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**UK COVID-19 INQUIRY
MODULE 5**

**WITNESS STATEMENT BY THE DIRECTOR GENERAL FOR HEALTH AND
SOCIAL CARE**

This statement is one of a suite provided for Module 5 of the UK Covid-19 Inquiry and these should be considered collectively. In relation to the issues raised by the Rule 9 requests served on the Scottish Government in connection with Module 5, the Director General for Health and Social Care will say as follows:

Introduction

1. This statement relates to matters relevant to Module 5 of the UK Covid-19 Inquiry which fall under the responsibility of the Scottish Government's Health and Social Care Directorates. It should be considered alongside the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024, which addresses matters within the remit of the Scottish Procurement and Property Directorate (SPPD) and the Directorate for Economic Development.
2. The Inquiry has been provided separately with details of the Scottish Government organisation structure, including the Directorates, groups, Ministers and senior officials within the Scottish Government relevant to Module 5, provided: [CL13/001 - INQ000499056].

3. This statement is split into sections to address the points raised in the rule 9 requests. The section headings are as follows:

Section 1: Scottish Government structure and key partners within the scope of Module 5

Section 2: Personal Protective Equipment (PPE)

Section 3: Infection Prevention and Control (IPC) guidance

Section 4: Intensive Care Unit (ICU) Equipment

Section 5: Testing

Section 6: Funding (including contracts)

Section 7: Lessons learned

Section 1: Scottish Government structure and key partners within the scope of Module 5

Scottish Government Health and Social Care Directorates

4. The Scottish Government (SG) is comprised of eight Director General families. Each family is headed up by a Director General (DG). Each family is comprised of Directorates and sitting below them are Divisions. The Health and Social Care Directorates are collectively responsible for maintaining and promoting a high standard of health and social care for the people of Scotland; providing support to Scotland's health and social care services and workforce; and promoting and improving the health of the population (this includes physical and mental health, and social well-being). The Health and Social Care Directorates have both a policy and delivery function with responsibility for the development of national policy for health and social care as well as the running of the National Health Service (NHS). The Health and Social Care DG family is led by Caroline Lamb. Ms Lamb holds the dual role of DG for Health and Social Care and Chief Executive of NHS Scotland (DGHSC) since January 2021. Prior to this, the role was held by Malcolm Wright (DG and Chief Executive - June 2019 to May 2020), John Connaghan (Interim Chief Executive – April/May 2020 to January 2021) and Elinor Mitchell (Interim DG – April/May 2020 to December 2020).

5. During the pandemic, Health and Social Care Directorates played a central role in the SG's response, mobilising and harnessing enormous support and effort from national and local partners – from NHS and social care staff and the scientific community to local authority and third sector partners.
6. Throughout the period of interest to the Inquiry (January 2020 – June 2022) no part of the SG was directly responsible for buying key healthcare equipment and supplies for health and social care. As is explained in full throughout this statement, responsibility for procurement activity in the NHS is delegated to NHS National Services Scotland (NSS). The exception to this are a small number of contracts for PPE-related supplies or logistics, either for non-health essential services or on behalf of the NHS which were awarded by SPPD. Fuller details of these awards are detailed in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024.
7. The Health and Social Care Directorates worked with a range of government departments and bodies on matters relating to the availability, procurement, manufacture and distribution of PPE.
8. Within Scottish Government:
 - SPPD, who were responsible for the issuing of procurement policy notices and undertook procurement on behalf of the SG. More detail on the role of is provided in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024.
 - The Directorate for Economic Development, who ensured effective engagement with Scotland's manufacturing supply chain in order to support procurement activity by stimulating the supply of consumable products and equipment, including PPE and other medical supplies. More detail on the role of the DG Economy family is provided in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024.

9. Other bodies and governments:

- Scottish Enterprise - working alongside DG Economy and Scotland's manufacturing supply chain in order to support procurement activity by stimulating the supply of consumable products and equipment, including PPE and other medical supplies. More detail on the role of Scottish Enterprise is provided in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024.
- NSS - responsible for procurement, storage and distribution of PPE, stockpile management, demand modelling and forward buy planning which is set out in further detail later in this statement.
- NHS Health Boards – on distribution of PPE to health and social care staff, and procurement of specialised / alternative PPE not available via centrally managed contracts.
- Health and Social Care Partnerships / Local Authorities / Convention of Scottish Local Authorities (COSLA) - distribution of PPE to social care and procurement of PPE for their own staff.
- UK Government, Welsh Government and Northern Ireland Executive (including Scottish Government they are often referred to as 'Four Nations Partners'). Four Nations Health Ministers met regularly to discuss the pandemic from 20 April 2020. A timeline of these meetings is provided: [CL13/002 - INQ000147475]. Between the period April 2020 and January 2022, there were 43 meetings. In addition to this, significant engagement was via the Strategic PPE Four Nations Board. Quarterly virtual meetings were set up, with sub groups meeting more frequently. The terms of reference set out the responsibilities and reporting requirements of the group. The board's remit as of April 2021 was as follows:
 - Provide oversight and assurance to Ministers of all four nations that the strategic aims of the UK-wide protocol to support collaboration on the sourcing and supply of PPE were being met.
 - Support the understanding of Covid-19-related PPE supply across the four nations through the sharing and consideration of country-level data and intelligence on PPE.

- Facilitate UK-wide PPE demand modelling, sharing information on each country's stock positions, modelled requirements and planned procurement strategies to meet these requirements and coordinate strategies for meeting expected demand and planning of future strategies.
- Consider the impact on supply and demand of any change in the use of PPE, including any changes to guidance on the use of PPE.

10. As stated in the Module 5 DG Corporate statement provided to the Inquiry on 29 August 2024, the SPPD is responsible for Scottish national procurement legislation and policy. Documents pertaining to the legal and regulatory framework underpinning Scottish public procurement are provided within that statement. However, SPPD is not, and has never been, responsible for setting sector or commodity specific policies, procedures or approaches. NSS were, and are, responsible for any specific health approaches, including the supply, and related contracts, for PPE and other medical equipment in Scotland. NSS will be able to provide further information on the legal and regulatory frameworks specific to their procurement of key healthcare supplies and equipment during the pandemic.

Pre-pandemic

Role of the Health Emergency Preparedness, Resilience and Response Division (EPRR)

11. The SG's Health Emergency Preparedness Resilience and Response Division (EPRR) is a division within the Directorate of the Chief Operating Officer. The Directorate sits within the family of Health and Social Care Directorates. The Directorate of the Chief Operating Officer was previously called the Performance and Delivery Directorate, with the name change in 2022. EPRR itself was previously named the Health Resilience Unit. From 2010 until April 2020, Michael Healy was unit head of this division. In April 2020, he became the Interim Deputy Director (he was confirmed as the permanent Deputy Director in early 2024).

12. The current structure of EPRR includes two teams reporting to the Deputy Director, namely the Delivery and Assurance Unit, which has a focus on providing support and guidance to NHS Boards, and the Strategy, Risk and Policy Unit, which has a focus on national policy development, risk and EPRR principles. During the initial stages of the Covid-19 pandemic, the division was structured as a single unit.
13. Prior to the Covid-19 pandemic, EPRR led on:
- The policy relating to national pandemic stockpiles of PPE, other consumables, antivirals and antibiotics, including working with other UK nations on common policy approaches; and
 - Supporting NHS Scotland in pandemic exercising, working with key stakeholders.

The Pandemic Influenza Preparedness Programme

14. EPRR held, prior to the pandemic, responsibility for pandemic flu stockpiles of PPE as above, working closely with NSS on the management of the stockpile on matters including stock rotation and disposal. Prior to the pandemic and delegation to NSS under the terms of a Scheme of Delegation in March 2020, provided: [CL13/003 - INQ000320482] any changes to the storage and distribution arrangements were made at the direction of SG. Further details on this are provided in paragraph 20.
15. EPRR liaised closely with NSS and Public Health England (PHE) (which subsequently became the UK Health Security Agency (UKHSA)) on the procurement of items into the stockpile and their delivery to Scotland.
16. EPRR attended a number of meetings with PHE in the early months of the Covid-19 pandemic as a continuation of the pre-Covid Clinical Countermeasures Board. These meetings featured discussion of issues relating to the emerging pandemic and usage of the existing stockpiles.
17. The Pandemic Influenza Preparedness Programme (PIPP) procurement programme was a joint procurement venture between the four nations to ensure

stockpiles of PPE and other consumable items. Each nation owned its respective stockpile. Procurements were coordinated by PHE on behalf of the four nations, and were intended to ensure there was a stock of PPE and other consumable items primarily for NHS acute services. The stockpiles also included the PPE requirements of primary care (GPs specifically) and social care (residential and non-residential). There was no explicit coverage for pharmacies under PIPP.

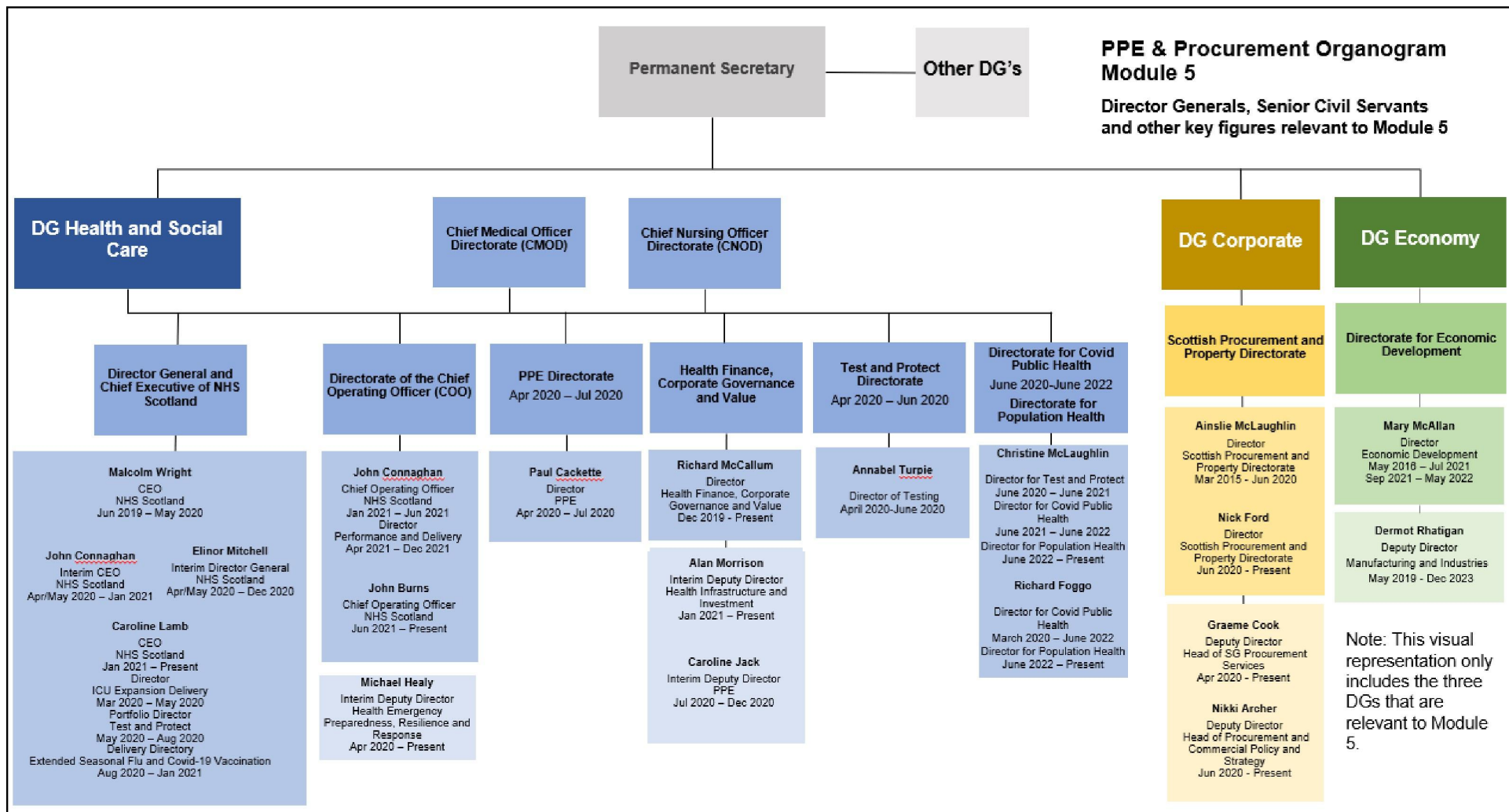
18. The four nations PIPP stockpiles were based on an analysis of the 'Reasonable Worst Case' scenario for an influenza pandemic, which was assumed to present in a single wave of 15 weeks. The standing assumption pre-pandemic was that the SG pandemic stockpile would be sufficient to manage the demands of a reasonable worst case pandemic over that 15 week period and normal procurement arrangements for the NHS and other sectors would be able to manage normal demand thereafter. As such, no additional arrangements were in place.

19. Prior to the pandemic, elements of the PPE stock in the pre-Covid pandemic influenza flu stockpile were revalidated before expiry to extend their shelf-life. This covered a large proportion (95%+) of both the facemasks and FFP3 respirators. This was to reduce re-procurement costs, while ensuring that the relevant items remained safe to use. The revalidation was generally carried out by the manufacturer and the activity was coordinated by PHE on behalf of the four nations. Some additional revalidation was carried out early in the Covid-19 response, again largely coordinated by PHE, though NSS also organised some revalidation. The testing carried out during the relevant period, which was not done through the original manufacturer, was guided by the Health and Safety Executive (HSE). Test reports were produced which demonstrated the products met standards required by the HSE during the Covid-19 pandemic. SG did not give permission for any PPE to be issued where it had not passed revalidation tests, where these were necessary i.e. because the original shelf-life expiry date had passed. NSS also arranged for other FFP3 masks to be revalidated to the same standard through the same testing house. Earlier, in February 2020, a company called Medline completed revalidation of stocks of their FFP3 masks in the pandemic stockpiles, as part of activity planned and commenced before the

outbreak of Covid. Though these passed initial testing by Medline and the shelf-life was extended by three years, they subsequently failed five-year shelf-life extension and at that point Medline withdrew any guarantee for the stock. The HSE advised PHE that any stock issued to Boards did not have to be withdrawn, given they had passed initial testing - and that the remaining stock could still be used, subject to further independent testing. Despite this and the fact that the remaining masks subsequently passed such testing, carried out by an independent testing company (again arranged by PHE), as a precautionary measure, the SG asked NSS to withdraw all Medline FFP3 stock from frontline usage in NHS Scotland Boards. These masks represented only a small proportion (8%) of the stockpile holding and had limited overall impact on the response.

20. In March 2020, EPRR and the Directorate for Health Finance, Corporate Governance and Value took the decision to delegate authority to NSS to use the items in the Scottish pandemic stockpile to respond to the pandemic. This delegation was finalised on 18 March 2020 and was a decision based on the emerging demand and supply issues resulting from the developing Covid-19 pandemic. Before that point, there had been specific instructions to issue volumes of PPE to GP surgeries in Scotland. NSS, as the distribution body, had plans in place for their response arrangements during a pandemic scenario, for such distribution. There was an assumption that any distribution to social care settings would be made in conjunction with local authorities, but there were no detailed plans for this. NSS would be best placed to comment further on the adequacy of the plans to distribute PPE and how long the Scottish pandemic flu PPE lasted during the Covid-19 pandemic.

21. The organogram below presents a visual representation of the Director Generals, Senior Civil Servants and other key figures relevant to Module 5, split according to their relevant Directorate:



Section 2: Personal Protective Equipment (PPE)

Health and Social Care Directorates

EPRR

22. During the early Covid-19 response, EPRR were involved in:

- The initial stages of supply and procurement of PPE to NHS Scotland (in close liaison with NSS) including liaising with the other UK Nations (until SG PPE Team was established in April 2020) and PHE; and
- Support for the Ministerial Group chaired by Ivan McKee, then Minister for Trade, Investment and Innovation, which had been established to lead on the procurement and supply of medical devices and equipment, alongside NSS and other SG directorates.

23. From a Health EPRR division perspective, there were various PPE issues during early 2020 including procurement decisions, developing principles of stock sharing with other UK nations in a limited number of cases (noting each stockpile was owned separately by each nation), delegating use of the pandemic stockpiles and providing spending authority for procurement to NSS, provided: [CL13/004 - INQ000496586], and the surveying of NHS boards on usage of FFP3 respirators.

24. Notwithstanding EPRR's role, NSS were the default leads on the operational aspects of sourcing, procurement and distribution of PPE.

25. In February 2020, EPRR began discussions with NSS to procure additional volumes of FFP3 respirators. Initial decisions to procure or not to procure the first batches of FFP3 in early to mid-February 2020, were driven by consideration of: high prices; lack of clarity on potential demand; and the drive to secure value for money through identifying other potential sources via the National Procurement team in NSS (NSS NP). Making procurement decisions within SG at this early stage involved judging the relative risks around potential overspending on the product against availability for the NHS response and the perceived threat level from Covid-19 at that point in time. An example of the considerations around such procurements is illustrated by the attached exchanges in February 2020,

provided: [CL13/005 - INQ000496463]. In March 2020, as well as delegating the use of the Scottish pandemic stockpiles to NSS (as set out above), the associated spending authority was also delegated.

26. An example of key decisions and developments EPRR were involved in is provided in a Ministerial submission, sent on 28 March 2020, provided: [CL13/006 - INQ000147374]. This submission sought Ministerial approval to procure seven million FFP3 respirator face masks for NHS Scotland, in response to the Covid-19 outbreak, with an order value of £17.3 million.

Establishment of the PPE Team and creation of the PPE Action Plan

27. In April 2020, in recognition of the developing situation, a new short term Directorate for PPE was established to provide strategic and coherent co-ordination in relation to all aspects of the provision of pandemic PPE in Scotland. The Directorate for PPE then became a Division of the Health Finance, Governance and Value Directorate in July 2020. It later became a Unit in the Health Infrastructure, Investment and PPE Division in January 2021 and continued to operate until 28 April 2023 when it ceased operation. For ease, the different variations are referred to as “the PPE team” throughout the statement.

28. The PPE Team led on the development and publication of the PPE Action Plan. The aim of Scotland’s Covid-19 PPE Action Plan, published 28 October 2020, provided: [CL13/007 - INQ000225992], was to ensure that the right PPE of the right quality reached the people who needed it at the right time. The Plan’s scope included health and social care settings and other workplaces where Covid-19 could put people at risk and they therefore need to wear masks, gloves and/or gowns to combat it. Further detail on PPE provision for non-health and social care settings is detailed at paragraphs 182-185.

29. The Action Plan set out work that had already been undertaken by SG and its partners to ensure Scotland had a robust and sustainable supply of pandemic PPE. This included:

- Clear clinical and workplace-specific guidance

- Support for social and primary care, working with community partners such as Integration Authorities
- A programme of work to support the manufacture of PPE in Scotland
- Actions to support all non-health and social care sectors in ensuring that the appropriate mechanisms were being put in place to deliver PPE
- A back-up commercial arrangement for employers that provide essential services but could not otherwise get the PPE they needed
- Better joint working in Scotland, including a senior-level Board to bring together the main parties
- Work on a four-nation basis across the UK.

30. The Action Plan also described SG's planning for the winter 2020 and also set out the work undertaken to develop a sustainable supply chain over the medium to long term. The Plan set out:

- SG's modelling work, allowing better understanding of how supply and demand is changing
- SG's work with the Scottish manufacturing sector, helping Scotland work towards sustainable domestic manufacture
- How Scottish public procurement policy is helping SG ensure Scotland's pandemic PPE supply is resilient and best value for the taxpayer
- How SG are working to support innovation, considering the environmental impact of PPE and promoting reusability, and how the needs of users are at the forefront of the SG's thinking.

31. Progress that was made in pursuit of the aims of the PPE Action Plan include:

- Gaining approval for continuation of support for Primary and Social Care PPE provision
- Extension of the Lyreco framework for PPE supply to non-health or social care essential services (discussed later in this statement)
- Updating PPE demand modelling and projections, including the impact of the winter reopening of services and vaccination programmes (as described above)

- The issuing of a Procurement Policy Note on supply chain resilience and diversity that advises public sector buyers of practical steps that should be taken to support supply chains and help reduce the risk of disruption to supplies caused by supply chain vulnerabilities and surges in demand.

32. As described in the Audit Scotland briefing, by May 2021, NHS NSS centrally held a minimum of three months stock of critical PPE items and two months supply of hand sanitiser. In addition, the Action Plan detailed the work that was ongoing to improve users comfort – the progress made on fit testing is described later in this statement.

33. We believe that the aim of the PPE Action Plan, to ensure that the right PPE of the right quality reached the people who needed it at the right time, was achieved by the systems put in place to enable this to happen. Where incidents occurred where NHS staff were not able to access PPE, local PPE Senior Points of Contacts (SPoCs) were in place to resolve them. Given the large scale of supply, there were some reported issues with deliveries which were resolved between NSS and their logistics providers. The size and complexity of supply means that even in non-pandemic situations there will be occasional challenges with the supply and delivery of PPE across Scotland.

34. Governance for the PPE Team was provided by the PPE Strategy and Governance Board. The Board membership was comprised of SG officials and representatives from NSS, Scotland Excel, Scottish Enterprise and Advanced Procurement for Universities and Colleges (APUC). Regular meetings of this board were set up, with the first meeting held on 6 May 2020, and the frequency of meetings was kept under review and adjusted as required. Initially, these virtual meetings were held weekly until 19 May 2020, with a move to fortnightly (until 29 October 2020) then monthly as the pandemic progressed and PPE supplies stabilised until the Board stood down after the final meeting on 28 April 2022.

35. As the pandemic progressed, the purpose of the Board changed and updates to their Terms of Reference were published on the SG website. The Board's initial remit was:

- To provide a framework for strategic decision making in relation to PPE in support of all areas of health and community PPE needs
- To understand manufacturing capacity and needs
- To plan and ensure supply and delivery/distribution of equipment that meets demand, both to secure current and ongoing delivery and adapt as delivery needs change over time as circumstances change.

36. From October 2020 to November 2020 the remit was as follows:

- Provide collective leadership and expertise to shape and guide the delivery of the PPE Sustainability Strategy
- Monitor the implementation of the PPE Sustainability Strategy progress using regular status reports, ensuring the programme remains on track
- Approve all PPE Sustainability Strategy implementation documentation including the risk and issue register and resolve or escalate risks and issues as appropriate
- Recognise and support where appropriate, indigenous opportunities to support Scotland's Economic recovery
- Progress niche pieces of work in support of the weekly Mr McKee (the then Minister for Trade, Investment and Innovation) meeting
- Collaborate to produce PPE demand usage signals across all sectors.

37. From November 2020 to January, the remit was as follows:

- Provide collective leadership and expertise to shape and guide the delivery of the PPE Action Plan
- Monitor the implementation of the PPE Action Plan via the Supporting Actions using regular status reports, ensuring the programme remains on track
- Approve all PPE Action Plan implementation documentation including the risk and issue register and resolve or escalate risks and issues as appropriate

- Progress niche pieces of work in support of ministerial aspirations
- Recognise and support where appropriate, indigenous opportunities to support Scotland's Economic recovery
- Collaborate to produce PPE demand usage signals across all sectors.

38. From January 2021 to June 2021, the remit was as follows:

- Provide collective leadership and expertise to shape and guide the delivery of the PPE Action Plan, provided: [CL13/007 - INQ000225992]. Further information on the Action Plan is detailed in paragraphs 28-33
- Monitor the implementation of the PPE Action Plan via the Supporting Actions, provided: [CL13/008 - INQ000320371] using regular status reports, ensuring the programme remained on track
- Approve all PPE Action Plan implementation documentation including the risk and issue register and resolve or escalate risks and issues as appropriate. Escalation routes would be determined by the nature of the risk or issue under consideration – operational issues would be escalated through the appropriate team, and strategic or high risk issues could be escalated to Ministerial level if necessary
- Progress bespoke pieces of work in support of ministerial aspirations, such as reducing the environmental impact of PPE, or improving PPE user experience
- Recognise and support where appropriate, opportunities to manufacture pandemic PPE in Scotland to support our front line services, build self-sufficiency and support Scotland's Economic recovery. This strategy comprised two parts: (i) a 'buy' strategy focussed on securing supplies rapidly on the global market and (ii) a 'make' strategy focussed on building supply capacity within Scotland's manufacturing base
- Collaborate across policy teams and with NSS, Scottish Enterprise, Scotland Excel and APUC to identify PPE demand across all sectors by modelling PPE usage.

39. From June 2021 until its last meeting on 28 April 2022, the Board oversaw the PPE Futures Programme, a collaborative programme of work between SG (PPE

Team, SPPD, Economy (Manufacturing and Industries, Enterprise and Innovation), Primary Care, Social Care, Early Learning and Childcare, Justice), NSS, Scottish Enterprise, Scotland Excel, APUC, COSLA, Police Scotland, Scottish Fire and Rescue, Scottish Prison Service (SPS) and Crown Office and Procurator Fiscal Service (COPFS). This was initiated in response to Audit Scotland's June 2021 briefing on PPE provision during the pandemic, provided: [CL13/009 - INQ000479725]. The Audit Scotland briefing said that SG and NSS need to learn from experience and to address a range of PPE issues for the future. The SG agreed with the recommendation and the Futures Programme was set up to take this forward. The Audit Scotland briefing also noted that in the early stages of the pandemic centrally held stocks of PPE were very low, however Scotland never ran out of PPE. The figures quoted in the briefing stated there was only a day or less of PPE stock - these figures were only for what was held centrally - PPE was being sent out to health boards as quickly as could be managed.

40. In relation to geographical variation in adequacy of PPE distribution, as noted in paragraph 100, the Scottish Government established a PPE helpline for health and social care staff to contact if they had concerns about PPE supply. All correspondence received in the mailbox was triaged by officials within the PPE Directorate and actioned depending on the content and the correspondent. For difficulties accessing PPE in Social Care, correspondents were referred to the Hub / triage system for assistance. There was no requirement for correspondents to provide geographical information for their correspondence to be actioned. As a result, correspondence was not categorised according to geographic area, and geographical statistics were not recorded for retrospective analysis. Queries in relation to NHS supply were referred to SPoCs at the local Health Board. The PPE team were aware of logistical issues associated with supplying island communities that had the potential to affect PPE deliveries. One incident of delayed PPE deliveries to an island location was brought to the attention of the PPE team. This was due to an issue with ferries and was resolved by NSS. As the professionals in this field, NSS lead on the logistical aspects of PPE distribution. The Health and Social Care Directorates were not given any cause to become directly involved in resolving individual challenges in the adequacy of

PPE distribution caused by geographical or regional variations. Local contingency measures were in place to mitigate this pre-pandemic, including, for island locations, holding levels of stock that were proportionally higher than on the mainland. Argyll and Bute Health and Social Care Partnership trialled using drones to deliver PPE in 2020 to help manage the logistical challenge of delivery to island sites and they would be better able to comment on the success of that trial. As NSS lead on the logistical aspects of PPE distribution, further information on PPE distribution may be sought from them.

41. The aim of the Futures Programme was to plan for new approaches to pandemic PPE supply in Scotland, which would ensure that experiences were learned from, promote innovation, and provide strong, sustainable foundations for any future epidemic or pandemic. This included implementing a strategic pandemic focus in Scotland with regards to the pandemic PPE stockpile, surge capacity and guidance, and to have both the public and Health and Social Care sectors buying pandemic PPE collaboratively. To deliver some of the aims of this programme, ongoing PPE innovation work was established as a workstream, with a completion timeframe of March 2022. This is covered in the Lessons Learned section of this statement.

PPE Supply Implementation Board

42. In May 2022, the PPE Supply Implementation Board (IPB) replaced the PPE Strategy and Governance Board in providing governance for the work of the PPE Team, its focus was to oversee the future pandemic PPE implementation project. This project was closed at the final meeting of the IPB on 26 April 2023.

Membership of the IPB was as follows:

- (Chair) Alan Morrison – SG Deputy Director, Health Infrastructure, Investment and PPE
- (Board Member) Gordon Beattie – NSS Director of National Procurement
- (Board Member) – Micheal Healy – SG Deputy Director, Health Emergency Preparedness, Resilience and Response (EPRR)
- (Board Member) Graeme Cook – SG Deputy Director, Procurement Services

43. This small group was directly concerned with the delivery of the Future Pandemic PPE Implementation Project and its aims, which are set out below. The group was supported by a Stakeholder Reference Group; a Project Team; and five Workstreams groups which fed into that Project Team.

44. The aims of the Future Pandemic PPE Implementation Project were to further develop the product design and implement the new pandemic PPE supply and resilience arrangements in Scotland, and to produce pandemic preparedness guidance, specifically to:

- Develop and publish two sets of pandemic preparedness guidance. The first to outline the steps those organisations not included in the collaborative procurement arrangements can take to put in place their own pandemic PPE stockpile and/or surge capacity and secondly to outline the stand up arrangements in the event of a future pandemic for collaborative working both within SG and for working with stakeholders
- Develop and implement a full service delivery and financial model for the new pandemic PPE supply arrangements, including the joint procurement of pandemic PPE within the public sector, an integrated stockpile, and a surge capacity.
- To ensure the lessons learned from the Covid -19 pandemic are considered and implemented into the development and operation of the new supply arrangements
- To engage with existing and potential stakeholders who may be interested in taking part in the collaborative arrangements being put in place.

45. The Future Pandemic PPE implementation project team included members from the SG's PPE Policy Team and NHS NSS NP. The five workstreams were:

- Inbound Supply - The purpose of this workstream was to develop an inbound supply strategy for the pandemic PPE, which included the sourcing, buying, storing, management and rotation of stock
- Data and Finance - The purpose of this workstream was to develop the demand profiles for pandemic PPE in business as usual and pandemic scenarios, and include a stock level strategy as appropriate. This

workstream also assessed the options for funding and the financial flows of the future supply and stockpile arrangements, and recommended a suitable financial model

- Surge Capacity - The purpose of this workstream was to evaluate the options available in regard to a surge capacity for pandemic PPE, and present a recommended strategy. In the pursuit of shorter and more robust PPE supply chains, this strategy aimed to support the Scottish domestic manufacturing base within the boundaries of public procurement legislation
- Stakeholder Engagement - The purpose of this workstream was to continue to manage the public consultation as an extension of the PPE Futures Programme, and work with the other workstreams to ensure that the results of the consultation report are considered as part of the development of the future supply arrangements. It was also to be responsible for supporting workstreams in their stakeholder collaboration, taking the lead where required in general and cross workstream engagement exercises
- Service Delivery and Infrastructure – The purpose of this workstream was to identify and appraise the options for the design of a service delivery model and make a recommendation of which option best meets the stated requirements. Once the delivery model was established the workstream was to progress the work to put this in place, including providing outline costs and how these will be met.

46. Stakeholder Engagement was a vital factor in ensuring that the arrangements were fit for purpose. The Stakeholder Reference Group (SRG) was set up with a broad range of stakeholders to act as a single point of contact with the full range of interested parties, and to inform and support the future pandemic PPE supply IPB's work.

47. The SRG membership included representatives from SG (PPE, Primary Care, Procurement, Early Learning and Childcare Covid-19 response and monitoring), NSS (including NP, Antimicrobial Resistance and Healthcare Association Infection (ARHAI), Incident Reporting and Investigation Centre (IRIC), Social Care PPE Steering Group), territorial health boards, Scottish Ambulance Service), Public

Sector organisations (COSLA, Scottish Fire and Rescue, Scottish Prison Service, Police Scotland, Crown Office and Procurator Fiscal), Public Sector Procurement (APUC, Scotland Excel), Scotrail and Scottish Water.

48. The remit of the SRG was:

- To receive updates on the work of the Future Pandemic PPE Implementation Project and its supporting workstreams
- To represent a broad cross-section of interested stakeholders. For those attending on behalf of an organisation or a group of stakeholders, also to communicate key messages back to others with an interest
- To provide insights and advice to the IPB and Project Team
- To communicate any issues arising which require resolution
- To identify where further joint work between one or more organisations/sectors and the Project Team may be required, and determine how this should be delivered (e.g. by allocation of staff time from those organisations/sectors).

49. The IPB's aim was to deliver robust cross-sectoral pandemic PPE provision in Scotland, to ensure a resilient supply is in place ahead of any future pandemic. Its remit was to deliver this aim by steering, directing and providing challenge to the work of the Future Pandemic PPE Implementation Project throughout financial year 2022-23, and specifically:

- To receive from the disbanded PPE Strategy and Governance Board a suite of foundational project documentation, including a Scope of Work paper [CL13/010 - INQ000479334], a Project Brief [CL13/011 - INQ000479332], a Benefits Realisation paper [CL13/012 - INQ000479327], a Stakeholder Strategy paper [CL13/013 - INQ000479348], and a Risk Register [CL13/014 - INQ000479331], signed off at its meeting on 28 April 2022, and to oversee the implementation of the work as set out in those documents
- To make decisions at key points throughout the year, securing sign-off from Scottish Ministers as required
- To provide strategic oversight of the management of risks and issues

- To provide strategic oversight to ensure the implementation project was delivered within an appropriate timescale during the lifetime of the project (financial year 2022-2023)
- To ensure benefits are monitored, realised and fully communicated to stakeholders as planned
- To make and record decisions about changes which may be proposed by the Project Team to the scope, deliverables, milestones, timeline or costs of the project (or such other changes as they may propose)
- To provide guidance and direction to the SG and NSS Project Team members;
- To ensure that the project was appropriately staffed and resourced
- To oversee and manage project spending and projected long term financial impacts; and to ensure project costs and risks are appropriately controlled
- To ensure strong strategic connections to other elements of pandemic preparedness such as the pandemic stockpile; wider work on pandemic countermeasures at Scotland and UK level; and the work of the Standing Committee on Pandemic Preparedness (a permanent advisory group to the SG comprising scientists and technical experts)
- To ensure engagement with stakeholders is appropriately undertaken by the Project Team
- To close down the project in March/April 2023, ensuring appropriate handover of responsibilities, including a Service Level Agreement between SG and NSS, a strategy for ongoing engagement with wider PIPP countermeasures work and transfer of responsibility for any lessons learned not addressed within the new supply arrangement.

