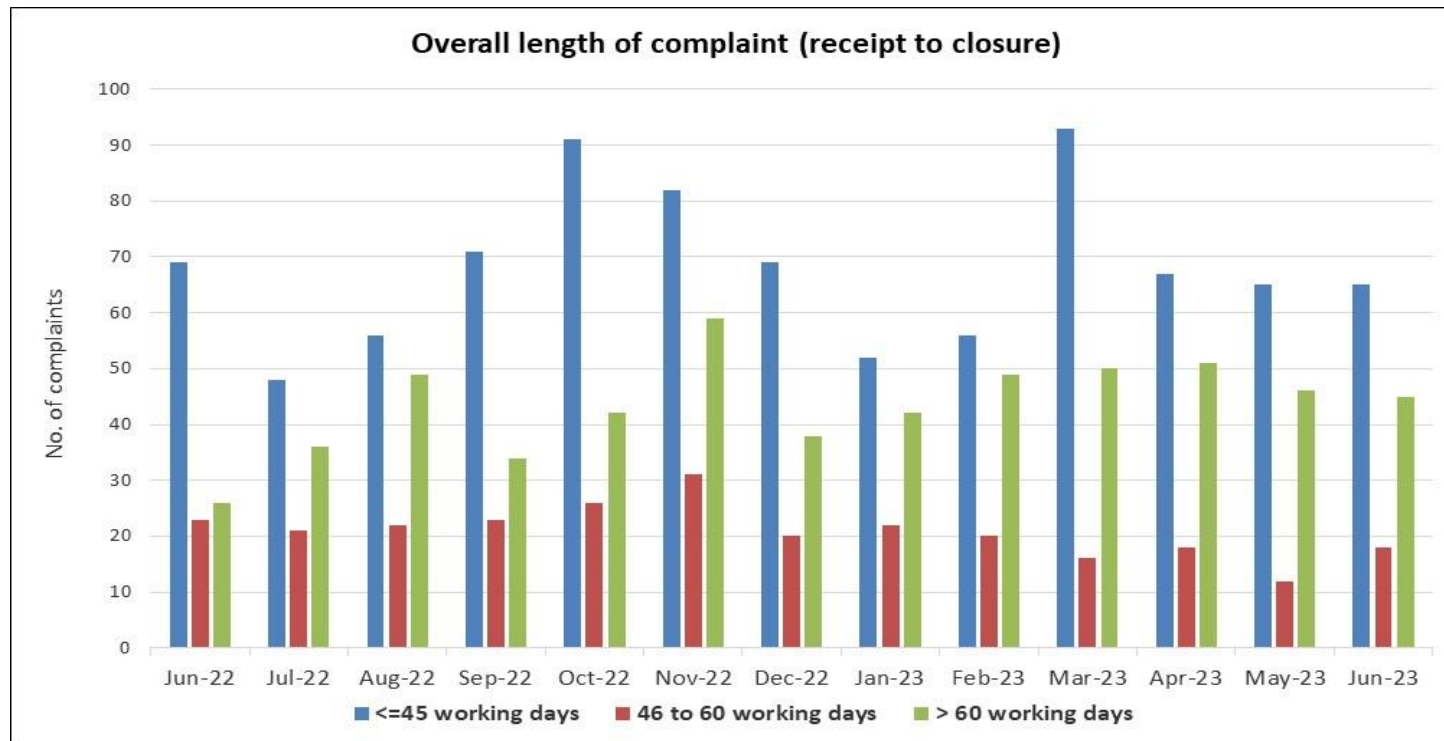
1. Rapid Incident Review and subsequent formal patient safety investigation carried out (already underway when complaint received).
2. Trust training sessions completed for staff in department in respect of the anaphylaxis algorithm, the drug, dose and route.
3. Alert added to patient's medical record in respect of their needle phobia.
4. Safety Brief for team regarding whereabouts of TIO epi-pens in the department.

Spotlight on complaint timescales

How long does it *really* take to resolve complaints?

