Witness Name: Dr Eleri Davies
Position: Deputy Medical Director Head of Healthcare Associated Infection and Antimicrobial Resistance Programme
Statement No: 1
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UK COVID-19 INQUIRY
MODULE 5 - PROCUREMENT

FIRST CORPORATE WITNESS STATEMENT OF DR ELERI DAVIES

I, **Dr Eleri Davies**, of Public Health Wales, Capital Quarter 2, Tyndall Street, Cardiff, CF10 4BZ will say as follows:

1. This corporate witness statement is provided by me in my capacity as Deputy Medical Director and Head of Healthcare Associated Infection and Antimicrobial Resistance Programme (HARP) at Public Health Wales in response to a request for evidence made by the Inquiry Team to Public Health Wales on the 28 June 2024.

2. Public Health Wales has not been appointed as a Core Participant for Module 5.

3. Where matters raised by the Rule 9 request fall outside of my area of expertise, I have sought input from colleagues who were involved and who are able to provide a response to the questions posed.

Structure, role and overview of Public Health Wales

4. Public Health Wales was established in 2009 by bringing together four distinct pre-existing entities:

    a) the National Public Health Service for Wales,
    b) the Wales Centre for Health,
    c) the Welsh Cancer Intelligence and Surveillance Unit, and
    d) Screening Services.

5. This meant that, for the first time, an independent NHS body was created in Wales with a clear and specific public health remit to provide professionally independent public health advice and services.

6. Since 2009, Public Health Wales has grown considerably and the organisation has taken on, and internally developed, additional and new functions. This has included developments in the areas of:

    a) policy, research and international collaboration (reflected in our designation as a World Health Organization Collaborating Centre in Investment for Health and Well-being).
    b) data, knowledge and research, with the establishment of a directorate specifically focused on maximising the use of digital, data, research and evidence to public health.
    c) our core public health services, particularly microbiology and health protection, along with adopting new diagnostic methods such as molecular diagnostics and whole genome sequencing, through our Pathogen Genomics Unit.

7. An overview of our latest organisational structure can be found at **[EXHIBIT ED/01 INQ000538637]**.

8. Public Health Wales protects and improves health and well-being and reduces health inequalities for the people of Wales. It is an NHS Trust, established for the purpose specified in section 1 of the NHS (Wales) Act 2006, and has four statutory functions set out in Part 3 of its Establishment Order. These are to:

a) provide and manage a range of public health, health protection, healthcare improvement, health advisory, child protection and microbiological laboratory services and services relating to the surveillance, prevention and control of communicable diseases.
b) develop and maintain arrangements for making information about matters related to the protection and improvement of health in Wales available to the public in Wales; to undertake and commission research into such matters and to contribute to the provision and development of training in such matters.
c) undertake the systematic collection, analysis and dissemination of information about the health of the people of Wales in particular including cancer incidence, mortality and survival, and prevalence of congenital anomalies.
d) provide, manage, monitor, evaluate and conduct research into screening of health conditions and screening of health-related matters.

9. Since its establishment in October 2009, Public Health Wales has been, and continues to be, a provider of public health related specialist advice to the Welsh Government and its Ministers. The role is implicit within the four statutory functions (as set out in The Public Health Wales National Health Service Trust (Establishment) Order 2009).

10. In addition, Public Health Wales is a Category 1 responder as defined by the Civil Contingencies Act (2004), and therefore plays a key role in relation to the preparation for, and response to, any emergency and major incident. This requires us to meet a range of civil protection duties as set out by the Act.

11. Over the years, we have expanded the core public health functions of the organisation in order to ensure that we are best designed to deliver our statutory functions and the strategy of the organisation, which is informed by the challenges and opportunities facing the nation, the policy and legislative environment and international developments.

12. The Public Health Wales Board is a unitary Board and functions as a corporate decision-making body, with Executive Directors and Non-Executive Directors being full and equal members and sharing corporate responsibility for all decisions. It comprises a chairperson, seven Non-Executive Directors (also known as independent members), all of whom are appointed by the Minister for Health and Social Services in the Welsh Government, and six Executive Directors, including the Chief Executive.

13. The Board has responsibility for:

    a) Setting the strategic direction of the organisation
    b) Setting the governance framework
    c) Setting organisational culture and development
    d) Steering the risk appetite and overseeing strategic risks
    e) Developing strong relationships with key stakeholders and partners
    f) Ensuring the successful delivery of the Strategic and Operational plans of the organisation.

14. In addition to their role as Board Members, Executive Directors also have responsibility for discharging Public Health Wales' corporate and public health functions.

15. The Chief Executive (and Accountable Officer) of the organisation has responsibility for maintaining appropriate governance structures and procedures. The Chief Executive has established an Executive Team for the collective execution of delegated responsibilities (in addition to the delegated individual accountabilities and responsibilities that each Director in the Executive Team has with their respective portfolios).

16. In terms of the roles and responsibilities Public Health Wales had during the pandemic, Public Health Wales played a key role in supporting the public, the Welsh Government and partners including the NHS, social care, local authorities, education, businesses and the third sector. We provided system leadership across

a number of key areas through the provision of specialist and expert public health advice, information, intelligence and support.

17. Public Health Wales was not (and is not) a decision-making body in this context.

Public Health Wales' functions and roles in respect of the topics outlined in the M5 Provisional Outline of Scope during the relevant period

18. Responsibility for procurement in NHS Wales sits with NHS Wales Shared Services Partnership Procurement Services (NWSSP). In line with arrangements for all NHS Wales bodies, the NWSSP undertakes procurement activity on behalf of Public Health Wales, including during the COVID-19 pandemic.

19. Public Health Wales' role in relation to procurement did not change during the COVID-19 pandemic. It undertook procurement activity in line with existing arrangements with NWSSP. During the specified period, this activity was particularly focused around the procurement of laboratory equipment and polymerase chain reaction (PCR) tests for our own laboratories.

20. Public Health Wales is not responsible for procuring on behalf of other NHS organisations. Any procurement activity is undertaken specifically to meet the needs of the organisation.

21. Public Health Wales was not responsible for, nor was it involved in, the following activity:

    a) **The procurement and maintenance of PPE stockpiles.** This activity was led by the UK Government Countermeasures Group and the Welsh Government Countermeasures Group. Public Health Wales infection, prevention and control (IPC) specialists provided some input to the Welsh Government Countermeasures PPE Sub-Group in relation to the interpretation of the UK COVID-19 IPC Cell guidance but had no role in the procurement or maintenance of the PPE stockpile.

b) **The distribution of PPE across Wales.** Distribution was led by NWSSP.

c) **Setting the forms and standard of personal protective equipment (PPE) to be used by workers.** These were set out in the UK COVID-19 IPC Cell guidance. Standards for PPE were also prescribed by the Health and Safety Executive (HSE).

d) **Testing the adequacy or suitability of PPE.** PPE is regulated by EU standards. The Surgical Materials Testing Laboratory (SMTL), which is part of NWSSP, are responsible for assuring the claimed standard for a product (i.e., piece of PPE) is met by scrutinizing the testing evidence and checking certifications.

e) **Contributing to changes and/or assisting NWSSP with its understanding of technical specifications of PPE.** Technical specification advice was led by the SMTL.

f) **Changes to technical specifications of PPE, or guidance on re-use based upon availability of supply rather than safety considerations.**

g) **Discussions around implementing 'regulatory easement' in relation to the manufacture or quality control processes for PPE during the pandemic.** These discussions were at a UK level, involving the UK Government, British Standards Institution (BSI), HSE, and the Medicines and Healthcare products Regulatory Agency (MHRA). It is our understanding that representation and advice for Wales were provided by the SMTL.

h) **The procurement of Lateral Flow Tests (LFTs)**. This was led by the UK and the Welsh Government.

i) **The procurement of ventilators and oxygen.**

22. The individuals in Public Health Wales who had involvement in the topics outlined in the M5 Provisional Outline of Scope can be found in the attached exhibit **[EXHIBIT ED/02 INQ000509407].** Public Health Wales was only the decision maker in respect of its own procurement of goods, which included PCR tests, equipment for use in the Public Health Wales laboratory network and PPE for use in the delivery of Public Health Wales screening programmes.