50. The items of PPE that fell within the remit of the IPB matched those within the remit of the PPE Unit, namely:

- FFP3 and Fluid Resistant (Type IIR) Surgical Masks
- Gloves
- Visors and goggles
- Aprons and non-sterile gowns
- Hand sanitiser (not PPE, but included in the remit).

51. The remit did not include any additional items of PPE that might be used routinely in other settings, nor face coverings.
52. The IPB played no role in reference to other key healthcare equipment and supplies needed during the pandemic.

Working Groups with Health and Social Care Directorates' involvement

53. A list of teams, working groups and committees that were stood up either by or with the participation of the Health and Social Care Directorates during the pandemic are set out below:
54. The **PPE Clinical Oversight Group / Expert and Clinical Oversight Group** held its first meeting in May 2020. It was set up and run by NSS, and operated as the Clinical Oversight Group (COG) throughout the pandemic. The group initially met weekly, then moved to monthly and then met when required. It offered clinical and staff-side expert input on PPE issues and supported the NHS's decision-making. It was renamed the Expert and Clinical Oversight Group (ECOG) latterly but without significant membership or activity changes (prior to which it was briefly called the Expert Advisory Group). Its remit at March 2022 was to advise on clinically related PPE matters but also matters related to the wider occupational use of PPE:
- It considered and advised on innovations in PPE and advised on any necessary work to appraise them for adoption within clinical and non-clinical settings.
 - It ensured staff/user perspectives were considered at every stage
55. The Chair of this group changed as the group evolved. Initially, the group was chaired by Alex McMahon, Executive Nurse Director of NHS Lothian and Chair of the Scottish Executive Nurse Director Group. The Chair role was then taken over by Jacqui Reilly, NHS NSS Nurse Director. Anna Lamont, Medical Director of NHS NSS Procurement, Commissioning and Facilities was also the interim Chair at a time when the remit and membership were under review. The Group's membership changed throughout the pandemic but had representation from the

Chief Nursing Officer Directorate (CNOD), NHS NSS, Scottish Government and other relevant parties as required, including UNISON, the British Medical Association (BMA) and Royal College of Nursing (RCN).

56. The **Adult Social Care PPE Steering Group** was established by SG in November 2020, to monitor the use of the PPE distribution network (PPE Hubs) and levels of supply and demand, in addition to addressing ad hoc issues of concern raised by members. This was an advisory group. The Group was established in an effort to bring together key stakeholder into one group, at the requests of primarily the third sector and NSS. The Group held meetings on a fortnightly basis. The group was initially chaired by SG, and latterly by NSS. The membership included SG officials, NSS, Social Care Hub and care provider group representatives.
57. A **four nations PPE governance group** was established at the beginning of the outbreak to ensure decisions on the procurement of PPE were transparent across the four nations, and to consider the different views and responsibilities across the UK. The Group was chaired by the Department of Health and Social Care (DHSC) and was attended by SG and other devolved governments' officials. Membership of this group is set out in the terms of reference [CL13/014a - INQ000508435]. This included SG and NHS NSS, as well as counterparts from the other four nations.
58. The **Primary Care PPE steering group** aimed to provide clinical leadership, insight and advice which supported work to ensure the supply, distribution and optimum use of PPE to meet the need of Primary Care Contractors across Scotland. The group was set up in May 2020 by NSS. The group was chaired by NSS' Associate Medical Director and Primary Care Cell Lead from May 2020 to July 2020. In July 2020, the chair role was split between the Practice Manager Lead in Health Protection Scotland (HPS) and the NSS Director of Dentistry, before being taken on solely by the NSS Director of Dentistry. The Group had representatives from various SG policy areas, including General Medical Services, Community Optometry, Community Pharmacy, General Dental Services and the PPE Team, as well as the NHS. Meetings were held virtually, initially

weekly before moving to fortnightly and then monthly. The Group also consulted with external organisations. Recommendations on the options on PPE for primary care were then submitted, after approval from relevant SG Health and Social Care Directors, to the Cabinet Secretary for Health to obtain a Ministerial decision in relation to supply for Primary Care Independent Contractors.

59. The **PPE Policy Forum** was an informal group of SG officials which aimed to keep colleagues across SG informed and aware of PPE issues as they emerged, and ensure that any issues being raised by stakeholders were appropriately escalated. The membership of this forum was fluid, and adapted depending on who the PPE team needed to engage with on PPE policy at any given time. Members included representatives from within the Scottish Government, including Procurement, Social Care, Justice and Safer Communities, CNOD, Transport Scotland and Education.
60. The **PPE Stock Short Life Working Group (SLWG)** was an informal group of SG officials and NHS staff which considered pandemic PPE stock issues such as donations. This group was chaired by the Scottish Government PPE Unit, and included junior civil servants as well as NHS NSS officials.
61. The **PPE Innovation Working Group** was an informal SG-led group set up as part of the PPE Unit's Innovation and Manufacturing work stream to oversee the implementation of positive changes to the provision of PPE in Scotland. It was accountable to the PPE Strategy and Governance Board. Membership included representatives from the PPE Unit, other relevant SG teams (i.e Circular Economy Unit, Chief Scientist Office, F.A.C.T.S. and Compliance Unit, Equality Unit, Fair Work Policy & Delivery, Capital Planning and NHS Facilities, Innovation and Life Sciences, Supply Chains Development Programme), Zero Waste Scotland, Scottish Enterprise, Scottish Enterprise, NSS, Public Health Scotland (PHS), NHS Tayside, and National Manufacturing Institute Scotland
62. The **Single Point of Contact Strategic Oversight (SPoC) Group** was an NSS run group. SG officials attended but did not set up nor formally seek advice from

it. It aimed to provide leadership, insight and advice which supported work to ensure the following:

- A clear understanding of the supply needs of the remobilisation of NHS Scotland services including PPE and other critical strategic products and equipment.
- To provide leadership and guidance in respect of maintaining the capacity and infrastructure to support remobilisation.
- To act as a senior point of contact within each board in matters related to remobilisation supplies.
- To escalate matters which could not be resolved at an operational level as required.
- To enable a clear view of risks and overall risk profile in relation to procurement, including mitigation activities.
- To communicate internally to each board.
- To enable boards to work collaboratively on practical solutions to emerging issues.
- To enable boards and NSS NP to work collaboratively on improvement activities.

63. The SPoC Group was chaired by the Director of NHS NSS and then the Head of Strategic Sourcing and Commercial, also within NHS NSS. Membership included NHS NSS, key health board officials, as well as Scottish Government PPE Team officials.

64. The SPoC Group also received updates from the PPE Clinical Advisory Panel (CAP). This group was mainly formed of clinical staff, as well as NSS and the PPE Team. The CAP's main input was on:

- Innovation and changes to PPE, for example reusable products and changes to HPS guidance
- What PPE to use and when in different procedures/clinical settings
- Any safety concerns and links to infection control procedures
- Variation between use of PPE in different Boards.

65. The **PPE Operational Group** is a sub-group of the SPoC Group. It discussed PPE supply at health board level. This group was attended by local procurement representatives within boards. More information on this group may be sought from NSS.

66. The **Winter Planning & Response Group** was attended by NHS Chief Executives, Chief Officers for Health and Social Care Partnerships (HSCPs) and various SG Directors. This group was co-chaired by John Connaghan, Interim Chief Executive of NHS Scotland and Chief Performance Officer. It provided strategic oversight of winter preparedness across the Health and Social Care Directorates, including PPE, in relation to the three winter strategic priorities:

- Securing exit from the acute pandemic phase through an effective mass population vaccination programme
- Suppressing the virus through sustainable precision public health measures, such as Test and Protect, Surveillance and Response
- Keeping people alive and well through provision of essential health and social care services, including those that promote wellbeing

67. It also provided a forum for dialogue and discussion between the NHS Boards, HSCPs and other relevant agencies and the Scottish Government.

68. The terms of reference for the group set out the full membership [CL13/014b - INQ000508436]. From SG, the following attended:

- Andrew Fleming - Deputy Director NHS Territorial Board Sponsorship
- Anna Kynaston - Winter Planning Lead Adult Social Care
- Caroline Lamb - Director Vaccinations
- Derek Grieve - Deputy for Richard Foggo Covid Vaccinations
- Donna Bell - Director Mental Health / Social Care
- Gillian Russell - Director Health Workforce - Leadership and Service Reform
- Gordon Frame - Director Elective Care

- Heather Campbell - Interim Deputy Director Primary Care Unscheduled, Urgent Care and Board Sponsorship
- Helen Maitland - Director Emergency Care (Acute)
- John Colvin - Medical Adviser Urgent Care (ICU) - Co-lead ICU Resilience Support
- Magnus Jeffrey - Advisor Health Resilience
- Mike Healy - Deputy Director Health Resilience
- Richard Foggo - Director Public Health
- Robert Williams - Deputy Director Business Intelligence
- Sean Neill - Director Health Workforce - Leadership and Service Reform
- Tracy Slater - Deputy Director Test and Protect
- Head of Operational Planning Re-mobilisation Planning
- Head of Division Primary Care - Urgent Care and Out of Hours
- Programme Director Re-mobilisation Planning

69.A **clinical Short Life Working Group (SLWG)** was developed, jointly sponsored by Scottish Association of Medical Directors (SAMD) and Scottish Executive Nurse Director Group (SEND). This group fed into the PPE Division via the SPoC group.

Non-health groups

70.In addition to the groups mentioned above, the following groups were also stood up during the pandemic, which are directly relevant to the scope of Module 5.

71.The **Collaborative Leads Group** (also known as the Centre of Expertise (CoE) group) was chaired by the SPPD and included representation from all procurement CoEs – Scotland Excel, NSS, APUC and SG. The group first met on 17 April 2020. The purpose of this group was:

- To share cross sectoral information on PPE supply
- To discuss operational outputs and procurement actions from Mr McKee, the Minister for Trade, Investment and Innovation

- To be a forum to discuss procurement rules and processes and how they can be applied.

72. More information on this group is provided in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024.

73. The **Justice COVID Sub-Group** was a Sub-Group of the SG's Justice Board (established in 2011) and was established in March 2020 in response to the outbreak. The Sub-Group's purpose was to oversee and manage the collective justice system response to the virus and to inform the SG's Resilience response to the pandemic, in particular resilience Situation Reports. The Sub-Group was focused on more immediate and practical issues, including matters relating to PPE supply, distribution and guidance relevant to the Justice sector. The Sub-Group was attended by Scottish Courts and Tribunal Service, COPFS, SPS, Police Scotland, Scottish Fire and Rescue Service, Scottish Children's Reporters Administration, Scottish Police Authority, Scottish Legal Aid Board and Community Justice Scotland.

74. The remit of the Sub-Group was as follows:

- Share the preparedness of each organisation, including their Business Continuity Planning
- Establish the preparedness of the justice system as a whole
- Seek to build a common understanding of the implications and potential impacts of the virus on the justice system
- Provide a forum for member organisations to collaborate and share information and updates
- Work together to address the challenges and risks the virus poses to the justice system
- Engage where appropriate with SG resilience colleagues to obtain their views and to keep them informed of the justice system response
- Report to the Justice Board following each meeting of the Sub-Group, including where appropriate making system-level recommendations.

Access to PPE / PPE provision to health boards

75. NSS is responsible for national PPE contracts in Scotland and was responsible for supplying PPE to Health Boards during the pandemic through its National Distribution Centre (NDC).
76. As noted earlier in the statement, in March 2020, SG delegated the use of the pandemic stockpile PPE holdings to NSS who provided this PPE to health boards free of charge. These stocks were augmented by procurement of further pandemic PPE, principally carried out by NSS using funds provided by SG for that purpose.
77. In the early days of the pandemic, NSS distributed PPE based on a 'push' basis. A push basis is one whereby the issuing organisation determines the amount of provision (in this case after consultation with relevant SG policy officials) and sends it out to organisations, in this instance the individual health boards, without them specifying the amount or mix of items required. A pull basis is one by which the recipient indicates the amount required.
78. The push model was adopted to reduce the administrative burden on boards, while ensuring optimum deployment of stock lines that were under greatest pressure. The PPE helpline is covered from paragraph 100, however, it is worth noting that after establishment and an initial rush of queries, the mailbox traffic decreased dramatically. In the four week period from 8 June 2020, a total of three new cases related to health and social care worker PPE were reported. No further correspondence relating to availability of PPE for frontline workers was received after 24 June 2020. The main criticism of the push approach was the supply of items that were not required in the volumes supplied. This was addressed in the move to the pull model of distribution. The decline in queries to the PPE helpline mailbox suggests the push model was successful in the early stages of the pandemic.
79. Health boards, including the Scottish Ambulance Service (SAS), were also able to procure their own PPE for use in the pandemic where the central offering did

not fully meet the needs of their workforce. This was managed via their local mobilisation plans. This was managed via their local mobilisation plans.

80. There was a daily call with the health board contacts, NSS NP and SG where issues could be raised. Boards continued to order business as usual stock as they did pre-pandemic and could also order any urgent stock requirements, with larger volumes of pandemic PPE being issued on a push basis.
81. After the initial 'push' period, supply reverted to a 'pull' model whereby NHS boards placed orders with NSS based on their own needs.
82. NSS set up the NHS Scotland Covid-19 PPE Supplies Portal to allow health board procurement teams to raise and track queries regarding PPE supplies. NSS will hold further information on this portal. SG had no role in relation to this portal.

PPE provision for the care sector and Primary Care

Primary Care

83. Pre-pandemic, Primary Care Independent Contractors (ICs) (GPs, Dentists, Community Pharmacists and Community Optometrists) provided their own PPE as part of the services they provide under contract to the NHS, but this provision was taken over by NSS NP in the early stages of the pandemic. As outlined previously, in the early stages of the pandemic, SG's EPRR were the lead policy area for the existing pandemic (flu) stockpiles of PPE, which included notional amounts in those stockpiles for both social care and primary care. At the outbreak of Covid 19, the pandemic (flu) PPE stockpiles consisted of aprons, gloves, eye protection facemasks and FFP3 respirators. EPRR co-ordinated the distribution of small and initial amounts of PPE to all GP surgeries in Scotland in the early stages of the pandemic, as detailed below:
- 24 January 2020 - First distribution of Fluid Resistant Surgical Masks (FRSM) (also known as 'Type IIR') to GP Practices in Scotland. As a precautionary measure, SG instructed NSS to issue facemasks to all GP surgeries in Scotland. This was the first issuing of any PPE from the

pandemic (flu) stockpile and consisted solely of surgical facemasks. As policy lead for the pandemic PPE stockpile, EPRR organised the distribution with NSS, after approval by the Cabinet Secretary for Health and Sport.

- 11 March 2020 - Second distribution of Surgical Face masks (FRSM) to GP Practices in Scotland. This time other items of PPE, such as aprons and eye wear, were also included.

84. With the changes to guidance that resulted in greater demand for PPE, along with a reduced global supply, GPs were supplied from the national stockpile. Health Boards received an initial push of PPE for distribution to GP surgeries following an instruction to health boards from Health Resilience Unit on 12 March 2020. Boards were asked to confirm that each Practice had indeed received its allocation and report back to the Health Resilience Unit by 23 March 2020. We have records confirming that the majority of Boards did issue allocations to all their GP Practices and those Boards who did not reply by the initial deadline were called directly for this purpose.

85. The Ministerial Briefing Note, provided: [CL13/015 - INQ000261832], provides further detail on the methods of supply to health boards, SAS and GPs as at April 2020. PPE was also supplied to Emergency Eyecare Treatment Centres (EETCs) to manage patients with emergency eye problems face-to-face.

86. As noted at paragraph 58, in May 2020, the **Primary Care PPE Steering Group** was formed to consider alternative supply options in order ensure the sector (dentists, GPs, pharmacists, optometrists) had access to an adequate supply of PPE throughout the pandemic. The Group was chaired by NSS and membership was comprised of representatives from various SG policy areas, including General Medical Services, Community Optometry, Community Pharmacy, General Dental Services and the PPE Team, as well as NHS staff. Proposals for NSS to continue to provide PPE free of charge to Primary Care Independent Contractors and the shift to a 'pull' model of provision were outputs from this group.

87. PPE was supplied to community pharmacies by NSS on a 'push' basis. From June 2020, PPE was supplied to dentists and optometrists by NSS on a 'push' basis. In February 2021, the process began to transfer most Primary Care contractors in to a 'pull' model with practices utilising online ordering of pandemic PPE. This change was brought in to allow practices to identify how much and what mix of PPE items were required rather than this being determined centrally. This was done to minimise the risk of overstocks or short supply at a contractor level.

The care sector

88. NSS did not, at any point, assume responsibility for the procurement of PPE for the care sector. However, the Health and Social Care Directorates worked with NSS to devise a delivery model for supplying PPE to social care providers where normal supply routes failed.

89. On 27 March 2020, the Director of Community Health and Social Care in SG and the Chief Executive of NSS wrote jointly to NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers and COSLA to inform them that an anticipatory process for getting PPE to Social Care was to be established, provided: [CL13/016 - INQ000496459]. They were asked to identify appropriate sites to act as PPE Hubs and to nominate a local procurement/supplies lead to help field enquiries. The Hub network allowed the care sector to access PPE free of charge when their pandemic PPE supply routes failed. The PPE Hubs were supplied by NSS, with governance arrangements set out in a Memorandum of Understanding (MoU) which was co-signed by Scottish Government, COSLA, NSS, HSCPs, Coalition of Care Providers Scotland (CCPS), Scottish Care and National Carer Organisations. A briefing note and the MOU are provided: [CL13/015 - INQ000261832], [CL13/017 - INQ000147351]. There were a number of extensions to the MoU, the last being to 30 September 2022.

90. On 30 March 2020, local PPE Hubs were established in addition to the reactive triage service to provide PPE supplies to priority social care providers on an anticipatory basis. The initial allocation of PPE for registered care providers to collect from the hubs had been worked out based on a general allocation approach, taking into account the number of registered care homes and care at home/supported living facilities in the HSCPs, and the number of staff in each (derived from Care Inspectorate and Scottish Social Services Council (SSSC) data).
91. In addition to this, on 17 April 2020, the Cabinet Secretary for Health and Sport announced that NSS would provide a one-off top up of supplies to all care homes in Scotland. That top up provided at least one week's supply of aprons, fluid resistant surgical masks and gloves. The 'top up' was completed by 23 April 2020. On that date, an internal submission to the Cabinet Secretary for Health and Sport noted that "on the balance of views from all parts of the social care sector, the use of Hubs as a co-ordinating centre is the most secure way to make good on the commitment to delivery of PPE to the whole sector in the timeframe required." Some correspondence was still being received after the top up about a lack of PPE supply. Where this occurred, correspondents were contacted and assisted with accessing required PPE through the PPE hubs or triage services. Other correspondents reported being in a better position after the direct drop off.
92. The local PPE Hubs expanded their provision to support the whole social care sector with all of its PPE needs where normal supply routes had failed; and also extended their support to unpaid carers and social care Personal Assistants with their PPE needs.
93. Under the terms of the MoU, Social Care providers committed to taking no more than one week's supply of PPE. This, in practice, may have been less than a week depending on when the next stock delivery was due at the Hub. Social care providers also committed to ordering and using PPE from the Hubs in line with national guidance and the joint statement by SG, Trade Unions and COSLA.

94. Social care providers could also recoup pandemic-related PPE costs from SG funding through Local Mobilisation Plans and in line with the COSLA/SG Principles for Sustainability Payments to Social Care Providers during Covid-19. PPE accessed from the Hubs was provided free of charge.
95. SG did not provide PPE to private care providers, with the exception of private care homes who could access PPE via hubs, where their supply routes had failed.
96. As noted at paragraph 56, the Adult Social Care PPE Steering Group was established by the SG in November 2020 to manage the Social Care PPE Hub Network from a strategic perspective.
97. Information on how the care sector was to gain access to PPE supplies, and any changes to the arrangements, was issued by SG to NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers, COSLA and carer organisations. A list of the documents and correspondence is provided below.
98. The changes that were made were within the timeframe covered by Module 5 is as follows:
- Issued 16 March 2020: To inform NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers and COSLA of the decision to set up triage arrangements [CL13/018 - INQ000496482]
 - Issued 17 March 2020: To inform NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers and COSLA that the triage arrangements would be up and running from 8am on Thursday 19 March [CL13/019 - INQ000496483]
 - Issued 17 March 2020: To inform NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers and COSLA of technical issues with the set up triage

arrangements and a slight delay to expected start (11am on Thursday 19 March) [CL13/020 - INQ000496484]

- Issued 19 March 2020: To inform NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers and COSLA that the triage arrangements were now live [CL13/019 - INQ000496483]
- Issued 24 March 2020: To inform NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers and COSLA to only use the phone line to access the triage service and not the e-mail address. The 'double entry' route was causing confusion and delays in the process [CL13/016 - INQ000496459]
- Issued 27 March 2020: To inform NHS Board Chief Executives, Local Authority Chief Executives, Chief Officers Integration Authorities, Chief Social Work Officers and COSLA introduction of the hub arrangements in addition to the triage service [CL13/016 - INQ000496459]
- Issued 26 April 2020: Guidance on how to access PPE sent to Carers organisations to be forwarded to unpaid carers [CL13/021 - INQ000496485]
- Issued 29 Apr 2020: PPE access for social care providers and unpaid carers [CL13/022 - INQ000496486]
- Issued May 2020: MoU for PPE supply to Social Care to September 2020 [CL13/017 - INQ000147351]
- Issued 07 October 2020: Extension of social care PPE Hub arrangements until March 2021 [CL13/023 - INQ000147352]
- Issued 17 March 2021: Extension of social care PPE Hub arrangements until 30 June 2021 [CL13/024 - INQ000496488]
- Issued 28 June 2021: Extension of social care PPE Hub arrangements until 30 September 2021 [CL13/025 - INQ000147353]
- Issued 29 September 2021: Extension of social care PPE Hub arrangements until March 2022 [CL13/026 - INQ000147354]
- Issued 30 March 2022: Extension of social care PPE Hub arrangements until 30 September 2022 [CL13/027 - INQ000496491]

99. Social Care Hub PPE reports were also shared with Adult Social Care Pandemic Response Unit (ASCPRU) and the PPE Team in the SG which provided detail of stock levels and use, use by provider and service type. The ASCPRU also continued to receive direct information about social care demand through regular meetings with PPE Hub Managers and via regular working with NSS.

PPE helpline mailbox

100. In late March 2020, there was significant email traffic related to PPE coming to the Cabinet Secretary for Health and Sport's mailbox, as well as other Scottish Ministers and MSPs. It was agreed on 31 March 2020 that there should be a central point for individuals to contact on matters relating to PPE supply and the Cabinet Secretary directed that a dedicated mailbox be set up to deal with PPE related queries.

101. Immediate action was taken to establish the PPE mailbox, which went live the following day, 1 April. The same day the Cabinet Secretary sent a letter to the Health and Sport Committee, copied to all MSPs, to provide an update on SG's Covid-19 response, which included notification of the new mailbox.

102. The mailbox ensured there was dedicated resource managing PPE queries from individuals and MSPs, guaranteeing these would be acted upon, had a standard response that told the sender action would be taken and provided follow up to each query.

103. The function of the mailbox was to give Health and Social Care staff a point of contact if they did not have access to the PPE that they needed, or if they had other concerns regarding PPE supply. This covered Acute, Primary Care, Social Care, and members of the public (including private contractors carrying out NHS functions).

104. At the same time, each Health Board nominated a Single Point of Contact (SPoC) for PPE. The SPoC was responsible for managing PPE supply in their

Health Board and were in place to resolve issues, and concerns and to be notified if the normal process was not working well. Relevant correspondence that had been received by other SG teams prior to the establishment of the mailbox, that had not yet been actioned, were redirected to the mailbox for response and/or further action.

105. Correspondence received in the mailbox was triaged by officials within the PPE Team and actioned depending on the content and the correspondent. Each email was categorised for a response and/or further action as required. Prior to 4 May 2020, the process for triaging correspondence was undertaken as outlined in the document provided: [CL13/028 - INQ000223089]. From 4 May 2020 onwards, the process followed was as outlined in the desk instructions, provided: [CL13/029 - INQ000496329].

106. The initial resourcing for the mailbox was by officials who were experienced in dealing with ministerial correspondence but had no background in the subject matter of PPE. Given the lack of run-in time, training had to be provided on the job. By 7 April 2020, there were 17 individuals staffing the PPE helpline mailbox (approximately 12 full time equivalent posts). By 4 May, there were 22 team members staffing the mailbox.

107. In the first instance, staff or members of the public enquiring about availability of PPE were directed to their local Health Board PPE SPoC. Where there were supply or distribution issues that could not be resolved at NHS health board level, the health board PPE SPoC engaged with NSS NP for action and resolution. Similarly, urgent requests for PPE were acknowledged and passed to the appropriate NHS Board SPoC for local resolution.

108. The Cabinet Secretary, Ministers and colleagues were kept informed of potential supply issues by demand and supply briefings based on daily stock information bulletins produced by NSS. These briefings were sent daily initially, with frequency reducing as PPE supplies stabilised, moving to five days a week in late May 2020, then twice weekly before becoming weekly and then monthly. These briefings specifically were issued with the contact details of a member of the PPE

Team who could be approached if there were any questions on the information provided. A small number of queries were received in response, examples include assurance about supply levels of specific types of PPE as well as plans to transition away from specific models of PPE. The low number of queries suggests that recipients were satisfied with the level of information provided within the briefings which incorporated details of risks, mitigations, opportunities and additional information on items in the suite of pandemic PPE, as they developed.

109. In terms of the volume of correspondence the mailbox received, from 1 April to 17 July 2020 (date of the last correspondence the mailbox received before closure), it received 2,481 correspondence cases. On initiation of the mailbox, the team were immediately passed a total of 177 outstanding cases from various Ministerial teams which had been received over the preceding days and weeks. During the first week, a further 315 cases were received, an average of 45 a day. On 7 April, the address of the mailbox was publicised on twitter. The following day (8 April) the number of emails received increased from 86 to 310, with another 158 coming in the following day. By the third week of operation, the mailbox had received or inherited 1700 cases.

110. A review of the overall approach to the mailbox was carried out and resulted in a change of process from 4 May 2020. The correspondence received into the PPE helpline mailbox was not categorised according to health and social care sector, geographical area, the quality or availability of PPE, interpretation of IPC guidance, fit issues, or any other issues that arose. A breakdown of correspondence according to these categories cannot therefore be provided. However, it was noted that prior to the closure of the PPE helpline mailbox, no correspondence relating to availability of PPE for frontline staff was received after 24 June 2020. The number of queries regarding clinical guidance that were redirected to the Chief Nursing Officer Directorate during the period 4 to 28 May 2020 was 38 (20 from 4 to 14 May, 18 from 15 to 21 May, and 0 from 22 to 28 May).

111.The median time to respond to correspondence received varied. During the first week of operation, the median time to respond was 20 days, due to volume of correspondence and because as much of the correspondence had been received by other mailboxes and forwarded to the PPE helpline mailbox. By the end of April, this had reduced to a median of 1 day.

112.It was proposed to Ministers that the mailbox close on 20 July 2020 due to the following factors:

- Stabilisation of PPE stock and supply lines
- A reduction in correspondence being received by the mailbox
- NSS Social Care PPE Triage helpline
- Expanded local PPE Hubs
- A SPoC to manage local PPE supply and distribution in each health board
- PPE Team providing strategic co-ordination in relation to all aspects of the provision of PPE in Scotland.

113.Ministers were concerned about effectively communicating the closure of the mailbox to Parliament and the public. It was therefore agreed that any emails to the box would be rerouted to a different monitored email address. Therefore, the box was effectively 'closed' but any emails that were sent would still be picked up. This would also allow a smooth transition back to it being 'live' should there be a need to restart the mailbox due to a second Covid wave during the winter.

114.The PPE helpline mailbox received both positive and negative feedback from Health and Social Care staff. In the first few weeks of the mailbox operation, correspondents raised concerns about the slowness of the response. The mailbox team worked hard to reduce response times and by the end of April 2020, this had reduced to a median of 1 day. The PPE team were very grateful to the correspondents who took the time to feedback when the process had worked well, and to let them know that their supply issues had been resolved. Significant learnings were captured and in May 2021, the innovation working group submitted a strategy paper to the PPE Strategy and Governance Board with

improved user experience highlighted as a priority area, provided: [CL13/030 - INQ000479589]. The group undertook to update the Board quarterly on progress.

Modelling

Modelling the epidemic

115. On 10 March 2020, in addition to the analytical capacity provided by Health and Social Care Analysis (HSCA) team, the Covid-19 Modelling and Analytical Hub (C-19 MAH) was established within the then DG Constitution and External Affairs (later renamed DG Strategy and External Affairs). The hub was developed to provide a centralised modelling function which interacted with UKG Scientific Pandemic Influenza group on Modelling (SPI-M) to undertake modelling that initially was circulated across SG via the Scottish Government Resilience Room (SGoRR) (SGoRR is activated to co-ordinate the work of the Scottish Government and its agencies, and brief Ministers during emergencies and significant events) and onwards to the UKG through Cabinet Office Briefing Rooms (COBR). C-19 MAH led on:

- Developing the model for Scotland that provided scenarios of numbers of infections, estimates of hospital/ICU beds, and fatalities using assumptions/data from SAGE and SPI-M. The model aimed to model the Reasonable Worst Case (80%) infected with Covid in Scotland, and the reduction of this based on the social interventions live in the community, for logistical rather than epidemiological purposes
- Sharing the central assumptions and parameters that fed in (through SGoRR) to subsequent mobilisation planning, including planning at Health Board, HSCP and Local Authority Levels
- Linking with equivalent modelling leads in UK and Wales to share assumptions and models
- Producing the daily UK Covid-19 dashboard which provided a high level assessment of the impact of Covid-19 across a range of social, economic, direct (Covid-19 related) and indirect health measures
- Producing the 'Scottish Impact of Covid-19' model – slide deck and spreadsheet

- Commissioning geographical analysis and mapping.

116. The first 'Modelling the Epidemic' slide pack based on Scottish estimates of the Reasonable Worst Case Scenario and logistics modelling of required hospital beds was available from 10 March. C-19 MAH began publishing its weekly modelling outputs with the first edition of *Modelling the Epidemic* published 21 May 2020, provided: [CL13/031 - INQ000302542]. This continued on a weekly basis until May 2022 when switched to fortnightly. Publication ceased on 22 December 2022 after 115 editions. This enabled the public to engage with the basic modelling that underpinned government decision making. In addition, a bespoke modelling pack was provided to NHS Chief Executives on a weekly basis to support NHS planning.

PPE Modelling

117. In March 2020, when the extent of the pandemic was becoming clearer, the need to carry out PPE modelling was recognised, in order to understand the scale of the requirement for PPE over the course of the pandemic.

118. PPE data modelling work for Health and Social Care had initially been carried out (March–June 2020) by a PPE Directorate Data team who were responsible for developing the original forecast model. This led to two papers detailing their work, provided: [CL13/032 - INQ000496413], [CL13/033 - INQ000496414]. The original modelling for acute care was initially based on patient numbers which were available from the central SGoRR analytical team, provided: [CL13/034 - INQ000479521].

119. The team worked closely with the NSS Data and Management Information (MI) team to predict PPE demand over the course of the first phases of the pandemic. One of the purposes of this work was to provide assurance and management information to Ministers showing supply and demand, and that there were adequate stocks of PPE to meet the need across Health and Social Care. A meeting was also established with Ministers holding responsibility for Trade, to

update on supplies (initially, during the response phase this was daily, but as need reduced it moved to weekly before being paused in the autumn of 2020).

Modelling Parameters and Assumptions

120. This work also included maintaining an accurate demand signal for PPE requirements to support Covid-19 care. A demand signal is a message issued within a supply chain to notify a supplier that goods are required. In May 2020, procedures were established regarding the governance process for demand signal changes and weekly sign off of social care PPE assumptions, provided: [CL13/035 - INQ000496416], [CL13/036 - INQ000496417].

121. NSS took over the responsibility for maintaining an accurate demand signal from the PPE Team in August 2020. A number of policy teams and their clinical advisors inputted into assumptions, including areas such as Primary Care, provided: [CL13/037 - INQ000496415]. The demand signal required NSS NP to reflect the reasonable worst case scenario in response to the ongoing waves of the pandemic. NSS NP periodically reviewed demand figures based on a number of factors:

- Actual shipments/usage by Health Boards over previous reporting period
- Staff numbers contained in the latest SG COVID-19 Susceptible- Exposed – Infectious – Recovered (SEIR) scenarios (same figures used by PHS in their modelling to ensure consistency across Health)
- Engagement with Clinical and Primary Care PPE public sector governance groups to reflect latest clinical practice and guidance
- NSS Strategic Sourcing Commodity Leads' market knowledge and understanding of suppliers and products
- SG or Clinical practice policy changes, such as use of Type IIR masks in all Health Care settings, provision of PPE to other sectors or the requirement to hold 16 weeks' worth of stock rather than 12 to mitigate any supply issues caused by EU Exit. This was changed back to 12 weeks' worth of stock during 2022 based on improvements to the supply and demand position by that time.

- External market pressures, such as the impact of EU Exit transition period on supply chain.

122.The impact of the revised parameters and assumptions were input into the PPE Demand Signal dashboard. This dashboard profiles the demand signal to the available stock and confirmed orders and is based on static demand for all sectors. The model provided an indication of:

- Where forecasting met demand across the core PPE products
- Impact of an increase in demand from a particular sector, for example, increase in dental appointments, and overall impact on stock availability
- Where supply did not meet demand, to enable NSS NP to take appropriate action.

123.An example of NSS preparing ad-hoc modelling in relation to possible changes to guidance was on the practical consequences of increasing access to FFP3 respirator masks. Another example related to the demand and supply impacts of potential strengthened risk assessment guidance in relation to full face visors. In December 2021 and in response to WHO recommendations on mask use by health workers in light of the Omicron variant, NSS NP produced a draft paper (Situation, Background, Assessment, Recommendation (SBAR)) which was discussed with colleagues in the ASCPRU and Chief Nursing Officer Directorate (CNOD) to get both policy and clinical input before further discussions with NSS NP in relation to a forward buy request following on from that draft. This meant that any likely impact on supply and demand could be ascertained ahead of time.

124.Reports regarding modelling work and plans were also shared with the PPE Strategy and Governance Board which contained representatives from a range of SG Directorates. They fed back on the information in the plans and at times requested provision of further information or development of plans.

