Witness Name: Ian Trenholm
Statement No.: 3
Exhibits: IT3/01 - IT3/481
Dated: 12 April 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF IAN TRENHOLM

I, Ian Trenholm, Chief Executive of the Care Quality Commission, Citygate, Gallowgate, Newcastle upon Tyne NE1 4PA, will say as follows: -

1. I am employed by the Care Quality Commission (CQC) as Chief Executive, a post I have held since August 2018.

2. Prior to this I was Chief Executive of NHS Blood and Transplant from 2014, and previously Chief Operating Officer at the Department of Environment, Food and Rural Affairs (Defra). Prior roles have included Chief Executive of the Royal Borough of Windsor and Maidenhead and Strategic Director for Resources at Buckinghamshire County Council. I began my career as an Inspector in the Royal Hong Kong Police Force and then served with the Surrey Police for four years, before moving to the commercial sector.

3. I make this statement in response to the request dated 2 June 2023 made under Rule 9 of the Inquiry Rules 2006 (SI 2006/1838) from the UK Covid-19 Public Inquiry (the Inquiry). I adopt the abbreviations or acronyms deployed in the Rule 9 Request where appropriate. I am duly authorised to make this statement on behalf of CQC.

4. Save where it is stated otherwise, the contents of this statement are within my own knowledge. This statement is to the best of my knowledge and belief accurate and complete at the time of signing. Notwithstanding this, it is the case that CQC

continues to prepare for its involvement in the Inquiry. As part of these preparations, it is possible that additional material will be discovered. In this eventuality the additional material will of course be provided to the Inquiry and a supplementary statement will be made, if required.

5. This statement has been prepared following consultation with current and former colleagues at CQC in order to provide as accurate an account as possible on behalf of CQC.

A. CQC's role, functions and aims

6. CQC was established on 1 April 2009 by the Health and Social Care Act 2008 (the 2008 Act) as the independent regulator of health and adult social care in England. CQC is a non-departmental public body, sponsored by the Department of Health and Social Care (DHSC), and accountable to Parliament through the Secretary of State for Health and Social Care.

7. Our functions, statutory duties and powers, which extend to England only, are set out principally in the 2008 Act[1], together with the Health and Social Care Act 2012, the Care Act 2014, the Health and Care Act 2022 and additional primary and secondary legislation. Our responsibilities include the registration, monitoring, inspection, assessment and regulation of services which fall within our regulatory remit. In addition, we have a duty, under the Mental Health Act 1983 (MHA), to monitor how services exercise their powers and discharge their duties when patients are detained in hospital, subject to community treatment orders or guardianship. We also monitor how the Mental Capacity Act 2005 (MCA) is being used by health and adult social care providers and how they use the Deprivation of Liberty Safeguards (DoLS).

8. Our objectives when fulfilling these functions are set out in section 3 of the 2008 Act. Our purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to

[1] As set out in Section 2 of the 2008 Act.

improve. We report on how care is being delivered in England in our annual State of Care report.

9. Although we adapted our approach to inspection during the pandemic, our statutory functions and objectives remained the same.

10. The Health and Care Act 2022 (the 2022 Act) received Royal Assent on 28 April 2022 and added to the list of regulatory duties held by CQC. The changes brought in by the 2022 Act include CQC's review and assessment of Integrated Care Systems (ICSs), which considers the end-to-end provision of healthcare services, within the area of each integrated care board (section 31). The 2022 Act also includes CQC's regulation of certain Local Authority functions relating to adult social care (section 163), which considers the exercise of regulated care functions and assesses the performance of those functions.

CQC's regulatory remit

11. Providers of 'regulated activities' must be registered with CQC unless a specified exemption or exception applies[2]. These regulated activities are:
    - 11.1. personal care;
    - 11.2. accommodation for persons who require nursing or personal care;
    - 11.3. accommodation for persons who require treatment for substance misuse;
    - 11.4. treatment of disease, disorder or injury (TDDI);
    - 11.5. assessment or medical treatment for persons detained under the 1983 Act;
    - 11.6. surgical procedures;
    - 11.7. diagnostic and screening procedures;
    - 11.8. management of supply of blood and blood derived products;
    - 11.9. transport services, triage and medical advice provided remotely;
    - 11.10. maternity and midwifery services;
    - 11.11. termination of pregnancies;
    - 11.12. services in slimming clinics;
    - 11.13. nursing care; and

[2] Set out in Section 10 of the 2008 Act, and defined in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

11.14. family planning services.

12. It is an offence to carry on a regulated activity without being registered, and we can prosecute those who do this. The 2008 Act gives CQC both civil and criminal enforcement powers to address issues of non-compliance with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations 2009, which registered persons are required to comply with.

13. We have a wide set of powers that are designed to protect the public and hold registered providers to account. CQC's statutory powers are detailed in the 2008 Act and include powers of entry and inspection (sections 60 to 63) and powers to require information and documentation (sections 64 and 65). Failing to comply without reasonable excuse is an offence.

14. We also have powers to undertake civil and criminal enforcement action against registered persons who fail to comply with a condition of their registration or the relevant Regulations[3], and those carrying on regulated activities without registration. CQC's civil enforcement powers as set out in the 2008 Act include powers to cancel or suspend a registered person's registration (sections 18 and 30 to 31), to impose, vary or remove conditions of registration in respect of a registered person (sections 12 (5), 15 (5), 30 and 31) or to serve a "warning notice" where the test set out in sections 29 and 29A is met. Criminal enforcement action can be taken, in response to breaches of certain regulations and sections of the 2008 Act, against any registered person, or against any unregistered person where they are carrying out regulated activities without registration persons defined under Section 91 and 92 of the 2008 Act. It can also be used against any person who obstructs us during an

[3] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (as amended by a) Health and Social Care Act 2008 (Registration and Regulated Activities (Amendment) Regulations 2005 and b) Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012) and Care Quality Commission (Registration) Regulations 2009 (as amended by a) Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 and b) Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012).

inspection and against registered or unregistered persons where they have made a false or misleading statement in any application to us. CQC's criminal enforcement powers include the power to issue simple cautions, fixed penalty notices and commence a prosecution.

15. We also have the power to conduct a special review of, or investigation into, the provision of NHS care; adult social care services; the exercise of the functions of NHS England or an integrated care board; the exercise of the functions of English local authorities in arranging for the provision of adult social care services; or the exercise of functions by English Health Authorities. Special reviews or investigations may be conducted at CQC's discretion (with the approval of the Secretary of State), or upon the request of the Secretary of State (section 48 of the 2008 Act).

16. The 2008 Act also gives CQC a general power to "do anything which appears to it to be necessary or expedient for the purposes of, or in connection with, the exercise of its functions"[4]. This includes co-operating with other public authorities in the United Kingdom.

Healthwatch England

17. We host Healthwatch England (HWE), the consumer champion for health and social care to ensure the voices of people who use services are listened to and responded to, leading to improvements in service provision and commissioning. HWE was established under the Health and Social Care Act 2012 as a statutory committee of CQC and is funded through grant in aid. The Chair of HWE sits on CQC's Board. It is operationally independent but supported by our infrastructure.

National Guardian's Office

18. We also host the National Guardian's Office (NGO). The NGO and the role of the National Guardian were created in response to recommendations made in Sir Robert Francis KC's report 'Freedom to Speak Up' (2015). The office leads, trains and supports a network of Freedom to Speak Up Guardians in England and conducts

[4] Paragraph 2, Schedule 4 of the 2008 Act

case reviews of organisations when it appears that speaking up has not been handled according to best practice. The NGO is funded mainly by NHS England (NHSE), with CQC's contribution paid for by grant in aid. The NGO has operational independence to CQC but is supported by our infrastructure and, as part of CQC, has no separate legal status.

19. The Care Quality Commission (Additional Functions) (Amendment) Regulations 2023 came into force on 28 November 2023. The regulations relate to clarifying the legal status of the NGO.

Maternity and Newborn Safety Investigation

20. On 1 October 2023 the functions of the Maternity and Newborn Safety Investigations (MNSI) programme were transferred to the Care Quality Commission pursuant to the Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023. Prior to the transfer, the maternity investigations function was an additional function of the Healthcare Safety Investigation Branch (HSIB) under the NHS England (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2022. Part 4 of the Health and Care Act 2022 established the Health Services Safety Investigations Body 'HSSIB' to carry out the safety investigations functions previously discharged by HSIB. The maternity investigations function was transferred to CQC.

B. Liaison and communication with Government and other stakeholders

21. The extent to which the CQC advised, collaborated with or otherwise worked with the following organisations between 1 March 2020 and 28 June 2022 ("the relevant period"), in response to the Covid-19 pandemic is set out below:
    - 21.1. Department of Health and Social Care (DHSC);
    - 21.2. NHS England (NHSE);
    - 21.3. Public Health England (now UKHSA);
    - 21.4. General Medical Council (GMC);
    - 21.5. British Medical Association (BMA);
    - 21.6. Royal College of General Practitioners (RCGP);
    - 21.7. Care Provider Alliance (CPA);

21.8. Healthcare Improvement Scotland;

21.9. The Regulation and Quality Improvement Authority in Northern Ireland;

21.10. The Healthcare Inspectorate Wales;

21.11. Any other key stakeholders not referred to above.

22. The extent to which CQC liaised with DHSC, predominantly, and other external stakeholders during the relevant period is illustrated by the attached chronology (IT3/01 [INQ000235485]), which sets out the meetings that we attended with the UK Government from March 2020 to February 2022 ("UK Government includes: the Cabinet Office, DHSC and other UK Government departments). The chronology was prepared for the purpose of responding to the Inquiry's Rule 9 Request to CQC for Module 2 where the focus was on CQC's engagement with UK Government in the context of core decision-making during the pandemic. Whilst preparing the chronology, we identified that we attended over 1,000 meetings with the UK Government where various issues relating to the Covid-19 pandemic were or may have been discussed. The vast majority of these meetings were also attended by representatives from some of the other external stakeholders listed above.