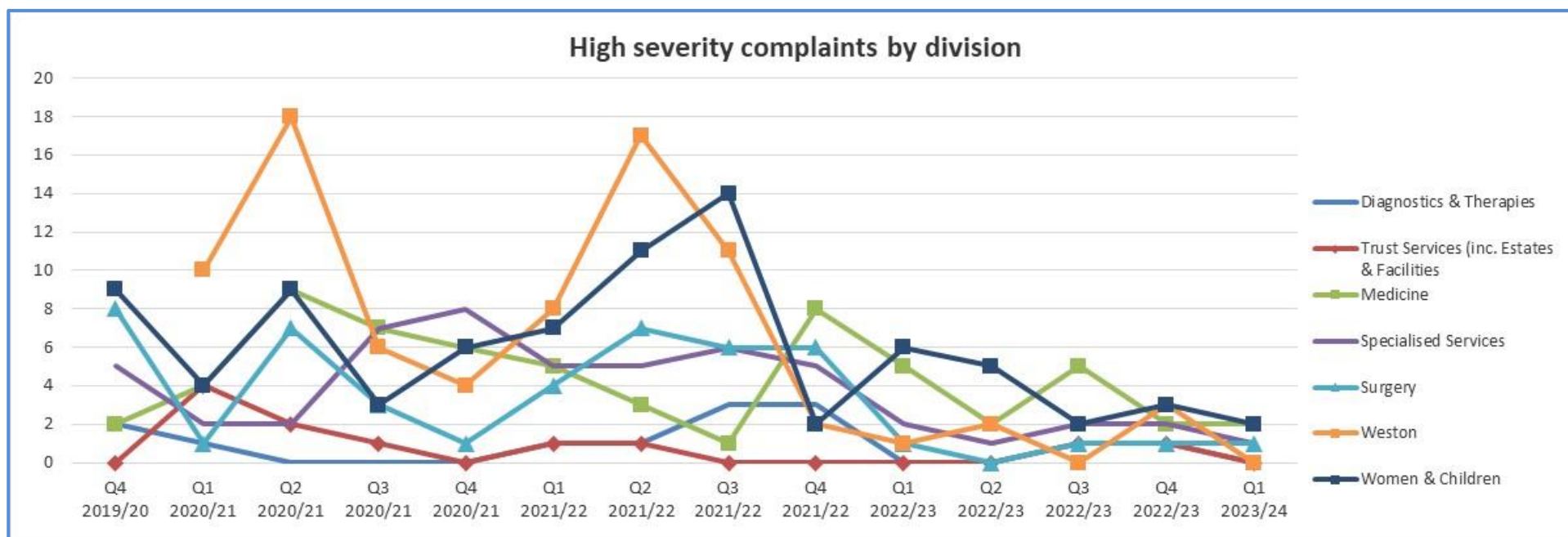
On slide 4, we looked at how the Trust performs against its target of responding to complaints within the timescale agreed with the complainant. However, this only tells part of the story, as the 'clock only starts ticking' when the complaint is sent to the division for investigation. The chart below shows how long it takes the Trust to resolve complaints from the moment they are received, until we respond to the issues raised, either via the formal or informal complaints process.

Most complaints are resolved in less than 45 working days. The challenge is to reduce the number of complaints which take 60 working days or more. There are a number of factors that contribute to the timeline of a complaint, even before it is sent to the division. As detailed on slide 5, this includes PSCT backlogs. Other factors include waiting for the appropriate patient consent to be received and the time taken to agree full details of the issues and questions the complainant wishes us to address.



Severity of complaints

We know from NHS data that trusts with high levels of incident reporting have fewer instances of severe harm to patients, i.e., organisations with cultures that encourage reporting when things go wrong, learn, and provide safer care. London School of Economics (LSE) research suggests a similar pattern of data associated with patient complaints, i.e., Trusts who receive high levels of low-level severity complaints receive lower levels of high severity complaints, again indicating that a culture of openness to receiving and learning from complaints is associated with safer and higher quality care. Put another way, receiving complaints should not be viewed as a bad thing *per se*; rather it depends what the complaint is about. The PSCT records the severity rating of all complaints, as either high, medium or low severity. The chart below shows the number of complaints rated as being 'high severity', by division. The long-term trend in all divisions is towards lower levels of severity in reported complaints, which is a key source of assurance about quality of care, learning and improvement. The most striking long-term reduction in severity of complaints is in Weston and Women & Children, which are now on a par with the other divisions in this respect.



PSCT activity and PHSO cases

Overall PSCT Activity

Including complaints, requests for information or advice, requests for support, compliments, feedback, and cases that did not proceed. The PSCT received 848 new enquiries in Q1 of 2023/24, as shown in the chart below. The apparent 20% reported reduction compared with Q4 of 2022/23 is in fact due to the administrative backlog mentioned in slide 5, which meant that not all enquiries received by the team had been logged on Datix at the time the figures were calculated. At the time of updating this report (Sept 2023) the PSCT backlog of cases awaiting acknowledgement and logging onto Datix has been cleared, which will allow retrospective adjustment of the monthly data in time for the Q2 2023/24 complaints report.

Did Not Proceed (DNP) enquiries

Each month, PSCT records a number of enquiries and complaints which subsequently do not proceed. These are cases where following initial receipt, the team has been unable to establish contact with the enquirer to obtain enough information to proceed, or where they have not received the appropriate consent and therefore cannot proceed. The Trust's Experience of Care Group has requested a more detailed analysis of DNP cases due to the significant impact on PSCT capacity.

Parliamentary & Health Service Ombudsman

During Q1, the Trust was advised by the Parliamentary and Health Service Ombudsman (PHSO) of their interest in four new complaints – three for the Division of Medicine and one for Weston Management Team. During the same period, eight cases remained under review by the PHSO, and one was closed with no further action taken.