125.Any changes to the forecast demand signal were carried out via NSS in collaboration with SG PPE Team, Clinical PPE Leadership Groups and via NSS Covid-19 Governance structure process.

126.NSS is a Procurement Centre of Expertise in Scotland. As such, they have appropriate due diligence procedures as part of their contract award process. DG Health and Social Care had no role in scrutinising the contracts awarded. However, the Health and Social Care Directorates has oversight and the decision making role over the funding for procurement of pandemic PPE. The SG PPE Team worked with NSS to establish the levels of procurement required for stockpile maintenance and business as usual supplies through demand modelling and forward buy meetings. The work on agreeing demand models fed through to forward buy proposals being submitted to the PPE Team which then fed back on any concerns with the proposals. The request for a forward buy was then provided to the Director of Health Finance Governance and Value for consideration and final approval.

127.As outlined earlier in the statement, SPPD coordinated the exchange of intelligence regarding PPE stocks in Scotland through the informal COE PPE Group, which was formed of procurement leads from NSS NP, Scotland Excel, APUC, and the Central Government sectors. The exchanges within, and between, members of this group enabled different parts of the public sector to highlight low stocks, imminent deliveries, or large stocks to one another.

128.The PPE Policy Forum, referenced earlier in the statement, was chaired by the SG PPE Team and also allowed SG Policy colleagues to advise on demand for PPE within their sectors should any issues arise.

129.As detailed above, responsibility for maintaining an accurate demand signal for PPE requirements to support Covid-19 care transitioned to NSS NP by 1 August 2020. A huge amount of effort was put into their tagging data elements correctly to ensure individual products were assigned to the correct core PPE category and identifying which sector the products were being shipped to, the aim of which was to continually improve the accuracy and integrity of the data being presented.

130.The move to a pull model for health boards and Primary Care ICs gave a clearer picture of demand compared with the previous push models. When the 'pull'

system was introduced, an allocation of PPE was established based on the expected usage. For example, for dental surgeries, the allocation was calculated based on the number of patients that could be accommodated per day while adhering to IPC guidance. In the first 12 weeks of operating under this model, it was clear that the majority of Primary Care Independent Contractors were ordering at levels well below the allocation. This was assumed to be because they were using up excess stock provided through the 'push' model, and were moving towards a more appropriate stocking level for their available storage space.

131. There were some instances where individual practices were ordering significantly more than their allocation. As a result, a process was put in place where Health Boards reviewed orders for some contractors and were able to intervene if they deemed orders to be excessive. NHS NSS monitored use levels and communicated with Health Boards to reduce over-ordering and lower the risk of PPE being used for non-NHS service provision. Advanced PPE (FFP3s and non-sterile gowns) was not available to Primary Care Independent Contractors other than dentists through the 'pull' ordering model owing to these items not being routinely required by the other contractor groups. In situations where access was needed, contractors were advised to contact their local Health Boards for supply and face fit testing, as required.

132. NSS also received regular reports about demand for PPE at Adult Social Care PPE hubs and via the triage service, which were then shared with SG teams.

PPE Demand Modelling Dashboard

133. A PPE Demand Modelling dashboard was developed to enable NSS NP to perform 'what if scenario analysis' and understand impact of changes in demand across different sectors.

134. As part of the NSS NP governance process, actual shipments versus forecast demand over the previous 12 weeks were constantly reviewed. The demand for products was consistently met over the period of the pandemic. In some cases,

where the supply exceeded demand by a reasonable margin, there has been the opportunity to review to bring more in line without impacting stock levels. As at March 2021, the modelling had stabilised, and while primary care services reopening caused a spike in demand, the model was set up in such a way that changes could be made to reflect this easily.

135.NSS and SG PPE Team agreed that there would be a continued need to review the demand model for changes such as:

- Increase in elective procedures
- Covid-19 vaccination programme rollout
- Flu vaccinations
- Potential increase in cases during winter
- Introduction of new products e.g. reusable items
- Changes in HPS guidance.

136.Modelling provided a range of different estimates based on different possible variables. As shown in demand model updates from NSS NP, provided: [CL13/038 - INQ000496418], [CL13/039 - INQ000496419], [CL13/040 - INQ000496420], some of the different possible variables considered were:

- Increase in elective procedures
- Covid-19 vaccination programme rollout
- Flu vaccinations
- Potential increase in cases during winter
- Introduction of new products e.g. reusable items
- Changes in HPS guidance.

137.Initial modelling was carried out using NSS data which did not offer information about sex or ethnicity at that time. This information was also not specifically covered in the modelling documents which have been referred to above.

138.In June 2021, NSS proposed a model change to a hybrid demand model. This had a higher demand period which was informed by peak use in the preceding twelve month period. This covered a possible Covid wave (as per SG's

modelling) while using steady state demand from the previous six months for the rest of the period. PPE Team and NSS agreed to then review the forward modelling monthly to see whether the anticipated demand, or length of the higher anticipated demand period, should be adjusted. This approach was agreed as it used knowledge of demand during the pandemic, while also allowing for regular monitoring of the demand model and reflecting the more secure supply chains which had been developed during the pandemic

PPE Daily Stock and Shipments Dashboard

139. The first PPE demand and supply dashboard – SG 12 Week Daily Oversight Dashboard – was created in collaboration with the SG PPE Team and Scottish Manufacturing Supply Chain Working Group, chaired by the Minister for Trade, Innovation and Public Finance. The aim of the dashboard was to provide assurance of supply and demand for the core PPE products, advising on a daily basis to stakeholders (SG, Scottish Enterprise, NHS, Primary and Social Care leads):

- Current PPE stock levels held at NP NDC
- Health Board stock levels (where data submitted)
- Weekly demand
- Orders placed and of those which are at risk of not coming in
- Estimated date stock of that core PPE category product will run out.

140. The dashboard refreshed daily at 0800hrs, 1430hrs and 1630hrs and allowed the SG PPE team instant access to the data. Data was included in the Daily Stock Bulletin (which was initially shared daily, and then sent out twice weekly as of March 2021) and provided a RAG status and associated comments for each core PPE category. Over 100 bulletins had been issued as of March 2021.

141. These bulletins did not highlight any instances where changes in IPC guidance were directly responsible for effects on the ability of NSS to procure PPE at the levels needed. However, it should be noted that given that PPE supply was so challenging early in the pandemic, and the need to undertake the procurement in

anticipation of what is likely to be required, it would be difficult to directly link procurement issues with any single change in IPC guidance.

National Procurement Information Bureau Service

142.The National Procurement Information Bureau service was launched in September 2020. This provided an avenue through which SG could request stock or other information from NSS NP, and this was utilised as well as requests via email to NSS NP.

143.NSS also issued a regular bulletin for people in health and social care with an interest in PPE supplies, with stock levels and wider updates. Members of the PPE Team were recipients of this bulletin.

Developing a new national inventory management system

144.As NSS NP and Health Boards needed clear visibility of the level of stock of Covid-19 critical products that were held locally and accurate consumption figures, the SG provided investment to NSS NP to improve stock management, to improve visibility and use of PPE.

145.There was a need for management information for demand forecasting to manage the risk of shortages, stockpiling, emergency orders and escalations. In addition, where there was a quality issue with PPE and a recall required, there were challenges in establishing where those products were held and to remove PPE stock quickly to ensure it was not available for clinical staff to use.

146.To ensure that pandemic PPE was available throughout the pandemic, it was essential that NSS NP work with health boards to ensure a robust NHS Scotland inventory management solution was in place on an accelerated basis.

147.A dedicated Short Life Working Group considered this requirement in relation to PPE and other Covid-19 stock confirmed that, in order to be successful, this required improvements to the existing stock management system, robust data collection and management information systems to provide NSS NP and Health

Boards with a real time view of Covid-19 critical stock location and consumption to inform National Demand Modelling and Forecasting.

148. Following a comprehensive procurement process involving Clinical colleagues, Procurement, Finance, Stock Management and IT representatives from across NHS Scotland Health Boards, a contract was awarded by NHS NSS to deliver a new national inventory management system. The new system offers a comprehensive package of software, analytics and implementation support which is built on modern cloud based technology to ensure it is future proof and aligns with Scotland's Digital Health and Care Strategy. The system is intended to allow for better inventory management, less waste, more information on costing and clinical variation which would help to ensure all health and social care workers who need PPE can access it to protect them from the Covid-19 virus. It also gives Health Boards current data regarding consumable stock levels.

149. As a result of an SBAR paper to SG, formal confirmation was given that SG would provide funding for implementation and ongoing support costs for a national inventory management system which addresses the issues above and provides a real time view of Covid-19 critical stock location and consumption that will inform National Demand Modelling and Forecasting. Roll out of this system began during the pandemic and is continuing across health boards in NHS Scotland outwith NSS.

Third Party Framework Modelling

150. As already set out earlier in this statement, there was limited procurement carried out by procurement teams within SG in relation to pandemic PPE, as the majority was done by NSS. However, SG did develop a third-party framework (also referred to as 'the Lyreco contract') at the start of the pandemic following urgent requests for help from public and private sector organisations, who were experiencing difficulties in obtaining PPE supplies. More detail on the third party framework is provided later in the statement at paragraphs 182-185, but information on the related modelling undertaken by SG is detailed here.

151. In relation to hand sanitiser, the initial procurement carried out by SG procurement teams was based on high level estimates of likely demand. Given the short period of time over which procurement was undertaken by procurement teams within the SG and its limited extent, no revision of the estimates were undertaken during these short term contracts.

152. A summary spreadsheet was used to collate details of modelling carried out during April and May 2020 in relation to likely demand for the third-party PPE framework, provided: [CL13/041 - INQ000496412]. This is one of a number of versions which were created using information gathered via policy teams, PPE Team and SPPD using information provided by the sectors. During the period of the framework, procurement officials overseeing the framework received management information from the framework provider as to use by sector to inform discussions about stock purchasing, including the maximum and minimum levels.

153. Officials from the SG PPE Team held regular meetings with the supplier Lyreco to discuss management information. The PPE Team also carried out two surveys of users of the framework which included questions about registered customers' access to PPE supplies outwith the framework.

Acute Modelling

154. The SG PPE Directorate Data team were responsible for developing the original forecast model. The Acute side of the model was based on patient numbers initially, which were available from the C-19 MAH. During May 2020, it became apparent that the approach was no longer optimal, with HPS guidance being focussed on staffing, and protection of front-line workers. Therefore, the SG PPE Data team transitioned from a patient-based model to a staff-based model. This also allowed non-Covid demand to be included, for patients in hospital for other reasons where staff treating these patients still required PPE. The SG PPE Data team began by building a relatively basic staffing model at a national level, using data on staffing numbers from NSS, and making high level assumptions about

PPE usage based on HPS guidance and how used was expected to change. This showed an increase on the patient-based model, but this was to be expected.

155.To refine this model, and in order to move towards using it for reporting, the SG PPE Data team developed a template to be filled out at health board level, which would allow a bottom-up validation of the national model to be created. Health boards were tasked with completing the template, which asked for total staff number, split between hospital areas where different PPE ensembles would be required (ICU Aerosol Generating Procedures (AGP), non-ICU AGP, COVID ward, outpatients, A&E etc.). They were also asked to estimate PPE use for each of these staff types and could vary number of shifts and the percentage of staff requiring PPE. Each health board returned their completed template, and there was initially a wide variation in expected PPE usage, as well as expected staffing splits between wards. The team gave individual feedback to each Board, and refined assumptions with them to ensure these reflected the most realistic picture of usage. During that process, health boards provided constructive feedback on the approach and template. One key change was to split out Allied Health Professionals (AHPs) separately.

156.While the forecasts returned from this exercise did improve, there was still a wide variation between boards. The need for more scrutiny and direction from a clinical perspective was noted and the SG team took the current modelling and approach to the Clinical PPE SLWG. This was discussed over two to three meetings, with the decision made that the best input would come from the CAP group. The SG PPE Data team presented the modelling there, and with the scale of the challenge in the modelling work, it was decided a sub-group was needed, which came to be chaired by a nominee from NHS Lothian.

157.Initially, acute modelling followed these assumptions:

- The model was based on staff numbers derived from latest PHS SEIR scenario modelling averaged per week.
- Staffing numbers were shown as Whole Time Equivalent (WTE)
- A WTE equates to one eight-hour working period

- All staff allocated to ICU activity were assumed to wear AGP PPE
- 25% of staff in a General ward would wear AGP PPE
- AGP PPE (FFP3 respirators and AGP Gowns) are changed four times in an eight hour period, except Visors which are changed two times in an eight hour period
- Standard PPE (Gloves, Surgical masks and aprons) is changed seven times in an eight hour period

However, following engagement with the PPE Clinical Lead, the following changes were proposed to acute assumptions to reflect clinical practice more accurately:

- FFP3 revised to two changes per staff member
- Type IIR and Aprons revised to 14 changes per staff member
- Gloves revised to 57 changes per 24 hours (average used over 12-week period)
- Visors revised to six changes per 24 hours (based on increased usage over a five week period).

PPE Social Care modelling

158. Social Care includes care homes, care at home, unpaid carers, personal assistants and respite care. The predictive modelling was built based on staff numbers (including numbers of unpaid carers). For each staff category, total staff numbers from publicly available information were identified and the team consulted with relevant policy colleagues and sector leads. The SG PPE Data team then subtracted a percentage from this staffing number for annual leave, part time working and sickness absence. Taking this total staff number, it was then multiplied by expected usage per day, so number of uses of PPE per shift, then multiplied by daily and weekly usage. SG and NHS PPE Data teams worked closely with policy colleagues, care providers, third parties, and consulted HPS guidance in forming assumptions. The figures were also adjusted to account for percentage supplied through NSS and percentage in operation, noting some procurement was done locally and not all services operated at usual capacity during the pandemic.

- The demand was based on the percentage of Social care services accessing the national pandemic stock.

- The impact of an assumed no deal end to the EU EXIT transition period was factored in to the January and February 2021 period using the weighted average figure below.

	Apr	May	Jun	Jul	Sept	Aug
Care homes	38%	38%	38%	38%	38%	38%
Unpaid carers	100%	100%	100%	100%	100%	100%
Care at home and personal assistants	42%	42%	42%	42%	42%	42%
Hospices	30%	30%	30%	30%	30%	30%
Weighted Average	40%	40%	30%	30%	20%	20%

Primary Care modelling

159.Primary care was modelled using the same method as social care, covering General Medical Services, Community Pharmacy, General Medical Services and Community Optometrists.

- The demand was based on number of staff and percentage of primary care services returned to service
- Dentistry had been capped at 10 sessions per day with five AGP and five Non- AGP Procedures for 2,000 surgeries.

Staff and % of Services Stood Up	Nov	Dec	Jan	Feb	Mar
GP	50%	50%	50%	50%	50%
Pharmacy	100%	100%	100%	100%	100%
Optometry	50%	50%	50%	50%	50%
Dentistry	100%	100%	100%	100%	100%
Community Assessment Hubs	100%	100%	100%	100%	100%

160. The demand signal for AGP Non-Sterile Gowns was increased in line with Dental expansion from five AGP procedures for a maximum of 2,000 dentists. This amount increased as dental stepped up more practices and increased the number of AGP procedures. The table below shows the forecast for dental AGP gowns per number of AGP procedures as at March 2021.

Number of ACP Procedures	Dentist AGP Gowns Forecast
5	100,000
6	120,000
7	140,000
8	160,000
9	180,000
10	200,000

PPE Fit Testing

161. Under the Personal Protective Equipment at Work Regulations (1992) it is the responsibility of employers to ensure that their employees have the correct PPE

for the tasks being undertaken. As the employer, individual Health Boards were responsible for ensuring that plans were in place for fit testing of PPE through their local preparedness plans, taking into consideration the specific functions and services provided.

162.NSS provided support for face fit testing (FFT) to Health Boards. NSS put in place a contract for dedicated face fit testers and supplied portacount machines to allow such FFT to take place. Several “train-the-trainer” approaches were developed by NHS Health Boards during the peak of the pandemic to expand internal qualitative testing capacity, these programmes allowed testers to spend time with NHS staff who would then be able to carry out FFT after walking through the process several times with a verified face fit tester. In order to facilitate robust quantitative testing, testers required access to a ‘TSI Portacount’ device which is a quantitative fit testing device that produces direct face fitting numerical results. SG providing funding to NSS to enable them to procure 20 Portacount machines.

163.As above, NSS put in place a contract to provide dedicated face fit testers, through the supplier ARCO. In October 2020, there were eight dedicated face fit testers, and by March 2021 this had increased to 35. In March 2021, NSS co-ordinated the migration away from a particular model of FFP3 mask that was being discontinued. In addition, a small scale three-week programme involving NHS Dumfries and Galloway was undertaken with Alpha Solway to provide detailed FFT Support.

164.SG are not aware of any concerns raised in relation to the performance of these companies.

165.NSS also took part in regular meetings with health boards regarding FFT and face masks, and ARCO provided NSS with reports on the utilisation of the service. NSS, in turn, provided SG with information on issues relating to FFT within their FFP3 update. The Health and Social Care Directorates maintained regular contact with health boards.

- 166.Primary Care contractors arranged face fit testing via their Health Board.
- 167.There is currently no national FFT policy. Each health board manages its own policy and they all capture and store the data from this individually. This includes the time between re-Fit Testing staff. Establishing a national approach to frequency of FFT and record keeping is currently under consideration.
- 168.The Social Care sector is split into three sub categories of provision: Public Providers, Private Providers and Third Sector Charitable Providers. Private and Charitable providers can obtain Risk Assessments and Face Fit testing support from private contractors and the cost of these services was recoverable through sustainability funds. Public Sector providers could secure these services through their local authority and regional HSCP networks. Care homes were usually supported in this through the care home oversight groups.
- 169.The HSE provides guidance on the types of Respiratory Protective Equipment (RPE) (including FFP3 masks) that require face fit testing to ensure that the PPE provided is suitable for the wearer. It is recommended by the HSE that a fit test should be repeated every two years or whenever there is a change to the circumstances of the wearer such as ageing, weight loss or gain, substantial dental work, facial piercings or scarring.
- 170.The National Infection Prevention and Control Manual (NIPCM) provides guidance on the circumstances where PPE that produces a continuous seal with the user's face should be used. In order to fully protect the user, the seal must be complete with no leaks. Users are face fit tested to different models of FFP3 masks, and are required to use only the models that they are successfully fitted to and that can produce a complete seal with no leaks. There are individuals for whom RPE that requires a tight seal is not suitable, for example those with pre-existing medical conditions (such as asthma) or those with facial hair. Health Boards were able to source further items to best suit the individual situation, where there was a particular need for a model not catered for by the central suite provided by NSS.

Ensuring PPE was suitable for all

171. On 7 May 2020, the Cabinet Secretary for Health and Sport brought to the attention of the Health and Sport Committee the issues women were experiencing getting face-fitted to FFP3 masks that were designed for male faces.
172. Oversight of provision of masks that fit all frontline workers fell within the remit of the PPE Strategy and Governance Board, described earlier in this statement.
173. The PPE Action Plan recognised the challenges that had been expressed by some women and minority ethnic individuals who rely on PPE. The Action plan detailed that work was ongoing to improve users' comfort.
174. In 2020, NSS agreed a contract for a Scotland-based company (Alpha Solway), flowing from collaborative work involving SG, NSS and Scottish Enterprise to support the supply of vital FRSM (Type IIR) masks, visors and FFP3 masks for Scotland's health and social care sector until summer 2021. This partnership led to NHS Scotland receiving FFP3 masks to a specification that recognises the staff demographic within the Health Sector. A small scale study carried out in late 2020, in which 90% of participants were female, showed that the overall 'fit pass rate' for this mask was 81.5%. The pass rate for comparable models sat between 55%–63%. The NHS Scotland supplier also provided teams of expert fit testers to help hospitals introduce the new products quickly.
175. The PPE Team made contact with HPS and the Deputy Chief Nursing Officer from NHS England and NHS Improvement to better understand the challenges in relation to PPE fit for ethnic minorities and in relation to gender. The PPE Unit also carried out a literature review in relation to this subject, provided: [CL13/042 - INQ000496460].
176. SG further recognised the challenges that had been expressed by some women and minority ethnic individuals who rely on PPE and detailed this in a letter to the

British Medical Association (BMA) on 20 January 2021, provided: [CL13/043 - INQ000398869].

177. Where there was a range of sizing options available for PPE items, NSS bought and made available a wide range of sizes, making it easier to ensure that the majority of healthcare workers could get items that fitted. For example, NSS were providing at least eight different models of FFP3 by March 2021 and were issuing four sizes of nitrile gloves from pandemic stocks. Where available, products were bought with adjustable attributes. Further initiatives that NHS Scotland took in relation to fitting PPE correctly and safely for staff were working with ARHAI Scotland within NSS and local infection control staff on specific guidance, including diagrams and processes to support staff in the fit of PPE; training staff in the use and fitting of PPE, as well as regularly reviewing fitting techniques; employing dedicated face-fit testers, either through local board personnel or contracted through external suppliers, to provide expert advice and support in ensuring fit of PPE for staff.

178. In May 2021, the innovation working group submitted a strategy paper to the PPE Strategy and Governance Board with improved user experience highlighted as a priority area, provided: [CL13/030 - INQ000479589]. The group undertook to update the Board quarterly on progress.

179. Prior to the pandemic, best estimates suggest that about 7,000 staff across the whole of NHS Scotland were Face Fit Tested (FFT) to FFP3 masks. By March 2022, this had increased to over 75,000 staff in acute settings alone.

180. SG monitored issues with FFT through:

- Information provided by NSS in their regular FFP3 update;
- The dedicated PPE helpline mailbox for HSC staff; and
- The SPoC Group

181. The issues of fitment highlighted from these sources led to NSS sourcing FFP3 masks that were to a specification that recognised the demographic within the health sector. As a result of the measures taken by NSS to provide a range of

types and sizes of PPE, the numbers of issues raised via these avenues rapidly declined. As noted previously, the PPE helpline did not break down the correspondence received into all possible categories and as a result cannot provide details of the specific reduction in correspondence related to fit-testing. Further information on the measures taken by NSS to provide a range of types and sizes of PPE may be sought from NSS.

Procurement of PPE for key industries with significant overlap with the health sector

The Lyreco Contract

182.As already set out earlier in this statement, SG supported the coordination of procurement of PPE for non-health organisations and essential services with no or limited access to supply through the development of a third-party framework (also referred to as ‘the Lyreco contract’). This was established at the start of the Covid-19 pandemic following urgent requests for help from public and private sector organisations, who were experiencing difficulties in obtaining PPE supplies. Organisations that were eligible to call-off from the framework agreement included all Scottish public bodies outwith either the NHS or the regulated care sector; registered Scottish charities and voluntary organisations; and authorised private sector organisations employing staff who provided essential public services where there was a risk to health.

183.The framework was set up by SPPD on an exceptional basis to respond to an unprecedented need and was awarded under a Non-Competitive Action (NCA). The initial contracted period of the Framework Agreement commenced on 26 May 2020 and continued until 30 April 2021.

184.SG exercised this right to extend the framework period to ensure that essential services still had access to appropriate PPE. The framework agreement was extended until 31 October 2021 by which time PPE supply had stabilised.

185. More information in relation to this procurement has been provided in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024.

Collection and disposal of bodies

186. Funeral directors and those involved in the collection and disposal of bodies were also eligible to procure PPE from the third party framework.

187. In April 2020, the Burial and Cremation Team within the Directorate for Population Health had a number of discussions with representatives of the funeral sector in relation to their ability to access appropriate equipment such as PPE and body bags. Until the PPE Action Plan could be put in place, in April 2020, the Minister for Public Health agreed a short-term solution to enable funeral directors to access stocks of health care PPE if they urgently needed it to continue to perform their services. This option was available until stock was secured in the longer term by the PPE Action Plan. The Cabinet Secretary for Health and Sport wrote to the Cross-Parliamentary Group on Funerals and Bereavement on 28 April 2020 confirming funeral directors who needed PPE would be able to access healthcare supplies.

188. The contract under the SG PPE Action Plan was not used by as many funeral directors as was initially anticipated, which may have been as a result of the time taken to set it up. However, the contract remained in place for some time in case it was needed. Following feedback from the industry that their PPE supply chains were strong, the Lyreco contract was terminated in October 2021.

189. Contractors carrying out NHS functions who were experiencing difficulties obtaining PPE supplies were referred to their Health Board SPoC for assistance. Similarly, contractors carrying out non-healthcare roles in healthcare settings who were experiencing difficulties obtaining PPE supplies were referred to their Health Board SPoC for help.

Competition to reduce single use PPE

190. On 1 March 2021, a Small Business Research Initiative (SBRI) competition was launched for cleaning and reuse of PPE and environmental decontamination. The competition was coordinated by NHS Tayside and funded by the SG, with additional contribution from Transport Scotland.

191. The aim of the competition was to develop solutions that aid prevention or reduce the spread of droplet and airborne biological hazards, reduce NHS staff reliance on single use disposable PPE, and allow the return of clinical procedures which were considered high risk because of their aerosol generating nature. This may be achieved through the development of re-useable PPE, methods of decontamination, or methods of area/surface/air cleansing which avoids the requirement for PPE use, or a combination of these.

192. The testing ("test-bed") environment was provided by NHS Tayside with additional support from the Balhousie Care Group, Zero Waste Scotland and a Programme Steering Group, with wide-ranging membership which included expertise from IPC, Decontamination, Health and Safety, Medical Physics and other technical, clinical and support areas.

193. The SBRI Stage 1 helped develop products but did not take them as far as becoming medically and commercially approved.

194. The SBRI highlighted some of the key issues that both companies and NHS Boards in Scotland face when wishing to introduce and procure reusable PPE. One of the main issues with face protection is the decontamination of the PPE and the need for nationally adopted standards for this.

195. Early in the pandemic, NSS purchased a large order of reusable gowns. This was largely as a way of insuring against failure of PPE supplies, a real threat at the time. A small review of the gowns was carried out, and it was found that after an initial upsurge in uptake, usage reduced to almost zero as the gowns were heavy and hot to wear.

196.The SG did not award any contracts for reusable PPE as NSS is responsible for national PPE contracts in Scotland and was responsible for supplying PPE to the healthcare system during the pandemic.

Surplus PPE

197.Amounts of pandemic PPE stock were written off during the pandemic. This stock was not used. Given that stock was procured to cope with a reasonable worst case scenario, however, this does not necessarily mean that it was not required. NSS NP undertook procurement with oversight and funding provided by the Health and Social Care Directorates. NSS advised that the amounts of pandemic stock written off were £1.96 million during Financial Year 2020-21, £0.64 million during Financial Year 2021-22 and £5.75 million (this figure includes test kits as well as pandemic PPE) in 2022-23. Slow moving stock adjustment and donations of pandemic PPE stock were also made by NSS during the above Financial Years. Further details can be provided by NSS.

198.From the outset of the Covid-19 pandemic, when demand for PPE suddenly spiked and international supply chains faltered and in some cases failed, SG has worked with NSS NP to ensure Scotland has adequate stocks of PPE supplies to meet the level of demand, including by importation and by building a new Scottish supply chain from scratch. This resulted in stock that is additional to requirements in health and social care settings.

199.At the outset of the Covid-19 pandemic, there were substantial stockpiles of PPE held on a four nations basis. These were based on modelled provision required in relation to an influenza pandemic and supplemented by supplies for day to day NHS usage. However, there was limited opportunity to rotate the PPE items within the stockpile, resulting in some stock going out of date and having to be revalidated before use.

200.Additionally, in the earlier phases of the pandemic rapid investment in PPE was necessary, and in line with the modelling of potential needs undertaken at that time, NSS purchased significant levels of stock against a potential worst case

pandemic scenario in order to ensure an adequate stockpile was held. Some items procured were labelled in a manner which shortened shelf life, such as hand sanitiser that was received with less than two-year labelled shelf life. In addition, there were a few instances of pandemic PPE stock not being correctly recorded when received. Issues identified by NSS and to be prevented by the new stock management system when it was later introduced.

201.Demand for PPE in health and social care during the pandemic was high, and challenging to forecast. For example, from February 2020 to the end of 2020, there was around a 350% increase in demand for PPE overall compared to the previous year. To illustrate this increase, NHS Scotland were using 3 million type IIR masks a day in August 2021, which was the annual demand in 2019. Demand was significantly higher in the first few months of the pandemic as a response to immediate demands and the need to build forecast demands. Demand has also fluctuated in response to variables such as the number of Covid patients, infection rates in the community, changes in IPC guidance on the use of PPE and the impact of the vaccine and changes in preference in relation to items such as tie back IIR masks.

202.For particular product lines, there may be specific reasons for stock not being used at the expected rate, such as the tie back Type IIRs mentioned above. When NSS procured type IIR masks, health boards were asked for their preference on the split between tie back and ear loop masks. They responded that a split of 20% tie backs to 80% ear loops was preferred. NSS procured masks on this basis. However, Health Board use of the tie back masks has reduced considerably below 20% of IIR use.

203.The precise volume of surplus stock is challenging to record because there continues to be fluctuations in the volume of stock moving in and out of NSS warehouses and in use by health and social care settings. In March 2022, NSS conducted an inventory of the NDC as well as contacting health boards to determine the level of stock for various PPE items. It was found that there was significant stock paired with particularly low usage rates of the following items: tieback type IIR masks, HX3 FFP3 masks, and re-usable non-sterile AGP gowns.

204.NSS will be able to provide information on what PPE remains in stock and what stock was held at the end of the pandemic. It should be noted that this stock is still available for use within NHS Scotland and is not, therefore, all excess stock.

205.As already set out SG worked with key partners throughout the pandemic to ensure an adequate PPE supply for Scotland. This resulted in PPE stock that was unlikely to be used in health and social care settings as the pandemic progressed or for which continued retention would not benefit the public purse. This PPE was directed to other areas of the public sector, donated internationally, or recycled to provide the best value for money for the taxpayer and minimise environmental impact. There were also a number of donations to charities such as food banks. In April 2021, NSS notified the PPE Team of a number of products held at the NDC that were unlikely to be used in health and social care. This included Type IIR masks, goggles, respirators (FFP2 and FFP3) and visors.

206.In June 2021, unused empty hand sanitiser bottles were identified as no longer required with the potential to sell and approval was given for NSS to pursue this option.

207.A short life working group (SLWG) was set up to reduce the stock of PPE held, which was identified by NSS as being no longer required, to minimise any wastage and maximise benefit to the public sector while ensuring that current Health and Social Care policy commitments continue to be met. The SLWG provided advice to Ministers and policy makers on strategies which should be adopted to reduce the overall stock of PPE identified by NSS as no longer required, as well as carrying out work to make sure that these strategies were carried out effectively. The terms of reference and guiding principles are provided. The priority identified by the PPE Stock SLWG for use of surplus stock (in order of priority) was:

- 1st - Health and Social Care users
- 2nd - Other public bodies
- 3rd - Charitable organisations registered with the Office of the Scottish Charity Regulator
- 4th - Private sector users.

208.The SLWG developed several additional overarching objectives to avoid wastage and to ensure that any opportunity to save public sector funds through the distribution of surplus PPE should be explored and evaluated on a case by case basis.

209.A commitment was made that all surplus stock should be provided following the principal that PPE provision is ethical:

- Any surplus stock for which demand cannot be identified or which can no longer be used due to expiry date/quality concerns should be disposed of in a manner which minimises environmental damage and economic loss.
- Provision of surplus PPE stock should be on a need basis rather than being driven by the availability of surplus stock.

210.The group oversaw several significant donations of PPE stock to public sector and charitable organisations in Scotland. In addition, in August 2021 the group received approval from the Cabinet Secretary for Health to co-ordinate several shipments of almost 26 million units of PPE to international development Partner Countries in Malawi, Zambia and Rwanda.

211.The distribution of the PPE that was unlikely to be used by health and social care was managed by NSS.

212.The PPE Stock Short Life Working Group Terms of Reference and Guiding Principles are provided: [CL13/044 - INQ000496528], [CL13/045 - INQ000496529].

Supply chain external mailbox

213.As well as PPE, there was an unprecedented demand on other global health supplies arising from the Covid-19 pandemic, and there was a need to secure additional equipment and supplies to help meet the immediate demand.

214.A Daily Ministerial call (initially seven days a week before reducing to five days a week, three days a week and then weekly) was chaired by Ivan McKee, Minister

for Trade, Investment and Innovation. This meeting was attended by SG officials, Enterprise Agencies, NSS and others where required.

215. This group was established to:

- Identify potential sources of materials and equipment required for the pandemic, with a primary focus on working with Scottish manufacturers to redirect or expand production to supporting national requirements
- Coordinate and oversee cross-agency activity to process the business offers received
- Scrutinise potential suppliers
- Support new domestic supply chains.

216. In addition, on 22 March 2020, the Minister for Trade, Investment and Innovation, Ivan McKee, wrote to companies Account Managed by Scottish Enterprise to invite them to consider how they could help us deliver critical supplies to NHS Scotland and other front-line services, and included a list of priority items.

217. This, along with a general desire to help from companies, resulted in wide areas of SG receiving emails offering help with supplies of equipment and PPE. In order to ensure the effective coordination of these offers, a mailbox was set up to receive these initial offers of support. Officials from the Health and Social Care Directorates worked with colleagues from Economy Directorates to set up the mailbox and were part of the workstreams looking at the various commodities.

218. This mailbox was supported by a team of data capture officers who transferred the information in the emails into a database. This was followed by a number of other levels of assessment in order to identify whether they are viable offers of support. In summary, the assessment levels were as follows:

- Level 1 - In the data capture process, data capture officers qualified enquiries against basic criteria including critical NHS supply needs such as ventilators, masks and gowns. Where the offer does not appear to be genuine or feasible at any stage of the process a polite reply declining the offer was issued

- Level 2 – Those offers of support that qualified at level 1 were shared with specialists, drawn from government and partner bodies, who considered the offer of support in more detail and reach a conclusion as to whether there is scope to pursue further.
- Level 3 - The NHS were engaged to link offers to critical needs and proceed to negotiate a supply contract with the potential supplier.

219. Information relating to the number of staff assigned to the supply chain mailbox, and the training or assistance they were given in respect of supply chains and logistics is not available.

220. In total the supply chain mailbox received 2,846 emails offering support. While it not possible to provide an average response time for correspondence received by this mailbox, all correspondence received by this mailbox had been responded to and closed down by 23 June 2020.