23. Other than those identified below, Public Health Wales did not have any interaction with the Welsh Ministers, Special Advisors, Senior Civil Servants.

Structures and processes

24. Within Public Health Wales, there were weekly reports to the Board on all contracts that had been awarded by the organisation. Additionally, there were regular reports to the Audit Committee.

25. In addition to the Welsh Government established groups which are listed below in paragraphs 40-58, Public Health Wales was also involved in the following:

UK IPC Cell

26. Myself, in my capacity as Head of HARP programme and former Infection Control Doctor, and the Consultant Nurse for Healthcare Associated Infection (HCAI) and IPC (within the HARP programme) became members of the UK COVID-19 IPC Cell at the beginning of the pandemic with the first meetings beginning at the end of January 2020. We advised, reviewed, and contributed to the development of the UK COVID-19 IPC Cell guidance as part of that group in collaboration with IPC leads from the Four Nations and Public Health England (PHE)/UK Health Security Agency (UKHSA). The UK COVID-19 IPC Cell guidance was the IPC guidance that, once it had gone through UK approval processes, Public Health Wales signposted, using the UK Government web link, to colleagues in NHS Wales (including health boards, primary care) and care homes for use / implementation in Wales.

Personal Protective Equipment (PPE) Decision Making Committee

27. Public Health Wales, via the Consultant Nurse for HCAI and IPC (within the HARP programme), also attended the Personal Protective Equipment (PPE) Decision Making Committee established by NHS England/Improvement in May 2020. We attended until September 2021, (initially three times per week, then twice weekly and eventually weekly until the Committee was stood down) and represented Wales alongside colleagues from the SMTL. At the meeting there were discussions about standards, types and innovation in PPE as well as any identified PPE problems, complaints or incidents reported by users in the health service across the UK.

28. These discussions, at the NHS England PPE Decision Making Committee (DMC), also included discussions as to the development of a standard for transparent masks. Public Health Wales representatives contributed to these specific IPC discussions at DMC meetings. Public Health Wales was aware that the call for transparent masks was a constant ask from key sectors, such as health and social care. Transparent masks were requested by the key sectors where additional communication needs were identified. The fluid- resistant surgical masks (FRSM) and filtering face-piece 3 (FFP3) masks cover the nose and mouth to protect the wearer. Some groups of people such as children, the critically ill, those with hearing and speech difficulties, learning disabilities, mental health conditions, dementia found it extremely difficult to communicate with staff or with others as they were unable to see movement of the mouth or were frightened by the masks. These issues also affected staff with hearing and speech disabilities. Transparent Face Masks were specifically requested to mitigate these problems. Transparent face masks are different to clear full-face shields/visors.

29. Prior to the pandemic there were no EU standards or specifications for transparent face masks. The Committee worked with all disciplines, experts in EU standards and IPC colleagues to develop a standard for transparent masks that manufacturers could comply with, which was then published on the GOV.UK website, which meant manufacturers now had a technical specification they could use to develop compliant transparent face masks **[EXHIBIT ED/03**

INQ000538638] This standard is still applicable today and available via the NHS Supply Chain. Safety and regulatory considerations were a constant backdrop to the discussions of the DMC and were overseen by experts from HSE, BSI and Wales SMTL experts. Public Health Wales role was to contribute existing UK COVID-19 Cell IPC advice to these DMC discussions. Public Health Wales did not lead on the approval or procurement of any transparent masks, nor did we consider the technical standards for transparent masks outside the DMC.

30. Early in the pandemic, the manufacturer Clear Mask advised that they had a transparent face mask available for use. It was reported into the Personal Protective Equipment (PPE) Decision Making Committee (DMC) that certain healthcare settings across the UK were purchasing these masks, without official guidance or approval being in place. A piece of work led by experts in the Personal Protective Equipment (PPE) Decision Making Committee (DMC), was undertaken to assess transparent masks produced by the manufacturer Clear Mask. It was discovered through assessment that they did not comply with the regulations as they had no filter capacity and therefore could not be used as a FRSM replacement. The DHSC, following approval from HSE and the MHRA, issued a note to health and social care settings, advising them on the limitations of use for this specific product. The note **[EXHIBIT ED/04 INQ000538639]** from the DHSC advised that the Clear Mask was a single use product and should not be reused. The note also advised that they should not be used:

    a) in the surgical/operating setting or for surgical/invasive procedures.
    b) where there is excessive splashing or spraying of body fluids (as potential splash-back from the impervious front).
    c) as an alternative to a filtering face-piece respirator, which is worn to protect the worker during aerosol generating procedures.

Transparent Mask Group

31. The Welsh Government established its own Transparent Mask Group in December 2021, led by Lisa Wise, Head of Operation Supplies (PPE) from the Welsh Government. This group was an operational (not decision making) Task and

Finish Group which in keeping with the role of a Task and Finish Group was a short-term group focused on implementation, review and evaluation of the new technical standard for Transparent Face Masks and use of products on the market. Public Health Wales, as a member of this task and finish group, contributed IPC advice and knowledge from its participation in the Personal Protective Equipment (PPE) Decision Making Committee (DMC) to assist in the drafting of the transparent facemask notice, which was approved and issued **[EXHIBIT ED/05 INQ000538640]** by NWSSP to health board procurement leads regarding purchasing compliant products against the approved standard. These masks were not intended for routine use. Public Health Wales had no role in the procurement of these masks.

32. An audit was undertaken by an audiology lead at Betsi Cadwaladr University Health Board, who had originally trialled the 'Clearmask'. The Welsh Government and Public Health Wales encouraged other health boards to participate in the audit. The audit questions were developed by the DMC. Public Health Wales does not know what the outcome of this audit was, nor did we issue any notices on the matter.

33. Public Health Wales worked closely and in partnership with the Welsh Government, NWSSP and NHS partners in relation to the advice we gave throughout the pandemic. In addition to the IPC UK-wide engagement, we also engaged with PHE/UKHSA on operational matters throughout the pandemic. These included PCR testing, the allocation of test kits and, on occasion contributing, together with four nations counterparts, in relation to UK wide testing strategies. We also engaged with the Department for Health and Social Care (DHSC) in England in relation to the establishment of sampling centres in Wales.