23. The chronology was compiled following the manual review of the Microsoft Outlook calendars of the key CQC colleagues who were engaging with UK Government officials during the pandemic. These colleagues, and the positions they held during the relevant period, are as follows:

23.1. Peter Wyman (Chair)

23.2. Ian Trenholm (Chief Executive)

23.3. Ted Baker (Chief Inspector of Hospitals)

23.4. Kate Terroni (Chief Inspector of Adult Social Care)

23.5. Rosie Benneyworth (Chief Inspector of Primary Medical Services and Integrated Care)

23.6. Mark Sutton (Chief Digital Officer)

23.7. Chris Day (Director of Engagement)

23.8. Joyce Frederick (Deputy Chief Inspector, Registration and Regulatory Assurance, then Director of Policy and Strategy from October 2021)

23.9. Rebecca Lloyd-Jones (Director of Governance and Legal Services)

23.10. Helen Louwrens (Director of Intelligence)

23.11. Stuart Dean (Director of Corporate Providers and Market Oversight) and

23.12. Debbie Ivanova (Deputy Chief Inspector).

24. In addition, the same review was conducted in relation to the calendars of the following colleagues:

24.1. three Heads of Inspection;

24.2. the Head of Adult Social Care Policy;

24.3. a Head of Provider Analytics;

24.4. the Head of Parliamentary Government and Stakeholder Engagement;

24.5. a Government Engagement Manager; and

24.6. a Senior Government Engagement Officer.

25. We identified the meetings that, on the information available in the calendar entries, encompassed issues relating to the Covid-19 pandemic. Our role in these meetings and the topics of discussion were varied. Generally, our role in these meetings was to provide information as required. Our input typically entailed information regarding:

25.1. our role as regulator;

25.2. our approach to regulation and adaptions that we made to respond to the challenges of the pandemic;

25.3. our unique knowledge of the sectors we regulate; and

25.4. our insight into the particular pressures being faced by providers of these services.

26. We drew attention to issues as they arose and sought to use our knowledge and understanding of the health and adult social care sectors to influence where appropriate. Examples of the issues in respect of which we were liaising with the UK Government as well as the other organizations outlined in paragraph 21 above, which are relevant to Module 3, are explained in detail throughout this statement to answer specific questions.

27. Below is an explanation of the information set out in the chronology:

27.1. Column A – the date of the meeting;

27.2. Column B – the time of the meeting;

27.3. Column C – the title of the meeting invitation taken from the relevant Microsoft Outlook calendar entry;

27.4. Column D – additional information about the meeting, summarised from the calendar entry, if available;

27.5. Column E – the sender of the meeting invitation;

27.6. Column F – whether the meeting was a regular meeting (For the purposes of this statement, we have defined a 'regular meeting' as where the meeting was set up as a recurring invite, or where repeated entries with the same meeting title appeared in calendars);

27.7. Column G – key external individuals (or their organisation) included in the list of invitees. The information in Column G is not intended to be an exhaustive list of invitees as it is not possible, from the meeting invite, to determine whether they in fact attended the meeting;

27.8. Column H – the names or roles of key CQC colleagues (as identified above) who received the meeting invite;

27.9. Column I – any documentation (such as minutes, agendas and slide packs) attached to the calendar entries, a sample of which (in relation to five meetings) are explained below and provided as exhibits. Any other documentation referred to in Column I, although not provided at this stage, can be provided to the Inquiry if required.

28. The information provided in Column C has been categorised by colour as follows:

28.1. The meetings which have been highlighted in light green ("Ministerial / Secretary of State meetings") are those meetings involving Secretaries of State and other Ministers of State. This category also includes Cabinet Committee Covid-19 Operations meetings, known as 'Covid-O' meetings. We have identified over 100 such meetings within the relevant period.

28.2. The meetings which have been highlighted in yellow ("high level departmental meetings") are those attended predominantly by Directors or Deputy Directors at DHSC in relation to a range of Covid-19 matters relating to the health and social care sectors.

28.3. The meetings which have been highlighted in light blue ("cell calls") are those set up by DHSC's Quality, Patient Safety and Investigations Directorate. These were held on a regular basis throughout the relevant period and involved discussion of issues relating to patient safety in the context of the pandemic. The attendees to the cell calls were usually individuals from DHSC, NHSE, and from arm's-length bodies including CQC, NHS Resolution and the HSIB.

28.4. The meetings which have been highlighted in light grey ("T&F groups") are the Task and Finish group meetings, for example relating to Care Act "easements", the Adult Social Care (ASC) workforce, Personal Protective Equipment (PPE) and Covid-19 testing. These were set up by DHSC and were held regularly during the period which they ran for.

28.5. The meetings which have been highlighted in pink are the final 'other' category of meetings identified, which may have potential relevance but which do not fall into the previous four categories.

29. We also attended a number of high-level meetings with Directors and Deputy Directors at DHSC on a range of Covid-19 matters touching on the health and adult social care sectors. These included meetings with Ed Scully (Director of Primary and Community Health Care), Michelle Dyson (Director General for Adult Social Care), Tom Surrey (Director of Adult Social Care), William Vineall (Director of NHS Quality, Safety Investigations) and Lee McDonough (Director General Acute Care and Workforce).

30. As can be seen from the attached chronology, we liaised with DHSC on a wide range of Covid-19 related issues. The chronology does not include the details of the conversations that took place in the meetings listed as to do so was not possible within the time limit set by the Inquiry for responding to the Module 2 Rule 9 Request. If further specific detail or information is required by the Inquiry we will of course endeavour to provide it where it is available.

31. With regard to CQC's engagement with the other stakeholders identified above in paragraph 21 above, it is not possible to summarise all of the matters in respect of

which CQC advised, collaborated or worked with those bodies in this statement. Therefore, we have chosen to highlight what we consider to be the key workstreams/decisions/projects/groups as examples of instances where we participated with the stakeholders listed above and which fall under the outline of scope of Module 3:

National Quality Board ("NQB")

32. The NQB champions the importance of quality and drives system alignment of quality across health and care on behalf of NHSE, NHS Digital, CQC, UKHSA, the National Institute for Health and Care Excellence, the Office for Health Improvement and Disparities, DHSC, and Healthwatch England.

33. During the relevant period NQB meetings were co-chaired by Professor Stephen Powis, the National Medical Director, NHSE, and Ted Baker. Representatives from the above mentioned organisations sit on the NQB along with others from Health Education England, the Chief Nursing Officer and lived experience experts.

34. The NQB met throughout the relevant period providing advice, recommendations and endorsement on matters relating to quality, acting as a collective to influence, drive, and ensure system alignment of the programmes and initiatives related to quality of care. The agendas, minutes and papers are publicly available on the NHSE website at https://www.england.nhs.uk/ourwork/part-rel/nqb/agen-mins-meet/.

35. During their meetings the NQB considered a range of topics relating to Covid-19. A relevant example is the meeting on 18 June 2020 which was attended by Ted Baker, Rosie Benneyworth, Kate Terroni and Victoria Watkins on behalf of CQC (IT3/02 [INQ000398477]; IT3/03 [INQ000398478]; IT3/04 [INQ000398479]; IT3/05 [INQ000398480]; IT3/06 [INQ000398481]; IT3/07 [INQ000398482]; IT3/08 [INQ000398483]). There was a discussion about patient safety and consideration was also given to the issue of capturing clinical innovations from the Covid-19 pandemic, identifying the beneficial changes in specialties and patient pathways that should be locked into the recovery phase and beyond. The NQB raised that it was also an opportunity to consider what had not worked well. At the meeting Victoria

Watkins presented her paper on Provider Collaboration Reviews (IT3/06 [INQ000398481]). NQB members were supportive of the work and noted the importance of it being a learning exercise across all health and social care providers.

36. CQC's role in the NQB continued throughout 2021 and 2022, and we attended all meetings held.

Primary Care Quality Board

37. The Primary Care Quality Board ('PCQB') was established before the pandemic (previously known as the 'Regulation of General Practice Programme Board' established in June 2016) and brought together the bodies responsible for the regulation and oversight of primary care in England. Its purpose was to ensure that patients received high quality, safe primary medical services from professionals and organisations that were competent and met national standards, and that services improved. Meetings were chaired by Dr Rosie Benneyworth, CQC's former Chief Inspector of Primary Medical Services and Integrated Care.

38. The PCQB was formed of the following organisations: CQC, DHSC, NHSE, General Medical Council (GMC), Nursing and Midwifery Council (NMC), Health Education England (HEE), National Institute for Health and Care Excellence (NICE), General Pharmaceutical Council (GPhC), Healthwatch (HWE), NHS Clinical Commissioners (NHSCC), NHS Digital, Public Health England (PHE), NHS Resolution (NHSR) and NHSX. The minutes of the PCQB meetings can be made available to the Inquiry if required.

39. The PCQB provided a forum for national bodies to work to a common framework as the basis for a joined-up approach to monitoring and improvement. Its aims are to co-ordinate and improve the overall approach to the regulation of primary care in England; identify opportunities to streamline working arrangements and minimise duplication; maintain oversight over the quality of care in primary care; share information on areas of concern as well as good practice and ensure primary care is supported to deliver high quality care and ensure the approach taken by practitioners

evolves to support the development of primary care, including greater integration with other health and care services.

40. One of the key themes discussed during the PCQB meetings that took place during the pandemic was the issue of patient access to general practice. The PCQB recognised the importance of continuing to emphasise that general practice was open as the message did not appear to be reaching the public; NHS England and NHS Improvement (NHSEI) noted through the complaints they had received that patients were saying general practices appeared to be closed.

41. The PCQB also discussed the issue of online primary care and, for example, the use of decision-making apps. It recognised that the pandemic had accelerated the need for the utilisation of many different kinds of software during consultations, and was mindful of the concerns around digital exclusion, particularly among deaf users and people with limited English. There were discussions around the use of technology during the pandemic and a representative from Traverse Ltd joined the meeting on 14 July 2020 to outline early findings of a joint report from Healthwatch, Traverse Ltd and National Voices into the benefits and criticisms of remote consultations titled 'The Doctor will Zoom You Now: getting the most out of the virtual health and care experience' (IT3/190 [INQ000366252]).

Primary Care Group SLT

42. CQC was also invited to attend the Primary Care Group Senior Leadership Team meetings from October 2021 which were subsequently attended by Rosie Benneyworth. The meetings were at director-level within NHSEI but brought in others from across the system to be part of relevant discussions. An invitation would therefore be extended to CQC where NHSEI considered there were matters that arose for discussion where we could provide relevant input.

43. This group, for example, considered the pressures on the primary care workforce, as the Omicron variant of Covid-19 had resulted in a vaccination booster programme which drew capacity from general practice and community pharmacies. This meant looking for ways to reduce the workload burden. We confirmed our expectation that

patients with long-term conditions would continue to have their conditions managed in the best way possible (IT3/09 [INQ000398484]).

Health & Social Care Regulators Forum

44. The Health and Social Care Regulators Forum ('the Forum') was established in 2014 and meets three times a year. The forum aims to jointly identify, develop, share and promote good practice across health and social care, specifically relating to professional system regulation. I chair the meetings of the Forum, and where I am unable to attend the meeting a CQC colleague will usually deputise in my place.