221. On 17 April 2020, NSS launched an online Portal to replace this mailbox and improve the supplier journey. Health and Social Care Directorates had no role in relation to the NSS portal other than to redirect offers from suppliers that had contacted the SG mailboxes to the portal. As such, information on average response times received by the NSS online portal cannot be provided. This portal closed on 30 June 2020 and received 2,047 supply offers in total. NSS will hold further information on this portal, including staffing and related training.

Cross UK working on PPE

222. In the early stages of the pandemic, Health EPRR worked to develop principles of stock sharing with other UK nations. A Four Nations PPE governance group was established at the beginning of the outbreak to ensure decisions on the procurement of PPE were transparent across the UK partners and consider the different views and responsibilities across the four nations. This group, the Strategic PPE Four Nations Board, was chaired by the DHSC and was attended by SG and other devolved governments' officials. Further details on the Board are provided earlier in the statement.

223. A protocol was initially drawn up to formalise agreement on the way in which the UK procured pandemic stock would be distributed as part of the Covid-19 response. The first protocol was drawn up to meet urgent temporary needs.

224. Early in the pandemic, the PPE being delivered to the devolved administrations (DAs) through the UK wide procurement was limited. This resulted in the DAs incurring significant costs to secure sufficient PPE to protect frontline workers. The DAs understood that DHSC could not guarantee that UKG-led PPE procurement could meet the needs of the devolved governments at that time. This situation meant that independent procurement of pandemic PPE by NSS provided the majority of Scottish PPE stock.

225. In May 2020, a joint letter from the three DAs Finance Ministers, provided: [CL13/046 - INQ000336538], raised these concerns. The letter also stated that before any formal protocol was agreed, assurance had to be given that funding to meet the costs already incurred to procure adequate PPE would be provided. There was also a commitment in line with the protocol that the costs of any further procurement that was necessary to meet demand would be fully funded by the UKG, regardless on which administration was undertaking the procurement.

226. The letter noted that despite it having been agreed that UKG and DA officials would work together to consider the basis of costs incurred to date, HM Treasury was providing all funding for PPE to the DHSC. The three DAs expected to receive funding to cover fully the costs already incurred, independently of the procurement route taken and asked for the Chief Secretary to the Treasury's support in securing the necessary budget transfers with the Secretary of State for Health and Social Care. Before any formal protocol was agreed, assurance had to be given that funding to meet the costs already incurred to procure adequate PPE would be provided. Assurances were provided and evidenced in HMT forecasts of consequentials, allowing the protocol to be approved by the Cabinet Secretary in February 2021.

227.The Audit Scotland briefing from June 2021, provided: [CL13/047 - INQ000108737], highlighted that during the period March 2020 to April 2021 NSS awarded 78 contracts worth £340 million to companies providing PPE.

228.The DHSC's PPE strategy was published on 28 September 2020 and was welcomed by SG. The strategy emphasised that mutual aid and cooperation across and between all four nations had been a key part of ensuring PPE gets to where it was needed. With PPE requirements having been met, and with an increase in PPE stock and domestic supplies, the protocol - which had initially been drawn up to formalise agreement on the way in which the UK procured pandemic stock would be distributed between home nations as part of the Covid-19 response - was redrafted to focus on longer term collaborative procurement.

229.The Cabinet Secretary for Health and Sport gave her agreement to the revised Four Nations PPE protocol on 16 February 2021. As laid out in that protocol, the SG retained authority over PPE procurement decisions. During the period covered by this module, pandemic PPE was sourced and distributed on behalf of the SG by NSS. Details of the extent to which procurement was a collaborative exercise will therefore be held by NSS.

230.The SG are aware that there was interaction between NSS and the UK Government in relation to the procurement of 3M FFP3 masks. There was also an opportunity to join in a non-sterile glove procurement led by DHSC in May 2021. Scotland did not join this procurement, but did provide relevant information to the four nations group to assist with their planning. There was also the provision of mutual aid between Scotland and England and between DAs.

231.Mutual aid for PPE was provided via NSS, who will hold full details of the exchanges. However, the SG is aware of the following mutual aid being provided to Four Nations partners:

- 2,016,000 Type IIR masks were issued to England in May 2020 by NSS NP, for which they were financially compensated

- 1,200,000 Type IIR masks (200,000 initially and a further 1 million in April/May 2020) were issued to Wales in response to a request following delays to their supplies. Wales returned 1,200,000 Type IIR masks soon after.

232. Where possible there was mutual aid and joint working for example on UK access to Renal Replacement Therapy fluids, sharing intelligence on suppliers from NSS. There was joint working on international donations including to India, Ukraine and Nepal.

233. The SG worked with the UKG and administrations in Wales and Northern Ireland to maximise efficiencies and collaborate where it made sense to do so. This included co-operation on the procurement and distribution of PPE across the UK as part of the Four Nations PPE Plan, which first launched on 10 April 2020.

234. In response to a letter from the Permanent Secretary for DHSC on 16 April 2020, provided: [CL13/048 - INQ000496582], which stated the Department of International Trade/Foreign and Commonwealth Office overseas networks should not support new contracts to supply DA needs, on 21 April 2020, the Cabinet Secretary for Health and Sport wrote to the Secretary of State. The Cabinet Secretary raised concerns about procurement of medical supplies, including PPE, highlighting that it was a devolved matter and the role and operation of the Joint Action Coordination Team (JACT) should not seek to supersede the DAs' individual procurement efforts. The UKG overseas network would normally be expected to provide support to the devolved administrations in areas of devolved responsibility. Procurement of PPE for the NHS in Scotland is a matter for the Scottish Ministers and not one on which the UK Government has powers to make decisions - it is not open for the UK to decide unilaterally that there should be a pan-UK approach.

235. There were challenges during 2020 in relation to accessing sufficient data about UKG's stocks of PPE which had an effect in relation to Scotland's PPE procurement decisions. SG were able to access information about pricing of DHSC stocks but not the extent of stock held or on order. The data sharing

improved following discussions in early 2021, after which the updated protocol was signed in February 2021 [CL13/048a - INQ000508437], with the protocol involving agreement to:

- seek value for money and will seek to minimise competition between the four nations on the international market – opting-in to joint procurement where this will secure better-value PPE purchases and sharing learning and intelligence from its own PPE purchasing operations, including generated leads that may benefit the other nations
- stand ready to collaborate on PPE sourcing and supply, drawing on the support of the established UK Government overseas network
- collaborate on improving resilience, including building up a stockpile against subsequent waves
- share information on PPE stock, forward orders and shortage items to enable a UK-wide view of the current stock position and supply priorities to be taken
- recognise that the UK Government and each Devolved Administration controls its own PPE funding envelope and any stock will be chargeable at a full cost recovery basis.

236.The 4 Nations Demand and Supply meetings showed the PPE demand and supply position across the four nations. One hurdle which arose in relation to procurement of PPE items which was discussed at these meetings, however, was the pricing of PPE stock. The UK Treasury would initially only agree to sell stock at cost price (which had been bought at a time when market rates were at a peak). There was an eventual change to move this to market value. If that decision had been made earlier, it may have increased procurement from UK stocks.

237.On PPE, as noted earlier, a four nations PPE governance group was established at the beginning of the outbreak to ensure decisions on the procurement of PPE were transparent across the UK partners and to consider the different views and responsibilities across the four nations. The Group was chaired by the DHSC and

attended by SG and other devolved governments' officials. Further information on the workings and remit of this group has been provided above.

Country Modelling Group

238. By 11 March 2020, sharing of modelling had been agreed between logistical modellers in NHS England and SG with contact between modellers made by 18 March. Modelling contact with the Welsh Government was made on 16 March and Northern Irish modellers on 24 March. This formed the starting point for four nations work through the '4 Country Modelling Group' which met throughout the pandemic and had its secretariat in the Welsh Government before transferring to JCB/UKHSA late in the pandemic [18 March 2020 to 24 June 2022]. The first meeting where modelling code was discussed was on 18 March. Modelling of the epidemic helped to inform modelling work for PPE and procurement.

Distribution of PPE and key equipment and supplies

Availability of PPE

239. The SPoC oversight group, detailed earlier, met virtually on a fortnightly basis.

The group had an information and advisory role, feeding into policy officials, Board Chief Executives and the Chief Nursing Officer. There was direct contact between officials and SPoCs for information sharing purposes and to address individual reports of localised PPE supply issues.

240. As the provision of PPE broadly stabilised and systems were in place to manage the operational aspects of continuing good supply, the content of the SPoC meetings became more operational in focus. It was identified that there was a need to ensure strategic matters were properly considered with operational aspects being dealt with by an appropriate forum.

241. As the response to Covid-19 moved into a recovery phase the purpose of the SPoC oversight group developed and became refocused on the wider strategic issues for procurement and supply for the remobilisation of acute services (one aspect of which continued to be PPE). The PPE SPoC group was, therefore,

amended to become the Strategic SPoC Group for Remobilisation Supplies (of which PPE was still part) in June 2020. The agenda was to focus on consideration of the impact and enabling work procurement services could do to support remobilisation and the ongoing Covid response. A separate PPE operational supplies group was established and was to meet weekly to deal with operational issues.

242. The Strategic SPoC group was to receive updates from the PPE operational supplies group and from the NSS Elective Recovery workstream on supply status and matters requiring escalation. Health and Social Care Directorates representatives attended but did not set up nor formally seek advice from the group. It was very active throughout the pandemic (and supported by an Operational Group). SG records indicate that this NHS-run group was stood down in March 2022.

243. On 2 April 2020, Chief Nursing Officer (CNO) and Chief Medical Officer (CMO) wrote to Health and Care system containing updates on PPE and guidance on its use, provided: [CL13/049 - INQ000259889]. Their message contained the following lines – *‘senior clinical and care leaders are asked to ensure that compliance with PPE is in line with the updated PPE guidance. We also ask that clinical leadership is provided to board procurement teams in this difficult time, to ensure local distribution is effectively managed to those areas which require it, and there is no over-ordering or stock piling at local level.’* This reflected the position with push allocations of PPE being sent out and was happening at a time when efforts were directed towards large scale PPE procurement and supply chain development. Given NSS’s role in purchase and distribution of PPE during the pandemic they will be able to offer further detail on communications disseminated to health boards and health and care staff.

244. In a letter dated 23 March 2020, provided: [CL13/050 - INQ000496458], the Chief Dental Officer wrote that *‘FFP3 is a limited resource and it is not practical or desirable to train, fit test and supply to every dental practice team. It will be available at the designated centres where patients, positive or asymptomatic COVID-19, are being assessed and treated.’* As of 15 April 2020, roughly 2,000

registered providers did not have access to PPE hub supplies, as supply issues meant stocks delivered to the hubs were prioritised for care homes, care at home, housing support and hospices. The other providers did, however, have access to the triage helpline and could access PPE in that way if their own supply lines failed. In a letter dated 20 May 2020, [CL13/051 - INQ000496492] the Chief Dental Officer wrote that *'[w]e are very much aware that the supply of appropriate PPE is an essential pre-requisite to support the phased remobilisation of NHS dental services. Which is why we are working very closely with National Services Scotland to ensure that dental teams have an adequate supply of appropriate PPE during each phase of the remobilisation plan. We will keep dental practices briefed on the supply of PPE. The intention is to match any phased remobilisation to the levels of PPE at the time'*.

245. Dental practices were subject to quite stringent guidance around the delivery of care in the pandemic. The provision of any AGP required staff to wear additional PPE and the surgery then could not be used for a period of time (fallow time) prior to rigorous cleaning. In early 2021, FFP3 masks and gowns were provided on the basis that each stood up dental surgery would get ten sets of PPE per day to support five AGP procedures. There was a national agreed overall allocation of stood up surgeries, which was agreed with SG, which was then split between health boards. This allocation increased as the phased remobilisation of NHS dental provision continued.

Cancellation of PPE orders

246. No record has been found of SG instructing NSS to cancel any Health Board orders for PPE. In May 2020, a news story [CL13/052 - INQ000496493] suggested that NHS Ayrshire and Arran had cancelled an order for visors from a local business. NHS Ayrshire and Arran responded, however, to say *"[w]e can confirm that the CEO of Tsukure approached NHS Ayrshire and Arran earlier this month with an offer to manufacture and supply PPE in the form of single use Full Face Visors. This offer was developed, and an agreement reached, to manufacture and supply an agreed quantity of this PPE. The CEO of Tsukure has confirmed this week that supply of agreed quantities will commence next week."*

Regulation of PPE

Easement of PPE Regulations

247. Under European PPE Regulation 2016/425/EU, certain kinds of PPE had to be conformity assessed before they could be placed on the market and certified by a conformity assessment body. When PPE had been assessed, it had to be conformity-marked accordingly. The mark applied was the CE mark.

248. Following the outbreak of the Covid-19, the European Commission made a Recommendation 2020/403 in March 2020 (updated in July 2020) which contained a number of temporary arrangements (referred to as “easements”) to facilitate the supply of PPE during the pandemic. However, this non-CE PPE (“eased PPE”) was still required to adhere to the relevant requirements and meet the approval of the HSE.

249. Recommendation 2020/403 would not carry over in domestic law in the UK as of 1 January 2021, as a consequence of the UK withdrawal from the EU. In response, England and Wales enacted Regulations within their respective territories to allow the temporary continuation of the PPE regulatory easement. The PPE Team therefore undertook work to establish whether similar Regulations should be enacted within Scotland to extend the PPE easement arrangements.

Key factors considered were:

- The security of Scotland’s PPE supply and the likelihood that Scotland would need to import PPE from other EU or UK nations.
 - This was determined to be unlikely.
- The quantities of eased PPE held in Scotland, both within Health and Social Care and private operators.
 - NSS had not used the easement arrangements to procure eased PPE for Health and Social Care use and had four months’ worth of CE marked PPE in stock. All the PPE purchased through SG’s Lyreco framework for non-health and social care provision was also CE marked. However, the circulation of eased PPE within the private sector was difficult to estimate and the possibility that individual buyers may be buying and using eased PPE could not be ruled out. For

example, private chemists could have been using eased PPE in Scotland purchased in England, which they would not be able to do after 1 January 2021. Enacting Scottish Regulations to continue the PPE easements would provide temporarily against this eventuality.

- The likely trajectory of the Covid-19 pandemic and the emerging variants.
 - This was uncertain, as was the overall impact of vaccinations and other treatments and measures. Extending the easement arrangements would help mitigate against the risk of an unexpected increase in PPE demand by medical services, and make provision to ensure that extra eased PPE ('eased PPE') could be sourced if required.
- The benefits of aligning with other UK nations in terms of regulatory arrangements.
 - A Four Nations approach and regulatory alignment was desirable.
- The impact of easement Regulations on the ability for new PPE products to be tested and enter the market.
 - It was determined that easement could aid this.
- The impact easements would have on the quality and safety of PPE.
 - There would be no impact on the quality or safety of PPE, the same HSE standards still had to be met.

250. It was therefore recommended to Ministers that Regulations be laid in mid-January 2021, via a negative SSI under the Coronavirus Act 2020, to come into force in early February 2021. The two relevant submissions, sent to the Cabinet Secretary for Health and Sport on 11 and 23 December 2020, are provided: [CL13/053 - INQ000496441], [CL13/054 - INQ000496585].

251. A stated in the relevant policy note, provided: [CL13/055 - INQ000398871], the regulations:

“provides that PPE that would usually require a conformity assessment by a conformity assessment body can be placed on the market without having completed this process. However, the conformity assessment procedure must have been initiated with the HSE and the HSE must have certified that the PPE

is compliant with the relevant parts of the essential health and safety requirements set out in the PPE Regulation. The HSE will perform this assessment process until 31 March 2021”

“provides that PPE that would usually require a conformity assessment by a conformity assessment body can instead be provided to frontline health and care sector workers without having completed this process. However, the PPE must have been purchased by, or on behalf of, the NHS in Scotland for use by healthcare or specified frontline health and care sector workers, and the HSE must have certified that the PPE is compliant with the relevant parts of the essential health and safety requirements set out in the PPE Regulation. The HSE will perform this assessment process until 31 June 2021”

252.The Regulations were only applicable to PPE necessary for protection against Covid-19. Under the Regulations, PPE still had to comply with the essential health and safety standards required by the HSE.

253.Ministers agreed with the recommendation and The Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Scotland) Regulations 2021 were laid before the Scottish Parliament, and made, on 28 January 2021 to come into force on 1 February 2021, using powers in paragraph 1 of Schedule 19 of the Coronavirus Act 2020. The relevant policy note and a letter to the Presiding Officer outlining why the negative procedure was required are provided: [CL13/055 - INQ000398871], [CL13/056 - INQ000496440].

254.It was not necessary to further extend the easement Regulations after the 31 June 2021 expiry date. NSS did not need to make use of the easement arrangements and in June 2021 had at least a four month stockpile of all types of PPE for the use of all NHS Scotland services, all of which was CE marked. The relevant submissions, making the Cabinet Secretary for Health and Social Care aware of these circumstances, is provided: [CL13/057 - INQ000496439].

255.The Directorates for Health and Social Care are not aware of SG liaising directly with regulatory bodies responsible for setting the standards for PPE in Scotland

during the pandemic. The regulations related to the use of PPE are not devolved - the Control of Substances Hazardous to Health (COSHH) falls within the remit of the HSE. Where revalidation of stock at a four nations level was required, the activity was coordinated by PHE on behalf of the four nations and guided by the HSE. NSS otherwise managed any stock revalidation work. This is covered earlier in the statement.

Section 3: Infection prevention and control (IPC) guidance

256. The Directorates for Health and Social Care disseminated (but did not contribute to) IPC guidance produced by the DHSC. Documentation of this is provided:

Date	Guidance Issued	Exhibit
14/08/2020	Directors' Letter on UK IPC Guidance for the Remobilisation of Health and Care Services	[CL13/058 - INQ000300497]
19/10/2020	CNO letter reiterating importance of IPC measures and sharing lessons learned	[CL13/059 - INQ000323681]
19/03/2021	CNO letter to NHS Scotland Chief Execs sharing the HSE report with their findings and recommendations from their COVID spot inspections	[CL13/060 - INQ000323773] [CL13/061 - INQ000323772]
25/11/2021	CNO Letter - Launch of the new Scottish Winter (21/22) Respiratory Infections Infection Prevention and Control (IPC) addendum	[CL13/062 - INQ000323231]

Date	Guidance Issued	Exhibit
17/03/2021	CNO Letter - De-escalation of enhanced infection prevention control measures in health and social care settings.	[CL13/063 - INQ000429280]

257. The Directorates of the Chief Nursing Officer and Chief Medical Officer (CNOD and CMOD) produced and issued the SG Clinical Guidance for Adult Social Care and the Scottish Government Visiting and Other Guidance for Adult Social Care (both provided in the table below). The Health and Social Care Directorates produced an extension of the NIPCM (developed and published by ARHAI Scotland) which came into use on June 2020 and was withdrawn on 16 May 2023, provided: [CL13/064 - INQ000496453].

258. The SG also supported the dissemination of NSS ARHAI guidance.

259. Any change to IPC measures or Covid-19 guidance was, and is, based on the latest and emerging evidence. This evidence continues to be reviewed. A timeline for respective changes to guidance is provided below in the tables titled "IPC guidance timeline", "Extended use of face masks and face coverings guidance timeline" and "Respiratory Protective Equipment (RPE) timeline".

260. On the subject of adult social care guidance, it should be noted that the SG does not have direct statutory responsibility for adult social care services in Scotland, this rests with local authorities. However, SG played an important role during the pandemic in supporting the care sector to respond to the challenges of Covid-19, including through the provision of national level advice and guidance to the care sector across a range of issues. The information below, in the table titled "Scottish Government clinical guidance for Adult Social Care timeline" describes only social care guidance published by the SG and not, for example, other bodies such as HPS (which subsequently became PHS).

261. For the remainder of the pandemic, Covid-19 guidance for social care was published by PHS, with SG publishing standalone detailed guidance for the sector on specific areas, as needed—for example in relation to face masks, care home visiting, etc. SG also developed specific guidance around addressing elements of care home life (e.g. at Christmas) that were not covered in PHS guidance. This guidance is provided in the table below titled “Scottish Government sector specific guidance timeline”.

IPC guidance timeline

Date of Change	Name of Guidance	Description of Change	Reason for Change
April 2020	Revised UK IPC guidance.	Publication of revised Covid-19 UK IPC guidance in light of emerging evidence and review of evidence by public health/health protection organisations across the UK and was a four nation's decision to update PPE guidance	In recognition of sustained community transmission of Covid-19 in the UK.

April 2020	Supplementary IPC guidance issued by SG (CNO).	Following a meeting with COSLA in early April 2020, the CNO wrote to Chief Executive of COSLA on 5 April 2020 providing supplementary guidance on the use of PPE in Health and Care settings. As a result, on 9 April, a joint statement issued on behalf of SG, COSLA and the SJC Unions confirming that the UK nations guidance published on 2 April was the official and fully comprehensive guidance on use of PPE in the context of Covid-19 and that the guidance made clear that social and home care workers could wear a fluid resistant face mask along with other appropriate PPE, where the person they were visiting or otherwise attended to was neither confirmed nor suspected of having Covid-19, if they considered doing so necessary to their own and the individual's safety. A link to this statement was reflected in the 17 April 2020 HPS COVID-19: Information and Guidance for Social or Community Care and Residential Settings Version 1.7 (HPS guidance	The supplementary guidance was developed and issued after discussions with COSLA and UNISON who sought clarity on the self-assessed use of PPE and expressed concern about the availability of appropriate PPE.
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Date of Change	Name of Guidance	Description of Change	Reason for Change
		which included care home settings), provided: [CL13/007 - INQ000225992], and subsequently in the first HPS standalone guidance for care homes on 26 April 2020, provided: [CL13/054 - INQ000496585].	
August 2020	Publication of the updated UK IPC Guidance.	Guidance for the remobilisation of Health and Care services.	This guidance superseded previous Covid-19 UK IPC guidance.

Date of Change	Name of Guidance	Description of Change	Reason for Change
October 2020	The Scottish Covid-19 Infection Prevention and Control (IPC) Addendum for acute healthcare settings was published by ARHA Scotland within NSS.		During the pandemic guidance on use of PPE in health and social care settings was guided by UK-wide guidance on PPE for health and social care workers until October 2020 when the Scottish Covid-19 IPC Addendum for acute healthcare settings was published. This addendum was to ensure IPC guidance worked within the Scottish context and provided all Covid-19 IPC Guidance on one platform within the established NIPCM.

Date of Change	Name of Guidance	Description of Change	Reason for Change
June 2021	Newly launched “Infection Prevention and Control Manual for Older People and Adult Care Homes” and “Care Home Cleaning Specification” published by ARHAI.	Older people and adult care home specific IPC guidance (disaggregated from general IPC guidance to support understanding)	To support IPC practice in older people and adult care homes.
August 2021	NHS Boards to undertake structured risk assessments in high risk (red) pathways updated guidance published by NSS ARHAI.	Risk assessments are advised to be undertaken regularly as determined by the NHS Board to ensure no change to the level of risk.	This change follows guidance issued by the WHO and SAGE UK, with subsequent advice from the Covid Nosocomial Review Group (CNRG).

Date of Change	Name of Guidance	Description of Change	Reason for Change
November 2021	Launch of The Scottish Winter 2021/22 Respiratory Infections in Health and Care settings - Infection Prevention and Control (IPC) Addendum published by ARHAI.	It aimed to support clinical services in managing an increase in all winter respiratory viruses within health and care settings during the Covid-19 pandemic.	Minimise the risk of harm from respiratory viruses to patients, residents, service users, staff and visitors within health and social care settings.
January 2022	Further updates to the Winter Respiratory addendum published by ARHAI.	Reduction of Covid-19 duration of precautions from 14 days to 10 days. Update to Non Covid-19 discharges (non-respiratory pathway) from hospitals to care homes. Addition of sections for primary care and care homes to reinforce and support assessment using the hierarchy of controls.	Update based on review.
February 2022	Further updates to the Winter Respiratory addendum published by ARHAI.	Additional information for visitors entering Aerosol Generating Procedures (AGPs) zones	Update based on review.

Date of Change	Name of Guidance	Description of Change	Reason for Change
March 2022	Covid-19 IPC measures in Health and Social Care settings published by SG	De-escalation of Covid-19 IPC measures in Health and Social Care settings	To support remobilisation of services and meet the needs of a wider cohort of patients.
April 2022	Further changes to the Winter Respiratory addendum published by ARHAI.	• Changes to management of contacts including inclusion of 28-day contact exemption • Changes to respiratory screening questions • Withdrawal of car sharing guidance • Update to include definition of fully vaccinated • Addition of testing responsibilities at an organisational level and clarity of testing language • Change to isolation advice for service users with Covid-19 • Removal of vaccination as part of contact management • Closure of the ARHAI Scotland Rapid Review - Assessing the IPC measures for the Prevention & Management of Covid-19 in Health and Care Settings V25.0, as agreed at CNRG.	ARHAI Scotland made several recommendations aimed to reduce pressures on NHS Boards, highlighting lessons learned during the pandemic, and recognising Covid-19 as a pathogen that will require management, to varying degrees, health, and care settings. CNRG endorsed the amendments.

Date of Change	Name of Guidance	Description of Change	Reason for Change
July 2022	Winter Respiratory addendum updates made to Appendices 21 and 22 published ARHAI.	Removing GP surgeries from Appendix 21 and including in Appendix 22.	To support greater understanding.
August 2022	The NIPCM formally relaunched published by ARHAI.		This followed a transition period away from the Scottish Winter Respiratory Infections IPC Addendum.

Extended use of face masks and face coverings guidance timeline

Date of Change	Change	Description of change	Reason for change
June 2020	Introduction of the 'Interim guidance on the wider use of facemasks'.	Decision to introduce the wider use of face masks in adult hospitals and care homes for the elderly.	Extended face masks/ face coverings use to reduce risk of nosocomial transmission of Covid-19 in hospitals and care homes.
September 2020	SG updated face mask guidance to cover primary and wider social care bringing these settings into line with acute and community hospitals.	Updated to cover primary care (GP practices, dentists, opticians and pharmacies) and wider community care (including adult social or community care and adult residential settings, care home settings and domiciliary care), in addition to acute hospitals (including mental health, maternity, neonatal and paediatrics) and community hospitals in areas where individuals are directly cared for and areas where they are not.	Expanding the scope of the guidance to reduce risk of nosocomial transmission of Covid-19 in those settings.

Date of Change	Change	Description of change	Reason for change
June 2021	9 June - Updated version of face mask guidance and frequently asked questions (FAQ) section.	Updated to include the wider wearing of Fluid Resistant Surgical Masks (FRSMs) by clinical and non-clinical hospital staff, the importance of FRSMs used by in-patients in hospitals and residents receiving direct care, or in communal areas in adult care homes as well as long stay/overnight visitors; and clarification around the need for outpatients, to wear face coverings, as well as encouraging individuals being cared for at home and their household to wear face coverings.	Expanding the scope of the guidance to reduce risk of nosocomial transmission of Covid-19 in those settings.
	23 June – ‘The use of face masks and face coverings in social care settings’ was published.	New guidance published to separate the use of face masks from healthcare settings and social care settings.	Separation of guidance to support sector understanding and awareness.

Date of Change	Change	Description of change	Reason for change
July 2021	Guidance for hospital staff to support visitors.	Questions and answers added to - guidance on the extended use of face masks and face coverings	Expansion of guidance for hospital staff and how to support visitors.
October 2021	Guidance sections updated to reflect latest position on the extended use of face masks and face coverings.	Change to physical distance requirements, waste disposal of face masks, update to the Health Protection (Coronavirus) (Requirements) (Scotland) Regulations 2021.	The Scottish Covid-19 Addendums were updated.
April 2022	Face mask guidance updated to reflect latest position.		Guidance was updated to reflect the change from legislation to guidance.

Date of Change	Change	Description of change	Reason for change
7 September 2022	Update to Coronavirus (Covid-19): use of face coverings in social care settings including adult care homes guidance and supporting poster.	Staff and visitors within social care settings no longer need to routinely wear a face mask or face covering. A face mask/covering should still be worn following personal judgement i.e. when poor ventilation, crowding or risk of splash, on advice from health protection teams, or if the individual receiving care and support wants staff to wear a mask. Personal choice to wear a mask is also noted within the guidance.	Change in advice from ARHA owing to different phase of the pandemic.
11 October 2022	Amendment to the face mask poster for social care settings (no change to guidance).	Clarifying that the sector should continue to follow the NIPCM. Re-ordering of points so choice is after IPC considerations.	Clarification following feedback from the sector.

Date of Change	Change	Description of change	Reason for change
9 May 2023 (deadline for health and social care to stand down guidance - 16 May)	Withdrawal of the Coronavirus (Covid-19): Extended Use of Face Maks and Face Coverings Guidance Across Health and Social Care	The withdrawal of the extended face mask guidance within social care. The associated guidance for healthcare settings was also withdrawn. Health and social care settings should continue to follow IPC guidance, including for face masks, as per the NIPCM (including the Care Home manual).	Based on the evidence provided by ARHAI's rapid review of literature.

Respiratory Protective Equipment (RPE) timeline

Note – the items below include change on RPE guidance based on staff preference and are not IPC-related.

Date of Change	Change	Description of Change	Reasons for Change
October 2020	Scottish Covid-19 IPC Addendum was first published. (ARHAI guidance, not SG policy)	Personal PPE Risk assessment: Airborne precautions are not required for AGPs on patients/individuals in the low-risk pathway provided the patient has no other infectious agent transmitted via the droplet or airborne route. However, recognition that some staff remain anxious about performing AGPs on patients during this Covid-19 pandemic and therefore when prevalence was high, and where staff had concerns about potential exposure to themselves, they may choose to wear an FFP3 respirator rather than a FRSM when performing an AGP on a patient in the low-risk pathway. This is a personal PPE risk assessment.	To minimise staff anxieties during the pandemic.

Date of Change	Change	Description of Change	Reasons for Change
April 2021	An update to the Scottish Covid- 19 IPC Addendum.	The change highlighted that the transmission of Covid-19 is mainly droplet or contact. However, recognised that some over-crowded and poorly ventilated areas may generate a risk of aerosol transmission of Covid-19 if used to care for cohorts of suspected and / or confirmed Covid-19 cases (environmental risk assessment).	Following the publication of interim WHO guidance <i>Covid-19 - Occupational health and safety for health workers</i> , (Feb 2021), a SAGE paper <i>Masks for HCW to mitigate airborne transmission of SARS-COV-2</i> and subsequent advice from the CNRG.
July 2021	Framework for the implementation of isolation exemptions for health and social care staff.	For those staff who are willing to return to work to relieve service pressures, they may be supported to do so through the additional provision of FFP3 masks, where this assists with allaying concerns that the staff member might have.	This was a workforce policy introduced as a result of a ministerial decision and did not follow a change in evidence. This was a Scotland only policy and was not replicated in the rest of the UK.

Date of Change	Change	Description of Change	Reasons for Change
March 2022	Personal preference access to FFP3s	Workforce policy introduced which offered health and social care staff access to FFP3 respirators if they wanted to wear one.	This was a workforce policy introduced as a result of a ministerial decision and did not follow a change in evidence. This was a Scotland only policy and was not replicated in the rest of the UK.

SG clinical guidance for Adult Social Care timeline

Date	Guidance
13 March 2020	Clinical Guidance for Nursing Home and Residential Care Residents and Covid-19 version 1.1 Letter from Cabinet Secretary with annex on care homes guidance , provided: [CL13/065 - INQ000147441] This was developed following calls from the sector for clinical guidance specifically in relation to care homes covering admissions, visitors and clinical considerations for care homes.
26 March 2020	Clinical Guidance for Nursing Home and Residential Care Residents and Covid-19 version 1.2 Updated guidance for care homes, provided: [CL13/066 - INQ000496476], [CL13/067 - INQ000147440] Updated to reflect revised HPS guidance and wider developments in understanding the nature of the virus and its likely impact on care homes and the wider social care sector, including additional advice on: • supporting staff and resident wellbeing • ensuring adequate staffing to ensure the safety and wellbeing of residents • updates on testing arrangements following recent announcements on care home admissions and enhanced surveillance testing • education and training • role of HSCPs, Local Authorities and NHS Boards in ensuring that the care home sector was supported.
26 March 2020	Clinical Guidance for the Management of Clients Accessing Care at Home, Housing Support and Sheltered Housing in relation to Covid-19

	6 March guidance Care at home and supported housing guidance, provided: [CL13/068 - INQ000276978], and cover letter, provided: [CL13/066 - INQ000496476]
15 May 2020	National Clinical and Practice Guidance for Adult Care Homes in Scotland during the Covid-19 Pandemic - Clinical guidance version 1.3 Letter and guidance document, provided: [CL13/069 - INQ000383486], [CL13/070 - INQ000261754] Updated again to reflect revised HPS guidance and wider developments in understanding the nature of the virus and its likely impact on care homes and the wider social care sector.