Key decisions, actions and documents

34. Public Health Wales was not involved in any reports or studies which are relevant to the matters set out within the provisional module scope.

Working with Counterparts

35. Public Health Wales' liaison with other nations in respect of matters outlined in the scope Module 5 was limited to:

    a) Being a member of UK COVID-19 IPC Cell.
    b) Engagement with the other nations in relation to PCR testing.

36. Public Health Wales also attended regular Devolved Administrations, Crown Dependencies and Overseas Territories (DACDOT) liaison meetings, where updates on the DHSC plans for UK-wide testing capacity and arrangements were shared. These meetings existed pre-COVID-19 and post COVID-19 and were the main route for information sharing on this topic. This was not a decision-making forum, and we were, on occasion, informed of decisions that had been made in England shortly before their publication.

37. Public Health Wales was also part of the allocation system run by a central team within the DHSC in England, to acquire weekly testing supplies of Roche test kits and other resources for Wales, such as reagents. This operated as a 'bid system', where we would put in a bid for a specified amount and the allocation, based on available supplies, was made by the DHSC.

38. Public Health Wales worked closely with NHS National Services Scotland and the British Military in April 2020 to coordinate flights to collect Seegene testing platforms from South Korea to expedite their arrival when manufacturing issues and problems with transport arose that threatened to delay delivery. Fortunately, this was not necessary as the issues were resolved, and the company arranged delivery, thereby avoiding the need to charter a flight. The first of these platforms was received at the end of April 2020.

39. Public Health Wales did engage with the UK Government and its representatives. This was mainly in relation to sampling and testing and through interactions with PHE/UKHSA and, on occasion, officials in the DHSC in England, for example when there were interactions about the establishment of sampling centres. There was close collaboration in terms of ongoing engagement and sharing of knowledge and experience. However, there were differences in approaches of the four nations that

meant there were some differences in our requirements and thereby limitations as to what we could collaborate on. For example, testing policy in Wales was set by the Welsh Government and the NHS in Wales utilised a dry swab approach, whereas the lighthouse network and most of England utilised Viral Transport Media "wet swab" approach.

Collaboration with Welsh Government

The Welsh Government Covid-19 Health Countermeasures Group and the Covid-19 Vaccination Consumables and PPE Supplies Subgroup

40. Public Health Wales was not directly involved in any procurement activity undertaken by the Welsh Government. We did however attend the groups below, which were established by the Welsh Government.

41. Public Health Wales attended the Welsh Government PPE Countermeasures Group throughout the pandemic from February 2020. The group was a sub-group of Welsh Government's Countermeasures Group and was chaired by David Goulding from the Welsh Government. It was made up of leads from the NWSSP, Welsh Government leads for Emergency Preparedness Resilience and Response, the Chief Pharmacist, social care leads, and an IPC specialist advisor from Public Health Wales.

42. The role of Public Health Wales was only to provide IPC advice for PPE and consumables (e.g. who needs what, products, guidance on packs for social and primary care, what type of mask was required for different clinical scenarios and level of risk) and to ensure that the group was up to date with the latest agreed four-nations UK COVID-19 IPC Cell guidance. Public Health Wales contributed to discussions about the application of this guidance by setting (health or care sector), including the use and supply of PPE in those settings e.g. acute, primary and community, social care. Advice was provided on interpreting the four nations UK COVID-19 IPC Cell guidance so that other members of the group could make informed decisions around how much PPE to procure and supply. Public Health Wales was not directly involved in any procurement activity stemming from this

group, nor did we provide advice on LFTs, PCRs or ventilators as these did not fall within the remit of the group or the expertise of the Consultant Nurse for HCAI and IPC (within the HARP programme). Non procurement related advice on LFTs and PCR tests was provided by Public Health Wales via different channels. Advice was primarily provided in relation to the clinical and public health utility of different tests, given their specific performance characteristics (i.e., sensitivity and specificity).

43. There were discussions and queries at the Welsh Government PPE Countermeasures Group regarding PPE issues, including fit testing of FFP3 masks, supply of solutions, anecdotal evidence of how health boards were applying or adapting the guidance, decontamination of reusable items of PPE and suitability of PPE offered by various manufacturers and companies selling their products to NWSSP for purchase and use. Specifically, these issues included:

    a) Poor quality of pandemic stock eye shields after complaints from IPC leads in various health boards and a health and safety incident which was raised in Cardiff and Vale University Health Board.
    b) The need for fit testing and stock in care homes.
    c) FRSM, and if these were available in alternative sizes due to poor fit in various staff groups.
    d) Health board decontamination of PPE. Some were reusing PPE at health board risk despite manufacturer guidance.
    e) Health board concerns on plastic thumb loop gowns.
    f) The availability of fit testing solutions. This was calculated by NWSSP for countermeasures and shortages were avoided and resolved by Pharmacy colleagues and NWSSP.

44. Attached are two examples of minutes from the PPE Countermeasures Group where Public Health Wales raised some of the above specific issues for discussion. [**EXHIBITS ED/06 INQ000538641 and ED/07 INQ000538642]**

45. Public Health Wales was asked to comment from an IPC perspective on various PPE that manufacturers were trying to sell to the NWSSP however, SMTL led on compliance. Public Health Wales had no direct involvement with suppliers.

NWSSP were responsible for the management of any supply issues that may have emerged.

46. Any major challenges or concerns raised were fed back into the discussions at the UK COVID-19 IPC Cell and the Personal Protective Equipment (PPE) Decision Making Committee so that views from Wales were considered in ongoing review and updating of the UK COVID-19 IPC Cell guidance. The UK COVID-19 IPC Cell and the Personal Protective Equipment (PPE) Decision Making Committee, were always receptive in discussing matters which were raised and tried to find solutions for all four nations to standardise the response if there was a possible solution.

47. We have been asked to consider comments made by the Welsh Local Government Association in its witness statement for this module **[INQ000518355]**. We have only been provided with extracts from the statement, namely:

'During the early stages of the pandemic, guidance relating to PPE and key healthcare equipment was an issue for local authorities. In terms of procurement, local authorities were uncertain what to purchase and at what scale – it appeared that guidance was driven by what was available on the market rather than by products which were fit for purpose or achieved the conditions to limit the spread and impact of Covid-19."

'Early in the pandemic, guidance was predicated on application within NHS or controlled hospital environments, rather than a whole system approach. Local authorities and care providers were required to interpret this guidance and apply it to care homes and domiciliary care settings. This resulted in differing interpretations and local authorities purchasing different supplies and specifications.

48. The Public Health Wales, Health Protection Division, has traditionally worked with the Welsh Local Government Association regarding communicable disease incident and outbreak management in social care settings. Public Health Wales' initial IPC guidance for COVID-19 was based on standard infection prevention principles at the time. The existing guidance for other respiratory illness arising in

a care setting was outlined in the document Infection Prevention and Control in Care Homes All Wales Guidance. **[EXHIBIT ED/08 INQ000538643]**. Public Health Wales did produce specific guidance for the care sector from 8 April 2020 which contained specific guidance for settings on IPC and the use of PPE. Public Health Wales' guidance was not driven by PPE availability considerations.