45. The Forum includes CQC, GMC, GPhC, Health and Care Professions Council (HCPC), Health Education England, Local Government and Social Care Ombudsman (LGSCO), NMC and Parliamentary and Health Service Ombudsman (PHSO). Representatives from the following organisations have also been included as provisional attendees: Patient Safety Commissioner, General Dental Council (GDC), Professional Standards Authority, Social Work England, General Osteopathic Council, General Chiropractic Council, General Optical Council, NHSE, Medicines and Healthcare Products Regulatory Agency (MHRA) and Health Services Safety Investigations Body. The minutes of the Forum meetings can be made available to the Inquiry if required.

46. A key aspect of the Forum's focus on Covid-19 was how to learn from its effects and the response to it in general. The Forum established a 'Covid-19 Learning Working Group' (IT3/10 [INQ000398485]) to look at learning across regulators in the health and social care sectors.

47. The member organisations provided updates to the Forum including how Covid-19 had impacted their particular area of regulation, as well as how it had affected them as an organisation. They discussed how the pandemic had impacted their strategic positions and how, in general, it had required them to move to working, and undertaking regulatory hearings, remotely. There was recognition among the members of the Covid-19 Learning Working Group that Covid-19 had shown

regulators that they could be agile in their approach and how this could be taken forward in the future.

48. Learning came through concerns and complaints raised via the member organisations. These covered a wide range of subjects during the course of the pandemic and included the following, non-exhaustive, list: the use of social media among healthcare professionals; profiteering by professionals in private practice; issues with PPE; delays in receiving information from health and social care organisations and registrants; the effect of Covid-19 on non-Covid healthcare and treatment; exacerbation of existing workforce; and capacity problems.

49. In addition to the work outlined above, CQC was also asked, by DHSC, to advise on and assist with the development of numerous guidance documents and legislation during the relevant period. Examples of the guidance documents that we worked on which relate to the issues that fall under the scope Module 3 Outline of Scope are as follows:

    49.1. Vaccination policy in NHS

        49.1.1. In July 2021, DHSC sought advice from CQC in relation to the practicalities of mandatory vaccinations applying in hospital settings. We explained at a high level the main differences in approach and some of the difficulties this might present, particularly from an enforcement point of view. We suggested that we could offer further advice if DHSC had a more clearly defined scope of their current thinking available for review (IT3/11 [INQ000235363]).

        49.1.2. Following a virtual meeting which took place on 14 July 2021 at DHSC's request, they wrote to us setting out the intended scope of the vaccination policy and seeking advice from us on how the same might be implemented. We highlighted potential difficulties with their proposals and suggested a settings-based approach with a suitable list of caveats / exemptions. We also set out our expectations in relation to enforcement and explained that these would be dependent on the precise amendments. (IT3/12

[INQ000235364]) We were then asked to comment on the draft policy, giving some limited comments on possible enforcement options, where proportionate, and general comments such as distinguishing between flu and covid vaccinations. (IT3/13 [INQ000235365])

49.1.3. In August 2021, we were asked to comment on some additions to the Code of Practice in relation to mandatory vaccinations in healthcare settings. We provided some limited and general comments on this and a draft consultation document. (IT3/14 [INQ000235366] and IT3/15 [INQ000235367])

49.1.4. In November 2021, DHSC asked for our input to establish an agreed position on activities to be considered 'in' and 'out' of scope of the regulations when referring to 'provision of the regulated activity' in relation to vaccinations. They put forward various scenarios and identified whether they would fall in or out of scope. They requested input from us on 'the definition of a regulated activity and to the extent it encompasses the activities that facilitate the activity' and asked whether there were any other scenarios that needed exploring. We provided some very limited comments and suggested that clarification on some of the terms used might be needed. (IT3/16 [INQ000235592])

50. We have set out below our involvement with the Medical Risk Panel, which was convened by NHS England as part of the national response to the pandemic and the National Emergency Medicine Specialty Advisor Forum which was set up by CQC to understand the problems being faced by emergency departments during the pandemic.

Medical Risk Panel ("MRP")

51. The Covid-19: Out-of-Hospital Clinical Risk Panel (also referred to as the 'Medical Risk Panel') first met on 27 March 2020. The panel was convened by Professor Keith Willett, NHSE's Strategic Incident Director and Medical Director for Acute Care & Emergency Preparedness, working with the Academy of Medical Royal Colleges

('AoMRC'), as part of the ongoing national response to the pandemic. (IT3/17 [INQ000398539])

52. Its purpose was to provide advice to the National Medical Director on changes to the out-of-hospital phase of care that was introduced in response to the Covid-19 crisis. Membership of the panel comprised CQC's Chief Inspector of Hospitals Ted Baker (who chaired the panel); CQC's Chief Inspector of Primary Care, Rosie Benneyworth; Chair of the AoMRC Professor Carrie McEwan; President of the Royal College of Emergency Medicine, Dr Katherine Henderson; President of the Royal College of Physicians, Professor Andrew Goddard; Joint Honorary Secretary of the RCGP/NHSE Director for Armed Forces and Veteran Health, Dr Jonathan Leach. The Chair of the panel was able to invite additional attendees as they felt appropriate.

53. Initially the panel was set up to convene three times per week with the Chair reporting any recommendations from the panel to the National Medical Director after each meeting. The secretariat role of the MRP was fulfilled by the AoMRC. The minutes of the MRP meetings can be made available if required.

54. In order to summarise the matters on which we worked together with the bodies identified in paragraph 21 above we have identified, by way of example, a selection of six areas considered by the MRP which are relevant to the issues being investigated by the Inquiry in Module 3 and summarised the discussions that took place in those meetings.

55. Abbreviated Pathways for Ambulances

55.1. On 30 March 2020 a briefing paper (IT3/18 [INQ000398549]) was presented to the MRP by Anthony Marsh (Chief Executive of West Midlands Ambulance Service) indicating that without significant change to triage processes, demand during the pandemic could outstrip ambulance service capacity. It proposed revision of the existing Pandemic Protocol[5] (IT3/19

[5] This is part of the Advanced Medical Priority Dispatch System (AMPDS). A unified system used to dispatch appropriate aid to medical emergencies. It is a set of standardised protocols to triage

[INQ000398560]) by introducing an alternative triage process when the ambulance service was under significant pressure. The panel also discussed the process for standing up and standing down the new triage process.

56. Abbreviation of 111 and 999 pathways triage option

56.1. On 30 March 2022 a briefing paper (IT3/20 [INQ000398571]) was presented to the panel by Darren Worwood (Deputy Clinical Director, NHS Pathways). The panel was asked to consider changes to 111 and 999 services including: deployment of a 'triage cut-off' after Primary Care 6-hour responses, directing callers to self-care[6]; facilitation of alternative management for Category 3 or 4 ambulance outcomes[7]; deployment of Chest Pain pathway amendments; and other Covid-19 pathway enhancements.

57. Workload prioritisation in GP services

57.1. On 30 March 2020 a briefing was presented to the panel by Dr Jonathan Leach about a combined BMA/RCGP paper on workload prioritisation during Covid-19. This was guidance (IT3/21 [INQ000398582]) for GPs setting out areas of general practice work across three categories: work which doctors should aim to continue regardless of the scale of the outbreak; work which should continue if capacity allowed and if appropriate for the patient population; and work to be postponed but revisited once the outbreak ended. The Panel noted this guidance.

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patients via telephone. Protocol 36 was created to handle the influx of emergency calls during the H1N1 pandemic and in March 2020 the protocol was revised to assist with mitigating the Covid-19 pandemic

[6] A Pandemic triage cut-off facility was to support providers in dealing with significantly increased call volumes. I would allow triage to be curtailed – for the majority of symptom pathways the last deliverable disposition is 'speak to primary care service within 6 hours' after which patients were to be directed to self-care, signposted to other sources of information and given specific worsening instructions.

[7] This functionality was to allow enhanced clinical assessment of all Category 3 and 4 dispositions. As the proportion of Covid-19 calls and demand on emergency care increased, it was considered beneficial to activate automatic rerouting of Category 3 and 4 ambulance dispositions reached via the Covid pathway, to clinicians.

58. Guidance on Ambulance Service Conveyancing

58.1. On 1 April 2020 a briefing (IT3/18 [INQ000398549]) was presented to the panel by Professor Carrie McEwen (Chair of the AoMRC) on proposed changes to the 999 ambulance conveyancing protocols which set out the way in which patients should be conveyed to hospital during the pandemic. The protocols were in relation to all patients, not just those with confirmed or suspected Covid-19 and included guidance on actions to be taken when a cardiac arrest patient was to be conveyed.

59. Change to NHS 111 Telephone Breathlessness Assessment

59.1. On 3 April 2020 a briefing paper was presented to the panel by Professor Jonathan Benger (Acting Chief Medical Officer, NHS Digital) on the proposed breathlessness guidance to be used by 111 service clinicians when assessing patients with confirmed or suspected Covid-19. The Panel supported this new guidance and agreed it would be circulated following discussion with NICE. The MRP members agreed via correspondence in March 2021 that this guidance could be withdrawn as it was no longer required.

60. Infection Prevention and Control (IPC) and the risk of nosocomial infections within hospital settings

60.1. In the panel meeting on 17 April 2020 (IT3/24 [INQ000398615]) Dr Katherine Henderson (President of the Royal College of Emergency Medicine) raised concerns about IPC within hospitals and whether enough was being done to address the risk of nosocomial transmission of Covid-19. She indicated that there were concerns within the system about patients and staff contracting Covid-19 and coming to harm through this route of transmission. She suggested that guidance around IPC practices to prevent nosocomial spread was required. There was agreement from other attendees that this was an important issue about which concerns were being raised across the system. Professor Jonathan Benger (Acting Chief Medical Officer at NHS Digital) explained that this was top of the agenda at

NHSEI and that some of the ideas being explored by NHSEI on this topic included whether there was a need to test staff systematically within a few hospitals to provide a better understanding of the extent of the problem, understand how transmission was occurring and identify potential solutions. Professor Andrew Goddard (member of the panel) added that unless this risk was dealt with then it would prove difficult to reverse the reduction seen in the uptake of non Covid-19 care pathways. Professor Carrie MacEwan (member of the panel) raised concerns about observing poor IPC practice demonstrated by clinicians during TV appearances. She queried whether this was indicative of widespread poor IPC practice amongst clinical staff within the system and if so, what could be done to improve this. Ted Baker explained that DHSC had recently issued guidance around IPC within residential settings and care homes. Professor Jonathan Benger explained that some of the feedback about this guidance had been that whilst it was robust and accurate, there was concern that it might prove difficult to implement or enforce within the sector where IPC standards may not be up to the standard expected or seen within hospital settings. Rosie Benneyworth also raised concerns about some of the technical language used in the DHSC guidance and a need to consider its accessibility to staff within the sector. A representative from the NHSE Legal Team also highlighted that within both hospital and community settings there is also a need to consider a new cohort of staff (mainly volunteers) who were working to support the Covid-19 response but may have limited IPC training. Ted Baker explained that CQC has a regulatory role in terms of IPC and would therefore raise the concerns discussed in the meeting with NHSEI directly.