SG sector specific guidance timeline

Date	Guidance
25 June 2020	Visiting Guidance for Adult Care Homes in Scotland version 1.1 SG published first dedicated/ standalone Coronavirus (Covid-19): adult care homes visiting guidance on a four-stage approach to the safe introduction of indoor visits to care homes. (Next update 7/8 August), provided: [CL13/071 - INQ000260002]
7/8 August 2020	Visiting Guidance for Adult Care Homes in Scotland version 1.2 SG updated visiting guidance to support the move to stages 3 and 4 of the visiting pathway – several outdoor visitors and one indoor visitor (stage 3) and controlled indoor visiting (stage 4) with IPC measures, restricted numbers, ventilation, a unified 'check list' that could be used by all homes regardless of operator, testing of visitors advised by DPH as part of local risk assessment processes. (Next update 3 September), provided: [CL13/072 - INQ000147432], [CL13/073 - INQ000496538]
3 September 2020	Implementing the staged approach to enhancing wellbeing activities and visits in care homes, including communal living version 1.1 Guidance outlining recommendations for the safe resumption of communal activities within care homes and of visiting people, professionals, and organisations into homes. Also provided advice about residents leaving the care home for day/overnight visits and residential respite. (Next update 12 October), provided: [CL13/074 - INQ000496539]
3 September 2020	Visiting by Family and Friends - Guidance for Adult Care Homes in Scotland Version 1.3 Updated advice on: changing designated visitor, continued to recommend moving to stages 3 and 4 visiting, clarified family visiting in residents' rooms, clarification on and importance of supporting essential visits. Review

Date	Guidance
	arrangements added for any temporary local restrictions to visiting. (Next update 12 October), provided: [CL13/075 - INQ000147433]
12 October 2020	Visiting Guidance for Adult Care Homes in Scotland Version 1.4 SG issued letter and guidance on “optimising stage 3 visiting by family and friends” recommending increase in visiting length - indoor (four hours maximum; one person); outdoor visiting (one hour with up to six people from no more than two households. Under 18s included in outdoor and essential visits). Also provided clarity on touch, gifts, pets/therapies, hairdressing and spiritual care. Essential visits definition widened to include circumstances when people are deteriorating and emphasising flexibility. Circumstances when designated visitors should be alternated or supported to change also included. (Next update 17 November), provided: [CL13/076 - INQ000147434], [CL13/077 - INQ000496544]
12 October 2020	Implementing the staged approach to enhancing wellbeing activities and visits in care homes, including communal living version 1.2 Adult respite admission arrangements added. Recommendations for singing updated. Clarification on spiritual care visits, provided: [CL13/078 - INQ000202181], [CL13/077 - INQ000496544]
17 November 2020	Visiting by Family and Friends - Guidance for Adult Care Homes in Scotland – version 1.5 Update visiting guidance to reflect Strategic Framework Protection Levels 0-4. (Next update 14 December), provided: [CL13/079 - INQ000147435], [CL13/080 - INQ000496546]
4 December 2020	Coronavirus (Covid-19): Christmas and New Year guidance for adult care homes and visitors

Date	Guidance
	Guidance for care homes on visiting arrangements over Christmas and New Year published. Provided details of ways to support Christmas activities in a safe way using appropriate IPC measures. Developed following questions from the sector about Christmas activities, provided: [CL13/081 - INQ000496547]
14 December 2020	Visiting by Family and Friends - Guidance for Adult Care Homes in Scotland – version 1.6. Visiting guidance updated to include clarifications and additions to outdoor visiting and using structures. Advice around the 28 day closure of care homes updated to become 14 days, with safety measures in place, provided: [CL13/082 - INQ000147436]
22 December 2020	Joint letter issued from the Chief Nursing Officer, Chief Medical Officer and Director of Mental Health and Social Care providing further details of care home visiting following the move to level 4 restrictions on 26 December. Letter issued about visiting following FM announcement of move to level 4 restrictions from Boxing Day. This meant move to: indoors: essential visits only and outdoors: visits to the care home to see loved ones via garden or window visits, arranged with care home in advance. Garden visits should now be limited to one visitor and visits by children and young people should be suspended, provided: [CL13/083 - INQ000496549]
24 February 2021	Open With Care: Supporting Meaningful Contact in Care Homes- main guidance document Guidance on return of managed indoor visiting to adult care homes so that residents have meaningful contact with their loved ones. Drew on advice from WHO ad hoc Covid-19 IPC Guidance Development Group which unanimously agreed that visiting should be supported, as long as a range of IPC measures are in place. Proposed starting with two designated visitors weekly, visiting one at a time then building up. Suite of guidance materials issued alongside guidance document including letter, FAQs, posters and a checklist, provided: [CL13/084 - INQ000147437]

Date	Guidance
	Open with Care: Supporting Meaningful Contact in Care Homes. Frequently Asked Questions (FAQ) Version 1.1 [CL13/085 - INQ000496551] Covering letter [CL13/086 - INQ000496552]
10 March 2021	Open with Care: Supporting Meaningful Contact in Care Homes. Supplementary Information Version 1.2 <i>(updated from 24 February 2021 FAQ and renamed Supplementary Information)</i> Supplementary information published (formerly FAQs) in response to questions from care homes. Document updated to remove FAQ phrasing for accessibility. Additional topics added based on feedback from care home staff at Open with Care workshops. Information covered in Open with Care guidance removed to avoid duplication, provided: [CL13/087 - INQ000496494]
18 March 2021	Open with Care: Supporting Meaningful Contact in Care Homes. Supplementary Information. Answers to practical questions and concerns. Version 1.3 <i>(updated from 10th March 2021)</i> Supplementary information updated on resuming visiting following an outbreak, additional information IPC, visitor consent for LFD testing, and arranging vaccines for staff. [CL13/088 - INQ000496553]
14 April 2021	Open for Care - Visiting health, social care and other services in care homes and communal activity Visiting health, social care and other services in care homes and communal activity - letter with guidance in an annex. provide updated advice on the return of health, social care and other services who contribute to the health and wellbeing of people living in care homes. Set out principles supporting the staged return of visiting professionals to care homes, recognising the importance of the provision of equitable, person-centred and holistic

Date	Guidance
	healthcare alongside wider services to improve the wellbeing and overall health of people living in care homes, provided [CL13/089 - INQ000496554]
16 April 2021	Open with Care: Supporting Meaningful Contact in Care Homes. Supplementary Information. Answers to practical questions and concerns. Version 1.4 Supplementary information updated on essential visits, number of visitors per resident, visiting professionals, leaving the care home to vote, outdoor visits, length of visit, use of screens and pods, physical contact, PPE for visitors, outbreaks and investigations, and visiting during an outbreak. [CL13/090 - INQ000496555]
19 April 2021	Open with Care – Supporting Meaningful Contact in Adult Care Homes – Supplementary information: Answers to practical questions and concerns version 1.5 (updated from 16 April). Supplementary information updated on number of visitors per resident, provided: [CL13/090 - INQ000496555]
14 May 2021	Open with Care: Supporting Meaningful Contact in Care Homes. Supplementary Information: Answers to practical questions and concerns. Version 1.6 (<i>updated from 19 April 2021</i>) Supplementary information updated on when care homes can begin resume meaningful contact, Covid protection levels and visiting, residents leaving their care homes, voting section (removed post-election). Also included resources for families, provided: [CL13/091 - INQ000496556]
17 May 2021	Guidance on residents’ outings away from the care home. Guidance: Open with Care – Activities and outings away from the care home – guidance for outings away from the care home. The guidance recommended that care homes should support opportunities for people to make personal and social visits out of the care home in line with general population’s Covid-19 restrictions.

Date	Guidance
	Recommended principles and actions for everyone to prevent Covid-19 infection and spread both inside and outside of the care home, provided: [CL13/092 - INQ000496557], [CL13/093 - INQ000496558].
2 June 2021	Open with Care: Supporting Meaningful Contact in Care Homes. Supplementary Information: Answers to practical questions and concerns. Version 1.7 <i>(updated from 14 May 2021)</i> Supplementary information updated on residents leaving the care home and returning, decisions on and frequency of outings, transport, younger adults, restrictions in different public settings, going out to eat, testing family and friends before outings, Covid-19 Care Home Addendum and NIPCM, provided: [CL13/094 - INQ000496559].
15 July 2021	Open with Care - Improving care home residents' meaningful contact and connection – on moving to and past Level 0 Open with Care - Improving care home residents' meaningful contact and connection – on moving to and past Level 0. Guidance on recommended relaxations within care homes for level 0 for visiting, communal activity and outings. Also recommended day services onsite in care homes resumes, provided: [CL13/095 - INQ000496560].
15 July 2021	Open with Care: Supporting Meaningful Contact in Care Homes. Supplementary Information: Answers to practical questions and concerns. Version 1.8 <i>(update from 2 June 2021)</i> [CL13/096 - INQ000496561]
22 July 2021	Coronavirus (Covid-19) living with dementia in care homes: Guidance on supporting people remain safe during period of isolation Guidance to help care home staff to support residents who have dementia and are identified as being required to isolate in their rooms, provided: [CL13/097 - INQ000496562]

Date	Guidance
6 August 2021	Relaxations to Covid-19 regulations / restrictions – 9 August ('Beyond Level 0) Associated updates to Open for Care Care at home Supported housing: clarity on guidance that applies to supported housing settings Relaxations to Covid-19 regulations / restrictions - 9 August ('Beyond Level 0') Associated updates to Open for Care. Clarity also provided on the terminology used within the guidance for different settings and what guidance applies to each setting, provided: [CL13/098 - INQ000496563]
1 September 2021	Changes to physical distancing Communicating recent changes to the AHRAI NIPCM addendum, provided: [CL13/099 - INQ000505933]
15 September 2021	Updated advice. Open with Care – named visitor to enable people in care homes to maintain contact with loved ones during Covid outbreaks. Guidance recommending that care home residents be supported to have a named visitor during Covid-19 controlled outbreaks. Recommended a framework whereby adult care homes should support residents to choose a named visitor who may visit indoors during a managed Covid-19 outbreak, where visiting can be safely supported, provided: [CL13/100 - INQ000505932]
2 December 2021	Updated advice. Open for Care – Visiting health, social care and other professionals/services in adult care homes. Updated advice on visiting professionals to care homes. Signposting to updated advice on PHS care homes guidance recommending a levels-based approach to the return of services, and recommending that visiting professionals should visit adult care homes if required to do so unless otherwise advised by the care home or local Health Protection Team, provided: [CL13/101 - INQ000496564]

Date	Guidance
9 December 2021	Updated advice. Minimising the risk of Covid-19 transmission over the winter period (care homes) Letter from Deputy CMO (DCMO)/ Deputy CNO (DCNO) highlighting measures to take to minimise the risk of transmission of Covid-19, including the new Omicron variant. Advice on testing, vaccination/boosters and visiting. Encouraged care homes to continue to increase opportunities for visiting, provided: [CL13/102 - INQ000496565]
9 December 2021	Minimising the risk of Covid-19 transmission over the winter period (care at home, supported housing and day services) Letter from DCMO and DCNO highlighting measures to take to minimise the risk of transmission of Covid-19, including the new Omicron variant. Advice on testing, vaccination/ boosters and visiting, provided: [CL13/103 - INQ000496566]
10 December 2021	Updated advice - Winter pressures - staff self-isolation exemption - Letter from Director of Adult Social Care Donna Bell indicating current exemption from self-isolation applies if people meet existing criteria and one additional criteria (double vaccinated and had their booster), provided: [CL13/104 - INQ000203128]
15 December 2021	DCMO and DCNO letter to adult care homes regarding visiting and Omicron 15 December 2021 Following announcement by First Minister on 14 December giving advice for general public that socialising should be kept to three households, this letter advised additional measures for care homes: recommending no more than two households meet with a resident inside the care home, that visitors take a lateral flow test and wear a fluid resistant surgical mask, and named visitors can visit during outbreaks. Visits outwith care home should still be supported if no outbreak, and large groups not yet supported in care home although activities should continue, provided: [CL13/105 - INQ000241683]

Date	Guidance
16 December 2021	DCMO and DCNO letter to supported housing settings regarding guidance on indoor socialising Following 14 December announcement by First Minister, letter recommends that no more than two households should visit a tenant in their home, to take LFD test before meeting, keep groups small, keep safe distance from those not in your household, no-one with symptoms or self-isolating should visit, practice good hand hygiene and keep rooms well ventilated, provided: [CL13/106 - INQ000241684]
22 December 2021	Update on protective measures including testing in response to Omicron - DCMO/DCNO letter adult care homes - additional guidance on visiting 22.12.21 - Care Homes 4 Follow-up to the letter of 15 December, responding to questions from sector, including FAQs. Continued to recommend that adult care homes support visiting, provided: [CL13/107 - INQ000496570]
6 January 2022	Updated Advice – Policy Framework On Return To Work For Health And Social Care Staff Identified As Cases Or Following Close Contact With A Positive Covid-19 Case. Letter from DCMO, DCNO, Director of Health Workforce and Director of Social Care, setting out the conditions for when health and social care staff who are isolating as a Covid-19 index case or contact can leave isolation in seven days in line with the general population, and when staff who are close contacts can return to work. The letter outlines the testing and vaccination required, provided: [CL13/108 - INQ000477440] Updated 17 January 2022.
17 January 2022	Updated Advice – Policy Framework On Return To Work For Health And Social Care Staff Identified As Cases Or Following Close Contact With A Positive Covid-19 Case.

Date	Guidance
	Letter from DCMO, DCNO, Director of Health Workforce and Director of Social Care with an update for fully vaccinated staff, identified as household or non-household contacts for testing and when this can end if they remain well, provided: [CL13/109 - INQ000323089] Updated 19 January 2022.
19 January 2022	Updated guidance on self-isolation for residents in adult care homes (precautionary self-isolation and cases/ contacts) and indoor visiting. Updated advice self-isolation for care home residents and length of time a care home is closed following outbreak. Reduce the isolation period for fully vaccinated (two doses plus third dose/booster) care home residents from the current 14 days to 10 days; retain the length of time a care home is closed following an outbreak at 14 days. Care homes to cease the requirement for 14-day precautionary self-isolation periods for residents who are transferred from healthcare settings (including another care home). Referred to PHS care homes guidance, which was to be updated, provided: [CL13/110 - INQ000242438]
24 January 2022	Updated Advice – Policy Framework On Return To Work For Health And Social Care Staff Identified As Cases Or Following Close Contact With A Positive Covid-19 Case. Letter from DCMO, DCNO, Director of Health Workforce and Director of Social Care providing update to guidance that for staff who have tested positive for Covid-19, they should stop testing after day 10 irrespective of the result and pause routine testing for 28 days, provided: [CL13/111 - INQ000469958]
24 March 2022	Letter to care homes with updates to guidance and on testing for care homes and Adult Social Care. Letter providing updates on changes to Covid-19 Guidance for Adult and Older People Care Homes. changes on HS guidance but summarised in letter including – increase in number of named visitors from 1 to 3, encouraging

Date	Guidance
	routine visiting, changes to self-isolation in outbreak, advice on face masks and asymptomatic testing (care homes to revert from daily PFDs to twice weekly LFDs and weekly PCR), provided: [CL13/112 - INQ000222889]
1 June 2022	Open with Care document: principles, family leaflet, easy read. Updated Open with Care visiting documents setting out principles for fully adopting normalised routine visiting in adult care homes. Published main principles document, family leaflet, and an easy read document for people living in care homes, provided: [CL13/113 - INQ000147438], [CL13/114 - INQ000496576]
6 July 2022	Updates to Covid 19 Guidance in Adult Social Care. Letter from DCMO, Chief Pharmaceutical Officer (CPO) and CNO on Covid treatment options and accessing them for selected groups of people with coronavirus who were thought to be at a greater risk, provided: [CL13/115 - INQ000496577]
28 September 2022	Open with Care documents: principles, family leaflet and easy read. Minor updates to care home visiting guidance Open with Care posters, leaflets etc, provided: [CL13/116 - INQ000353784], [CL13/114 - INQ000496576], [CL13/118 - INQ000496579], [CL13/117 - INQ000496578]

262.Representatives from CNOD attended the Workforce Senior Leadership Group (WSLG). The terms of reference, provided: [CL13/119 - INQ000389186], states that this group was established to:

- Inform, engage and take collective action on key issues identified that require national senior strategic leadership in the health and adult social care workforce response to Covid-19
- Work in partnership to ensure that the healthcare system is as prepared as it can be to respond to the peak of the virus, during and post response
- Ensure timely feedback from NHS Boards and Trade Unions/Professional Organisations for the WSLG to address key issues.

263.The WSLG was established to provide strategic guidance and oversight in order to co-ordinate the health and adult social care workforce response to the pandemic in Scotland by identifying and supporting opportunities to:

- Increase workforce capacity to respond to the Coronavirus (COVID-19) pandemic during the virus peak
- Maintain staff wellbeing, both physical and psychological
- Share relevant and timely information to enable anticipation of needs both during and post response to Covid-19.

264.Its remit was to focus on issues of national impact. The principle of subsidiarity would apply, in that issues were to be dealt with at the most immediate (or local) level that is consistent with their resolution. Members were able to highlight local issues to the WSLG in the context of identifying common themes that become of national interest.

265.The SG has worked with Trade Unions and other official representative bodies during guidance development at various points. This was to support IPC guidance implementation (making it easy to understand and considerate of all personnel/personal circumstances). An example of this is when the Healthcare Associated Infection (HCAI) Policy Unit attended WSLG meetings to discuss changes to guidance.

266. The following notes were produced on the engagement with staffside / unions after a meeting of WSLG:

"We have been engaging with staffside representatives on the issue of PPE. It has been raised with us that refreshed messaging of what PPE should/shouldn't be worn would be welcome by staff, who may not have looked the guidance recently and instead staff are just wearing PPE based on practice, rather than knowing if it is the right PPE to wear. On the specific issue of FFP3 masks being more widely used, this has been raised by UNISON at the Workforce Senior Leadership Group. They were satisfied from the response from IPC colleagues. They have asked for clear, simple messages on PPE and the different requirements in different settings so that Union representatives can explain this to their members. We are working on a crib sheet for our union members that addresses the specific questions being raised by staffside representatives to address this. They have offered to then share national messages on these issues with their members, and help us with targeted local interventions where we identify them. Staffside representatives now sit on the Health and Social Care Compliance Taskforce. Alongside refreshing the PPE guidance, and the clear information for staffside, we are also developing a communications strategy for the health and social care workforce, as part of the Compliance Taskforce, to better articulate to staff where transmission is happening in the workplace and how they can help to reduce transmission. The evidence shows that transmission is happening between healthcare worker to healthcare worker, and not with patients, and the focus of our campaign will be to remind staff of how they should be acting when they are not with patients. It is worth noting that we are aware that BMA are running several campaigns at the moment, and we are unsure of their position on the wider roll out of FFP3. Following the discussion, an IPC guidance 'crib sheet' was developed and issued to staff-side employers with the intention to provide answers to questions that staff and employers were receiving related to IPC and to support wider discussions."

267.CNOD engaged with WSLG in relation to their feedback on communications issued by SG regarding updates to IPC guidance. Recognition was given quite early on in the pandemic to the impact of communications being issued immediately prior to the weekend impeding the ability of Boards to operationalise new guidance (over the weekend) and every effort was made to ensure that communications were issued earlier on in the week. While the UKG and subsequently ARHA Scotland held and maintained IPC guidance for Scotland, the SG played a role in communicating updates and changes in IPC guidance to NHS Boards and other stakeholders, including unions. This did lead on occasion to misinterpretation of the guidance, particularly in the early stages of the pandemic and highlighted the need for strong partnership working. Through the WSLG, officials and trade unions made a commitment to work together in order to support national communications in relation to IPC.

268.PPE guidance in the context of Covid-19 was jointly published by DHSC, HPS, Public Health Wales, Public Health Agency Northern Ireland, PHE and NHS England on 2 April 2020. SG initially sent out a communication to update the workforce detailing that social care workers did not have to wear a FRSM if the person they were caring for was not displaying symptoms of Covid- 19. This was contrary to what was stated in the PPE guidance and was based on earlier guidance.

269.Staff associations were reluctant to accept this guidance and were considering media intervention and advising their social care staff not to work. Unions/staff associations sought urgent clarification, provided: [CL13/120 - INQ000496454]. On 9 April, a joint statement from SG, COSLA and trade unions was issued, provided: [CL13/121 - INQ000489903], to clarify that social care workers could wear a FRSM along with other appropriate PPE if the person they were caring for was neither confirmed nor suspected of having Covid-19, if they considered doing so was necessary. This statement confirmed that the UK nations guidance published on 2 April was the official and fully comprehensive guidance on use of PPE in the context of Covid-19 and that the guidance made clear that social and home care workers could wear a FRSM along with other appropriate PPE, where the person they were visiting or otherwise attended to was neither confirmed nor

suspected of having Covid-19, if they considered doing so necessary to their own and the individual's safety.

270. A link to this statement was reflected in the 17 April 2020 HPS Covid-19:

Information and Guidance, provided: [CL13/122 - INQ000189304], for Social or Community Care and Residential Settings Version 1.7 (HPS guidance which included care home settings) and subsequently in the first HPS standalone guidance, provided: [CL13/123 - INQ000189331], for care homes on 26 April 2020.

271. On 18 February 2021, Royal College of Nursing (RCN) and other staff groups wrote to the then Prime Minister Boris Johnson and the Health Ministers across the UK to share their concerns related to the UK IPC guidance and the use of PPE as they believed that the guidance did not accurately depict the airborne risks in health and care settings. A four nations response was issued.

272. The RCN published an Independent Review of Guidelines for the Prevention and Control of Covid-19 in Health Care Settings, provided: [CL13/124 - INQ000114357], in the UK on 7 March 2021. Much of the report focused on the guidance and evidence reviews produced by ARHAI. As such, ARHAI developed and published a full response, provided: [CL13/125 - INQ000496499], to this report. The key points from this report are listed below:

- The report used the WHO's 'Rapid reviews to strengthen health policy and systems: a practical guide.' (Tricco et al., 2017) as a tool for critical appraisal of the rapid review, using selective elements of the practical guide to direct a critique. This is not a validated tool for appraisal of guidance.
- The UK IPC and Scottish COVID-19 IPC guidance was not based on this rapid review, but wider evidence considered by the UK IPC cell, therefore to infer the UK IPC cell guidance was based on this rapid review alone was factually incorrect.
- The UK IPC cell IPC guidance and Scottish guidance was completely aligned with the WHO IPC published guidance.
- The purpose of these rapid reviews was to supplement the evidence which emerged from key organisations and other intelligence for the pandemic

response - this was in line with what other national groups did in the UK for wider public health measures during the pandemic and beyond. They included systematic reviews from other countries, including those underpinning international guidance. It took account of SAGE and other UK Covid-19 guidance and this was in line with what other national IPC organisations did during the pandemic as well as wider clinical groups and public health.

- The RCN report made inaccurate comments on the methodology used for the production of the NIPCM - the NIPCM guidance is based on systematic review methodology. ARHA Scotland was not approached by RCN to provide background or detail on this and the comments made on this were inaccurate.
- The report concluded that 'The UK guidelines are over-reliant on the Rapid Review at the expense of other sources of evidence' however there was no appraisal in the report of any other sources of evidence being used. UK IPC Guidance clearly stated "This IPC guidance will be updated in line with service need and as the evidence evolves. The administrative measures outlined in the guidance are consistent with World Health Organization (WHO) guidance." The evidence considered took into account intelligence shared by Public Health bodies across the UK and national committees set up within the four nations to monitor nosocomial transmission.
- The RCN review stated that 'updated guidance from WHO indicates that aerosol spread is much more significant and the original advice [hand hygiene for droplet spread] from the WHO has been superseded' however the WHO guidance stated that the predominant route of transmission is droplet and fomite spread. The WHO guidance, provided: [CL13/126 - INQ000349135], from December 2020 states:

Mask use in health care settings

- *WHO continues to recommend that health workers (1) providing care to suspected or confirmed COVID-19 patients wear the following types of mask/respirator in addition to other personal protective equipment that are part of standard, droplet and contact precautions:*

- *medical mask in the absence of aerosol generating procedures (AGPs)*
- *respirator, N95 or FFP2 or FFP3 standards, or equivalent in care settings for COVID-19 patients where AGPs are performed; these may be used by health workers when providing care to COVID-19 patients in other settings if they are widely available and if costs is not an issue.*

273.The UK IPC guidance was aligned with this position.

274.A briefing, provided: [CL13/127 - INQ000496501], [CL13/128 - INQ000496500], was prepared for the Cabinet Secretary Jeane Freeman in preparation for a meeting she was having with RCN. The briefing detailed the concerns RCN raised throughout the pandemic related to FFP3 mask access, FRSM use and other IPC issues. It is worth noting that the Infection Prevention Society (IPS) did not support the claims made by RCN, provided: [CL13/129 - INQ000496503]. Rather than a blanket demand for enhanced ventilation and PPE, IPS considered that IPC measures need to be informed by evidence about the set of circumstances which may increase the risk of transmission by aerosols from patients with Covid-19. This enabled risk assessment and targeting of precautions, assuring staff and patient safety whilst also maintaining high standards of patient care.

275.The four UK CMOs also received a letter from the RCN and other groups sharing their concerns about the IPC guidance in place at the time and specifically about staff not having access to FFP3 masks.

276.A meeting between SG and RCN took place on 5 May 2021. The meeting had been called to address concerns raised by healthcare workers following the recent SAGE review paper “Masks for healthcare workers to mitigate airborne transmission of SARS-COV-2”. This review had been undertaken in March 2021 and published on 26 April. The RCN asked for clarification from the SG on whether its position had changed as a result of the review.

277. In response to RCNs concerns, SG made the point that the SAGE paper did not contradict the existing recommendations for PPE/RPE use set out in the UK Covid-19 IPC guidance and that transmission remains mainly droplet or contact. Rather, it recommended the extended use of FFP3 respirators for use with Covid-19 patients only in high risk environments (i.e. red pathway areas), where all other elements of the hierarchy of controls (HoC) have been considered fully, if there are no other optimal low risk clinical areas available and if it is felt that an unacceptable risk remains.

278. It was further stressed by SG that a full organisational workplace risk assessment should already be undertaken, regardless of the working area. An update was made to the Scottish Covid-19 Infection Prevention & Control Addendum (published by NSS ARHAI). The update was to the environmental risk assessment reinforcing the use of the HoC. This slight update simply meant that a review of that rigorous risk assessment using the HoC should be undertaken specifically in high risk pathways where Covid-19 positive patients are cared for and there is no other suitable area for these patients. Such an assessment should be carried out by health and safety teams and involving Estates and Facilities representatives, Occupational Health services, the Infection Control team and the clinical team.

279. Officials were alerted to the publication (on Monday 27 December 2021) on the Royal College of Midwives (RCM) website of new guidance, provided: [CL13/130 - INQ000492668], on what PPE to use in maternity care. In terms of process, the SG was not consulted on the production of this guidance, nor were ARHAI Scotland. In terms of content the guidance:

- It was not consistent with UK guidance on IPC for seasonal respiratory infections in health and care settings (including SARS-CoV-2) for winter 2021 to 2022 or the NICPM, nor did it refer to the Winter Respiratory IPC Addendum therein
- Did not use a risk-based approach to PPE selection (e.g. gloves and aprons are not required if there is no contact with blood/body fluids)

- Recommended FFP3 masks for staff who were dealing with Covid-19 suspected/confirmed patients over prolonged periods or where ventilation is poor (including community) – here it should have referred to the Winter Respiratory guidance and the risk assessment based on the hierarchy of controls set
- Did not take account of the fact that the delivery of maternity care is very different from (for example) emergency care, as it is more often delivered in single room accommodation.

280. Officials recommended that the CNO discuss this with RCM in a phone call.

Following a meeting, provided: [CL13/131 - INQ000496505], on 7 January 2022 with CNO and CNOD colleagues, the RCM confirmed that they would amend the publication in line with feedback, and ensure alignment of messages and clearer signposting to current IPC guidance in Winter Respiratory Guidance.

281. The RCN published a risk assessment toolkit on 23 December 2021. The CNO advised RCN that current Scottish Winter Respiratory Guidance in relation to IPC/PPE continues to stand, and should continue to be implemented. The UK IPC cell made a statement in relation to the published toolkit, provided: [CL13/132 - INQ000496506]. The HSE response to the toolkit is also provided: [CL13/133 - INQ000496507].

282. A submission sent to Ministers in January 2022 detailed that concerns had repeatedly been raised by opposition parties, staff side, unions, media, Fresh Air (NHS lobby group), some healthcare workers and IPC specialists throughout the pandemic regarding the type of face masks healthcare workers have access to in light of the perceived risk of patient-to-healthcare-worker Covid-19 transmission.

283. The briefing went on to describe that the BMA had stated in their recent survey (which they flagged to the Cabinet Secretary at their meeting on 10 January 2022) that only 15% of doctors said they were regularly provided with FFP3 masks or respirators when working in clinical areas with patients who are Covid positive or suspected positive. A further 7% say they were provided with a FFP2

mask. It was noted in the briefing that the concerns raised by the groups above are theoretical in nature in that the available evidence from NHS Scotland outbreak clusters and published literature does not support a change from FRSM Type IIR masks to FFP3 respirators, even in the light of emerging SARS-CoV-2 variants. Neither did these concerns take into account the HSE guidelines for use of RPE, including the necessity for face fit testing.

284. In a submission sent to Ministers in February 2022, it was noted that concerns had been raised repeatedly by trade unions and professional organisations (in particular the RCN, BMA and Unite) on the lack of discretionary access to FFP3 respirators in NHS settings, where staff were not performing AGPs. Norman Provan, RCN Associate Director (Employment Relations) and Chair of Staffside, described it as “one of the biggest mistakes the Scottish Government has made in the pandemic response”.

285. The BMA has also repeatedly raised concerns on this issue in the context of psychological safety for staff.

286. The supplementary guidance on the use of PPE in health and social care settings was amended in light of engagement with stakeholders.

287. In June 2020, following WHO guidance reflecting emerging evidence about potential transmission from symptomatic, pre-symptomatic and asymptomatic people in areas of sustained community transmission, the SG published guidance ‘Coronavirus (COVID-19): extended use of face masks and face coverings in hospitals, primary care and wider community healthcare’. This was an extension of the NIPCM and came into use in June 2020. It strongly recommended routine use of FRSM in health and social care settings until it was withdrawn in May 2023.

288. During the pandemic, guidance on use of PPE in health and social care settings was guided by UK-wide guidance on PPE for health and social care workers until October 2020 when the Scottish Covid-19 Infection Prevention and Control (IPC) Addendum for acute healthcare settings was published. This addendum was to

ensure IPC guidance worked within the Scottish context and provided all Covid-19 IPC Guidance on one platform within the established NIPCM.

289. Subsequently, in June 2021, the Infection Prevention and Control Manual for Older People and Adult Care Homes and "Care Home Cleaning Specification" guidance launched, to specifically support IPC practice in older people and adult care homes.

290. Requests were also received from the BMA and national staffside partners for discretionary access to FFP3 masks in NHS settings, where staff are not performing AGPs. Although not solely related to these requests, discretionary access, provided: [CL13/134 - INQ000429256], was introduced in April 2022. The guidance was welcomed by the BMA at the WSLG meeting on 13 April 2022. It should be noted that this was not a change or addition to IPC guidance/policy. Any change to IPC measures or Covid-19 guidance was, and is, in relation to the latest and emerging evidence.

291. The Health and Social Care Directorates sought advice from the CNRG, Clinical and Professional Advisory Group (CPAG) and/or ARHAI Scotland in relation to IPC and/ or PPE guidance. Meeting notes from both CNRG and CPAG have been provided to the Inquiry previously.

292. Advice was commissioned and received from both CNRG and ARHAI on the extended use of facemask guidance in health and social care settings. SG Social Care colleagues also sought advice from PHS.

293. CNOD sought advice on the use of RPE in Scotland from the CNRG. CNRG concluded that wider use of RPE was not required for care of Covid-19 patients. The CNRG conclusion was based on the epidemiology of Covid-19, nosocomial infection risks, new evidence of transmission risk, aerosol science on masks and the precautionary principle.

294. CNOD also engaged with the UK IPC Cell on the issue of RPE provision following an update to WHO guidance (details below).

295.The WHO published updated IPC guidance (October 2021):

- WHO maintained their original recommendation of the use of fluid resistant (Type IIR) surgical masks (FRSM) when providing care to a suspected/confirmed Covid-19 patient, and that RPE (face filtering piece 3 masks (FFP3) is recommended when performing an AGP or in settings where AGPs are performed.

296.However, they further added that, “Based on health workers values and preferences about having the highest perceived protection possible to prevent SARS-CoV-2 infection, and where widely available, particulate respirators can be used instead of medical masks in all settings when providing care to Covid-19 patients (even settings where AGPs are not performed).”

297.After consideration, CNRG advised that the WHO annex recommendation could be considered as part of a risk assessment process, however advised seeking views from the UK IPC Cell and HSE to ensure four nations consistency. The UK IPC Cell stated that no changes were required to the guidance in relation to FRSMs and FFP3s. The UK IPC Cell reinforced that staff and organisations should continue to undertake risk assessments using the HoC and where an unacceptable risk of transmission remains, it may be necessary to consider the use of RPE in clinical areas with suspected/confirmed cases of Covid-19. This position was endorsed by CNRG. UKHSA then published “Face Coverings in Mitigating Transmission of SARS-CoV-2”.

298.SG does not hold records of IPC/PPE guidance published by the UKG or NHS England or their rationale for development/publishing, so cannot provide all differences between guidance. However, two differences of which officials are aware of are:

- At the beginning of the pandemic when Scotland was still following UKHSA guidance, UKHSA published guidance on 3 May 2020 on considerations for the reuse of FFP3s due to PPE shortages. The CNO at the time issued a Director’s Letter to NHS Scotland, provided: [CL13/135 - INQ000398868], on 26 May stating that single use PPE must not be reused and should be

disposed of after use into the correct waste stream. The letter provided information on PPE guidance, single use PPE, sessional use PPE and reusable PPE. The letter further stated, *"to be clear at the outset, there is no intention to reprocess single use PPE. However, there is work being undertaken to understand what might be practicable in the unlikely event that supplies became unavailable. The work is being undertaken by a collaborative group of experts from across the UK"*

- Secondly, Scotland was the only country across the UK who allowed access to FFP3 masks as a results of a health/social care worker's personal preference. As detailed above, this was as a result of engagement with staff/unions, as well as the First Minister stating that her preference would be to provide discretionary access to FFP3 masks in order to improve confidence and wellbeing of health care staff. This was formalised in a Director's Letter, provided: [CL13/134 - INQ000429256], in April 2022.

299. IPC guidance was issued by ARHA, who should be approached for further information on differences between their guidance and the guidance published by DHSC, UKHSA and/or PHE.

300. Regarding the extended use of facemask and face covering guidance, the CMO and the then CNO communicated updated guidance to the health and social care sector regarding the extended use of face masks and face coverings. The letter advised that if a mask is removed for any reason, it should not be reused, it should be disposed of in the correct waste bin.

301. In addition to the Director's Letter from the CNO on single use PPE, described above, it should be noted on the subject of reusable PPE that although it is not directly referenced in these terms, the current Coronavirus in Scotland guidance, provided: [CL13/136 - INQ000474199], does recommend that face coverings are made of cloth or other textiles and should be two, preferably three, layers thick in line with WHO recommendations.

302. The only guidance issued by the Health and Social Care Directorates relevant to asymptomatic patients was the extended use of face mask and face covering

guidance across health and social care settings. The timeline is presented above along with a description of and reasons for changes.