49. The care home sector, as independent organisations, are responsible for purchasing their own PPE. Therefore, at the start of the pandemic, before the Welsh Government provided PPE support, there may have been some confusion, but Public Health Wales were not aware of this. Public Health Wales' role is not in procurement or supply of PPE.

50. The Welsh Government was responsible for decision making in relation to the supply and purchase of products to local authorities and approved the roll out of PPE to various settings via the PPE countermeasures group from February 2020. Public Health Wales contributed to an advice note, based on the UK IPC guidance, which reflected best practice for IPC, and which was distributed with PPE packs. Social care and domiciliary care PPE packs were distributed by NWSSP.

51. Advice was provided to the group both verbally and in written format. Verbal advice was captured in minutes of each meeting and included various lines of discussion and the challenges for clinical staff related to countermeasures. If Public Health Wales was asked to provide comment on letter drafts or advice (e.g. draft Welsh Government Chief Medical Officer (CMO) advice letters or draft letters from the Director for Social Services), comments would be returned in a written format signed off by an Incident Director or Strategic Director for that day. Our feedback would have been based on the UK COVID-19 IPC Cell guidance. Public Health Wales did not always see final versions of letters that were issued to services by the Welsh Government.

52. The Welsh Government PPE Countermeasures group narrowed its focus in July 2020, when it started to focus solely on issues related to the delivery of the vaccination programme in Wales. At this time, the group became a subgroup of the Welsh Government's COVID-19 Vaccination Programme Board.

53. Public Health Wales continued to contribute to this group, in the same way, through the provision of advice on how to implement the UK COVID-19 IPC Cell guidance. The focus of the advice was on the elements of PPE, consumables, waste, use of needles and decontamination needed to support the vaccination roll out programme. We worked with NWSSP and the group to agree packs of equipment for the supply of essential consumables to vaccine centres. These packs were assembled by NWSSP, and Mass Vaccine Centres (MVC) could order from a list according to their requirements in addition to their vaccine orders. These packs were then delivered to the MVC by NWSSP within a given timeframe, so as to meet their needs but also to reduce over-ordering and waste. These packs contained all the appropriate PPE, waste bags, sharps boxes, sharps mats, cleaning materials. The quantities of PPE were not calculated by Public Health Wales. NWSSP calculated quantities with the pharmacist based on the numbers of people being vaccinated. These equipment pods/boxes were on call-down rapid ordering. Our recollection is that there were no shortages in supplies to vaccination centres as they tended to over order disposables and consumables and, at one point, we were asked to take out eye protection as they had plenty of stock at sites.

54. Public Health Wales also produced resources, and provided advice based on the UK COVID-19 IPC Cell guidance to support this process. Colleagues from our Vaccine Preventable Diseases Programme (VPDP) also attended this group to ensure that the latest information on vaccine consumables or PPE was included in the training and information provided to vaccinators. We also worked with the group to provide several elements of advice to the COVID-19 Vaccine Programme Board as part of their dashboard.

55. We considered that the IPC advice provided by Public Health Wales was welcomed by members of the group. We noted that our advice/suggested amendments to documents were often accepted, there were helpful discussions in meetings, and we received thanks from the Programme Lead for Vaccines for the work that we were undertaking. Vaccine IPC advice was well received at training webinars, run to support vaccine coordinators, who were anxious about issues such as not being required to wear gloves when giving vaccinations.

56. All concerns or queries raised by the group were fed back to the UK COVID-19 IPC Cell to ensure that feedback from Wales' position was represented at the UK discussions and fed into any updated guidance.

The PPE Procurement and Supply Group

57. Public Health Wales was a member of the Health and Social Care PPE Procurement and Supply Group (PPE Group), established by the Welsh Government and chaired by Simon Dean, the then Deputy Chief Executive of NHS Wales.

58. The purpose of the Consultant Nurse for HCAI and IPC (within the HARP programme) attending these meetings was to update and advise on the UK COVID-19 IPC Cell Guidance and assist the Welsh Government and NWSSP colleagues with their procurement decisions for PPE. We also provided updates from the Personal Protective Equipment (PPE) Decision Making Cell and the transparent face-masks sub-group of the Personal Protective Equipment (PPE) Decision Making Committee. There were many discussions around transparent face masks and innovations in PPE to support vulnerable groups such as children, the critically ill, those with hearing and speech difficulties, learning disabilities, dementia and mental health conditions.

59. Our view is that our advice on the interpretation of UK COVID-19 IPC Cell guidance was well received and that updates in the guidance were noted by members, as evidenced by the discussions that were had during the meetings.

60. Our IPC specialist also supported the Welsh Government and the NWSSP who were responsible for exploring and evaluating alternative equivalent manufacturer products to support the supply of PPE to the NHS, to ensure that, in the event of a shortage of items, alternative supply was available. We were asked to describe the current PPE and levels of protection required in line with the UK COVID-19 IPC guidance e.g., what any new product needed to achieve. Public Health Wales had no involvement in discussions regarding the quantities of items being held in

stores or to be procured, nor were Public Health Wales involved in The Critical Equipment Requirement Engineering Team, CERET, established by the Welsh Government.

61. Whilst Public Health Wales was not part of the procurement and supply of PPE, we were aware that some health boards did procure PPE above the levels of specifications stated in the UK COVID-19 IPC Cell guidance. This is not an issue in itself as the IPC guidance sets the minimum standard that needs to be put in place by health boards, noting that they must not go below the minimum requirement. We became aware through our discussions with IPC colleagues in health boards that there was anecdotal use of FFP3 masks for non-AGP care in some areas, where they had defined their own risks and others were sourcing respiratory hoods which enabled respiratory protection without fit testing.

62. Public Health Wales does not believe the above actions reflected a general lack of confidence in the guidance being issued, but could be attributed to a fear of the unknown risk and wanting the highest possible level of protection. Respiratory hoods were used where fit testing had failed or was not done.

63. Any challenges or queries on the advice provided were fed back to the UK COVID-19 IPC Cell Guidance group to ensure that feedback from Wales' position was represented at the UK discussions and fed into any updated guidance issued by the Cell.

64. As stated above, Public Health Wales was not directly involved in any procurement activity undertaken by the Welsh Government. The Welsh Government did consult with us via the above groups, in relation to the interpretation of the UK COVID-19 IPC Cell guidance and how it could impact on their procurement of the PPE.

65. The NWSSP provide a professional shared procurement service to all health bodies in NHS Wales which facilitates efficient procurement, contracting and supplier management. Whilst they ensure that proper procurement processes are followed, prepare all the relevant paperwork, negotiate contracts, the legal responsibility for signing contracts with the supplier still sits with the relevant health

body on whose behalf they are acting. Public Health Wales therefore signed contracts which related to its own procurement activity.

66. Public Health Wales was responsible for managing the contract, ensuring that the supplier delivered the contract to the quality required. Payment was then made accordingly. We also worked closely with the NWSSP who would provide professional and legal advice, if required.

67. Public Health Wales managed its own stock levels, requesting delivery of goods as demand required. Stock was held with the supplier until requested and then held at individual laboratories or at regional larger labs for onward distribution.