60.2. On 17 April 2020 Ted Baker emailed the National Medical Director, Professor Stephen Powis, outlining the concerns discussed by the Panel (IT3/22 [INQ000398593]; IT3/23 [INQ000398604]). Professor Powis replied the same day to confirm there was a working group looking at the issue, co-chaired by Sharon Peacock (PHE) and Ruth May (Chief Nursing Officer for England).

61. The Medical Risk Panel meetings continued until 20 May 2020, after which date the remaining scheduled meetings were cancelled and it was agreed between the panel that meetings would only be convened when there was something to be discussed.

National Emergency Medicine Specialty Advisor Forum

62. The National Emergency Medicine Specialty Advisor Forum ('the Emergency Medicine Forum') was set up in April 2020 by CQC's National Professional Advisor on Emergency Medicine. It brought together a group of emergency department leaders from across the country, including emergency medicine consultants, lead nurses and matrons, together with representatives from CQC including Ted Baker, Chief Inspector of Hospitals and Heidi Smoult, Deputy Chief Inspector of Hospitals. Its aim was to understand the problems of the current situation and come up with solutions to help emergency departments. It recognised the unprecedented situation of Covid-19 and focused on how to mitigate and manage the situation. It met approximately every 2-3 weeks throughout the relevant period.

63. During the relevant period there were discussions between the Forum members on the experiences and challenges facing emergency departments throughout England and some of those areas are set out below.

63.1. Fluctuations in Emergency Department presentations

63.1.1. Hospitals faced challenges in the numbers of patients presenting to emergency departments throughout the pandemic, but from the contributions of Forum members there were local and regional variations in those numbers with not all Trusts experiencing the same numbers of patients at the same time. High numbers presented issues around capacity in emergency departments and challenges in maintaining social distancing in crowded waiting rooms.

63.2. Flow

63.2.1. The Forum's members discussed concerns surrounding the flow of patients through the system. A regular theme throughout the meetings was the issue of exit blocks, i.e. moving patients from

emergency departments to further care, either inside or outside the hospital in question. Bed occupancy, delays in obtaining test results and problems in discharging patients to care homes were given as examples affecting the flow of patients within the system.

63.3. Delays in ambulance handovers

63.3.1. The Forum discussed the problems with ambulances becoming 'stacked' outside emergency departments, unable to discharge their patients. In some instances, it was reported that care or treatment in ambulances or hospital corridors was the only way of coping with the high volumes. For some trusts, the issue of ambulance queuing was reported to be due to strict restrictions on crowding in corridors. Ted Baker said that all Trust resources should be channeled in addressing ambulance delays and it was not acceptable to have those delays normalised as winter pressures (IT3/25 [INQ000398625]).

63.4. Accessing Primary medical services

63.4.1. A common theme discussed within the Forum, which related to the high numbers presenting in emergency departments, was patients presenting because they were unable to access primary care appointments. There were concerns that patients were being triaged by GPs or the 111 service and then referred to emergency departments for treatment, and that some patients were reported to have presented in emergency departments for a face-to-face appointment for a second opinion following a virtual appointment with their GP.

63.5. Staffing

63.5.1. The issues affecting emergency departments were exacerbated by the impact on staffing in those departments and within trusts in general. Forum members reported that staff sickness and requirements to self-isolate were causing difficulties and, after the initial peaks of the pandemic, that staff that had been re-allocated to emergency departments were returning to their own

specialties. As the pandemic wore on, the impact of working in emergency departments and dealing with challenging circumstances had an effect on staff morale and the retention of health workers.

63.6. Patient FIRST

63.6.1. CQC brought together a team of senior emergency department clinicians to develop 'Patient FIRST' (IT3/26 [INQ000398635]), a support tool that included practical solutions that all emergency departments could consider. Implementing those solutions supported good, efficient and safe patient care and included guidance for senior leaders at trust and system level. The areas that were looked at were: Flow; Infection control, including social distancing; Reduced patients in emergency departments; Staffing; and Treatment in emergency departments. Patient First was approved in September 2020 and we began to hold calls with trust executive teams using the Transitional Monitoring Approach in October 2020 to facilitate its implementation.

The National Joint Strategic Oversight Group

64. The National Joint Strategic Oversight Group (NJSOG) was established prior to the pandemic and is a forum of healthcare regulators and related Arms-length bodies (ALBs) which meets bi-monthly in the months of January, March, May, July, September and November. The original remit of the group was to: a) advise on national policy and intensive support for challenged systems, including the approach to special measures for quality and financial reasons; b) review and recommend intensive support for challenged providers and/or systems escalated by Regional JSOGs, taking into account the context of the local health system and including support from JSOG partners; c) share information about emerging concerns and risks across providers and systems; and d) exchange learning, intelligence and information to aid future improvement.

65. During the relevant period the members of the group were: NHSEI; the GMC; the NMC; HEE and CQC. From March 2020 until April 2022, Ted Baker co-chaired the meetings along with the NHSEI Medical Director.

66. At the meeting which took place on 25 March 2020, it was proposed that that there should be a move from bi-monthly meetings to shorter, virtual, monthly meetings, with the first monthly meeting posited to take place on 21 April 2020. During this meeting, the NJSOG discussed its role in supporting the response to the COVID-19 pandemic and where it could have the most impact. It was considered that this national group would add most value in acting as a reference group to the work that, from a national focus, would consider the impact and risk of potential harm on patients with non-Covid-19 conditions.

67. In light of the above, on 17 April 2020, the NJSOG Terms of Reference (ToR) were revised (IT3/27 [INQ000398646]) to include the following: -

    67.1. Act as regulator reference group to the NHSEI work on maintaining critical services, particularly concerning the unforeseen consequences of the current Covid-19 focus on care and outcomes for non-COVID patients; and

    67.2. Share concerns about challenged trusts; resilience in managing Covid-19 or ability of challenged trusts to recover.

68. It was also recorded in the revised ToR that meetings would take place on a monthly basis, although, subsequently on 22 July 2020 the meetings reverted back to bi-monthly. The frequency of the meetings, along with the ToR, was kept under review during the relevant period.

69. The "purpose" of the NJSOG was further revised in January 2021 to reflect that: "During the period affected by the Covid-19 pandemic, consider and advise on concerns about the resilience of challenged organisations and systems in managing and recovering from Covid-19."

70. In March 2021, the NJSOG aligned with the Executive Quality Group (EQG), which was set up in June 2019 to provide assurance to the NHSEI Quality Committee. The

main purpose of the alignment between the two forums was for the sharing of information, with the two groups coming together once a year to review strategic issues. The Terms of Reference were revised once more to reflect this.

71. The Terms of Reference were revised on several further occasions during the relevant period, but these changes were not Covid-related.

72. Some of the main Covid-19 related topics that came before the group for consideration during the relevant period included:

72.1. Emergency pathway work: During the relevant period, CQC was collaborating with a group of emergency department consultants on work we were undertaking to support improvement in patient experience and the quality of care received across urgent and emergency care. Through the course of this project, it was observed that emergency department attendances had significantly reduced during the first phase of the pandemic. We provided regular progress updates to the NJSOG on this work. Subsequent NJSOG discussions focused on the changing pathways and what proactive work could be done, as a group, to take positive learning from Covid-19 into future models.

72.2. Infection Prevention Control: In June 2020, NHSEI Covid-19 National Incident Response Board (NIRB) approved a proposal to develop an Infection Prevention Control (IPC) Safety Support Programme to support those trusts facing the biggest infection and prevention control challenges and address issues in variations in IPC measures. Regular updates were provided to the NJSOG on this piece of work.

72.3. Staffing levels and deployment: On 25 March 2020 the NJSOG heard updates from the General Medical Council around preparation that was being put in place to enable doctors to return to the register, and from the NMC who informed the group that an emergency register had been put in place. HEE advised that it was supporting students and trainees across regions with a focus on making trainee redeployment safe.

72.4. PPE: Members of the NJSOG would provide regular updates as to PPE supply chain and other issues. The NHSEI informed the group about the

PPE good practice guidance that they were developing with Health Protection Scotland and PHE.

72.5. Care provided to Covid and non-Covid patients: As well as hearing updates from Regional Leads on the issues surrounding the care provided to Covid patients, which is set out in more detail below, the NJSOG membership also heard regular updates on non-Covid care, such as the challenges faced by maternity services. Updates on this were provided by the Maternity Support Programme (MSSP) at each meeting.

72.6. Nightingale hospitals: In March 2020, discussions took place about supporting the setting up of the infrastructure of the Nightingale hospital (ExCeL) and the development of similar regional centres.

72.7. Non-Covid 19 Mortality reviews: On 27 May 2020, Dr Jean MacLeod, Intensive Support Mortality Clinical Lead, presented a programme of work being developed to focus on: understanding the change in practices in preparation for and response to the pandemic; and capturing and learning from changes in practices and processes for those inpatients not admitted with Covid-19. The NJSOG membership was supportive of the review and there was discussion about how the outputs from the review could be used to influence planning for a potential second wave, future planning and winter flu.

72.8. Lessons Learned: On 29 October 2020 Health Education England presented a paper on the discussion and actions of the education workshop about their Learning and Experience from Covid-19. The workshop covered 3 areas: Reforming Education; Quality of Education and Training during Covid 19; and Digitally and Technology Enhanced training during Covid.

72.9. Regional Updates: At each meeting, the NJSOG would also hear from Regional Leads who provided updates on the Trusts where concerns/issues had been reported. Throughout the relevant period, such updates were mainly Covid-19 related and covered such issues as: the spread of the virus across certain areas; nosocomial transmission of Covid; reduced bed capacity; Covid-19 deaths and the impact of Covid on already challenged systems. Discussions would then take place around whether any further action was required.