303. The extended use of facemask guidance was developed and communicated via a letter initially only signed by the then CNO. However, from June 2020 onwards, letters related to the extended use of facemask guidance were signed by both CNO and CMO. As this is the case, and due to robust internal governance, both CNO and CMO will have reviewed briefings to Ministers and letters to health and social care settings prior to any public announcements. A series of Director's Letters were produced that related to the extended use of facemask guidance:

Date of Letter	Letter subject
18/09/2020	Health and social care worker access to FFP3 masks, based on staff preference during the transition period - 19 April 2022 [CL13/134 - INQ000429256]
08/06/2021	CNO letter on updated extended use of face mask guidance [CL13/137 - INQ000496497]
23/06/2021	CNO letter RE use of face masks in social care settings guidance update- 23 June 2021 [CL13/138 - INQ000496514]
05/07/2021	CNO letter Extended use of Facemask Guidance for hospitals and community Version 4 - 22 June 2021 [CL13/139 - INQ000496515]
14/04/2022	CNO letter extended use of Facemask Guidance Hospitals [CL13/140 - INQ000496516], [CL13/141 - INQ000496519]
22/08/2022	CNO CMO - Asymptomatic testing patients and care home staff - 22 Aug 2022 [CL13/142 - INQ000468170]
16/05/2023	COVID19 - facemasks - email with DL and social care letter on withdrawal of the Extended use of face masks and face covering guidance - 9 May 2023 [CL13/143 - INQ000496521], [CL13/144 - INQ000496524], [CL13/145 - INQ000469959]

304. The CNRG was set up by the then CNO. However, it subsequently became a subgroup of the CMO-led Covid-19 Advisory Group (C19AG). CNRG recommendations were therefore presented to both the CNO and CMO - CNO directly via email, and CMO via the C19AG.

305. Generally during Covid-19, when developing a policy or guidance, officials prepared and presented the evidence and advice received from expert groups and bodies into a briefing to support Ministerial decision-making. Briefings were developed in collaboration with other SG policy teams (e.g. CMOD, National Clinical Director, Primary Care, Adult Social Care, Health Workforce, Testing Policy) as necessary. Briefings were reviewed and cleared by Professional Clinical Advisors and SG Directors (CNO and CMO) prior to issuing to Ministers.

Section 4 - Intensive Care Unit (ICU) Equipment

Provision of ICU equipment and the SG ICU Resilience and Support Group

306. Procurement of ICU equipment was undertaken by NSS, in collaboration with the SG ICU Resilience and Support Group (initially called the SG COVID Critical Care Support and Resilience Group). This work was led by the Director for ICU Resilience (John Connaghan and then Caroline Lamb from March 2020 to May 2020), within the SG Performance and Delivery Division in the Directorate of the Chief Operating Officer.

307. Under that leadership, the Group started to meet from 15 March 2020, meeting daily and, during the initial months, at least twice daily. The Group included all the key organisations and clinical and technical expertise, to ensure a direct line of two-way engagement with NHS Board critical care and clinical engineering leads who were represented on the Group. Membership included:

- SG Director of ICU Resilience (John Connaghan and then Caroline Lamb from March 2020 to May 2020) who were leading on ICU capacity in NHS Boards
- SG Medical Devices and Legislation Unit (CMO Directorate) – Official provided SG policy support and co-ordination and a clinical engineer provided technical expertise and intelligence gathering

- SG Health Workforce ICU Clinical Advisor and Clinical Leadership Fellows provided clinical expertise and leadership
- Scottish Critical Care Delivery Group Chair – Rory McKenzie (NHS Lanarkshire) provided front line clinical expertise
- NSS leads for ICU equipment
- NSS Assure (then known as Health Facilities Scotland (HFS)) – provided technical expertise on medical gases.

308.As agreed by Scottish Ministers, this Group provided central co-ordination and made decisions on the distribution of ICU equipment to NHS boards, using the latest intelligence available on the number of Covid-19 positive cases and number of ICU beds to be available under ICU expansion. It facilitated co-ordination between all key NHS organisations: the SG itself (specifically the Performance and Delivery, Medical Devices Policy and Health Workforce divisions), NHS Boards' ICU critical care and clinical engineering leads, NSS, and HFS. The Group was responsible for identifying Board ICU equipment requirements, Board requests for ICU equipment and supporting Boards with any issues in equipping their ICU beds. The Group worked directly with Board Critical Care and Clinical Engineering leads to deliver this.

309.The Group led co-ordination and decisions on procurement and distribution to Boards in the following ways:

- In the absence of a national medical equipment management system, manually gathering intelligence from the health boards on the number of ventilators they had on site, including their makes and models.
- Assessing the numbers of anaesthetic machines with integrated ventilators in NHS Boards, including makes and models.
- Assessing the oxygen (O2) consumption required for ICU ventilators and anaesthetic machines, feeding into NSS Health Facilities who led on modelling of overall O2 consumption.
- Ensuring all health boards had adequate supplies of ICU equipment and ventilator supporting equipment through the audit of Health Board equipment and agreed ICU escalation plans. This included syringe pumps,

volumetric infusion pumps, patient monitors and specialised equipment such as Renal Replacement Therapy machines.

- Arranging for the clinical and technical assessment and evaluation of equipment of unfamiliar brands through the setting up of a facility in NHS Greater Glasgow and Clyde and reporting back to the ICU Resilience and Support Group on their conclusions.
- Using updates from the Scottish Intensive Care Audit Group on number of ICU cases in Level 3 ICU to ensure that Boards had access to the equipment they needed.
- Regular reporting to officials and Ministers on the position in relation to the supply and demand for ICU equipment and mitigations in place for the long lead times for ICU equipment due to the global demand.

ICU equipment modelling

310. The international standard for ICU response in a pandemic situation is to double ICU capacity. Accordingly, this was the capacity agreed with NHS Boards as part of prior pandemic planning, and duly formed the starting point at the beginning of the Covid-19 response in Scotland. The modelling used for ICU equipment was the number of ICU beds to be provided by NHS Boards. The number of ICU beds were set by Scottish Ministers, informed by the work of the ICU Resilience and Support Group (Chief Operating Officer Directorate).

311. From 9 March 2020, regular audits of the ICU equipment held by NHS Boards were undertaken by the ICU Resilience and Support Group in order to assess the shortfall in ICU ventilators and equipment. This was the modelling that the ICU Resilience and Support Group used to inform the number of ICU ventilators and equipment required to be purchased by NSS. The first audit was completed on 15 March 2020, provided: [CL13/146 - INQ000496411]. This initial audit provided the baseline position for Boards, with the data used by the ICU Resilience and Support Group (including NSS) to inform the procurement of ICU equipment. This was ongoing work and discussed in daily meetings by the ICU Resilience and Support Group.

312. There was some modelling work undertaken by SG statisticians to which the ICU Resilience and Support Group provided input, but it did not provide any results that could be used as the results indicated levels of patients in hospital far beyond the maximum ICU capacity in NHS Scotland.

313. The audit of Board ventilators was undertaken by a clinical engineer working in the SG Medical Devices Policy Unit, with input from the ICU Resilience and Support Group to ensure that the information required was collected. This work required clinical and technical expertise and knowledge input provided by the ICU Resilience and Support Group, which included the Chair of the NHS Board Critical Care Leads. As stated above, modelling was also provided by SG statisticians in March 2020 but that did not provide results that could be used by the ICU Resilience and Support Group. The audit of Board ICU ventilators and equipment being procured by NSS was shared with SG statisticians for the modelling work they were undertaking.

314. For ICU ventilators and equipment, the focus was equipping up to the maximum surge Level 3 ICU beds to deliver double capacity (406 beds) up to the maximum surge Level 3 ICU beds (714 beds), caveated by the ability to staff ICU beds. The approach adopted by the ICU Resilience and Support Group from the start was to take a human factors approach – i.e. purchasing and using only familiar brands or brands that NHS Boards were using already where possible. This meant that staff working under extreme pressure were not also having to learn to work with new specialised equipment and enabled the equipment to be utilised by Boards post-Covid.

315. In the context of ICU ventilators and equipment, there was no modelling to provide a range of different estimates on the basis of different possible variables. All modelling for ICU equipment was based on the policy position of increasing ICU capacity up to a maximum surge position of 714 ICU beds, and that maximum surge capacity directly informed the buying strategy for ICU ventilators and equipment.

Establishing the ventilator requirement in the early pandemic

316. Information on the number of ventilators in Scottish hospitals which could provide invasive ventilation at the start of the pandemic was only held by NHS Boards and not centrally collected. The audit of NHS Boards completed on 15 March 2020, provided above, was undertaken to establish the number of ICU ventilators that existed within NHS Scotland. As at 15 March 2020, there were 363 adult ICU ventilators.

317. Similarly, an audit of NHS Boards anaesthetic machines with integrated ventilators was initially undertaken on 9 March 2020 by the Medical Devices Policy Unit. This indicated there were 686 anaesthetic machines in NHS Boards with further work undertaken to quality assure the data. As of 28 March 2020, there were 693 anaesthetic machines with integral ventilators available which could be used to supplement ICU ventilation, if required.

318. Non-invasive ventilators were outwith the scope of ICU equipment and the ICU Resilience and Support Group. An audit to specifically look at all non-invasive ventilation was not undertaken by SG. However, the 9 March 2020 audit referred to above confirmed that NHS Boards had 105 sub-ICU (e.g. High Dependency Unit) ventilators that were essentially non-invasive ventilators with limited invasive modes, such as Philips Trilogy 202 and V60. Upon further investigation, it was established that NHS Boards had 124 such devices. The 9 March 2020 audit collected some limited data on continuous positive airway pressure (CPAP) machines but not all Boards returned this data. A total of 1,005 CPAP machines were held by NSS for distribution to NHS Boards as required. Approximately 200 CPAP machines were provided from the DHSC stockpile and, as noted, approximately 500 CPAP machines were procured by NSS (who will hold precise numbers).

319. The policy position for the number of ICU beds was used to assess the shortfall of ICU ventilators and equipment that was available to NHS Boards. This was monitored daily by the ICU Resilience and Support Group to ensure that NHS Boards had the ICU ventilators and equipment they needed to provide intensive care. The monitoring of Boards' ICU requirements included NHS Board access to

the whole ICU kit needed for an ICU bed. The policy position for ICU beds was for a maximum of 714 ICU beds, subject to staffing being available, so sourcing of ICU equipment was planned by the ICU Resilience and Support Group to meet this requirement.

320. ICU equipment was also secured on loan from the DHSC. While most of the DHSC stockpile for ICU were not preferred brands/specifications, NHS Scotland benefitted from a range of medical equipment that helped to bolster resilience across the service. NSS hold a list of the equipment provided to NHS Boards. Deliveries were made directly to NHS Boards from the DHSC stockpile warehouse to ensure that these were delivered as quickly as possible, by arrangement with NSS.

321. HFS led on oxygen resilience and were part of the ICU Resilience and Support Group for ICU requirements. The ICU Resilience and Support Group provided clinical engineering input to calculations on oxygen and medical air consumption in ICU to ensure oxygen resilience in ICU. The work undertaken to repurpose anaesthetic machines from oxygen to air driven was part of the effort to conserve oxygen supplies.

322. The total additional number of ventilators needed in order to provide the maximum ICU beds of 714 was 527. A small number of ventilators from the DHSC stockpile were obtained through this route with NSS procuring the balance needed. For the DHSC procurement, SG was not directly involved. However, the devolved administrations and Crown Dependencies were regularly kept updated on the DHSC procurement progress through regular meetings.

The Ventilator Challenge

323. The SG had no role in the Ventilator Challenge (an initiative launched by the UKG, challenging manufacturers and medical device companies to step up production of existing designs and design new ventilators from scratch), but the DHSC did offer supply of these devices to NHS Scotland and the other DAs and Crown Dependencies. Two NHS Boards trialled the Penlon ES02 to consider if it was a product that could be used in Health Boards in May 2020. Following assessment, it was decided by the ICU Resilience Group that these did not meet NHS Scotland requirements. The feedback from clinicians and medical physics teams was that these offered a slight advantage over anaesthetic machines but were not to full ICU specification. The ICU Resilience and Support Group requested that Scotland's allocation of these should be held by the DHSC in reserve in the event of an extreme surge scenario.

ICU equipment and the UKG Government Stockpile

324. There was regular and effective communication and collaboration between the DHSC and DAs and Crown Dependencies on the UK Government stockpile. NHS Scotland was allocated up to an 8.2% share of all the equipment procured by the DHSC (this was calculated by DHSC on a per head of the population basis for the DAs and Crown Dependencies). The SG did not have any direct involvement in developing the figures, but the calculations/derivations were shared with SG and other DAs. Available ventilators were assessed by NHS Scotland medical physics and clinicians and a small number manufactured by the brands familiar to NHS Scotland were accepted. It was felt that the resilience supplied by anaesthetic machines was less of a risk than introducing unfamiliar brands. All DAs were appraised of the medical equipment available through the UK stockpile.

ICU equipment costs

325.Regarding costs, all procurement, deliveries and distribution was undertaken by NSS, so they will hold detailed information on specific costs. NSS engaged with some procurement activity from abroad in the early stages of the pandemic and will also be able to provide full details of this.

326.Owing to global demand, the cost of ICU ventilators and equipment increased after the start of the pandemic and lead times for deliveries were longer—months, in some cases, which was why mitigation through repurposing anaesthetic machines was required. The UKG stockpile also had these delays in delivery times, which meant that there was no certainty on when any of their supplies would be available so they could not be used in our planning assumptions.

327.The process for allocating ICU equipment was to respond to the specific equipment needs of individual Health Boards to provide for their ICU beds and to support the prioritisation of clinical need. Distribution of ICU equipment was managed by the ICU Resilience and Support Group.

328.There was direct contact with NHS Boards through the ICU Resilience and Support Group, Board critical care and clinical engineering leads. Regular updates and submissions were provided to Ministers from the Director for ICU Resilience (initially the Chief Operating Officer and then Caroline Lamb as the Director for ICU Resilience) on the ICU equipment position.

ICU equipment challenges

329.The main challenges experienced in relation to ICU equipment were, firstly, the auditing of Health Board ICU ventilators and equipment, which needed to be undertaken manually in the absence of a national medical equipment management system, including cleansing (i.e. fixing or removing incorrect, corrupted, incorrectly formatted, duplicate, or incomplete data) and harmonising the data to account for differences between boards, as well as errors. As a key part of learning from Covid-19, a national Medical Equipment Management System Project is currently being implemented. Once established, this will

provide a 'Once for Scotland' joined up data view for the operational and strategic management of the medical equipment inventory across Scotland. This project includes Data Cleansing and Data Harmonisation of Medical Equipment by all territorial NHS Boards to ensure data quality.

330. The second key challenge was the impact of global demand, which applied to both the Scottish and the DHSC orders by creating long lead times for deliveries. Ventilators are generally made to order without large stocks held by manufacturers. There is no manufacturing base for ICU ventilators in the UK. This meant all stock had to be sourced from abroad with the more familiar brands coming from the EU. As Covid-19 was world-wide, many countries were vying for limited stock and it resulted in several issues, such as long lead times and pop-up vendors who offered access to machines manufactured in East Asia at increased prices. Some did not actually have the stock or access to the machines as they claimed. These processes were managed by NSS who vetted all potential suppliers as far as possible with the preference being to use known suppliers. The UKG stockpile also included brands, makes and/or models that were unfamiliar in NHS Scotland, with NHS Scotland staff already working in a pressured environment, it was important to avoid introducing new equipment that they were unfamiliar with or required extensive training to use. The DHSC has since disbanded the UKG work but there continues to be cross UK collaboration on medical device topics, particularly with the DHSC MedTech Directorate and the UK Clinical Engineering Group which both meet regularly with the Scottish Government and NHS Scotland representatives. As part of Scotland's future preparedness, all NHS Boards now hold ICU equipment to support double ICU capacity.

ICU equipment and working with other bodies

331. Examples of where SG worked or coordinated with other organisations in the provision of ICU equipment are as follows:

- In April 2020, the charity KidsOR (Kids Operating Room) loaned Ninewells Hospital in Dundee, NHS Tayside, 10 brand new Mindray Wato EX35 anaesthetic machines with integral ventilators and 10 Mindray ePM-12M

patient monitors to work with them, plus an additional 16 patient monitors and 18 pulse oximeters.

- A small number of syringe pumps were loaned to NHS Scotland from the veterinary schools in Edinburgh and Glasgow. They were very early to offer equipment but not all types they used were suitable.
- In October 2020, ICU equipment was delivered to NHS Western Isles, to set up a small four-bedded unit. The ventilators were loaned by Drager, the ventilator manufacturer, who had received them as recent trade-ins. NHS Greater Glasgow and Clyde provided a clinical engineer to commission and set up the ventilators and associated patient equipment to support NHS Western Isles.

332.Co-ordination of this type was managed by NSS, so further details on the examples described here and on any other similar exercises (included assessments of successes and challenges) should be sought from them.

ICU and Four Nations working

333.Procurement of NHS Scotland ICU equipment was undertaken by NSS independently of UKG. However, DHSC regularly shared information and intelligence on their procurement of ICU equipment, including on delivery lead times. The DHSC, DAs and Crown Dependencies worked collaboratively from early March 2020. The DHSC team worked diligently to ensure ICU equipment was identified and distributed directly to NHS Boards, where those were needed and not available from the stock held in Scotland.

334. An inventory of equipment in the DHSC stockpile and their expected delivery times was shared regularly by the DHSC. It was helpful to see what DHSC had ordered, though the key challenge was the long lead time for deliveries due to the global demand. This meant that available equipment was only known on the day and so the UKG stockpile could not be used for forward planning due the uncertainty of when it would be available. However, these were similar issues for NSS in the early months.

335. On ICU equipment, regular meetings were held between the DHSC team and the DAs and Crown Dependencies. NSS representatives attended these meetings.

Section 5 - Testing

Mass Testing

336. In Scotland, polymerase chain reaction (PCR), lateral flow device (LFD) and loop-mediated isothermal amplification (LAMP) tests were rolled out across a number of pathways. Testing eligibility expanded in line with testing capacity and clinical advice. Additionally, antiviral tests were used for antibody surveillance. While Test and Protect was formally established on 28 May 2020, there was testing and eligibility prior to that date. Key events include:

- 24 February 2020 – the first two people were tested for Covid in Scotland. Both individuals tested negative
- 15 March 2020 – surveillance testing was expanded to GP practices to monitor the spread of Covid in the community, covering up to 1.2 million people in Scotland
- 15 March 2020 – SG updated health boards on the pause to the locally-led test, trace, isolate strategy for the general public. All symptomatic people are advised to stay at home for seven days regardless of travel or contact. Testing of the general public stops but is maintained in hospitals for admissions with suspected Covid, and all ICU admissions with upper respiratory-related conditions, for the purposes of clinical care and diagnostics
- 15 March 2020 – the First Minister announces all symptomatic patients in care homes will be tested, not just initial cases to establish the cause of an outbreak
- 24 March 2020 – SG publishes guidance for NHS health boards in Scotland to prioritise testing to enable health and social care staff to get back to work
- 25 March 2020 – SG announces the creation of its C19-AG to supplement UK-wide Scientific Advisory Group on Emergencies (SAGE)

- 5 April 2020 – the first UK PCR site (Glasgow drive-through regional test site) opened for testing on 5 April 2020. Online ordering also opened for those eligible
- 23 April 2020 – SG publishes the Framework for Decision Making which includes setting out the role of testing, contact tracing and supporting self-isolation as part of transitioning out of lockdown
- 1 May 2020 – testing eligibility was expanded in line with additional capacity
- 4 May 2020 – the test, trace, isolate, support strategy was published
- 18 May 2020 – testing eligibility was extended to those over five with symptoms.
- 28 May 2020 – Test and Protect was established and those with Covid symptoms were encouraged to book a test and self-isolate if positive
- 23 June 2020 – health and social care staff were offered weekly PCR testing
- 21 July 2020 – testing was expanded to under 5s
- 17 August 2020 – Scotland's Covid-19 Testing Strategy was published
- 25 August 2020 – increasing capacity and accessibility of testing was announced, with 11 walk-through test sites to be set up
- 26 August 2020 – NHS Scotland procures 300 point of care testing machines and 500,000 tests
- 2 October 2020 – SG announces an antibody survey for education staff
- 23 October 2020 – SG publishes its Strategic Framework
- 11 November 2020 – SG announces a Covid-19 student testing scheme to support the safe return of students ahead of the winter break
- 25 November 2020 – SG announces an expansion in testing for hospital patients, health and social care staff, and communities in Level 4 areas
- 2 December 2020 – SG announces the opening of Scotland's first Community Asymptomatic Test (CAT) site in Johnstone, Renfrewshire. The trial lasted to 9 December 2020
- 6 December 2020 – SG announces lateral flow testing of designated visitors will be trialled in 14 care homes in North Ayrshire, Fife, Argyll and Bute, Inverclyde, and Aberdeenshire

- 23 December 2020 – SG announces community testing in areas with high coronavirus prevalence from January 2021
- 5 January 2021 – SG announces a new way of testing, small-scale test sites, coronavirus testing will be available from two fire stations in Thurso and Lochgilphead between 6 and 29 January, as part of a trial to increase testing access in remote and rural areas
- 2 February 2021 – SG announces expansion of testing in order to try to drive down rates of Covid-19 in Scotland. The expansion includes routine testing for patient-facing primary care workers, regular testing offered to support the return of schools and nurseries, an expansion of targeted community testing, routine testing for certain workplaces and tests offered to all close contacts of people who have tested positive for Covid-19
- 17 February 2021 – SG announces an expansion of testing to include anyone who is identified as a close contact of somebody who has tested positive for Covid-19, from 18 February 2021
- 18 January 2021 – targeted community testing formally commences, following pilots in Johnstone, Renfrewshire
- 23 February 2021 – SG publishes its Strategic Framework update
- 26 February 2021 – SG announces access to testing is now available from 21 fire stations across Highland and Argyll & Bute, completing the rollout of small-scale test sites in rural and remote areas of NHS Highland
- 17 March 2021 – SG published an updated testing strategy, including a £13 million investment in 2021/22 to establish Scotland's own genomic sequencing service to track new Covid-19 variants and manage future outbreaks
- 25 April 2021 – SG announces free lateral flow test kits to be available for anyone without symptoms from Monday 26 April
- 9 June 2021 – SG announces rapid test kits to be rolled out to community pharmacies from 9 June
- 17 June 2021 – SG publishes its Strategic Framework update.
- 22 August 2021 – UKG launches UK-wide antibody surveillance programme for the general public for the first time. Home antibody tests

available for up to 8,000 people a day across the UK who opt in to the service through NHS Test and Trace

- 22 September 2021 – SG announces more than 10 million Covid-19 PCR tests have now been carried out in Scotland over the past 19 months since testing got underway
- 16 November 2021 – SG publishes its Strategic Framework update
- 23 November 2021 – SG announces that from 6 December, people attending venues covered by Scotland's COVID certification scheme are to be given the option of providing a recent negative lateral flow test for the virus, as an alternative to proof of vaccination
- 27 November 2021 – SG imposes new travel restrictions as a result of the omicron variant – fully vaccinated arrivals will need to take a PCR test within two days of arrival and to self-isolate until a negative result is received
- 6 December 2021 – SG announces that from Monday 6 December, the domestic Covid certification scheme will include provision for a negative test for Covid-19, as an alternative to proof of vaccination
- 29 November 2021 – SG announces that priority for PCR test site slots will be given to essential workers, those at highest risk and anyone eligible for new Covid treatments. A self-isolation exemption scheme is also available for essential workers
- 3 January 2022 – SG advises all secondary pupils to take at-home Covid-19 tests before they return to school to limit the spread of Omicron
- 5 January 2022 – SG announces changes to self-isolation and testing. From 6 January, new cases can end self-isolation if they don't have a fever and test negative on a LFD on Day 6 and again at least 24 hours later. Anyone who tests positive on a LFD will no longer be asked to take a PCR test to confirm the result
- 24 January 2022 – fully vaccinated arrivals into Scotland will no longer be required to possess a negative test result from 4am on 11 February. Non-vaccinated arrivals will still be required to take pre-departure tests and a PCR test on or before day two – but the requirement for isolation will end – and they will no longer have to take a day eight test

- 22 February 2022 – Scotland's updated Strategic Framework is published
- 15 March 2022 – SG's Test & Protect transition plan is published. People without Covid-19 symptoms will no longer be asked to take regular lateral flow tests from 18 April. From this date, free lateral flow devices (LFDs) will no longer be available except for any purpose for which testing continues to be advised. People with symptoms should continue to isolate and get a PCR test until the end of April
- 30 March 2022 – SG announces that from 18 April most people without symptoms will not be required to take tests. Lateral flow devices for twice weekly testing will no longer be available. PCR tests for people with Covid-19 symptoms will be available until 30 April, when test sites will close
- 28 April 2022 – SG announces public health advice will change to a 'stay at home' message from 1 May All contact tracing will end. Testing for the general population will end on 30 April, with test sites closing. Testing will remain available to certain groups. NHS Scotland will be taken out of emergency footing at the end of 30 April
- 25 September 2022 – SG announces that health and social care workers will no longer be required to test for Covid-19 every week as asymptomatic testing is paused by 28 September.

337. Developments regarding international travel testing, contact tracing and supporting self-isolation are not covered above.

The purpose of mass testing

338. "Test & Protect" (testing, contact tracing and supporting isolation) are simply defined for the purposes of this statement as population approaches that sought to reduce harms of the virus, primarily by reducing transmission (there are other reasons for Covid-19 testing that applied including testing for clinical care reasons (to indicate treatment) or testing for surveillance purposes – these are set out below). The overarching purpose of population wide or 'mass' testing was to identify positive cases, provide them and their contacts with public health information through contact tracing, and ultimately to support people to self-

isolate to reduce transmission of Covid-19 and therefore reduce the risk of health harm that Covid presented.

339.SG's approach to Test and Protect evolved over time, particularly as various aspects of the Covid-19 crisis changed and as the technologies available through the UK Four Nations National Testing Programme increased. Following the March 2020 'lockdown', it covers four broad phases:

- The early phases of the development of Test and Protect including the publication of the Test Trace Isolate Support Strategy on 4 May 2020 and the national rollout of population wide testing and launch of Test and Protect from 28 May 2020
- The strategic and delivery adaptations to Test and Protect between the launch in May 2020 and winter 2021, as over this time period the pandemic changed; evidence and scientific research on the nature of the virus and how it transmitted changed (including evidence on asymptomatic transmission); innovations came on stream through the UK National Testing Programme; and harms changed with the impact of vaccination and higher population immunity
- The transition phase for moving Covid testing, tracing and supporting isolation to a steady state and the stopping of whole population Covid testing, post the emergency phase, as the overall Strategic Intent changed to become "To manage Covid-19 effectively, primarily through adaptations and health measures that strengthen our resilience and recovery, as we rebuild for a better future"
- The period of implementation of the Test and Protect Transition Plan published on 15 March 2022 up to the maintenance of capabilities developed for wider surveillance purposes into 2023 and beyond.

340.SG's approach to Test and Protect sought to suppress the virus, including consideration of how to ensure ease of access to Covid testing across all communities in Scotland including those disadvantaged by deprivation and remote and rural communities. It outlines the public health reasons for Covid testing and how the main purposes of testing changed as capacity increased and

technologies changed. It describes how the use of Test and Protect was part of the SG's broader approach to pandemic management set out in the COVID-19 Strategic Framework. It describes the development and adaptation of approaches to contact tracing and supporting isolation. It notes that many other countries, including those within the UK, were pursuing approaches with varying degrees of similarity to that pursued in Scotland.

341. The six key purposes for Covid 19 testing that applied in Scotland (as in other parts of the UK) at different points in the pandemic are:

- Testing to enable keyworkers to return to work if Covid negative
- Testing to support the clinical care of individual patients – including in hospital
- Testing to reduce transmission at a whole population level (Contact Tracing and Supporting Isolation link)
- Testing a sample of cases to support surveillance of the virus
- Testing people without symptoms to find asymptomatic cases to protect those in vulnerable settings or support the restart of key public services
- Testing for case finding to reduce transmission at community level.

342. Because health is devolved, responsibility for much of the management of the pandemic in Scotland fell to Scottish Ministers. However for Test and Protect - and in particular the development and application of testing capacity and technologies - Scotland was part of the UK 4 Nations National Testing Programme, along with Wales and Northern Ireland, which significantly impacted the approach to testing taken at all times in the pandemic.

343. The SG's overall approach was to minimise the overall harm of the pandemic, and to deliver this, it developed an approach to making decisions that supported consideration of both the potential harms caused by Covid-19 with the potential harms caused by some public health interventions (eg. the effects of isolating people on business, economic effects, health effects of people self-isolating). SG published the way it would take future decisions on its pandemic response in April 2020 in the *Framework for Decision Making*, provided: [CL13/147 -

INQ000369689]. This document set out the SG's principles and approach to managing the pandemic, including in relation to the use of testing, contact tracing and supporting isolation. The *Framework for Decision Making* represented the first document setting out the Scottish Government's overall strategic approach to managing the pandemic. This *Framework* was the first in a series of overall strategy documents, which were updated as pandemic conditions changed, and as knowledge about the virus grew as scientific evidence developed.

344.As the overall *Strategic Intent* evolved, so did the strategy and rationale for Covid testing. As both the nature of the Covid-19 crisis changed and the government's overall strategy evolved in response, so did its approach to Covid testing in general and Test & Protect as a whole population intervention. From the initial use of testing to enable keyworkers to return to work if Covid negative through to the whole population testing, contact tracing and supporting isolation for almost two years from May 2020 to April 2022, through to the Transition Plan to a steady state for Covid testing including the cessation of population wide testing and the introduction of Stay at Home public health advice for people with symptoms of respiratory infections, including Covid-19.

345.The following table sets out testing strategies and when they were published.

Publication	Exhibit
Move to delay phase – 13 March 2020	[CL13/148 - INQ000496466]
Testing expanded to NHS health and social care key workers – 24 March 2020	[CL13/149 - INQ000496422]
Test, Trace Isolate Support Strategy published 4 May 2020	[CL13/150 - INQ000093618]
Refreshed strategy published 17 August 2020	[CL13/151 - INQ000147448]
Strategic Framework published 23 October 2020	[CL13/152 - INQ000339830]
Clinical & Scientific Review of the Testing Strategy October 2020	[CL13/153 - INQ000496425]
Refreshed strategy published 23 February 2021	[CL13/154 - INQ000343997]
Refreshed strategy published 17 March 2021	[CL13/155 - INQ000351878]
Refreshed strategy published 17 June 2021	[CL13/156 - INQ000235137]
Refreshed strategy published 16 November 2021	[CL13/157 - INQ000353777]
Test and Protect Transition Plan published 15 March 2022	[CL13/158 - INQ000235186]

Groups/individuals with a key role in SG's mass testing policy

346. On 6 April 2020 Annabel Turpie was appointed Director of Testing, with Ian Davidson and Wendy Wilkinson as the Deputy Directors until 29 May 2020, leading on the Testing capacity across Scotland to support a Test, Trace, Isolate approach to reducing transmission of Covid-19. The Directorate for Test and Protect took on policy and operational oversight responsibility from the Directorate for Covid Health Response from 6 April 2020 to 21 May 2020. Policy responsibility for Test and Protect was transferred to Directorate for Covid Public Health in June 2020, operational oversight remained separate, with Jill Young. Christine McLaughlin was appointed Director of Test and Protect 8 June 2020. Christine joined the Directorate for Covid Public Health on 1 June 2021 to share duties with Richard Foggo.
347. Caroline Lamb was Delivery Director for the contract tracing and isolation elements of Test and Protect from May 2020 until August 2020, then took on the role of Delivery Director for Vaccinations until she became DGHSC from 11 January 2021, taking over from Elinor Mitchell.
348. On 1 June 2020, Richard Foggo was appointed Director for the newly established Directorate for Covid Public Health. The Directorate for Covid Health Response was run as effectively a single team with flexible resource working seven days a week on shift patterns. With the creation of the Directorate for Covid Public Health, a more traditional Divisional structure was introduced. The Covid Testing and Contact Tracing Policy Division was one of the divisions that made up the directorate. It was led by Niamh O'Connor, before she was joined by John Nicholson as joint deputy director in July 2020.
349. A table outlining the key testing policy governance groups has been provided to the Inquiry previously as part of an overview document detailing the SG organisational structure, including the Directorates, groups, Ministers and senior officials relevant to Module 5. The *closure report for the Testing Transition Board* dated December 2022, provided: [CL13/159 - INQ000496428], further summarises the governance arrangements throughout the life of the programme,

including links between different governance groups, key deliverables and pathways.

350. Notes from of Test and Protect meetings that the SG holds records for has been provided as general disclosure.

The Scientific Advisory Group for Testing

351. SG's clinical advisors (including but not limited to CMO, DCMOs and senior medical officers, CNO and other clinical consultants) and PHS senior public health and clinical consultants were closely engaged and regularly consulted in the development and delivery of Test and Protect. Many of these individuals were directly involved in formal governance structures where testing was discussed regularly. Those groups include the Scientific Advisory Group for Testing (SABoT). This was a sub-group of the SG's overall Scientific Advisory Group. The C19AG was established to provide scientific and technical advice on COVID-19, specifically tailored to Scotland's needs. Chaired by Professor Andrew Morris, the group included public health experts, clinicians, and academics from various fields. It interpreted advice from the UK's SAGE and other sources to guide local decisions and inform NHS and social care planning. The group also engaged with other advisory bodies and produced regular modelling and analysis reports.

352. SABoT considered the scientific and technical concepts and processes key to supporting the delivery of Covid-19 testing; and informed SGs strategic use of testing to manage the pandemic including supporting the development of options for Ministers. The advisory group considered emerging scientific evidence and other appropriate sources of information to inform Scottish Ministers decisions in Scotland during the pandemic. The advisory board provided expertise and advice to inform Scottish Ministers but did not take a role in policy decision making.

353. The SABoT's remit was to:

- Provide an ongoing review of testing strategy within Scotland in light of emerging scientific evidence and changing prevalence of the disease

- Recommend strategies for the delivery of testing, including the evaluation of different testing types, considering new methods of testing, and the need to have sufficient testing capacity to meet demand
- Consider emerging evidence to inform current testing priorities and recommend which groups within the Scottish populace should be prioritised for testing
- Provide an expert point of contact with, and strategic input to the C19AG
- Evaluate the efficacy of Covid-19 testing strategy and practice across the UK and thereby provide advice to inform Scottish testing practice.