68. Public Health Wales did not undertake any specific work to ensure that PPE was available in a manner that fitted and provided adequate protection for ethnic minorities, religious minorities or female staff.

69. Public Health Wales was aware, from discussions with health board colleagues, of the challenges faced by organisations (including its own) in ensuring that the provision of PPE, was suitable to fit a frontline workforce that was ethnically and religiously diverse and was composed mainly of female staff.

70. The challenges faced by staff around the fit of the PPE products were acknowledged across the UK and were discussed at the UK COVID-19 IPC Cell. However, Public Health Wales understands that the technical specifications/regulations surrounding the use of these products made it difficult to provide alternatives outside these standards.

71. FRSM masks are only available in one universal size and are subject to technical specifications. We were aware of the issues being raised by the health boards around poor fitting of FRSM masks and were involved in discussions around the use of "toggles" being added to the FRSM masks to improve fit. Whilst we do not have a role to advocate for specific cohorts of NHS staff, we did raise awareness of the issues with poor fitting FRSM with groups such as the Welsh Government's Nosocomial Transmission Group and Welsh Government's PPE

Countermeasures Group, and the UK COVID-19 IPC Cell. We also attended a BAME meeting with the Welsh Government to explain the UK COVID-19 IPC Cell guidance as risks were identified and we supported the Head of Patient Experience Leads (HOPE) network to develop a risk tool for staff investigation which was later published by the Welsh Government alongside an investigation tool for patient acquisition. Public Health Wales was not responsible for securing alternative PPE for the health sector in Wales nor could we make changes to technical specifications which may have addressed the difficulties with the fitting of FRSM. Technical specifications are set at a UK level. Public Health Wales' role was to advise when PPE should be used and how to use it correctly in line with the UK COVID-19 IPC Cell Guidance. Responsibility rested with procurement teams (NWSSP and local health boards) to source PPE of the required standard and fit as prescribed by the UK technical specifications and regulations.). Health Boards were also responsible for risk assessing all of their staff for vulnerabilities to COVID-19, not limited to their BAME staff, and for taking action based on the assessed risk and the Welsh Government's guidance.

Work with NWSSP

72. Public Health Wales assisted the Welsh Government with modelling for demand for PPE. For example, in April 2020, Public Health Wales was invited by Brendan Collins, Head of Health Economics and Andrea Street at the Welsh Government to comment upon PPE estimates and meet with representatives of Deloitte, who had been engaged by the Welsh Government to model volumes of PPE required for primary and social care. The Welsh Government and NWSSP had already done a piece of work on estimating quantities (draft estimation of PPE per week) and Public Health Wales provided comments on these estimations. **[EXHIBIT ED/09 INQ000509408]**

73. Our IPC advice was based on the IPC tables that were in existence in the UK IPC guidance and we provided advice on the number of items of PPE required per person per shift to assist modellers to work out volumes of PPE required for distribution to the care home sector. **[EXHIBITS ED/10 INQ000117822, ED/11 INQ000300411, ED/12 INQ000343941, ED/13 INQ000300616].** We noted that

some of the modelling assumptions, for example in relation to the frequency of PPE changes required per shift, had been missed by the Welsh Government's modellers from Deloitte. Public Health Wales cannot comment upon whether the modelling data was utilised by NWSSP and the Welsh Government.

74. Public Health Wales also met with the Welsh Government team for modelling to specifically discuss the PPE for care homes estimations and gave verbal feedback at a meeting on the 4 May 2020, regarding some under-estimations of items needed per shift, taking into account frequency of change of PPE, numbers of shifts and staff per shift. Public Health Wales cannot comment upon what the estimations were used for and was not asked to meet with the Welsh Government again.

75. Modelling work was led by the Welsh Government. Public Health Wales is unable to comment upon or assess any assumptions that were built into any modelling demand or whether these assumptions were revisited during the pandemic.

PPE and Infection Prevention and Control Guidance during the pandemic

76. From the beginning of the pandemic in January 2020, Public Health Wales contributed to the development of UK COVID-19 IPC Guidance via its membership of the UK COVID-19 IPC Guidance Cell. Gail Lusardi, Consultant Nurse IPC, and I, a former Infection Control Doctor and Head of HARP programme Team, were members of the UK COVID-19 IPC Guidance Cell throughout the pandemic. The guidance was published on the gov.uk website and referenced for use in Wales throughout the pandemic. The chronological list of all iterations of the UK COVID-19 IPC Cell guidance is held in the National Archives.

77. All versions of the UK COVID-19 IPC Cell Guidance between 2020 and 2022 are available on the National Archives website. Approximately 45 significant updates to the guidance were made during this period. The UK COVID-19 IPC Cell guidance was withdrawn when the Cell was stood down on the 27 May 2022, following which Public Health Wales published its own IPC guidance. This guidance has now become the *"Acute Respiratory Infection IPC guidance for*

healthcare services in Wales", which includes management of COVID-19 and is updated annually in preparation for the winter season.

78. Additional documents, such as Advisory Notes and Frequently Asked Questions (FAQs), were produced by the HARP IPC programme team during the pandemic and published on the Public Health Wales website. These were developed to assist specific parts of the NHS in Wales such as primary care and social care with interpretation of the overarching UK COVID-19 IPC Cell guidance. At no point did Public Health Wales prepare or publish any IPC guidance that was at odds with the UK COVID-19 IPC Cell guidance.

79. Guidance for care homes was produced by the Closed Setting Cell of Public Health Wales in the early part of the pandemic, followed up and revised and updated over the course of the pandemic by the Health Protection Guidance Sub-Group. A chronology of this guidance is provided as **Exhibit ED/14 INQ000513252.**

80. Public Health Wales was a member of the UK COVID-19 IPC Cell and was involved in the development of the four-nations guidance. All IPC advice prepared by the Public Health Wales HARP programme IPC team during the pandemic was developed in line with the UK COVID-19 IPC Cell guidance to ensure consistency.

81. Changes to the guidance issued by Public Health Wales on the use of PPE within the care sector during the pandemic were consistent with UK adult social care guidance issued by DHSC. PPE guidance also took account of the UK COVID-19 IPC Cell guidance which evolved in line with the changing understanding and learning during the pandemic.

82. Reference to the use of PPE was first included in the Public Health Wales Guidance '*Admission and Care of Residents during COVID-19 Incident in a Residential Care Setting in Wales'* **[EXHIBIT ED/15 INQ000283271]** first published 7 April 2020, and subsequent updates, using wording that was consistent with/taken from the adult social care guidance issued by DHSC and the UK COVID-19 IPC Cell guidance at the time.

83. Staff in the Enclosed Settings Cell in Public Health Wales, which provided specialist support in the management of cases and outbreaks in residential settings up until July 2020, also provided verbal advice on IPC (including PPE) and checked people's understanding of use of PPE when dealing with individual care settings. When required, specific advice, focused on the care sector, was provided to all care settings in contact with the Cell.

84. The use of PPE in all health settings evolved during the pandemic. Over the course of the pandemic our understanding of the virus and modes of transmission evolved and learning from the spread of the infection in our own communities resulted in updates and revisions to the UK COVID-19 IPC Cell guidance including the use of PPE in health settings.