British Medical Association (BMA)

73. From 8 April 2020 to 1 July 2020 we attended weekly liaison meetings with the BMA and the RCGP. The purpose of these meetings was to keep the BMA and the RCGP updated on our current response to Covid-19 and to source feedback from the primary care sector on impact; their needs for information; and views on our response, which we could then feed into our organisation-wide engagement planning. These meetings took place virtually, were attended by colleagues from each organisation and were usually led by our Chief Inspector of Primary Medical Services and Integrated Care, Rosie Benneyworth.

74. On 1 July 2020, the meetings moved to biweekly until March 2021. Thereafter, they took place monthly, until January 2022. The meetings covered a wide range of topics around general practice, most of which do not fall within the scope of Module 3. Those issues that were discussed and which do fall within the scope of Module 3 included, but are not limited to, the following:

    74.1. The Covid-19 risk assessment tool, which had been developed by the British Association of Physicians of Indian Origin (BAPIO) at the request of Mark Drakeford, First Minister of Wales, to calculate an individual's risk of contracting Covid-19 and to find ways of mitigating those risks. The tool was available to NHS Wales and social care staff, and the Welsh public, as well as Westminster and Parliamentary staff in England (IT3/28 [INQ000398656]);

    74.2. the use of shielding and face masks in primary care;

    74.3. CQC Provider Collaboration Reviews, looking at how providers were working collaboratively in Integrated Care Systems or Sustainability and Transformation Partnerships, in response to COVID-19 (IT3/29 [INQ000398667]);

    74.4. supply chain issues which impacted on laboratory testing (IT3/30 [INQ000398678]);

    74.5. CQC's Covid insight report focusing on IPC (IT3/31 [INQ000398684]);

    74.6. updates on our section 48 DNACPR thematic work (IT3/30 [INQ000398678]; and

74.7. discussions around the prospect of Covid-19 vaccinations for staff i.e. for those having face-to-face contact with patients (IT3/32 [INQ000398685]).

75. It does not appear as though all of the meetings were minuted but we would be able to provide the Inquiry with any minutes we do hold, if required.

C. CQC's Registration and Notification Regime

Registration

76. Any person (individual, partnership or organisation) who carries out a regulated activity in England must be registered with CQC otherwise they are committing an offence. To be registered, an application must be made to CQC providing details about the applicant, the regulated activities applied for, and the places at which, or from which, they will be carried out.

77. Providers can apply to us to be registered to carry out one or more regulated activities. As an example, acute NHS Foundation Trusts would usually be registered to carry on regulated activities such as treatment for disease, disorder or injury (TDDI), surgical procedures, diagnostic and screening procedures, maternity and midwifery services, and termination of pregnancies depending on the trust. Similarly, GP providers are usually registered to carry on the regulated activities of TDDI, surgical procedures, and diagnostic and screening procedures, often along with others such as maternity and midwifery services, and family planning services, depending on the practice. The Registration Programme - Product Cover Sheet (IT3/33 [INQ000235491]) provides guidance to providers around how regulated activities and services may link together, but it is for the provider to determine which regulated activities it carries on and therefore which activities it requires registration for. When CQC decides whether to grant or refuse an application for registration of a service provider we must apply the test set out in section 12 of the 2008 Act. This provides that we must be satisfied that the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations 2009, and any other enactment which appears to us to be relevant, are being and will continue to be complied with in

relation to the regulated activity for the application to be granted, otherwise we must refuse it.

78. We have the power to grant an application subject to conditions and the power to impose, vary or remove conditions on the registration. In some cases, registration of a provider is subject to a registered manager condition (section 13 HSCA 2008). The Care Quality Commission (Registration) Regulations 2009 set out the circumstances in which a service must have a registered manager as a condition of its registration.

79. These are:

79.1. Any service provider that is an organisation, whether corporate (for example, a company) or unincorporated (for example, a partnership or a charity), must have a registered manager for every regulated activity that it carries on, unless it is a health service body. Health service bodies such as English NHS trusts do not need to have a registered manager unless we impose a condition on their registration that requires one. Others, including independent organisations that work under contract to the NHS, must always have a registered manager.

79.2. If the service provider is an individual, they do not need to have a registered manager unless they are not a fit person[8] to manage the regulated activity, or they do not intend to be in day-to-day charge of how the regulated activity is provided.

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[8] Regulation 7 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:
The intention of this regulation is to ensure that people who use services have their needs met because the regulated activity is managed by an appropriate person. This is because providers who comply with the regulations will have a registered manager who:
Is of good character.
Is able to properly perform tasks that are intrinsic to their role.
Has the necessary qualifications, competence, skills and experience to manage the regulated activity.
Has supplied them with documents that confirm their suitability.
CQC cannot prosecute for a breach of this regulation or any of its parts but we can take regulatory action.
CQC must refuse registration if providers cannot satisfy us that they can and will continue to comply with this regulation.

80. When we register NHS trusts that provide the regulated activity of accommodation for persons who require nursing or personal care in a care home, we will use our discretion and may impose a condition to have a registered manager. This is because we consider the role of a manager who is in day-to-day charge of these services to be fundamental to providing positive outcomes for people who use the service.

81. In deciding whether to grant or refuse an application for a registered manager, CQC must apply the test in section 15 of the 2008 Act, which is the same as that set out in section 12. We also have the power to grant a manager's application for registration subject to conditions and the power to impose, vary or remove conditions on the registration.

82. At the point of registration we are required to issue a certificate of registration. This sets out the regulated activities that the provider is permitted to carry on, and the locations at which the provider may carry on the regulated activities in a locations condition which forms part of the conditions of registration. There are other conditions that may be placed on the registration of providers, some routine and some not, depending on the type of provider and the type of service being operated.

83. Registered persons, that is providers or their associated registered managers, may apply to us to vary or remove any conditions on their registration (other than a Registered Manager condition); or to cancel their registration; or for the cancellation of, or the variation of, the period of any suspension of their registration as set out in section 19 of the 2008 Act. However, there are several exceptions to when this is permissible.

84. As part of CQC's contingency planning at the start of the pandemic, we acknowledged the need to ensure that our registration operations were aligned with the evolving situation. To help us respond to the spread of Covid-19, we therefore adapted our methodology and approach to registration to apply a specific response, where required, to Covid-19 related applications and to ensure the continued delivery of registration activities.

85. In March 2020 we began drafting the "Covid-19 Registration Principles and Decision-Making Tool" to be used to ensure that we had a framework through which to consistently assess risk, identify escalation measures and the actions needed in response to registration issues in the context of the changing Covid-19 situation. The tool sought to do this by:

    85.1. setting out how we risk assess an application if we need to minimise the completion of site visits; and

    85.2. setting out how an application for a Covid-19 related service should be assessed; and

    85.3. setting out what temporary Covid-19 registration arrangements may apply to any both Covid-19 and routine registration applications and how these would be recorded and managed.

86. Initially specific queries regarding registration from providers were dealt with by the Query Handling Group. However, in March 2020 we formed a dedicated Registration Covid-19 Advisory Panel to provide advice to colleagues regarding questions from providers about supporting the national response to Covid-19 and any implications on their registration, as well as ensuring consistent decision making on applications. The panel's first meeting was on 20 March 2020 and it continued to meet on Monday's and Friday's and ad-hoc as necessary during the early stages of the pandemic. The panel's Terms of Reference; the "Covid-19 Registration Principles and Decision-Making Tool" and the Registration Covid-19 Panel Supporting Guidance are attached as (IT3/34 [INQ000398702]).

Notifications

87. Registered persons are required to submit notifications to us about certain matters (IT3/35 [INQ000398713]; IT3/36 [INQ000398724]). There are a number of circumstances set out in the Care Quality Commission (Registration) Regulations 2009 which require a 'statutory notification' to be submitted to us. We hold a range of forms to enable providers to submit statutory notifications to us depending on the event. The framework regarding notifications is set out in regulations 12, 14-18, and 20-22 of the Care Quality Commission (Registration) Regulations 2009.

88. Regulation 18 sets out a range of events or occurrences which providers must notify us of so that, where needed, we can take follow-up actions. Registered persons must send these notifications directly to us unless the provider is a health service body and it has followed the below process. A health service body is defined by the Care Quality Commission (Registration) Regulations 2009 as an English NHS body or NHS Blood and Transplant body. An English NHS body is further defined in Section 97 of the Health and Social Care Act 2008 as:

"*a National Health Service trust all or most of whose hospitals, establishments and facilities are situated in England, NHS England, an integrated care board, an NHS foundation trust or a Special Health Authority performing functions only or mainly in respect of England*".

89. Registered persons must notify us of incidents that affect the health, safety and welfare of people who use services. The list of notifiable incidents includes: certain types of injury; abuse or allegations of abuse; incidents involving the police (not applicable to an English NHS body); applications regarding deprivation of liberty; and events which could prevent the provider's ability to continue to carry on the Regulated Activity safely (IT3/37 [INQ000398745]). Some examples of events which have necessitated a regulation 18 notification include: staff shortages; utility access; damage to the premises; and malfunction or failure of safety devices such as fire alarms. In addition, regulation 18 also requires providers of psychiatric units whose service is normally intended for persons over the age of 18 years to notify the CQC about the placement of a child or young person in that service where the placement lasts for a continuous period of longer than 48 hours.

90. Regulation 12 requires that a registered person must provide a Statement of Purpose containing specific information about the service, and the details of any revisions to this within 28 days of the revision. The information required in the Statement of Purpose includes details of the locations at which the services are provided for the purposes of carrying out the Regulated Activity. As mentioned above, the approved location or locations are then listed in the location conditions of the provider's registration certificate. Occasionally, a provider will carry out a Regulated Activity at a satellite site of a location listed in their location condition. Details of all locations at

which the services provided are carried out, including any satellite sites, should be listed in the provider's Statement of Purpose.

91. We must also be notified in relation to: the absence of the registered person, changes to details of the registered person, and what suitable arrangements are put in place for this (Regulations 14 and 15); where there is a death of a service user (Regulation 16); where there is a death or unauthorised absence of a person detained or liable to be detained under the Mental Health Act 1983 (Regulation 17); any circumstances relating to the regulated activity of termination of pregnancies (Regulation 20); where there is a death of the service provider (Regulation 21); and where a liquidator or similar person is appointed in relation to the carrying on of a regulated activity (Regulation 22).

92. A failure to comply with the requirements of regulations 12 and 14-20 is an offence.

National Reporting and Learning System – NRLS

93. The Care Quality Commission (Registration) Regulations 2009 state that in some circumstances, where the provider is a health service body, notifications about the death of a service user and other incidents impacting on the health or safe care and treatment of a service user do not need to be submitted to the CQC. For this to be the case, the provider must have already submitted the information to the NHS Commissioning Board (now NHS England). In practice this would be through the National Reporting and Learning System (NRLS).