354. The minutes, agendas and papers from the SABoT have been provided to the UK Covid-19 Inquiry previously as part of general disclosure.

The Clinical Governance Group (CGOG)

355. The Clinical Governance Group (CGOG) was regularly consulted on matters relating to Test and Protect. CGOG's membership included senior clinicians and representatives from across SG, PHS, NSS and from health operational delivery. The group's remit included, amongst other things, assessment of concerns about tests for use cases (different scenarios where specific testing equipment could be deployed). For example, lead CGOG member David Stirling sat on both CGOG as well as groups such as UKHSA's Patient Safety Panel (PSP). This enabled the group to consider UK wide assessment of any potential testing efficacy or quality concerns for the Scottish context.

356. Additionally, the table included above sets out the governance for Test and Protect, where scientists, clinicians and public health and testing and screening experts were brought together to discuss key developments.

Scale and timeline of mass testing

357. Targeted community testing was intended to undertake asymptomatic testing of people who were otherwise not eligible under other testing pathways in areas of highest transmission to improve identification of cases that were being missed,

and to better use mobile testing units to enhance symptomatic testing. This programme was led by SG with input from territorial health boards, NSS, PHS and local authorities.

358. Targeted community testing was piloted in eight communities with high prevalence from 26 November 2020 to 9 December 2020. Over the course of the community testing pilots in Scotland, 22,133 tests were completed and 850 positive cases identified (3.8% positivity). Additionally, the interim evaluation report, provided: [CL13/160 - INQ000488599], from community testing in Liverpool found that “large-scale, intelligence-led, targeted, and locally driven community testing for SARS-Cov-2, in concert with other control measures and vaccination, can support Covid-19 resilience and recovery.” This also informed the development of the targeted community testing approach and was a key basis for its rationale. The growing evidence base underpinned decisions around deployment.

359. The targeted community testing programme commenced on 18 January 2021. In line with the Test and Protect Transition Plan, symptomatic test sites and LFD collection points closed on 18 April 2022, from when the SG no longer asked the general public to test themselves regularly if they were well and not experiencing Covid symptoms. On 1 May, population testing for those with symptoms ended, this included for targeted community testing sites with symptomatic testing provision.

360. The focus of targeted community testing changed in line with pandemic response priorities and the emergence of variants of concern. However, in programme board terms of reference documentation from January 2021, provided: [CL13/161 - INQ000496431] and June 2021, provided: [CL13/162 - INQ000496432], it was defined as:

- *The strategic application of testing and other public health measures to reduce COVID-19 community transmission by identifying and isolating positive cases that would otherwise be missed, and encouraging local compliance with non-pharmaceutical interventions (NPIs), achieved through:*

- *Use of Public Health Scotland community level test positivity data, waste water testing data and local intelligence from directors of public health to identify areas with concerning levels of community transmission*
- *The rapid deployment of local and national resources to that community to enhance symptomatic testing provision, offer asymptomatic testing options, promote isolation support and encourage compliance with NPIs.*

361.As the Omicron variant emerged, SG further expanded the availability of lateral flow tests and encouraged people to test regularly to reduce asymptomatic transmission. This was done via the targeted community testing programme at pop-up collection points located in high traffic areas, such as shopping centres, train stations and garden centres.

362.An evaluation was undertaken by the SG that summarises evidence and insights at a national level from the evaluation of targeted community testing. The report covers the period 18 January 2021 to 26 September 2021 and was published on 14 December 2021, provided: [CL13/163 - **INQ000243924**].

363.Targeted community testing ended in line with the dates and timelines set out in the Test and Protect Transition Plan, provided: [CL13/158 - INQ000235186].

Provision of Covid-19 tests

364.Regarding the procurement of Covid-19 tests to support the testing programme, SG did not procure PCRs or LFTs directly. Prior to the testing programme MoU being implemented, the devolved administrations and the UKG worked collaboratively on the testing programme. Devolved administrations established high-level principles for the 4 Nations UK Testing Programme in September 2020 and shared them with DHSC officials.

365.In April 2021, the health secretaries of the four nations of the UK signed an MoU, provided: [CL13/164 - INQ000203654], relating to testing and laboratories.

Section 3 of the MoU sets out in detail what services were to be procured and delivered. Namely:

- Physical test sites for people to attend for the purposes of providing samples
- PCR home testing service
- Organisation Led Testing e.g. care homes, prisons
- Laboratory services for the assaying of samples
- Antibody testing
- LFD Testing.

366. Any other services agreed in writing by the Parties in accordance with clause 12.

367. The MoU covers the key principles of consultation, discussion and joint decision-making between the four nations, and provides a clear framework for the UK and devolved governments to work from. It was imperative that open engagement and close, productive relationships were fostered at an official level in order to support the application of the MoU.

368. The MoU sets out the services the UKG were responsible for procuring and delivering, these are also set out above. As outlined in the MoU, devolved administrations were entitled to a *“Barnett share of National Testing Programme capacity in lieu of the consequential funding they would otherwise receive from health spending in England”*. This translated to approximately an 8% share of all UK testing programme capacity. In line with the MoU, SG could opt in or out of services received. The MoU states:

“At the point of Significant Procurements, Scottish Ministers can request to opt-out of a particular technology and receive equivalent funding calculated according to the Barnett Formula. Such requests can be exercised at the Investment Board, in accordance with the following key principles: The opt-out provision only applies to Significant Procurements of technologies; Scottish Ministers should seek to exercise formal opt-out in writing in advance of the

Investment Board where possible (during formulation of business case), but can also do so verbally at the Investment Board, or in writing within one business day of the Investment Board. Once Scottish Ministers have exercised their right to opt out, it is not possible to opt back into the same business case. If Scottish Ministers choose to opt out of a Significant Procurement of technology, they can choose to:

- receive Barnett funding calculated using the Barnett Formula. Officials will agree the detailed mechanics of how the Barnett funding calculation will be made; or*
- choose an alternative technology to deliver equivalent testing capacity, where logistically feasible, up to the value of the original Significant Procurement they are opting out of.”*

369.NHS health boards were responsible for procuring PCR tests used in NHS labs (the Regional Hubs, the first of which opened in December 2020, and diagnostic labs).

370.The UKG as part of the Four Nations Testing Programme was responsible for distributing PCRs and LFDs that were ordered through the UK online ordering portal, at UK test sites (walk-through local test sites, drive-through regional test sites, mobile testing units) and for distributing tests to pharmacy wholesalers for onward distribution.

Application of Standard Operation Procedure (SOPs) for Covid-19 tests

371.Standard operating procedures were developed to distribute tests in different locations and scenarios and to ensure testing programmes were operated safely and effectively. The key SOPs in place for different aspects of the testing programme are set out below.

372.The process of distributing PCRs through these sites was governed by the In Person Testing SOP, provided: [CL13/165 - INQ000496331]. The process of distributing LFDs through walk-through sites was governed by the Local Testing

Site (LTS) Operation Eagle Testing SOP, provided: [CL13/166 - INQ000496332]. The process of distributing LFDs through drive-through regional test sites was governed by the Regional Test Sites (RTS) Operation Eagle Testing SOP, provided [CL13/167 - INQ000496333]. The process of distributing LFDs through mobile testing units was governed by the Mobile Testing Units (MTU) Collect SOP, provided [CL13/168 - INQ000496334]. The process of distributing LFDs through pharmacies was governed by the Pharmacy Collect pharmacy SOP, provided [CL13/169 - INQ000496335], and Pharmacy Collect wholesaler SOP, provided [CL13/170 - INQ000496338].

373.As part of population symptomatic testing, the SG, the UKG, NHS Highland, NSS and the Scottish Fire and Rescue Service collaborated to develop bespoke small-scale test sites to distribute PCR tests in remote areas of NHS Highland to ensure remote and rural communities in NHS Highland had comparable levels of in-person testing access to the rest of Scotland, and to overcome the problem at the time of more limited access through the UK testing online ordering portal, where some NHS Highland and NHS Forth Valley postcodes were excluded from the ability to order. The UKG provided the tests to NSS, NSS managed orders and stock and the Scottish Fire and Rescue Service distributed them on behalf of NHS Highland and SG. This process was governed by the small-scale test site SOP, provided: [CL13/171 - INQ000496339]. Page 23 of the SOP sets out changes made with accompanying explanations.

374.As part of asymptomatic testing, NHS health boards, SG and partner organisations developed SOPs to govern the distribution and use of tests. As part of targeted community testing, the SG, NHS territorial health boards and local authorities developed asymptomatic test sites to distribute PCRs and LFDs. The UKG provided the tests and local partnerships comprised of territorial health boards and local authorities distributed them. This process was governed by the community testing LFD distribution and dual testing PCR and LFD SOP, provided: [CL13/172 - INQ000496341], (pages 6 and 7 set out changes and explanations) and the door-to-door test kit delivery model SOP, provided: [CL13/173 - INQ000496352] (page 4 sets out that the first version of the document was the final version).

375. Additionally, the following table summarises additional testing SOPs held by the SG in relation to Covid-19 testing:

SOP	Exhibit	Version control and explanation of changes
Schools & ELC Testing - LFD Collect	[CL13/174 - INQ000496368]	Pages 2-3
Public & 3rd Sector Workplace Testing - LFD Collect	[CL13/175 - INQ000496370]	Pages 4-5
Private Sector Workplace Testing - LFD Collect	[CL13/175 - INQ000496370]	Pages 4-5
Colleges Testing - LFD Collect	[CL13/176 - INQ000496372]	Pages 2-3
Higher Education Institutions Testing - LFD Collect	[CL13/177 - INQ000496374]	Pages 2-3
Individuals in Prison Custody Testing - LFD Collect	[CL13/178 - INQ000496375]	Page 6
Prison employees Testing - PCR Regional Hub	[CL13/181 - INQ000496378]	Previous Versions: <u>[CL13/179 - INQ000496376]</u>
Test Site Staff Testing - LFD ATS	[CL13/182 - INQ000496379]	Pages 5-6
Community Testing-Small Scale Test Site-Rural Access - Symptomatic PCR	[CL13/171 - INQ000496339]	Page 23

SOP	Exhibit	Version control and explanation of changes
Mental Health and Children & Young People's community Services Testing - LFD Collect	[CL13/183 - INQ000496381]	Pages 2-3
Workplace Testing (general) LFD ATS model - LFD ATS	[CL13/184 - INQ000496383]	Pages 4-5
Universities LFD ATS	[CL13/185 - INQ000496384]	Page 4
Schools Supervised Self-Test - LFD Supervised Self-Test	[CL13/186 - INQ000496385]	Pages 4-6
Social Care Testing Workstream 2 – LFD Collect	[CL13/187 - INQ000496387]	Page 4
Visiting Professionals	[CL13/188 - INQ000496391]	Page 4
Care Home Visitors	[CL13/189 - INQ000496393]	Pages 4-6
Universal offer – test site/pharmacy collect	[CL13/169 - INQ000496335]	Single version
University Collect LFD	[CL13/190 - INQ000496394]	Pages 3-4
LFD Clinical SOP Framework	[CL13/191 - INQ000496397]	Page 14
University Staff and Student Testing – LFD ATS	[CL13/192 - INQ000496399]	Page 4

SOP	Exhibit	Version control and explanation of changes
Employees – Control Room Staff – LFD Collect	[CL13/193 - INQ000496400]	Page 3
Care at home staff – LFD	[CL13/194 - INQ000496401]	Page 4
Healthcare workers – LFD	[CL13/195 - INQ000496403]	Pages 3-6

376.As part of Test and Protect programme, NSS led procurement efforts, where required, for NHS laboratories in Scotland. This included organising courier services for Scotland's regional laboratories and sourcing PCR test supplies and assembly to meet the specific requirements of NHS laboratories. Swabs and supplies were locally sourced during the early phase of the pandemic.

377.The Enhanced Testing Outbreak Marketing and Communications toolkit was shared with local authorities after the emergence of the Delta variant (v1 [CL13/196 - INQ000496404], v2 [CL13/197 - INQ000496405]) – the difference between the two documents are two additions, one on slide 3 which reads, “This toolkit is intended for use in all outbreak situations, though specific comms principles mentioned (e.g. SG involvement in a press release) should be applied as needed in the situation” and one on slide 11 which reads, “The template signage on slide 36 can be adapted as needed to include messages about photography and that photography is not allowed without prior permission”).

378.The Enhanced Outbreak Management Toolkit, provided: [CL13/198 - INQ000496406], was shared with local authorities and health boards after the Delta outbreak (changes with explanations are on page 2).

Modelling and prediction of volumes of Covid-19 Tests

Covid-19 test modelling

379. In relation to testing, requests for technical test demand modelling were met by the HSCA team, who developed regular test capacity modelling from May 2020 until approximately May 2022, that mapped the eligible groups for PCR testing to support key operational decisions around system capacity. They also undertook test demand modelling including for both PCRs and LFDs. This analysis was designed to inform key decision-makers across the SG system, rather than exclusively for the use of procurement. For the avoidance of doubt, the data was not used by SG procurement teams as they were not involved in the purchase of testing supplies. Nonetheless, the information was used to feed into UKG procurement processes regarding modelling forecasting volumes of tests. NSS managed the storage and distribution of LFD stocks held in Scotland, and with the UKG, they led on demand modelling to support this, which was discussed in regular meetings with SG officials. This helped to ensure stocks ordered covered demand.

380. The testing model outputs, provided: [CL13/199 - INQ000496421], were regularly shared with Deputy Directors and Directors in the Health and Social Care Directorates, including in response to requests for scenario modelling by Covid-19 Directors and Testing SROs, and as a component of advice to Ministers. This data was presented and discussed both via email and in calls, and was widely disseminated and debated as part of the Test and Protect oversight structures. These included the Test and Protect Steering Group, Testing Operational Delivery Group and Test and Protect meetings. These groups included SG and external members working in NHS Health Boards in Scotland. For example, the Test and Protect Steering group regularly had attendees from the public health teams of NHS Health Boards in Scotland, who often asked questions about the national level data and how it related to their local area. Through the aforementioned testing governance groups and working with NHS in Scotland, test demand was closely monitored to ensure settings where testing was required were appropriately supplied. These fora allowed for open discussion of data interpretation and bringing together diverse model outputs.

381. With regard to testing, HSCA developed a 'pipework' diagram that explained how eligible groups mapped to different testing pathways which informed the modelling, provided: [CL13/200 - INQ000496465], and on which subsequent modelling was based. Which groups were eligible for tests varied throughout the pandemic but at various times included groups such as: symptomatic individuals, hospital admissions, patients in hospital aged 70+, organ transplant patients, NHS staff, care home staff, care home residents, prison service workers, agricultural workers, close contact testing, surveillance testing (ONS Infection survey), and other key workers like teachers and police.

382. Testing models were based on eligibility for PCR and LFDs, which were not restricted by gender or ethnicity.

383. The testing model was capable of scenario analysis very early on using different parameters. Later innovations in the models to improve modelling outputs brought in displaying uncertainty around particular scenarios provided by the C-19 MAH. This meant that rather than giving single-point estimates of potential test demand, output ranges based on statistical uncertainty could be provided. For example, testing projections would be produced based on the latest low/central/high projections from C-19 MAH. Different assumptions on positivity rates, in particular the impact that positive LFD tests would have on PCR re-testing, were also repeatedly tested. In one project, the likely impact of the cold/flu season on Covid test demand was analysed due to the similarity between cold and flu symptoms and the eligibility criteria for Covid testing at that time. The model also allowed for the testing of different scenarios that changed eligible testing groups.

Testing Programme costs

384. The Scottish Budget did not have to directly fund the costs arising from the Four Nations Testing Programme during 2020–21 and 2021–22, as a UK-wide funding pot was established by UKG (with the use of that funding discussed and agreed by the four nations). All lateral flow test procurement for Scotland was carried out via this four nations procurement framework coordinated by the DHSC and

subsequently UKHSA. UKHSA holds the detail about cost in relation to these years.

385. For the year 2022-23, SG estimated an indicative full year cost requirement for Test and Protect of up to £350 million, with a large proportion of those costs falling in the first quarter of the year as the Test and Protect response was scaled back. Over the course of the year, this requirement reduced as UKG testing plans and associated funding became clearer and in the end, the actual spend was c£135 million. This excludes SG contributions totalling £0.8 million for UKHSA reserved activities, the cost of which was deducted from the overall UKHSA testing settlement paid to SG. The reserved activities programmes include global health security initiatives, protecting the public from radiation, developing the centre for pandemic preparedness, developing integrated UK-standalone early alerting and surveillance systems, deploying the UK's sequencing and virus assessment capabilities to help other countries respond to COVID-19 and strengthen global health security. It also excludes approximately £54 million of Scotland's share of UK-wide costs for the Testing Programme, which were deducted from the overall UKHSA testing settlement paid to SG. This included:

- Supply logistics – supply of tests and delivery
- Lighthouse laboratory network
- Decommissioning laboratories (Glasgow and Berkshire and Surrey Pathology Services Lighthouse labs)
- Decommissioning/disposals (inventory and equipment)
- Test supply chain capability
- Wider technology platform & development costs
- NHS Digital costs to run the online ordering portal and associated services
- 119 Service
- Public Health Clinical costs
- Genomics (non-Pillar 1)
- SIREN
- Science costs
- Rosalind Franklin Laboratory costs
- Public Inquiry

- Testing & Central workforce costs
- Community Infection Survey.

386. In 2023–24, anticipated spend for Test and Protect was £86 million versus actual spend of £38 million. This excludes SG contributions totalling £1 million (based on available interim projections) for UKHSA reserved activities, the cost of which was deducted from the overall UKHSA testing settlement paid to SG. The reserved activities programmes include global health security initiatives, protecting the public from radiation, developing a centre for pandemic preparedness, developing integrated UK-standalone early alerting and surveillance systems, and deploying the UK's sequencing and virus assessment capabilities to help other countries respond to COVID-19 and strengthen global health security. It also excludes £9.7 million (based on available interim projections) of Scotland's share of UK-wide costs for the UK Testing Programme, which were deducted from the overall UKHSA testing settlement paid to SG.

These costs relate to:

- Supply logistics – supply of tests and delivery
- Lighthouse laboratory network
- Decommissioning laboratories (Glasgow and Berkshire and Surrey Pathology Services Lighthouse labs)
- Decommissioning/disposals (inventory and equipment)
- Test supply chain capability
- Wider technology platform & development costs
- NHS Digital costs to run the online ordering portal and associated services
- 119 Service
- Public Health Clinical costs
- Genomics (non-Pillar 1)
- SIREN
- Science costs
- Rosalind Franklin Laboratory costs
- Public Inquiry
- Testing & Central workforce costs
- Community Infection Survey.

Selecting tests for use in mass testing

387. The evaluation and testing of new technologies was carried out by the UKG, as outlined in the Memorandum of Understanding, provided: [CL13/164 - INQ000203654], signed by the four health secretaries. Validation of LFDs was conducted by PHE Porton Down, with the findings and analyses disseminated to the devolved administrations. NSS's National Laboratories Programme then carried out further validation studies on LFDs for additional verification. UKG and NSS will hold records regarding their processes.

388. From an SG perspective, a variety of tests that were validated through these processes were used for testing. Tests were selected on the basis of having been validated and product availability. As the UKG procured tests, they retain records of all tests used across the UK's Four Nations. The following table summarises the advantages and disadvantages of different types of test:

Method type	Advantages	Disadvantages
Molecular (PCR)	High clinical and analytical sensitivity and specificity Samples can easily be moved off-site and sent to labs far away Can use self-collected samples Possible to conduct at scale Can indicate some variants in advance of genomic testing	Turnaround time longer than LFD (this varied depending on a number of factors – see main text) Cannot easily distinguish between whole virus and viral fragments, so can continue to show positive after active infection has subsided
Molecular (RT-LAMP)	Rapid results (<20 minutes) Performed well in pre-infectious and infectious phase Comparable performance to RT-quantitative PCR (qRT-PCR)	RT-LAMP machines usually need to be on-site with regular quality checks Staff training requirements to use

Method type	Advantages	Disadvantages
Antigen (LFD)	Rapid results (10-30 minutes) Results at point of testing (convenient) Does not require laboratory process or specialist knowledge to interpret results and can use self-collected samples, decentralising testing Possible to conduct at very large scale Lower cost than RT-LAMP (for example for asymptomatic testing) Can indicate infectiousness	Lower clinical and analytical sensitivity and specificity than PCR Results can be misinterpreted by inexperienced users
Serology	Enables retrospective analyses of outbreaks (for example highlighting asymptomatic disease) Enables surveillance of seroprevalence	Results only available when antibodies detectable, which may be outside window for informing interventions

Concerns relating to Covid-19 tests procured for mass testing

389. Concerns regarding the efficacy of tests were discussed at SaBoT and the CGOG including whether any action was required, and escalation routes.

390. Given the profile of Covid in public life, concerns from various sources on the different use of both LFD and PCR tests were raised throughout the pandemic including from members of the public and academics. Examples include: :

- 9 January 2021 – Submission to Ministers – Following a UKG decision to remove the need for a confirmatory PCR test result following a positive LFD result, advice sets out a recommendation to Ministers to retain confirmatory

PCR tests – this was based on advice from the CMO/DCMO, PHS Senior Clinicians and Directors of Public Health and early data from December 2020 that suggested at that point a c.30% false positive rate for LFDs, provided: [CL13/201 - INQ000241381]

- 18 November 2021 – Paper considered at CGOG from the Scottish Microbiology and Virology Network – recommendations regarding the use of LFD tests for clinical pathways, provided: [CL13/202 - INQ000496467]
- 7 January 2022 – report provided to CGOG – a potential exceptions issue related to LFD testing where a group of care home staff tested negative on LFDs but tested positive with PCRs a number of days later.

391. Additionally, concerns regarding tests were discussed at the following meetings and raised in the following papers:

- SABoT
 - 9 June 2020 – Minutes provided: [CL13/203 - INQ000324949] – Views provided at that meeting included concerns about use of PCR for screening rather than case identification.
 - 15 June 2021 – Minutes provided: [CL13/204 - INQ000496468] – Presentation on TestEd, University of Edinburgh on research on saliva based testing – discussion on potential efficacy of testing model (later to become LFDs), provided: [CL13/205 - INQ000496469].
 - 16 November 2021 – Minutes provided: [CL13/206 - INQ000496437] – Discussion of current scientific advice around the reliability of LFD testing, as compared with PCR, including the limitations in LFD sensitivity vs. PCR tests.
- Jon Deeks – Institute of Applied Health Research, University of Birmingham
 - Published article in the BMJ, 22 September 2020, provided: [CL13/207 - INQ000496470] – considered by CGOG (discussed in more detail at paragraph 398).
- Scottish Microbiology and Virology Network
 - Review paper, provided: [CL13/202 - INQ000496467], considered by CGOG 18 November 2021, provided: [CL13/208 - INQ000496471].
- General Correspondence

- Around 100 items of correspondence on MiCase (the correspondence management platform used by SG) were received from members of the public who had various concerns about the suitability of tests.

392. Different testing technologies were deployed for different use cases throughout the pandemic and Scottish Ministers, in arriving at decisions on deployment, considered the evidence base and efficacy for test types in relation to the proposed use case. For example, on the advice of the DCMO, LFD tests were not deployed in 2021 to enable contacts of positive cases to be released from isolation. At this time, close contacts of all cases were requested to self-isolate after contact with a person who had tested positive. Following DCMO consideration of potential risks, and the early evidence on LFD efficacy, LFD tests were not deployed to enable these close contacts to stop self-isolating, if they tested negative.

393. All tests used in Scotland were assessed by the UKG for suitability and that they performed as manufacturers claimed, were approved for the specific use case by the Medicine and Healthcare Products Regulatory Agency (MHRA). LFDs were also assessed in relation to their ability to detect new variants tested at Porton Down.

394. By mid-2020, an evaluation process for testing technologies was established within the national testing programme, including performance assessment in real-world settings. The validation and assessment of new technology was conducted on a four nations basis as outlined above.

395. On individual deployment decisions, the Scottish Ministers considered advice from SG officials that set out the regulatory status (i.e. whether MHRA had approved it, whether it complied with standards for safety, efficacy, and quality for specific applications, such as clinical use or at home use), in addition to the policy and clinical risks and benefits including advice from SG clinicians.

396. DHSC regularly reviewed and updated their traceability and batch recall processes to meet MHRA requirements. As set out, the MHRA, in their role as the

regulator for healthcare products and with input from DHSC and latterly the UKHSA, assessed test and instruction suitability for self-use. SG worked closely with the UKG to ensure Scottish requirements and relevant Scottish health service information were included in the development of specific test instructions. MHRA had extensive compliance requirements for tests, including SOPs, guidance materials, deviation specifications, test results, detailed data on adverse incidents, and lessons learned.

397. It is important to remember that testing was just one component of pandemic response and used in conjunction with many others. If there was concern about the performance of tests (for example, in relation to their effectiveness in relation to new variants), SG could implement additional control measures. Such measures could include strengthening isolation requirements: for instance, revised guidance meant that people testing positive for the Omicron variant were requested to self-isolate, where previously people who were fully vaccinated could end self-isolation after testing negative. These would remain in place until data was available through Porton Down on the performance of the main lateral flow tests in use in the Four Nations Testing Programme.

398. There were concerns raised throughout the pandemic related to various test types, and their use cases. For instance, in late 2020 the British Medical Journal (BMJ) published an opinion piece by Jon Deeks, Institute of Applied Health Research, University of Birmingham, and others, provided: [CL13/207 - INQ000496470], which queried the proposed use of LFD tests for asymptomatic testing based on a study of LFD testing pilots carried out in Liverpool and their efficacy for use by self-trained members of the public vs. in clinical settings.

399. On 10 June 2021 the US FDA issued a letter which shared the result of a recent inspection on Innova rapid antigen tests (also known as Innova LFDs), which occurred on March 15 through April 9 2021 at the Innova office in Pasadena, USA. The FDA in their statement warned the US public to stop using the Innova SARS-CoV-2 Antigen Rapid Qualitative Test for diagnostic use. The FDA cited significant concerns that the performance of the test has not been adequately established, presenting a risk to health.

400. Following the FDA recall of the LFDs, a full risk assessment was completed by the DHSC as the legal manufacturer of the Innova LFDs in the UK. The MHRA reviewed this risk assessment and was satisfied that no further action was necessary or advisable as outlined in their statement. Consequently, the MHRA confirmed that the tests could continue to be used, through their extension of the Exceptional Use Authorisation for the DHSC manufactured Innova tests to be used as self-tests, as part of the UK National Testing Programme and published a statement to confirm this, provided: [CL13/209 - INQ000496438]. Formal updates on this were prepared and circulated to Ministers by the SG Covid-19 Testing and Contact Tracing Policy Division on 14 and 17 June 2021, provided: [CL13/210 - INQ000240270].

401. LFDs procured by UKHSA used a Triton-X buffer solution which contained a substance (4-tert-OPnEO) subject to control under UK REACH Regulations which regulate the use of chemicals and heavy metals. Triton X was prohibited by UK Reach Regulations from 21 December 2023 and tests containing it were not able to be distributed beyond this date. SG, UKG and the other DAs worked closely to plan for further procurement of tests and the quarantining of stock affected by the Triton X prohibition.

Covid-19 Testing - Cross UKG and SG working

402. In relation to testing, in June 2021, Scottish Ministers agreed to loan the UKG 10 million lateral flow tests which would be paid back within a month to cover a short-term shortfall. Similar loans were made to UKG in November 2021 (12 million) and December 2021 (2 million). Additionally, UKG loaned 15 million tests to Scotland at short notice, and then at the next test procurement, Scotland agreed to purchase 15 million tests from UKG in order to replenish the UKG's stock. On this occasion it meant the net balance of tests owed by Scotland was 0.

403. Scottish Ministers considered aligning public health measures across the four nations where that was appropriate, but would ultimately take decisions related to potential impacts or needs in Scotland, on the basis of clinical and other advice from sources including the CMO and PHS. This meant that at times there were differences in the detail of the approaches taken. However, high-level clinical

advice in the use of testing was broadly aligned across the four nations, and approaches to testing policy were very similar.

404. In the early stages of the pandemic, setting up the infrastructure required to support the testing response benefitted from a four nations approach in terms of the scale and expertise. Examples include the creation of a supply chain for PCR test distribution and analysis and later, for lateral flow test procurement and distribution. Other examples include the pace of vaccine deployment and the procurement of PPE. Other benefits included the resilience that allowed nations to 'loan' assets to match demand, which occurred in relation to loaning PPE and LFDs between nations.

405. UKG decisions which resulted in the announcement of additional funding were not always aligned with either the rate and spread of the Covid-19 pandemic across the four nations within the UK or the preferred public health responses across different parts of the UK. The lack of alignment in funding was both in terms of timing and scale and this was problematic for the SG in planning its response to the pandemic as it constrained options for public health measures.

406. This meant the SG was reliant on UKG funding for measures that would likely involve significant costs to the SG or its funded bodies, for example, creation of a testing infrastructure.

407. In early 2022, the UKG's decision to cease testing in most circumstances in England impacted on available consequential funding for the SG. The outcome of this limited the SG's ability to decide on the length and nature of transition of Test and Protect. The *Coronavirus (COVID-19): Test and Protect Transition Plan*, provided: [CL13/158 - INQ000235186], including the changed strategic intent, was set out online. While the SG chose to continue testing for slightly longer than in England, the lack of any further consequential funding to support this meant that the testing regime for the general population in Scotland was brought to a close, with testing of non-symptomatic people closing at the end of March 2022 and for symptomatic people at the end of April 2022.

408. The then-First Minister set this out in a statement to Parliament on 15 March 2022, provided: [CL13/211 - INQ000353720], saying:

“Regrettably, our freedom of manoeuvre here is severely limited by the fact that our funding is determined by UK Government decisions that are taken for England. However, we have sought, as far as we can, to reach the right decisions for Scotland. It is important to note that we are aiming for the same long-term position as England on testing. However, we consider that the transition should be longer. In England, testing for people without symptoms ended in mid-February and will do so at the end of this month for those with symptoms.”

409. The Scottish Budget did not directly fund the costs arising from the Four Nations Testing Programme during 2020-21 and 2021-22. With some exceptions, the SG agreed to receive a population share of testing services/equipment in lieu of consequential funding.

410. The MoU relating to testing and laboratories, provided as paragraph 365, allowed devolved nations access to four nation/UKG procurement frameworks and contracts which are likely to have been less cost effective and more time-consuming to establish separately. The validation and assessment of new technology was conducted on a four nations basis, where the validation was carried out by PHE Porton Down and the results and analysis shared with devolved governments. Colleagues in NSS’s National Laboratories Programme also undertook comparator validation on LFDs for reassurance. Devolved governments and their Ministers could also request to opt out of a significant procurement in a particular technology and receive equivalent funding calculation according to the Barnett Formula, or an alternative technology.

411. From January 2021, there were some considerable governance changes for the Testing Programme due to the transition of part of DHSC and PHE into UKHSA. During this period of evolving governance arrangements, top level decisions were considered at UKHSA’s Executive Committee (“ExCo”) including for the testing programme. Devolved governments were not represented at this forum, despite requests for representation. As a result of these requests, the UK-DA Board was

established to sit alongside ExCo, which Professor Jenny Harries chaired. This board became the key route for senior officials from all four nations to engage, discuss, raise issues and make decisions to be carried forward to ExCo and beyond.

412. The governance which existed within UKG departments was not designed to facilitate decision making on an equal basis for the four nations, particularly in areas such as health, where decision making is devolved. Particularly in the early set up of services, but also through the peak of the pandemic response, decisions were routinely made within UKG governance structures, with Scotland being informed of the decisions taken and therefore largely becoming 'recipients' of the decisions made by UKG. This way of operating was of lower impact in areas where policy in each nation was fully aligned, but became problematic where policies differed or where timescales for implementation differed. An example of this would relate to the timing of school terms, which differ particularly in the start of summer holidays and therefore meant a differing timescale for return to school testing because Scottish schools return earlier in late summer than schools in England. This required a different, and earlier timescale for return to school testing. Similarly on decisions on the level of funding available for Covid services such as testing, these have remained decisions taken by the UKG, rather than being decisions taken on a four nations basis.

413. The UKG and DAs worked together to support joint aims of securing additional testing capacity, stocks of tests, scientific expert advice and rapid decision-making.

414. Decisions made by the UKG for England on continued funding for testing had an impact on the funding available for population testing in Scotland. That in turn influenced decision making in Scotland as to the timescale for transitioning to the 'steady state' Test and Protect model from May 2022, in terms of both the timing and the length of that transition.

415. Four Nations Meetings in which SG participated are provided in the table below. SG had the opportunity to input on procurement and related operational plans

primarily at the UKG-DA Board, the weekly DA Operations meetings, and the Investment Board. UKHSA acted as secretariat at all three.

Four Nations governance and decision-making groups in relation to testing

Meeting	Procurement decisions taken?	Overview
Testing Programme Investment Board	Yes, taken by senior UKHSA/UKG finance officials.	The Investment Board provides overall oversight of testing commercial spend, aligning to overall testing programme strategy, flagging risks and issues, and reports to ExCo DHSC, Cabinet Office and HM Treasury as required. SG had the ability to opt in and out of significant procurements of new technologies. Chaired by: UKG (UK HSA) Membership: Senior UKHSA commercial officials. Attended by SG and DA senior officials from 1 March 2021.
UKG-DA Board	No. Though discussions in relation to formal decisions (or decisions to be made / escalated) were had. UKG Secretariat shared minutes, actions, etc.	Senior official meeting to discuss the four nations' testing programme. UKG-DA secretariat held minutes, action logs and Terms of Reference (ToR). UKG-DA engagement team often organised targeted "breakout" meetings based on discussions in this call, e.g., finance, operations, policy, etc. The UKG-DA Board has had short-life working groups or extra meetings running between the monthly call. For example, in relation to facilitating the smooth transition for all nations for the National Testing Programme or; reviewing outcomes and implications for a spending review.