85. For example, when there was a re-categorisation of COVID-19 as no longer being a High Consequence Infectious Disease (HCID) in March 2020 by Public Health England and the UK Government, this resulted in a change to the PPE requirements and protocols, and this change was reflected in the UK COVID-19 IPC Cell guidance. As far as Public Health Wales is aware, the recategorisation was not based on the availability of PPE, but rather it was based on evidence against the classification of COVID-19 as a HCID e.g., severity and transmission.

86. There were also ongoing rapid reviews of evidence from Antimicrobial Resistance and Healthcare Associated Infection (ARHI) in Scotland and in England as well as updates from the New and Emerging Respiratory Virus Threat Advisory Group (NERVTAG) and the World Health Organization (WHO) which all contributed to our knowledge and understanding of the virus and its spread, and which contributed to updates to the UK COVID-19 IPC Cell guidance and recommendations for PPE use.

87. As stated above, throughout the pandemic Public Health Wales' IPC advice was in line with the UK COVID-19 IPC Cell guidance.

88. Fit testing of Respiratory Protective Equipment (RPE) is a requirement of the HSE and the Control of Substances Hazardous to Health Regulations 2002.

89. Advice on how to follow and implement the HSE guidance was explicit in the UK COVID-19 IPC Cell guidance and in the advice from Public Health Wales into the Welsh Government (via the above groups) and the NHS in Wales. As part of the PPE Countermeasures Group, the liquid solutions needed to undertake the qualitative test were part of the consumables considered by the Group.

90. The UK COVID-19 IPC Cell guidance was clear that it was the responsibility of health boards and trusts to determine which staff required testing and to then test those staff required to wear RPE based on risk and procedure according to the UK COVID-19 IPC Cell guidance. The Public Health Wales HARP Team published frequently asked questions (FAQ) on FFP3 masks on its COVID-19 pages, which also linked with the HSE guidance **[EXHIBIT ED/16 INQ000474304]** to aid understanding in this area.

91. It was/is not Public Health Wales' role to deliver training on RPE. If, however, Public Health Wales was holding a webinar or meeting with IPC leads, we would advise on when individuals would need to wear RPE or FRSM based on the UK COVID-19 IPC Cell guidance and would emphasise that fit-testing would be required as part of the correct use of RPE. We also provided links to training materials as another form of support to health boards and trusts.

92. The UK COVID-19 IPC Cell guidance was based on the understanding of transmission routes as laid out in WHO communications and guidance.

93. Public Health Wales did not advise the Welsh Government that COVID-19 was only communicable following AGPs. We were aware that modes of transmission included droplet/aerosol and contact. Our communications with the Welsh Government were regarding the UK COVID-19 IPC Cell guidance and ensuring that the Welsh Government were familiar with any updates to that guidance.

94. In respect of the matters contained within the scope of Module 5 and within the context of the procurement of PPE and our attendance at the above groups, Public Health Wales did not have specific communications with the Welsh Government

in relation to asymptomatic infection. Communication with the Welsh Government through the above groups focused on interpreting the UK COVID-19 IPC Cell guidance. The UK COVID-19 IPC cell discussed asymptomatic transmission in respect of the guidance that was issued. Public Health Wales did have separate conversations with the Welsh Government regarding asymptomatic infections, but PPE and procurement related issues did not form part of those conversations.

95. Public Health Wales did not have any liaison with the NWSSP, Health and Social Services Group (HSSG) and NHS Trusts by way of advising PPE buyers on technical specifications, fit requirements and quality testing. IPC advice was provided by Public Health Wales HARP team via the above groups. Technical specifications and advice on these were provided by the SMTL.

96. Public Health Wales was in constant liaison with NHS organisations. At the start of the pandemic, guidance was being updated very frequently, and as an organisation we were doing our utmost to ensure that there was open communication and as much sharing of information (both ways) as possible. We took feedback from front line IPC teams and healthcare workers back into our discussions at the UK COVID-19 IPC Cell guidance group and, following these discussions, informed our health board IPC teams and partners of any updates due in the UK COVID-19 IPC Cell guidance. On occasion there were delays in the publication of the guidance due to the publication protocols required in England by the UK Government, DHSC and PHE/ UKHSA to publish onto GOV.UK website.

97. UK COVID-19 IPC Cell Guidance did have to change and evolve in response to the increased understanding of the COVID-19 pandemic and SARS CoV-2 virus.

98. Concerns were raised with Public Health Wales regarding changes in the UK COVID-19 IPC Cell guidance. The main concern raised was around the timing of changes, which made implementation of the guidance including procurement of supplies difficult. For example, the change in April 2020 where there was a move to increased use of masks on a sessional basis, resulted in some concerns being raised with Public Health Wales in terms of the ability to implement the change in community nursing/care home sectors. We understood that issuing changes to the

UK COVID-19 IPC Cell guidance on a Friday afternoon was problematic for organisations who were then implementing guidance over the weekend period. However, as stated above, publication of the UK COVID-19 IPC Cell guidance was a UK Government, DHSC and PHE/UKHSA managed process on behalf of the UK COVID-19 IPC Cell Guidance Group, and Public Health Wales had no control over the timing of publications.

99. Public Health Wales was not made aware of specific concerns in regard to health risks to front line staff associated with changes to UK COVID-19 IPC Cell guidance.

Procurement of PCRs, testing kits and LFTs

100. As stated above in paragraph 21(h), Public Health Wales had no role in the procurement of LFT's during the pandemic. Public Health Wales did however engage with the NWSSP in relation to the procurement relating to PCR testing.

101. In normal circumstances, Public Health Wales delivers the large majority of microbiology diagnostic testing for the NHS in Wales, using multiple testing platforms, particularly testing for viral diseases.

102. During the COVID-19 pandemic, Public Health Wales led the delivery of laboratory-based PCR testing for NHS Wales. Diagnostic testing and the identification and assessment of platforms and consumables was an element of business-as-usual for the Public Health Wales Microbiology Service. The specifications of tests were based on the level of detection, sensitivity, and specificity of the test. The specifications of non-test kit supplies were as usual for the diagnostic service.

103. Public Health Wales coordinated the identification and procurement of required resources, across Wales and including non-Public Health Wales laboratories, managed by three health boards, Aneurin Bevan University Health Board, Cwm Taf University Health Board and Hywel Dda University Health Board. These health board laboratories prior to, during and post COVID-19, undertake their own laboratory testing in relation to certain health conditions, including

respiratory infections, with Public Health Wales providing additional support for some laboratory services including supporting the procurement of equipment and reagents.

104. Public Health Wales did not advise, nor did we undertake any procurement activity for laboratories which were non-NHS Wales laboratories (i.e. lighthouse labs).

105. In January 2020, Public Health Wales had a number of molecular testing platforms in five laboratories across Wales, plus the Welsh Specialist Virology Centre (WSVC) in Cardiff, with the potential for the development and delivery of bespoke in-house diagnostic testing for SARS-COV-2. At the height of the pandemic, twelve different platforms were deployed in varying combinations across seventeen NHS Wales hospital sites. These different platforms are described in more detail in paragraphs 101-110 below.