94. This would include those notifications relating to: deaths of people using the service (Regulation 16); allegations of abuse (Regulation 18(2)(e)); events that stop or may stop the service from running safely and properly (Regulation 18(2)(g)); or serious injuries of people using the activity (Regulation 18(2)(a) and (b)). Submitting these notifications is mandatory.

95. The Care Quality Commission (Registration) Regulations 2009 allow for providers of NHS Primary Medical Services such as GPs to make notifications via NRLS. However, in reality, very few GP practices have access to this method of notification

as the NRLS system was originally designed for use primarily within secondary care, where local risk management system (LRMS) software is common. GPs are required to notify CQC using our forms, similar to other non-NHS providers, although they may also use NRLS (in addition to the forms) on a voluntary basis.

96. The notifications to NHSEI done via NRLS are shared with us under a data sharing agreement and are incorporated into our intelligence and monitoring (IT3/38 [INQ000398758]). NRLS is currently in the process of being replaced by the Learn from Patient Safety Events (LFPSE) service (IT3/39 [INQ000398767]). Our Data Sharing Agreement continues to apply to the LFPSE service.

Changes to "Regulated Activity"

97. The definition of regulated activity as set out in Schedule 1 of the 2014 Regulations did not change during the relevant period. A change was made to the specified "general exemptions" in Schedule 2 to exempt Covid-19 testing from being a regulated activity.

98. Schedule 2 was amended by the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020 to include paragraph 12 as a general exception as follows:

> *12. Any activity which—*
> *(a) is carried on for the purpose of testing for the presence of severe acute respiratory syndrome coronavirus ("SARS-CoV-2") in an individual, or for the presence of antibodies to SARS-CoV-2, or*
> *(b) is carried on for the purpose of processing, analysing or reporting the results of a test for the presence of SARS-CoV-2 in an individual, or for the presence of antibodies to SARS-CoV-2.*

99. In September 2020 CQC colleagues had discussions internally, and with relevant stakeholders, about the best way to take forward DHSC's proposed Covid-19 testing programme as part of their 'Project Moonshot' (the UK Government programme to introduce rapid mass testing for Covid-19 in England).

100. Initial discussions canvassed the possibility of CQC having a prominent accreditation and assurance role for registration and inspection of non-NHS testing providers, for example by registering all emerging providers, and once registered inspecting, and potentially rating, services so that the Government could issue a list of assured providers. We shared our view that CQC's regulatory role would not fit the accreditation model being proposed. It was felt that this could be an obstacle in terms of providing timely assurance considering the number of providers who would be involved. It was agreed that the UK Accreditation Service (UKAS) was a better organisation for undertaking provider accreditation.

101. We also flagged, with reference to testing falling within the scope of our regulations, that taking an exemption approach to the CQC regulated activities had precedent under similar Covid-19 emergency regulations from earlier in the year (Safeguarding Vulnerable Groups Act 2006 (Regulated Activities) (Coronavirus) Order 2020): This order, relating to Article 2, provided for the activity of 'removal of saliva or mucus from the mouth or nose of an individual where that is done for the purpose of testing an individual for coronavirus' to not be treated as a regulated activity within the meaning of the Act).

102. We met with DHSC, KPMG, the MHRA, and UKAS on 18 and 22 September 2020 and agreed on the way forward.

103. The discussion with DHSC regarding amendments to legislation to exempt Covid-19 tests themselves from being a regulated activity and thereby removing the requirement for registration continued into October 2020. Our legal and registration colleagues attended several meetings with DHSC and provided some views. (IT3/40 [INQ000235380])

104. On 15 December 2020 the law changed and testing was exempted as a regulated activity under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (IT3/41 [INQ000398788]). This meant that any testing activity in relation to Covid-19 was taken out of scope of CQC registration. Regulation 6 of The Health

Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 instead required all private coronavirus test providers to become accredited by UKAS.

Changes to Notification Requirements

105. Providers are required by law to notify us of the death of a person accessing their service under Regulation 16 of the Care Quality Commission (Registration) Regulations 2009. We ask for a range of demographic information about the person who died, using a structured reporting form (SN16).

106. We did not waive any notification requirements during the relevant period. In Spring 2020 we amended the scope of the information collected as part of Regulation 16 notifications to collect additional information regarding the relevance of Covid-19 to the death.

107. When receiving death notifications during February and March 2020, colleagues in the NCSC reviewed free-text information contained within the forms to identify whether the death involved Covid-19 or not. However, testing was not yet widely available, making deaths attributed to Covid-19 hard to confirm.

108. Our SN16 notification form was updated on 9 April 2020, and from 10 April 2020 providers were informed that when making a notification they should use the revised form to notify us if the death of an individual under their care was as a result of confirmed or suspected Covid-19 infection. This information was then recorded within our Customer Relationship Manager System (CRM) to enable us to analyse it. At this time, we also used a new specified field in CRM to record place of death information for analysis purposes. The new information regarding Covid-19 deaths was included in our daily Sitrep Reports to DHSC from 27 April 2020 (IT3/42 [INQ000235392] and IT3/43 [INQ000235393]).

D. Suspension of routine inspection activity

CQC's pre-pandemic inspection regime

109. At the start of the Covid-19 pandemic, our operational teams were organised into three overarching directorates covering the specific service types as set out below. Our pre-pandemic inspection model can broadly be described across three main phases (set out below from paragraph 117 to 128, and these were largely similar across all the sectors and service types regulated by us. Detailed guidance on the inspection model as it applies to each service type can be found in the provider guidance provided alongside this summary (IT3/44 [INQ000398804]; IT3/45 [INQ000398805]; IT3/46 [INQ000398806]; IT3/47 [INQ000398807]; IT3/48 [INQ000398808]; IT3/49 [INQ000398809]; IT3/50 [INQ000398810]; IT3/51 [INQ000398811]).

Adult Social Care

110. The Adult Social Care Directorate covered the following services:
    - 110.1. care homes;
    - 110.2. home care;
    - 110.3. specialist colleges;
    - 110.4. extra care;
    - 110.5. personal care provided in supported living settings; and
    - 110.6. Shared Lives schemes (which provide for an approved carer to be matched with someone with learning disabilities, mental health problems or other needs that make it harder for them to live on their own).

111. As Adult Social Care is due to be examined by the Inquiry in a separate module, the remainder of this response will focus on health services.

Primary Medical Services

112. The Primary Medical Services Directorate covered the following services:
    - 112.1. GPs (NHS GP practices);
    - 112.2. independent doctors and clinics, including private GP services and clinics providing primary care;

112.3. dentists;

112.4. online primary care;

112.5. urgent care;

112.6. Sexual Assault Referral Centres;

112.7. Healthcare in secure settings (such as prisons, young offenders institutions, immigration removal centers, police custody facilities) in collaboration with HM Inspectorate of Prisons (HMIP) and other inspectorates;

112.8. Defense (Military) Medical services; and

112.9. Children's services.

Hospitals

113. The Hospitals Directorate covered the following services:

113.1. NHS Trusts, including NHS acute, ambulance, community health, mental health and substance misuse services; and

113.2. independent healthcare, including independent hospitals, ambulances, community health, hospices, mental health and substance misuse services.

114. The Health Assessment Framework, which sets out the Five Key Questions and Key Lines of Enquiry (KLOEs) and related prompts for inspectors of health services, applies to all health services. The Five Key Questions ask whether services are safe, effective, and caring; whether they respond to people's need; and whether they are Well-Led (IT3/52 [INQ000398812]).

115. Each of the Five Key Questions is broken down into a further subset of questions, called the 'Key Lines of Enquiry' (IT3/53 [INQ000398813]). When CQC carries out inspections, we use KLOEs to help us decide what we need to focus on. For example, the inspection team might look at how risks are identified and managed to help them understand whether a service is safe. We use different KLOEs in different sectors.

116. Using the KLOEs helps us make sure we are consistent in what we look at under each of the Five Key Questions and that we focus on the areas that matter most.

The three broad phases of the inspection approach are: monitoring and information sharing; inspection; and after inspection. Each is outlined below.

Pre-pandemic Inspections: (1) Monitoring and Information Sharing

117. This involves the review of information we have on a service. The exact information reviewed varies depending on service type. "CQC Insight" is used to monitor quality of care and we have specific insight tools for the different health and care sectors which aim to: incorporate data indicators that align to our key lines of enquiry for the relevant sector; bring together information from people who use services, knowledge from our inspectors and data from our partners; indicate where the risk to the quality of care provided is greatest; monitor change over time for each of the measures; and point to services where the quality may be improving. In those services where there is less nationally available data (for example the Independent Healthcare sector), we relied on Provider Information Requests to gather supplementary quantitative and qualitative data directly from the provider to inform the monitoring reports.

118. Through this phase, we also gathered information directly from a service via statutory notifications and relationship management meetings, as well as information from national, regional and local stakeholders.

Pre-pandemic Inspections: (2) Inspection

119. Frequency principles, based on a service's existing rating, were the primary trigger for inspection, although information of concern received through the monitoring and information sharing phase could trigger a smaller focused inspection to examine specific KLOEs.

120. Some inspections were either unannounced or had a short notice period (normally two weeks). In other instances inspections were announced, for example an inspection of the Well-Led key question across an NHS Trust, which necessitates interviews and discussions with all senior board members and therefore requires a degree of coordination.

121. The size of an inspection team varied according to the provider and service type, but broadly was made up of our inspectors supported by Specialist Professional Advisors and Experts by Experience. The former were akin to peer reviewers, who provided specialist advice to support our regulatory activity in an ad hoc role undertaken alongside their existing employment. The latter were patients, people who use services and carers who have experience of a service.

Pre-pandemic Inspections: (3) After Inspection

122. Following an inspection, and after a period of quality assurance and factual accuracy review with the provider, a written report and ratings were published on our website. The characteristics for ratings are included in the Health Assessment Framework and the provider guidance for each sector details the process for aggregating ratings. It was, and remains, a legal requirement for providers to display their ratings, although there are a small number of services that we did not have the duty to rate (for example dentists).

123. If the inspection identified regulatory breaches, further regulatory action was taken following the inspection. A range of powers, from requiring that further information be provided to cancelling a provider's registration, were (and remain) available to us and these are set out in the enforcement policy (IT3/54 [INQ000398814]).