Meeting	Procurement decisions taken?	Overview
Four Nations' Health Ministers' call	No. High level discussion between health ministers and updates from respective nations.	Ministerial level meeting to discuss a range of health issues, often including Covid-19 related matters. Frequency varied from weekly, to fortnightly to monthly. A rough agenda was sent out by Secretary of State (SoS) private office in advance, with input from DG offices if anything they wished to raise should be added. No official minutes or actions were taken but there were unofficial internal notes / distributed by SoS private office. SG officials also circulated a note of these meetings for Cabinet Secretary approval.
Change Board (renamed the Strategy, Prioritisation and Change Board)	No. Though discussions in relation to formal decisions (or decisions to be made/escalated) were had. UKG Secretariat shared minutes, actions, etc.	Chance to raise issues directly with UKG senior officials. Focussed on areas within the Test and Trace portfolio of significant change. ToR and scope varied. UKG-DA engagement team often organised targeted "breakout" meetings based on discussions in this call, e.g., finance, operations, policy, etc. UKG-DA team updated via email or call on any actions taken from the call.

Meeting	Procurement decisions taken?	Overview
UKG NHS Test and Trace Portfolio Delivery and Oversight Board	No. Invited for awareness, no DA input.	Meeting used to gain early sight of UKG plans and subsequently raise issues where SG not being involved.
"Front Door" Meetings (has had various names under different iterations, e.g., Portfolio Delivery Forum)	No.	This acts as a triage forum for programmes looking to enter the Test & Trace portfolio. Offered SG early sight of upcoming UKG work.
Finance QUAD	No. For awareness in advance of Investment Board meeting later in week.	This was a heads up for Business Justification Templates that will go to Investment Board that week. This was primarily a meeting between UKHSA, HMT and Cabinet Office, we often raise a question or two we may have at the end of each BJT discussion. But otherwise observe.
Technologies Validation Group (soon turned into UKHSA Testing Supplies Governance)	No. Updates around testing technology in pipeline, validation and evaluation exercises, etc.	DAs fed into UKG process on validation new testing technologies, decisions made in respective DG administrations around applicability to own setting

Meeting	Procurement decisions taken?	Overview
Design Authority Review Group (DAR) (UK) (eventually merged with Service Design Authority)	No	To receive early sight of new technologies procurement by UKG on behalf of DG administrations and potential new testing pathways to be onboarded.
DA Weekly Operations Meeting and Policy meetings (soon turned into a combined “Operations, Policy and Strategy” meeting)	No. UKG DA team catalogued minutes, tracked actions, etc.	Opportunity for DG Administrations to raise issues with specific operational, policy and strategy leads. Leads of UKG teams used this to share updates on developing operations and/or policy and horizon scanning. UKG-DA engagement team engaged via email and/or organise meetings based on discussions or issues raised from this call, usually to sort operational issues.
DSHC – MHRA Meeting A and Meeting B	No.	To hear updates on DHSC/UKHSA discussion with the MHRA and raise issues.
UKHSA sit-rep	No.	Frequency varied from daily, to 3 times a-week, to 2 times a-week. Daily performance report on capacity and demand – troubleshooting opportunity for various UKHSA team leads.

Meeting	Procurement decisions taken?	Overview
		DG administrations received invites to observe and listen. Able to reach out to UKG DA engagement team or specific UKHSA leads for further information afterwards.
Testing Evaluation Board, and Quality Group (has had various names under different iterations)	No	Provides the latest information on evaluation of the Testing Programmes. Feeds into SG Clinical Governance Group and CADI.
Testing Supply and Demand Management meeting(s)	Overall no, however small operational decisions were made at this meeting (e.g., movement of LFD stock between warehouses, etc)	DG administrations invited to attend for information and sometimes input. UKHSA demand modelling and operational colleagues received modelling data and operational updates from DAs which inform decision-making around supply, etc. Meeting minutes stated the group's purpose was: "Managing testing demand acceptance into operations. Responsible for providing rigour for use case performance. Reviewing, recommending & approving new testing capacity requirements and replenishment. Engaging wider enterprise from the outset in both decisions and the alignment of planning."

Meeting	Procurement decisions taken?	Overview
National Testing Programme Memorandum of Understanding (NTP MoU) meetings	No decisions on procurement taken specifically, but the overarching framework of the MoU was decided here.	The creation of the NTP MoU and the subsequent revisions and iterations of the past few years were done by UKHSA and DG administration officials. All of these were ultimately signed off by respective health ministers for approval.

Covid-19 Testing - Co-ordination across Scottish Government and with other bodies

416.SG as one organisation, delivered its Covid response coordinating policy and delivery across a broad range of directorates and areas. This included the involvement of a wide range of policy interests in relation to decisions and delivery of the Covid response. As already set out, SG also coordinated and worked in partnership with a wide range of external partners and public agencies including PHS, NHS territorial health boards, NSS and local authorities.

417.Test and Protect governance forums such as the Testing Operational Delivery Group and Testing Programme Board operated across the SG, involving key sector leads such as economy, food and drink, schools, universities, health and social care, prisons, and emergency services; in addition to key clinical, public health, communications, marketing, workforce, finance, data and digital staff. Forums such as the Test and Protect Steering Group included representation from the COSLA, Chief Executive representation from local authorities through SOLACE, NHS Health Board representation from a large number of boards, senior leadership representation from a wide range of SG policy areas, and clinical representation including DCMOs and the National Clinical Director, Jason Leitch.

418.These forums facilitated regular discussions and coordinated efforts to address testing in their respective areas, ensuring a comprehensive and integrated approach to managing the pandemic.

Section 6 – Funding (including contracts)

Health Budget

419.Since 2010-11, SG has committed to passing on any resource funding consequential arising from spending decisions on health in England to the Scottish Health and Social Care portfolio in full.

420. Health is the single largest area of SG resource spend and accounts for c.40% of the total resource budget. Health capital accounts for c.9% of total SG capital budgets.
421. The draft Scottish budget is typically published in December following publication of the UKG's budget (typically November). The budget is informed by the UKG projection of expenditure on public services, as well as by estimates of the Scottish Rate of Income Tax as published by the Scottish Fiscal Committee.
422. Priorities within the budget are partly informed by Parliamentary subject committees, which meet throughout the year to scrutinise the work of SG, and who submit spending proposal 'pre-budget reports' in October. These reports recommend how SG should spend money in the upcoming year, and SG is required to respond to each report to set out how it has influenced spending plans. Priorities otherwise represent agreed policy commitments.
423. The budget is typically amended twice a year, via Scottish Statutory Instruments, in order to better reflect known spending patterns. The revisions are known as the Autumn and Spring Budget Revisions and they are laid in Parliament in September and February, respectively.
424. The Scottish Health and Social Care budget typically allocates around 70% of its total annual budget (resource and capital) as baseline funding to NHS Territorial and National boards. Baseline funding is provided to boards in order to address national and local priorities for health and wellbeing services. Baseline funding is uplifted each year to support known pressures such as the impact of pay awards, noting that a significant proportion of annual spend by boards is incurred in staff costs.
425. Around 10% of the budget is used to fund primary care independent contractor groups for i) general practice; ii) dentistry; iii) pharmacy; and iv) ophthalmology.
426. Budget directly allocated through the baseline of reserved for payment of independent contractor groups is retained within the SG for allocation across the

Health and Social Care Directorates. Directorate budgets are agreed between Health Finance and policy area at the time of budget-setting and are based on estimated need as adjusted for new policies and/or known committed spend.

427. Budgets are used to fund:

- Additional funding to NHS boards through an in-year allocation process
- Funding to other organisations, including third sector, where this is in direct furtherance of the strategic aims for health and social care
- Direct expenditure on programmes
- Civil service staff and, where appropriate, professional advisors and/or seconded staff to support the delivery of health and social care in Scotland.

428. In addition to the Health and Social Care Directorates, some of the health budget is allocated annually to the Improving Health and Wellbeing Division which forms part of the Children and Families Directorate. This Directorate forms part of DG Education and Justice family, however overall ministerial responsibility for this Division sits with the Cabinet Secretary with responsibility for Health.

429. It is the responsibility of the Directorate for Health Finance, Corporate Governance and Value to ensure there is effective financial management across all areas of the health system. This involves working with all areas of the system to agree savings targets, performance of regular budget monitoring and scrutiny; and assessment of future financial risks, challenges and necessary mitigations. The Director-General for Health and Social Care acts as the Accountable Officer for the Health and Social Care Directorates and the wider Health Portfolio including public bodies, such as NHS Boards.

Money allocated by the UK Government in the event of civil emergencies

430. The funding mechanisms and fiscal relationship between SG and UKG as set out in the *Statement of Funding Policy* (2021), provided: [CL13/212 - INQ000102912], and the *Fiscal Framework Agreement* (2016), provided: [CL13/213 - INQ000102914], continue to apply in the event of civil emergencies

and govern the ways in which any financial response to such an event can be delivered by the SG.

431.SG only receives financial resources to respond to an emergency event when the UKG increases spending on devolved areas in response to that same event or funds the SG specifically for that purpose. Any additional in-year expenditure, in a given area where the UKG has not agreed to provide additional funding, has to be paid for by reductions elsewhere in the Scottish Budget. Existing arrangements in relation to borrowing also continue to apply, meaning the SG cannot borrow to support additional discretionary resource spending or to respond to an emergency situation.

432.The associated mechanisms and operation of the SG's finance functions delivered by the Financial Management Directorate and Scottish Exchequer therefore also continue to apply in the event of a civil emergency. The SG has only limited flexibilities available to it within the established framework to support decisions taken by Scottish Ministers, and nothing more, at times of civil emergency.

Consequential received

433.In relation to the Covid-19 pandemic, any additional block grant funding made available by the UKG to respond to the crisis was allocated to the SG in accordance with the principles set out in the Statement of Funding Policy with additional funding being calculated in proportion to allocations to equivalent UK Departments.

434.Where additional funding is provided for devolved matters in England (e.g., in health, education etc), this gives rise to Barnett consequential which then flow to SG. Since 2010-11, consequential associated with health funding have been protected for direct pass-through to the Health Portfolio and this continued to be the case for additional funding pertaining to the Covid-19 response.

435. Additional consequentialia were received during the pandemic and passed to the Health and Social Care Directorates at the extraordinary Summer *Budget Revision* (May 2020), provided: [CL13/214 - INQ000182938], and at the routine Autumn (September 2020), provided: [CL13/215 - INQ000182939], and Spring (February 2021) Budget Revisions, provided: [CL13/216 - INQ000182940].

Local Mobilisation Plans

436. Within the Health and Social Care Directorates, the Directorate for Health Finance, Corporate Governance and Value adhered to existing governance arrangements but then ensured appropriate pandemic-related financial governance principles were implemented with effect from 13 March 2020. This was to support necessary decision making, often at short notice, while ensuring that pandemic response activity complied with revised SG financial policy in force at the time. These principles remained in place throughout the entire period of pandemic response from 13 March 2020 and through 2020-21, and included:

- Revision of delegated authority to allow Directors and Deputy Directors within the DG to approve spend up to £1 million
- Agreement of all spending decisions in excess of £1 million by the Planning and Assurance Group (while in existence) or Health and Social Care Management Board prior to formal approval by Ministers.

437. Budgets for 2021–22 were then set with consideration to additional financial need arising through the necessary Covid-19 response, however Health and Social Care directorates continued to operate financial governance principles in respect of further additional funding requested. Further consequential funding, rising from the pandemic response in NHS England, was allocated to the Scottish Health Portfolio.

438. All spending requests for Health and Social Care were accompanied by an AO template aligning to the wider corporate approach taken across DG Corporate and DG Scottish Exchequer for Covid-19 accountability across the whole of SG. The AO template required that the following were taken into consideration prior to allocation of funding:

- Whether proposed spend was novel or contentious
- Under what statutory or budgetary powers the spend was to be directed
- Cash availability, ensuring that the SG's Treasury and Banking team were sighted on significant outlays
- Whether spend would have implications for procurement on either existing or pending contracts.

439. Similar arrangements were agreed for use across NHS Scotland Boards, with:

- Initially, delegated authority to the Board accountable officer (Chief Executive) of up to £1 million for Covid-19 spend, with requests over this level subject to scrutiny by SG officials
- Latterly, authority to spend against signed-off local mobilisation plans, with spend in excess of this still requiring further approval from SG.

440. On 11 March 2020, a letter was issued by the Chief Performance Officer for NHS Scotland, provided: [CL13/217 - INQ000326477], asking Boards to set out the measures they were undertaking to prepare and, as the pandemic progressed, respond to the changing healthcare needs posed by Covid-19. Boards were asked, as an initial step, to scale up their intensive care and bed capacity, while simultaneously scaling back elective and daycase activity and managing throughput through reduction of delayed discharges. The purpose of this communication was to ensure that all areas of Scotland were maximising extant NHS bed capacity, thereby allowing for the treatment of patients potentially presenting with Covid-19 and requiring hospitalisation. The plan also asked for indication of other measures being taken by Boards, such as reconfiguration of primary and community care, to respond to the pandemic while continuing essential services.

441. Given the additional costs incurred in delivering these system changes, a further letter, provided: [CL13/218 - INQ000399522], was issued to all NHS Board Directors of Finance and Integration Authority Chief Financial Officers by the Interim Director of Health Finance and Governance on 20 March 2020.

This letter provided a template finance return [CL13/219 - INQ000496495] and set out the requirement for NHS Scotland to identify an overall financial baseline for the additional costs of Covid-19 response. Further guidance to establish a regular rhythm of financial reporting and allow for the continual refinement of estimated costs of pandemic response was then issued on 30 March 2020, provided: [CL13/220 - INQ000399523].

442. The extraordinary financial monitoring stood up by the instruction on 30 March 2020 ran in addition to extant monthly reporting processes as operated by SG's Health Finance Directorate for a number of years and which focused on overall financial performance and forecast outturn. The extraordinary monitoring of the costs of Covid-19 response continued throughout 2020-21 and comprised quarterly returns from Boards detailing the spend incurred to date by both NHS Boards and their related Integration Authorities in delivering health and social care services. These quarterly returns were completed on templates provided by SG, thereby ensuring consistency and comparability of response as categories of activity were provided and costs reported against these. The categories of spend against which costs were recorded are set out below:

- Cost of additional beds, both general and intensive care use, in operation and including all direct and indirect costs associated e.g. patient catering, linens, drug costs
- Costs of any local virus testing undertaken, excluding costs of testing kits which were centrally provided
- Costs of any locally sourced PPE provided, excluding equipment provided centrally through NSS
- Additional costs arising from increased deep cleans, mortuary use and estates/facilities running costs
- Costs of any additional equipment procured through either revenue or capital budgets
- Additional costs arising from Covid-19 community hub provision and/or increased costs of primary care such as enhanced out-of-hours services
- Costs arising from increased activity to reduce delayed discharges

- Costs associated with ongoing social care provision including costs of home and residential services
- Additional cleaning and PPE requirements, and additional staffing costs including sick pay
- Additional IT costs
- Additional drug spend, excluding that already included under additional beds provided
- Additional staff costs e.g. overtime, increased numbers of temporary staff, and additional costs to primary care contractor groups
- Financial adjustments associated with opportunistic savings (e.g. activity not undertaken due to prioritisation of pandemic resource) and unrealised planned savings.

443. The quarterly returns from Scotland's 14 Territorial, 7 National NHS Boards and Healthcare Improvement Scotland, and including the spend incurred by the 31 Integration Authorities, were collated each quarter in order to summarise the costs incurred at i) Health Board and ii) Integration Authority level. Individual Board returns contained a vast amount of information and, while separately reviewed and interrogated by officials to verify costs, were ultimately consolidated by SG's Health Finance Directorate officials to facilitate allocation of resource.

444. A further email, provided: [CL13/221 - INQ000496473], to NHS Directors of Finance and Integration Authority Chief Financial Officers from the Interim Deputy Director of Health Finance on 3 April 2020 set out the financial governance arrangements to be implemented for the 2020-21 financial year and noted that:

“additional spending in excess of the thresholds set out below should be shared with [Scottish Government] Mobilisation Team contact[s] at the earliest opportunity to request formal approval. For avoidance of doubt, this is referring to spending in excess of these thresholds (per annum) for additional staffing, equipment or measures specifically for the purpose of responding to

Covid-19, and for which you would be anticipating additional funding from the Scottish Government. This relates to both individual and packages of spending activity.”

445. Mobilisation plans were then updated by NHS Boards, setting out activity and associated additional costs incurred throughout 2020-21 and 2021-22, with quarterly allocations made reimbursing the same, following scrutiny by officials. During the initial response, a specific delegation was provided for NSS NP of up to £2 million to support increasing stocks of consumables, including PPE.

446. The guidance was designed to ensure that financial and related activities were performed in accordance with SG policy at all times. This aimed to ensure adherence to the following key principles of managing public money: probity, accuracy, economy, efficiency and effectiveness.

Spend and contracts

447. As noted earlier in this statement, the delegation of procurement of PPE to NSS also contained the delegation of spending authority. SG did not award any specific contracts for distribution of PPE as NSS NP were responsible for supply through the NDC. Likewise, SG did not award any contracts for the storage, instead NSS NP were funded to arrange such storage. As part of the forward buy planning process, NSS, as the subject matter experts with knowledge of the market conditions, advised on the pricing options for PPE. This would include advice on whether the prices available under the prevailing market conditions were reasonable when considering PPE procurement needs.

448. The Health and Social Care Directorates did not issue formal guidance to NSS regarding pricing during the pandemic.

449. PPE procurement requirements and available pricing were part of forward buy proposals brought to “forward buy” meetings where PPE officials considered and fed back on any concerns within the proposals. The request

for a forward buy was then provided to the Director of Health Finance Governance and Value for consideration and final approval.

450. In total, the following costs were incurred by SG on PPE:

Year	Spend and rationale
2020/21	Total spend of £172.764 million As well as two large purchases of items £112million and £59.130million respectively, this covers the PPE Innovation Project and the Lyreco PPE Framework (aligning to market value).
2021/22	Total spend of £79.6 million Broken down as: £150.1 million to NSS for PPE purchasing £12.4 million to frontline NHS Boards £1.2 million on an inventory management system (£84.1 million favourable accounting adjustment – use of brought forward stock)

451. A total of £544,296 was spent on PPE (including hand sanitiser) and £2,009,000 for other services (£9,000 for reports on suppliers offering PPE products for non-health organisations, validating whether the supplier is qualified to be able to supply PPE with the appropriate quality and conformity thereby reducing the risk of counterfeit product, and £2,000,000 for freight forwarding services). It should be noted that this only includes spend on SG contracts, and does not include funding allocations to Health Boards for PPE.

452. It is not possible to provide equivalent figures for lateral flow or PCR tests as these were procured through NSS rather than directly.

453. A total of nine contracts were awarded outside of NSS. The guidance note for access to the third-party framework contract (Lyreco) is provided: [CL13/222 - INQ000496445].

Financial risk assessment and Direct Awards

454. The subject of financial risk assessment and due diligence is largely addressed in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024. Due diligence for medical devices in general was carried out by NSS. However, it is worth noting again in this context that for ICU ventilators, there was some assistance from Scottish Enterprise in checking an overseas manufacturer where they had personnel in that country.

Direct awards

455. The subject of direct awards is addressed in the Module 5 DG Corporate statement, provided to the Inquiry on 29 August 2024. Procurement was handled by NSS, so additional information will be best sought directly from them.

Contractual monitoring, compliance and enforcement

456. All procurement of PPE, medical devices and ventilators was handled by NSS. NSS is a Procurement Centre of Expertise in Scotland. As such, they have established due diligence procedures as part of their contract award process. The Health and Social Care Directorates had no role in scrutinising the contracts awarded.

457. However, the Health and Social Care Directorates had oversight and the decision making role over the funding for procurement of pandemic PPE.

458. The Directorate for Health Finance, Corporate Governance and Value acts as lead sponsor for NSS, and is required to submit a return on internal controls in operation each year as part of the Scottish Government's Certificates of Assurance exercise, as mandated in the Scottish Public Finance Manual and which informs the Permanent Secretary's Annual Report and Governance Statement. Regular sponsor meetings take place with the NSS Senior Management Team to review governance and performance of the organisation in the delivery of its strategic objectives.

459.The Audit Scotland briefing from June 2021, provided: [CL13/047 - INQ000108737], highlighted that during the period March 2020 to April 2021, NSS awarded 78 contracts worth £340 million to companies providing PPE.

The third-party framework contract with Lyreco

460.The contract with Lyreco included default provisions within the Standard Terms of Supply. This included the ability to terminate the contractor's interest in the Framework Agreement under the following circumstances:

- The Contractor had not remedied the Default to the satisfaction of the SG within 20 Working Days, or such other period as was specified by the SG, after issue of a notice specifying the Default and requesting it to be remedied
- The Default was not in the opinion of the SG, capable of remedy
- The Default was a material breach of the Framework Agreement.

461.Under this Framework Agreement, any sum of money recoverable from or payable by the contractor to the SG could be deducted from any sum due to the contractor. The contractor was required to ensure that, unless otherwise agreed, product specifications would be aligned with those in force in the NHS.

462.Suppliers were required to supply products which met or exceeded the specified requirement. Where an equivalent product was offered, it was provided subject to end user acceptance. Such acceptance would be provided based on the supplier's evidence of equal quality and/or specification.

463.For late delivery of goods, or goods that had been damaged in transit, the Framework Agreement included provisions where the purchaser could notify the supplier of that fact and the supplier would deliver substitute goods or repair the goods within the timescales specified by the purchaser.

464.When non-delivered or faulty goods were reported to the customer helpdesk, the helpdesk investigated, arranged for the collection of faulty goods,

arranged a refund, and advised the customer of the outcome. The contract did not limit liability resulting from misrepresentation.

465. As a framework agreement, rather than an exclusive contract to supply goods to those on the framework, there was no guarantee of volumes of goods to be ordered.

466. The contractor was required to manage the stock procured for the framework, including on expiry dates, and to report regularly to SG the stock levels and any approaching expiry dates. In addition, the contractor was required to alert SG of any unusually large single orders or sequence of orders whose fulfilment may have a detrimental effect on product stock levels.

467. The agreement could be terminated at any time by giving not less than one month's notice to the contractor. The agreement could also be terminated with immediate effect due to default, insolvency or change of control.

468. The initial contracted period of the Framework Agreement commenced at 26 May 2020 and continued until 30 April 2021. The SG retained the right to extend the contract as required up to a maximum of two years after the commencement date, and could do so on multiple occasions.

469. SG exercised this right to extend the framework period to ensure that essential services still had access to appropriate PPE. The framework agreement was extended until 31 October 2021, by which time PPE supply had stabilised.

470. Monitoring was undertaken via fortnightly meetings between SG and the contractor to allow for issues to be raised and resolutions discussed. In addition to these meetings, the contractor submitted stock, usage and sales reports for review. No issues arose in relation to contract performance or management, so no enforcement processes were required. There was also therefore no requirement for SG to recoup money from the contractor.

471. Due-diligence to check that Lyreco met statutory duties, including equalities duties, was carried out during the award of the Office Supplies Framework (in 2016).

Section 7: Lessons learned

PPE

472. SG has undertaken work to identify the successes, challenges and lessons to be learned relating to PPE supply during the Covid-19 pandemic. Several reviews and exercises have been carried out in relation to PPE, both commissioned by the SG or with which the SG has been involved, which are set out in the chronological list summarised below:

- April 2020: NSS – PPE and Essential Equipment Review, provided: [CL13/223 - INQ000496526]
- July 2020: Covid-19 Health Supply Chain Programme Feedback, provided: [CL13/224 - INQ000470064]
- August 2020: PPE Division Survey results summary, provided: [CL13/225 - INQ000470065]
- February 2021: PPE Single Procurement Framework Deep Dive Outcomes Paper, provided: [CL13/226 - INQ000470066]
- June 2021: Audit Scotland Publication: Covid-19 PPE, provided: [CL13/047 - INQ000108737]
- June 2021: KPMG Report – Lessons Identified from the initial health and social care response to Covid-19 in Scotland, provided: [CL13/228 - INQ000470067]
- July 2021: National Clinical PPE Oversight Group – Lessons Learned, provided: [CL13/229 - INQ000470068]
- October 2020: Centre of Expertise Lessons Learned Exercise, provided: [CL13/230 - INQ000470069], [CL13/231 - INQ000470070], [CL13/232 - INQ000470071]
- December 2021: Lyreco PPE Framework Lessons Learned, provided: [CL13/233 - INQ000470072]

- December 2022: A consultation on the future supply of pandemic PPE in Scotland – Analysis of consultation responses – Final Report, provided: [CL13/234 - INQ000470073]
- April 2023: Pandemic PPE future supply – lessons learned, provided: [CL13/235 - INQ000470074], [CL13/236 - INQ000470075].

473. The main themes identified within these reviews were communication, collaboration, and the fundamental inadequacy of the traditional just-in-time PPE supply system in the context of the Covid-19 pandemic.

474. In addition to these general themes, a series of independent, official audit reports (the Audit Scotland brief; published in June 2021; and the KPMG report, published in August 2021) highlighted specific points for action. The key issues set out in these reports were that:

- SG could have been better prepared and should have acted fully on recommendations of preparedness exercises
- New approaches to stockpiling and supply chain resilience are required
- Longer term solutions for PPE supply to primary and social care should be implemented.

475. This work has informed the development and implementation of the future pandemic PPE supply arrangements to secure a resilient and robust supply of PPE for the future. The main themes identified were further tested in a public consultation on future pandemic PPE supply. SG consulted on the key lessons identified, whether any others should be considered, and for respondents' views on the proposed supply arrangements.

476. All but a few respondents who engaged with the lessons learned section of the consultation agreed with the key lessons identified. Some respondents also proposed additional lessons for consideration within the free text element of the section. The key themes here were:

- The need for improved collaboration and communication
- Criticism of PPE allocation

- The importance of domestic supply
- Prioritisation of quality and suitability of PPE
- Addressing PPE cost inflation
- Reducing PPE waste.

477. From December 2021, work to consider lessons learned and incorporate them into future PPE preparedness policy continued as part of the PPE Futures Programme.

478. The Programme's Future Supply workstream used this work to develop and propose new pandemic supply arrangements for the future, which the Cabinet Secretary agreed to take forward in December 2021. Briefly, these were:

- A strategic pandemic focus in Scotland with all public sector organisations who chose to opt in procuring pandemic PPE collaboratively, managed by NSS
- A national pandemic PPE stockpile and surge capacity, managed by NSS.

479. The PPE Futures Programme closed in April 2022 and was superseded by the PPE Supply Implementation Project, designed to develop and implement the new pandemic PPE supply arrangements through the remainder of 2022 and into 2023. This project has now ceased and its outcomes are detailed below. Implementation of arrangements will be taken forward by NSS and remaining relevant SG policy teams.

480. The key lessons to be learned from the Covid-19 pandemic in relation to PPE are that:

- We must ensure that effective mechanisms for collaboration and communication between the SG and stakeholders are in place in the event of a future pandemic. This is especially relevant in regard to real time data sharing, stockpile management and being able to effectively prioritise PPE supply where it is most needed.

- Scotland's traditional PPE supply routes, just-in-time supply model and PPE stockpiling arrangements were not sufficient in pandemic circumstances. A reformed stockpiling and buying approach for pandemic PPE is required
- Long term and sustainable PPE supply arrangements are required for the primary care sector to ensure the challenges of any future pandemic can be met
- During the Covid-19 pandemic, Scotland always had a sufficient supply of PPE. However, as the traditional routes of supply failed under worldwide demand pressures, new supply chains had to be set up quickly in order to meet demand. Therefore, surge capacity needs to be available to ensure that anticipated PPE demand is met during the volatile early stages of any future pandemic.

PPE supply chain resilience

481. The future pandemic PPE implementation project board (IPB) was formed in May 2022 with an aim to deliver robust cross-sectoral pandemic PPE provision in Scotland, to ensure we have a resilient supply in place ahead of any future pandemic in response to the lessons learned from the Covid-19 pandemic. The board's remit is provided earlier in the statement, as are details about the five workstreams the project was comprised of, in paragraphs 42-45.

482. The outcomes of the project are as follows:

- There is agreement as to how inbound supply of pandemic PPE for NHS should be achieved, along with a surge capacity element
- There are proposals for providing access to the national PPE buffer stocks for health and social care and essential public service organisations during a health emergency
- Plans have been developed to enable public sector organisations with high Business As Usual (BAU) use to access PPE in both BAU and health emergency situations on a collaborative procurement basis. This will maximise rotation of the pandemic PPE stock, increase resilience and

reduce waste. This would also help to create the critical mass of demand needed to make supply to NSS a feasible opportunity for domestic PPE manufacturers

- Sectoral pandemic PPE preparedness guidance for health and social care and non-health and social care has been drafted by the project team and discussed with the stakeholder engagement group and project board during the drafting process
- PPE Standup guidance has been drafted and has been shared with the SG population health resilience and protection division to develop further in line with wider pandemic preparedness work.

483. Following the cessation of the PPE Unit in 2023, EPRR Division now have oversight of NSS's management of pandemic PPE stocks. The EPRR Division are working with the four nations on reviewing a range of national countermeasures and reviewing our procurement and deployment arrangements with NSS.

ICU equipment

484. Lessons identified through the ICU ventilator work were captured by a short-life working group (SLWG) on the legacy of ICU equipment. This group was commissioned by the Director for ICU Resilience to explore and develop a strategy for the short and medium-to-long term management of medical equipment procured as part of the Covid-19 expansion. The group included NHS Board critical care and clinical engineering leads, plus representatives from SG and NSS. The first Legacy report was completed in June 2020 and the second in March 2021. Both reports were agreed and supported by the then Cabinet Secretary, provided: [CL13/237 - INQ000496442].

485. The first report produced by the SLWG, entitled "Strategy for allocation and distribution", set out arrangements put in place including all territorial Boards holding enough additional medical equipment on site to double baseline ICU capacity. As noted earlier, in order to reach the maximum surge limit of 714

beds, the remaining equipment was stored centrally to be distributed to NHS Boards if and when required, co-ordinated by NSS.

486. The first report noted that the overall resilience plan included a commitment from Boards to double ICU capacity within 48 hours and more than triple within 7 days. It further stated that a policy steer on the maximum surge capacity for planning purposes as part of future pandemic planning, to be maintained by NHS Scotland, should be retained at 714 ICU beds. A review of this position was to be undertaken in 12 months. The other key recommendations within this first report, taking into account short and long-term considerations, were as follows:

- Minimising variation and limiting manufacturer of each device to a maximum of 2 per Board where possible thereby reducing the risk of human error and supporting NHS Boards longer term investment in replacement programmes
- Setting up of a process to exchange medical devices where feasible following discussions with critical care leads
- Retention of equipment to support double baseline capacity within NHS Boards to be incorporated into capital asset registers as part of NHS Board readiness and local contingency planning
- Exploration and establishment of a central storage facility which holds a National Medical Equipment stockpile and incorporates servicing of the devices as well as a training facility for equipment technicians and clinicians. This can be achieved through the commissioning of a Working Group
- Discussions within the Directorate for Health Finance as well as discussions with NHS Boards on the financial implications of maintaining both Board-held and centrally-managed equipment stockpiles. Commitment from NHS Boards to continued workforce resilience through ongoing training of core and support staff
- Priority and support given to the urgent development of a National Medical Equipment Management database with national oversight and locally managed

- Improvements to IT system that support monitoring of ICU escalation and strategic and tactical decision-making around levels required, particularly the Scottish Intensive Care Society Audit Group (SICSAG) Wardwatcher (a data collecting platform that was instrumental in the daily monitoring of ICU capacity and occupancy across NHS Scotland).

487. The second Legacy report, entitled “Framework for longer term management of Scottish ICU Stockpile”, further considered the practical implications of the strategy and recommended a framework for the management of critical care medical equipment held in the central stockpile, including where and how the equipment would be stored and managed, and who would be responsible for the storage and management in the short and longer term. In summary, the key lessons identified were that:

- Partnership working between SG, NHS Boards and clinicians and medical physics colleagues was and is essential and bolsters Board readiness
- NHS Scotland had by this point increased the number of baseline of level 3 ICU beds from 173 to 203
- All health boards that have ICU facilities should maintain, on site, sufficient numbers of ICU ventilators and associated bedside equipment to escalate to double the revised baseline capacity of level 3 ICU beds from 203 to 406
- The policy position in pandemic in-extremis position of attaining 714 level 3 ICU beds was reduced to 406 (double ICU capacity)
- NHS Boards have minimised the variation of ICU ventilators types, held on each site, to two
- Holding a central stockpile of ICU medical equipment is expensive to own and difficult to manage. Work was underway to de-commission the NHS Scotland central stockpile of medical equipment with Health Boards having the option to absorb stock into medical equipment rolling replacement programmes to minimise write-offs
- The lack of easily accessible central intelligence on the baseline position of ICU related medical equipment stocks in territorial health boards was a key inhibitor to assess needs at the early stages. Work was underway to introduce a National Medical Equipment Management System to allow

national oversight of medical equipment held in boards. This project was to provide for future pandemic preparedness and also enhance intelligence on equipment age profile and improve investment decisions

- The introduction of brands and models of life-support ICU medical equipment, such as ventilators, that are unfamiliar to NHS Scotland presents a human factors risk. Should a position arise where ICU ventilation is required above the double baseline capacity of 406 ICU beds, it would be safer to rely on the use of anaesthetic machines that have integral ventilators and patient monitoring
- Oxygen supply was an identified risk during the pandemic. Although there were no occurrences in Scotland, there were reported instances of shut-down in NHS England. Many types of ventilators and anaesthetic machines use oxygen to operate the mechanics of their ventilator systems. To preserve this valuable commodity in the future, where possible, neither ICU ventilators or anaesthetic machines should be specified with oxygen as the mechanical driving gas
- Establishment, at the earliest stage, of a multi-disciplinary team, such as the SG ICU Resilience and Support Group, is essential. An expert team should consist of SG, Clinical Leads, Facilities Leads, Technical Leads and National Procurement Leads from across Scotland working to achieve the required national outcomes.

ICU Supply Chain resilience

488. For ICU equipment, since the period in question, NHS Boards have maintained the ability to increase ICU beds, including equipment, for double capacity (406 ICU beds).

489. All Health Boards are now using a Medical Equipment Management System. Data is being harmonised across Boards and a National Medical Equipment Management System is being implemented.

490. A national Inventory Management System has also been implemented across all NHS Boards for consumables procured through NSS.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed:

Personal Data

Dated: 21 October 2024