106. Initially, there were no commercial assays available which could test for SARS-COV-2. All testing was done at Public Health England laboratories. Public Health Wales began an informal dialogue with platform and kit manufacturers about their developments of SARS-CoV-2 assays. At the same time, our Welsh Specialist Virology Centre ordered primers and reagents to develop an in-house PCR assay for SARS-COV-2 on 16 January 2020. This assay was then developed, and validation was completed on the 31 January 2020. The Chief Medical Officer for Wales approved the Public Health Wales test on the 7 February 2020. **[Exhibit ED/17 INQ000147297].** Public Health England testing ceased after that date, with commercial assays beginning to become available at the end of March 2020.

107. In the early stages of the pandemic, Public Health Wales was aware that there were issues about the availability of high-quality tests and platforms and the confidence in the supply chain to be able to provide them. During these early stages, we received a large number of approaches and offers from companies, often with theoretical machines and reagents. As a result, we undertook a research exercise to ascertain what was available on the market in terms of test and extraction platforms, and the availability of associated consumables (e.g., pipettes,

salines, lysis buffer and guanidinium isothiocyanate). We made the most of our existing relationships with suppliers and the Life Sciences Hub in Wales provided support as a portal for any companies or others who might be able to assist in the response to the pandemic. Public Health Wales would assess any offers made by these companies, either via a paper-based exercise or through laboratory assessment and decide whether or not to recommend procurement from them. Technical criteria assessed included consideration of the levels of detection and the evidence to support the claims being made by these companies. Other criteria considered was the practicality of using the test or the testing platform as well as assurance of logistics and supply chain. This led to Public Health Wales recommending the procurement of multiple different platforms to the NWSSP, both to give capacity, and also to ensure resilience within Public Health Wales' laboratory network. Public Health Wales is not aware of any issues with the procurement of platforms or tests not being fulfilled, nor did Public Health Wales have any issues with the procured platforms failing to perform tests.

108. At the time, Public Health Wales did not issue any guidance to the NWSSP which specified its own requirements for the identification of consumables and testing supplies such as reagents, swabs, and sample packaging. The Welsh Government Testing sub-group of the Technical Advisory Group, which was chaired by Public Health Wales, did however publish *"Core principles for utilisation of RT-PCR tests for detection of SARS-CoV-2"* on 15th July 2020. **[EXHIBIT ED/18 INQ000066281]** to support organisations who were procuring PCR tests.

109. The majority of procurement activity undertaken by Public Health Wales was by single tender actions through the NWSSP. Public Health Wales, after careful consideration (as stated above), would identify what it was that we required and request NWSSP to undertake the commercial elements of the procurement process to procure these items.

110. The provision and suitability of tests for mass testing was not a role that Public Health Wales performed.

Testing Platforms

111. Prior to the pandemic, Public Health Wales already had a high throughput Roche platform which was used for other purposes. In March 2020, a Roche assay became available. Subsequently, there were discussions with Roche about a supply of up to 5,000 tests/day for Wales. In mid-March 2020, there was a decision by the UK Government to take the Roche test kit supply under central control, and subsequently Public Health Wales received a weekly allocation of tests of around 5,000 from the DHSC.

112. As a consequence of this, it became clear that there would be a need for a mixture of high throughput testing but also rapid testing, and the Roche test allocation meant that other high throughput platforms would be required.

113. Engagement and market exploration was not linear. Public Health Wales, the Welsh Government and wider system were trying to identify options for testing platforms against a global demand. In the same month (March 2020), the Seegene platform was also identified as an option in terms of anticipated assay performance, but also potential availability of platforms and test kits. Seegene was one of the companies (and potential providers) that Public Health Wales already engaged with, and they were able to evidence that they could meet the technical requirements and the logistical/supply chain requirements that Public Health Wales had put in place. There was already a pre-existing Seegene platform in our Cardiff laboratory, and a decision was made to procure additional platforms by way of a single tender action (direct award) via the NWSSP. The issues with delivery of these platforms have already been set out above in paragraph 38. These platforms were delivered at the end of April 2020 and became fully operational in early May 2020.

114. In late March 2020, Public Health Wales submitted a capital funding request to the Welsh Government to purchase three Starlet (high volume) and seven Nimbus (medium volume) platforms for distribution around laboratories across Wales, including non-Public Health Wales laboratories. This request was approved by the Welsh Government, and we procured these platforms by way of single tender action via the NWSSP.

115. At the beginning of April 2020, a SARS-CoV-2 PCR test also became available for our medium-throughput Abbott platform present in our laboratory in Cardiff and these were procured by way of single tender action via the NWSSP.

116. We also had a number of Cepheid, BioFire and ePlex platforms already available within the Public Health Wales laboratory network. During this initial period, we were aware that the manufacturers of these platforms were working to include SARS-CoV-2 as a target in their rapid test kits.

117. At the end of March 2020, a capital request for funding for additional ePlex and BioFire platforms was submitted to and agreed by the Welsh Government. We procured these platforms by way of single tender action via the NWSSP. The ePlex platforms became operational in June 2020. The availability of BioFire platforms and kits was delayed due to export restrictions from the USA and these did not go live until July 2020.

118. In early April 2020, a further capital request for funding for nine additional Cepheid platforms for distribution across Wales was submitted to and agreed by the Welsh Government. These platforms were procured by way of single tender action via the NWSSP and became operational in May 2020.

119. In addition to the above activity, Public Health Wales was approached by Perkin Elmer at the end of March 2020, regarding their high-throughput test platforms and kits for SARS-CoV-2 that were becoming available. In early April 2020, we received a proposal from Perkin Elmer to enter into a partnership agreement with them involving capital acquisition of platforms plus associated test kits. A capital request for funding was agreed by the Welsh Government in early April 2020. These platforms became operational in May 2020.

120. Prior to the pandemic, Public Health Wales had a Hologic platform. At the end of April 2020, Public Health Wales engaged with the DHSC in England regarding the use of this platform for testing SARS-CoV-2. This platform became operational in June 2020 when the Hologic testing assay became available. Public

Health Wales utilised the DHSC allocation system to obtain the necessary test kits and resources.

Laboratories

121. At the end of April 2020, it became clear that additional laboratory space was required for the delivery of centralised high-throughput testing. A business case for the establishment of an additional COVID-19 laboratory at Imperial Park 5, Newport, to support the scale up in COVID-19 testing, was submitted to the Welsh Government on 7 May 2020 and was approved on 2 June 2020. **[EXHIBITS ED/19 INQ000056275 and ED/20 INQ000509399]** At the end of May 2020, a contractor was appointed for the development of a laboratory at Imperial Park 5, known as Lab 1. At the request of the Welsh Government, contracts in respect of IP5 laboratory 1 novated on the 10 August 2020 to the DHSC in England to support the UK pandemic response and lighthouse laboratory testing capacity.