Pre-pandemic Inspections: Monitoring the Mental Health Act

124. As set out in paragraph 7 above, CQC has certain statutory duties in relation to the monitoring of mental health services. We have a duty, under the MHA, to monitor how services exercise their powers and discharge their duties when patients are either detained in hospital, subject to community treatment orders or subject to guardianship orders. We also have duties to review and powers to investigate MHA complaints raised by or on behalf of individuals, and to provide a Second Opinion Appointed Doctor Service (SOAD) to review or certify treatment.

125. MHA monitoring visits focus on monitoring the use of the formal powers of the MHA, the exercise of duties under the MHA and the experience of detained patients. Standard ward visits focused on speaking with detained patients, seeing the

environment in which they were detained and reviewing records relating to detention and treatment.

126. Our MHA Reviewers visit all places where patients are detained under the Act and meet with them in private. Where requested, arrangements can also be made to meet patients who are on a community treatment order. We also look at the day-to-day operation of powers and duties under the MHA. If we identify concerns this can trigger further monitoring or inspection activity. The frequency of visits varies, up to a maximum of two years.

127. Standard MHA monitoring visits were carried out to individual wards that treated detained patients on a regular cycle of 18 or 24 months, the frequency was determined by the service type. A smaller number of focused or thematic MHA monitoring visits were carried out in response to risks or concerns. An MHA monitoring visit report was written following each monitoring visit and was sent directly to the service provider of the ward. The visit report included a summary of our findings and raised actions arising from the visit. Providers were required to provide an action statement in response to our reports advising of the action they would take/had taken in response to the issues raised.

128. MHA reviewers carried out the MHA monitoring visits and were integrated into our wider mental health inspection teams, reporting directly to mental health inspection managers. MHA reviewers shared intelligence and findings with the mental health inspectors in their teams.

Changes to Inspections

Pausing routine inspections – CQC's rationale

129. During the pandemic we recognised that we had an important role to play in offering assurance to the public (and Government) around the safety and quality of services, but that doing so wholly through on-site inspections was practically difficult during lockdowns. At the start of the pandemic, we moved to an increasingly risk-based approach to our work, as set out below.

130. Before the pandemic we had already considered pausing some routine inspection activity, albeit only for short periods (IT3/55 [INQ000398815]). In January 2018 we paused routine inspections of NHS Acute services, GP practices, and Urgent Care services in response to increased pressure on the health and care system driven in part by a rise in respiratory illness and flu and conducted risk based inspections.

131. During the early stages of the pandemic, prior to suspending routine inspections, we cancelled a number of routine inspections and directed our activity at areas which we considered to have the most risk. We considered that there were some environments (such as social care settings, domiciliary care, closed mental health wards, and geriatric wards in hospitals) which presented inherently more risk in terms of opportunities for people to suffer unseen harm and that they would therefore need to be monitored carefully (IT3/430 [INQ000466432]). The cancellations were based on daily assessments of risk within the relevant sector and were personally overseen by the three Chief Inspectors. This was communicated by me in a letter to the Rt Hon Jeremy Hunt MP, Chair of the Health and Social Care Select Committee on 13 March 2020 (IT3/56 [INQ000398816]). We were also actively working to develop an interim targeted methodology for inspections, with internal workshops held on 9 and 10 March 2020 attended by over seventy colleagues from across all directorates at CQC looking at how to ensure we could continue to deliver our purpose during the pandemic.

132. On 13 March 2020 we took the decision, in consultation with relevant stakeholders and with the approval of the then Secretary of State for Health and Social Care as set out below, to move from conducting routine inspections to focusing on more responsive and targeted ways of supporting providers to keep people safe. This decision took effect from Monday 16 March 2020.

133. The decision to initially redirect our inspection activity, and then to move away from conducting routine inspections was considered necessary on the basis of our continuing assessment of three key operational principles. Firstly, that our focus would be on ensuring the public received safe care by responding where we believed risk was highest and where we could make a difference. Secondly, to support

providers at a challenging time by reducing what we asked of them wherever we could without compromising people's safety, and by ensuring that we were not contributing to the risk of spreading the infection. And thirdly, to prioritise the health, safety, and wellbeing of our staff and reduce the risk they were exposed to [IT3/56 INQ000398816].

134. Our intent was always to balance the value to be gained from a full physical inspection with the risk posed by inspectors moving between services, alongside the recognition that every provider was operating an 'exceptional' service. Whilst information on the exact method of spread of the virus and the exact role that asymptomatic spread played was unclear at the start of the pandemic, we tried to avoid placing the public at risk by asking inspectors to physically move regularly between services.

135. The effect of the decision to pause routine inspections was that all routine inspections were stopped, with the intention that they would not return in their then form during the peak of the pandemic. In so doing we aimed to support providers to keep people safe, whilst continuing to provide Government, decision-makers, and local and national partners with an accurate picture of pressures being faced on the ground to inform national response and planning.

136. Whilst we did continue to inspect providers as part of this risk-based approach, we rapidly developed new assurance approaches which deliberately limited on-site activity. These approaches were, in the main, not designed to change the rating of the provider, but did examine specific aspects of the safety of services. These revised approaches are described in greater detail later in this statement.

137. We took a flexible and proportionate approach to deciding which inspections would take place. It was important for us to continue to regulate, and where appropriate inspect, to provide assurance to the public and to Government, as well as continuing to be a route for intelligence from the sector into Government.

138. Our National Customer Service Centre (NCSC) remained open throughout the relevant period. The NCSC supported both providers and the public in answering questions and recording concerns. During the pandemic the number of concerns raised by the public increased by approximately 50% per annum, with comparable increases in reports from members of staff working for providers. In addition, we upgraded our digital contact channels to make them easier to use.

139. Taken together, the information from the public and members of staff gave us a picture of concerns as they arose, which in turn drove our risk-based approach to inspection. We were then able to provide an appropriate regulatory response, up to and including an on-site inspection. About half of our continued inspection activity during the pandemic was driven directly by information from the public or those who worked in services.

140. We were also able to identify and work with Government on emerging concerns. Examples included inappropriate use of Do Not Attempt Cardiopulmonary Resuscitation orders, deployment of Covid-19 positive staff and the challenges of visiting care home residents and patients during a pandemic.

141. Our overall aim was to contribute to sharing information in the exceptional circumstances the nation found itself in, rather than to continue to try and carry out our work using our traditional methods and approaches. Following the pandemic, we did not return to a programme of routine frequency-based inspections. Our post-pandemic new regulatory approach is set out in detail later on in this statement.

External input into the decision to pause routine inspections

142. Throughout the early pandemic we continued to engage with our key stakeholders, including the DHSC, NHSE, the Royal Colleges, Ofsted and HM Inspectorate of Prisons, on how we could best adapt our approach to inspections to meet the needs of the rapidly changing situation IT3/57 [INQ000398817]; IT3/58 [INQ000398818]; IT3/60 [INQ000398820]; IT3/59 [INQ000398819]; IT3/61 [INQ000398821]; IT3/62 [INQ000398822]; IT3/63 [INQ000398823]; IT3/64 [INQ000398824]; IT3/65 [INQ000398825]; IT3/66 [INQ000398826]; IT3/67 [INQ000398827]; IT3/68

[INQ000398828]; IT3/69 [INQ000398829]; IT3/70 [INQ000398830]; IT3/71 [INQ000398831]).

143. Whilst we engaged with a number of stakeholders around our approach to inspections, the decision to pause routine inspections was taken by CQC's Gold Command group on the basis of our assessment of how to best respond to the pandemic's impact on our inspection programme and broader regulatory approach. The board was notified of the decision to pause routine inspections on 16 March 2020 (IT3/72 [INQ000398832). I also notified all staff and colleagues of the decision on 16 March 2020 (IT3/73 [INQ000398833]).

144. In terms of direct engagement with Government or any non-Governmental bodies on the decision to suspend or adapt our routine inspection activity, this was predominantly with DHSC. As our sponsor department they were kept informed of any proposed changes to our approach to inspections and regulation, and ultimately the Secretary of State approved the decision to suspend routine inspection activity as referenced above and explained below.

145. On 27 February 2020 Lee McDonough (Director General, initially leading the Acute Care and Workforce team before then becoming Director General for the NHS Policy and Performance team) at DHSC, was able to confirm to me directly that there wasn't an intention to use emergency legislation to direct us to stop inspections, as we were already not carrying out routine inspections at locations dealing with Covid-19 outbreaks.

146. On 3 March 2020 we met with DHSC colleagues on a number of points (IT3/74 [INQ000398834]). We updated them on our revised regulatory response, including moving towards a risk-based approach, and there was agreement in principle for us to suspend inspections or undertake them differently during DHSC's 'Reasonable Worst Case Scenario' period. We also confirmed to DHSC that we had developed a decision making framework for use by our inspection teams to be followed alongside national guidance (IT3/75 [INQ000466472]). Similarly between 4 and 6 March 2020 we engaged with DHSC to confirm the governance processes by which a decision

to suspend routine inspection activity would be formally agreed with the Government (IT3/76 [INQ000398835]).

147. On 9 March 2020 we met with the then Minister of State for Care Helen Whatley MP to provide an update on our approach. She enquired about the impact of the pandemic on our inspection programme and we confirmed our view that continuing with the targeted inspection programme was important for providing assurance both to the public and to DHSC. We also highlighted that we were already in the process of developing a more targeted and intelligence-led inspection programme.

148. On 11 March 2020 we issued a response to clarify comments made by then Chief Executive of NHSE, Simon Stevens, regarding cancellation of our NHS inspections and explaining our position (IT3/77 [INQ000398836]). On 12 March 2020 we responded to a request received from DHSC for an urgent briefing on our approach during Covid-19, as well as providing a letter to the then Secretary of State for Health and Social Care (IT3/78 [INQ000398837]; IT3/79 [INQ000398838]). In these we set out our risk-based approach. We noted that the developing targeted inspection methodology (which would later become the Emergency Support Framework) would enable us to provide assurance during the pandemic whilst minimising any burden on providers. We also noted that we did not expect to be taking significant enforcement action during the pandemic as, in the main, it would not pass the public interest test.

149. We received feedback from other stakeholders, including the Royal College of Emergency Medicine, who expressed concerns around continuing inspections of emergency departments (IT3/60 [INQ000398820]). We also worked closely with Ofsted on our joint approach to inspections of Special Educational Needs and Disability inspections.

150. On 13 March 2020 I responded to letters received from the RCGP, the BMA, and the NHS Confederation over the preceding days which touched on our ongoing inspection activity (IT3/80 [INQ000398839]; IT3/81 [INQ000398840]; IT3/82 [INQ000398841]; IT3/83 [INQ000398842]; IT3/62 [INQ000398822]; IT3/63

[INQ000398823]). In my response I stated our view of the essential function of regulation, outlined the ways in which we were already adapting our approach to inspections, and summarised the approach we were taking to developing our new methodology.