122. During this period, we were also working to develop a further laboratory at IP5, Lab 2, to provide complimentary testing capacity for Wales which did not include COVID-19 PCR testing. In September 2020 we began discussions with the Welsh Government about reverting Lab 2 to COVID-19 testing due to challenges with the lighthouse laboratories, reductions in available slots at sampling centres and poor testing turnaround times in the lighthouse laboratories. It was subsequently agreed that IP5 laboratory 2 would undertake PCR testing and we worked with NWSSP Specialist Estates to develop the laboratory. On the 7 December 2020, laboratory 2 in IP5 was handed over from the contractors to Public Health Wales. The Public Health Wales Covid-19 testing laboratory 2 became fully operational on the 4 January 2021.

123. In early August 2020, Public Health Wales submitted a business case, to improve turnaround times (TAT) and enhance the laboratory resilience to manage the COVID-19 demand. The Welsh Government approved the business case on the 10 August 2020. **[EXHIBIT ED/21 INQ000056277]** As well as funding for additional staff, this included the development of six new local 'Hot Laboratories' in acute hospitals (Llandough Hospital, Prince Phillip Hospital, Morriston Hospital,

Prince Charles Hospital, Princess of Wales Hospital and The Grange Hospital) equipped with Cepheid, Biofire, and ePlex rapid testing platforms, with additional equipment for the pre-existing nine 'Hot Labs'. In developing the six new local Hot Laboratories, we advised the local health boards of what we required in terms of the floor space in which the laboratories would operate. Capital funding was provided to refurbish the health board sites, with the health boards being responsible for procuring all fixtures and fittings. Public Health Wales was responsible for providing the testing platforms and associated consumables. These new Hot Laboratories became operational at the end of November 2020.

124. In early 2021, Variants and Mutations of Concern (VAMC) of the SARS-CoV-2 virus became an issue. An assay had been developed by a company for use on the Seegene platform which could identify a number of mutations within the virus and enable differentiation of variants. Public Health Wales was already using the Seegene platform and had a contract with this company to provide generic SARS-CoV-2 assays. The company was the only provider of the variant assays for use on Public Health Wales' testing platforms. Public Health Wales used the existing contract, to purchase both the 'generic' SARS-CoV-2 assays and the new variant assays for use in our Welsh Centre for Specialist Virology initially and then rolled-out across Wales in April 2021. There were no other testing platforms being used in Wales at this time which had assay to enable differentiation of variants.

125. Public Health Wales did not have a significant collaboration with Swansea University.

126. Public Health Wales also worked closely with Cardiff University which assisted with sourcing of certain reagents such as guanidinium isothiocyanate. Cardiff University had a local supply of guanidinium isothiocyanate that they gifted to Public Health Wales. They also loaned Public Health Wales space in their teaching laboratory adjacent to our Cardiff laboratory to undertake testing.

127. Public Health Wales did not provide advice/guidance to the Welsh Government regarding the selection or procurement of LFTs. Public Health Wales did however provide advice to the Welsh Government to assist with the clinical and

public health interpretation of the LFT results and their appropriate use after they were procured.

128. Public Health Wales did not provide any guidance on the selection of suitable contractors/suppliers or the criteria upon which specific tests were deemed suitable for mass testing, to the Welsh Government/NWSSP/those making direct awards for LFTs.

129. Public Health Wales did not lead on any evaluation of PCR/LFT tests with regard to mass testing. This is because we did not feel it was necessary to evaluate the use of PCR testing in this context as we had not identified specific problems pertaining to PCR use. At this point in time, there were also a number of reports on LFTs in this context that Public Health Wales could reference. Whilst we did not lead our own evaluation, we supported a collaborative evaluation of mass testing using LFT's led by Cwm Taf Morgannwg University Health Board in 2020. This evaluation by Cwm Taf Morgannwg University Health Board supported the previous studies. As Public Health Wales did not lead on this evaluation, we cannot comment whether any conclusions or recommendations were shared with NWSSP/HSSG/NHS Trusts.

Recommendations

130. Large-scale testing of the population was not a function performed by Public Health Wales during the pandemic.

131. Public Health Wales would recommend clear plans and preparations being in place (including logistics planning, which should also address the needs of e.g., specific population groups and any potential impacts of inequality e.g. on access to sampling sites) and these being tested periodically, by the relevant organisations, for the purposes of mass testing and sampling of the population. These should incorporate a number of scenarios that would need to be further refined and amended given the public health threat at the time. This should include each NHS organisation having in place surge plans to enable population level

sampling and testing that can be adapted to the various types of sampling and testing available and needed over the course of any given pandemic.

132. What was clear during the pandemic was that a seamless end-to-end sampling and testing process was required in order to optimise performance and issue a result to an individual in a timely manner. This includes individuals getting or doing a sample, how that sample is delivered to a laboratory, the processing of that sample in the laboratory and the issuing of test results. Recognising that different organisations have different roles and responsibilities in the different steps and logistics of such an end-to-end process, clarifying these roles and establishing performance measures to monitor and manage this is key. It would also be important for the Welsh Government to establish a sampling and testing process cell early on in a pandemic to monitor and manage the end-to-end process.

133. Agreeing a protocol for the equal engagement, co-design and agreement amongst the four nations in the context of requiring surge planning, allocation and delivery for population level sampling and testing in a pandemic would be of benefit.

Concerns about the accuracy/performance of testing kits

134. Public Health Wales delivered laboratory-based PCR testing across Wales within an existing quality framework in laboratories accredited at ISO15189 by UKAS (UK Accreditation Service). Within this framework, performance of testing was monitored by the Public Health Wales laboratory teams conducting the testing, and any concerns were investigated by Public Health Wales and any resulting actions were led by the Public Health Wales Infection Division. The UKAS does not have an enforcement role in respect of their quality accreditation.

135. Monitoring of results from outside the Welsh NHS testing network enabled identification of potential issues through the passive monitoring of results.

136. For example, in January 2021, the Public Health Wales quality system identified a potential contamination issue with batches of test swabs supplied by

Copan. The issue was communicated to the DHSC in England to establish if other parts of the UK system were affected; the swabs were predominantly used in Wales. Affected batches of swabs were quarantined. An investigation with the company involved did not identify a source for contamination and we continued our contract with them.

137. In March 2021, Public Health Wales identified a high rate of positive results coming from the Immensa Laboratory in the DHSC's in England's testing network which suggested a high false-positive rate and potential laboratory issues. This was communicated by Public Health Wales to the Director of Laboratories, at NHS Test and Trace in England. **[EXHIBITS ED/22 INQ000509401 and ED/23 INQ000509404]** Subsequently, in October 2021, an issue with the Immensa laboratory reporting high false-negative rates was identified and announced, and testing operations were suspended at the Wolverhampton laboratory pending a further investigation by the UKHSA. **[EXHIBIT ED/24 INQ000509406]**

138. In November 2021, the Public Health Wales quality system again identified an issue with possible false positive results from one of the Public Health Wales Biofire platforms. The use of the platform was suspended pending our investigation. The investigation suggested that there was not an issue of false positive results, but rather that the Biofire platform was more sensitive than other platforms. It was re-introduced with modified use criteria in December 2021. No action was taken in respect of any contracts associated with this platform.

139. Public Health Wales has not undertaken or been involved in internal or external reviews, lessons learned exercises or similar relating to any of the issues in the Outline of Scope for Module 5 since January 2020.

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: ____ PD _____

Dated: _____20.01.2025_____