151. We took the decision to stop all routine inspection activity and move to risk-based assessments as of Monday 16 March 2020 at a meeting of our Gold Command group on Friday 13 March 2020 (IT3/84 [INQ000398843]). Jennifer Benjamin, Deputy Director of the Quality, Patient Safety and Investigations Branch at DHSC attended this Gold Command call and it was agreed on the call that we would share with DHSC our planned communications with the sector around this. This would be communicated to senior colleagues and Members of Parliament later that day and to providers, the wider organisation and the public on 16 March 2020.

152. On 16 March 2020 Lee McDonough texted me to say that the then Secretary of State Matt Hancock was not happy with our interim proposals regarding cessation of inspections and that he had asked William Vineall to follow up with me "on specifics" (IT3/426 [INQ000419146]).

153. On 16 March 2020 Mr Hancock sent a message to Peter Wyman stating that he needed CQC "to pull back more than they are currently planning on inspections & data collection" (IT3/427 [INQ000419146]). In response, Peter noted that CQC had "pulled right back on inspections" and that they would only be taking place "where we believe abuse or serious harm may be happening". Peter also asked Mr Hancock whether he had seen the letter that we were intending to send to providers on 16 March 2020 regarding the pausing of routine inspections. Mr Hancock replied to note he had made amendments to the letter.

154. This exchange, and that referred to in paragraph 153 above, related to two letters, one for healthcare providers and one for adult social care providers, which we sent out on 16 March 2020, entitled 'immediate cessation of routine CQC inspections' (IT3/85 [INQ000235535] and IT3/86 [INQ000235536]). The draft letters were shared with DHSC on 15 March 2020 who provided their comments and feedback and

instructed us not to send the letters until the necessary clearance had been obtained (IT3/428 [INQ000466430]).

155. The final letters were sent to the then Secretary of State on 16 March 2020 and we received confirmation of his approval based on his revisions to the letters later that afternoon. (IT3/431 [INQ000466433])

Continued Monitoring of Risk and Ensuring Safety (during and post pandemic)

156. We had already begun to review our approach to regulation and our inspection methodology prior to the pandemic in order to make better use of intelligence to target inspection activity where it was most valuable (IT3/90 [INQ000398847]). From early on in the pandemic, both prior to and following the suspension of routine inspection activity, we utilised a responsive and increasingly intelligence-led and risk-based approach to inspection activity to ensure patient safety and the proportionality of inspections. We rapidly developed new tools and methods for continuing to deliver on our purpose of ensuring safe care in difficult and changing circumstances and there were a number of changes to our approach during the course of the pandemic. The most relevant tools which were developed during the pandemic, in terms of the scope of Module 3, are as follows:
    156.1. Emergency Support Framework (ESF);
    156.2. Transitional Regulatory Approach (TRA);
    156.3. Transitional Monitoring Activity and Application (TMA); and
    156.4. Monitoring Approach 2021/22 and the Direct Monitoring Activity (DMA)

157. Each of these tools is explained in detail below.

158. CQC's inspection activity in the Adult Social Care Sector, Hospitals Sector and Primary Medical Servies Sector during the relevant period is demonstrated in the graphs shown on exhibit IT3/481 [INQ000470224]. These graphs have been prepared specifically for use as an exhibit to this statement and show how many inspections were undertaken in each of named sectors during the relevant period. When reading and analysing the graphs, the following should be noted:

158.1. Inspections in larger institutions such as hospitals can take more than a month to complete, and the volume of work required for inspections of larger institutions is greater per inspection when compared to the volume of work involved in conducting an inspection in a small care home. Therefore the numbers of inspections per sector should not be treated as an indicator of increased focus in one sector over another.

158.2. The PMS graph does not include Oral Health Services (P1 services omitted[9]) as these services are not within the scope of Module 3.

158.3. Once a provider is registered, an Organisation ID (also known as a 'CRM ID') is assigned for each location included in the registration certificate. All inspections are linked to a 'CRM ID'/Organisation ID and where there is no ID this is considered an erroneous record. We have run a blanket check for the inspections included in the graphs and found that there were no blank CRM IDs for the relevant period.

Emergency Support Framework (ESF)

159. Following the suspension of routine inspection activity in the three sectors as outlined above, we continued to fulfil our regulatory purpose by embarking on a series of rapid changes and new ways of working. CQC deployed a number of alternative methods of regulating which revolved around the use of remote means to monitor, assess and/or inspect providers. We continued to inspect in response to risk and concerns raised, with services remaining the subject of close monitoring, using a range of intelligence sources and tools (IT3/91 [INQ000398848]).

160. One such monitoring tool was the Emergency Support Framework (ESF), a software application designed for inspectors to be able to review their portfolio and prioritise according to a risk model that indicated which services were the most at risk, leading to a structured phone conversation between the registered manager and the inspector ("ESF call"). The ESF call was intended to be supportive and

[9] CQC uses codes to identify/categorise the services, known as 'Primary Inspection Categories', which we regulate. For example, 'P2' is 'General Practice'. 'P1' refers to 'Oral Health/Dental' services and these have been excluded from the PMS graph.

predominantly focused on ensuring that the provider was managing Covid-19 related risks adequately.

161. The ESF process followed a series of six steps, as follows (IT3/470 [INQ000469883]; IT3/471 [INQ000469884]; IT3/94 [INQ000398851]):

161.1. The ESF tool provided inspectors with a list of locations, usually based on locations normally within their portfolio. Each location or core service (depending on sector and directorate) was assigned:

161.1.1. A risk level which was automatically calculated from data and intelligence held in our records. The four risk levels were "very high", "high", "medium" and "low"; and

161.1.2. A priority ranking.

161.2. Inspectors used the risk level, priority ranking and their own knowledge of services to make judgments about the order in which they made ESF calls.

161.3. The ESF call took place.

161.4. The information discussed during the ESF call was recorded in the ESF tool.

161.5. The information from the ESF call was assessed to provide an assessment outcome based on the answers given against the framework questions. The tool recorded whether the service was 'Managing' or 'Needs Support'.

161.6. The ESF tool produced a 'Summary Record' in a standard format setting out the answers to the ESF questions and the inspector's overall summary. A copy of the Summary Record was sent to the provider.

ESF Process

Step one: Risk Level and Priority Ranking

162. For step one of the ESF process, the risk level was calculated using existing information held in our systems from sources such as notifications, National Reporting and Learning Systems reports (for NHS locations), current ratings, enforcement activity, whistleblowing activity and the length of time since our last inspection. The specific criteria used to model the probability of risk in a service provider varied by sector, with different risk models used for NHS GPs, prisons, independent doctors, urgent care services, and dentists, as well as independent

health providers of dialysis, ambulances, standalone services for people with a learning disability and/ or autism and both residential ASC services, and community ASC services.

163. To demonstrate the criteria used to model the probability of risk we have exhibited the ESF risk model guidance applicable to independent health providers of dialysis, ambulances, and standalone services for people with a learning disability and/ or autism as an example (IT3/473 [INQ000469886]). This risk model used an automated data led five-step scoring process to create an actionable risk level as follows:

163.1. A preliminary assessment based on the previous inspection rating was conducted:

163.1.1. If the most recent overall rating was "inadequate", the location was automatically placed in the "very high" risk category;

163.1.2. If the most recent overall rating was "Requires improvement" and it had been over 12 months since that inspection, the location was automatically placed in the "High" risk category. Such a location could be moved into the "Very high" risk category based on its risk score.

163.2. For each location a score of zero, one or two was given against each of the indicators below based on certain thresholds:

163.2.1. Whether the length of time since the last inspection was within frequency rules;

163.2.2. Whether the location had never been inspected;

163.2.3. Whether a registered manager was in place (if applicable);

163.2.4. Whether any whistleblowing notifications had been received;

163.2.5. For services for people with a learning disability or autism only, whether notifications relating to the following were received:

163.2.6. Deaths in detention of people detained under the Mental Health Act;

163.2.7. The authorized absence of people detained under the Mental Health Act; and

163.2.8. The admission of a child to an adult psychiatric unit.

163.3. Step three:

163.3.1. An assessment of risk was undertaken against each of the following universal notification types:

163.3.1.1. Complaints;

163.3.1.2. Serious injuries;

163.3.1.3. Unexpected deaths;

163.3.1.4. Safeguarding;

163.3.1.5. Police incidents;

163.3.1.6. Events that stop services; and

163.3.1.7. Abuse or allegations of abuse

163.3.2. The risk assessment was used to highlight changes in the reporting pattern or unusual numbers of notifications reported by a location, based on its previous reporting history.

163.3.3. For each of the notification types, three underlying indicators were used to review the pattern of reporting within different time periods within the last complete 12 months:

163.3.3.1. Indicator 1: Notifications received in the last month;

163.3.3.2. Indicator 2: Notifications received in the last three months:

163.3.3.3. Indicator 3: Notifications received in the last complete 12 month period.

163.3.4. For each of the indicators, a location was scored as either high risk, risk or no risk

163.3.5. Some notification types were identified as rare or exceptional events. Where such a rare event occurred, a rules system was used to flag these instances in the risk model as per:

163.3.5.1. 1 notification = high risk (i.e one risk point);

163.3.5.2. 2 or more notifications = very high risk (i.e two risk points).

163.3.6. The risk scores for the three underlying indicators were then combined to produce an overall score for the notification type.

163.3.7. The methodology for combining these three indicators into one assessment incorporated preventative measures to avoid double

counting of notifications and added weight to notifications received more recently.

163.4. These scores were then added together to provide a risk score out of 22 for an Independent Health ambulance service or dialysis service, or 28 for an Independent Health service for people with a learning disability or autism.

163.5. The risk level for each location was then compared against all other locations of the same service type to determine the overall risk level. This was done by identifying which percentile the location sat in:

163.5.1. Very high = 95th percentile

163.5.2. High = 85th percentile

163.5.3. Medium = 75th percentile

163.5.4. Low = below the 75th percentile

164. The high level risk model methodologies underpinning each of the intelligence risk models for the different services within the respective sectors are set out in exhibit IT3/474 [INQ000469887].

Steps Two, Three and Four: ESF calls

165. ESF calls were not inspections, but supportive conversations with providers about the challenges they were experiencing at that time (IT3/93 [INQ000398850]; IT3/94 [INQ000398851]. The ESF calls were normally 1:1 conversations but if the service managers wished to invite other colleagues to join the calls they were welcome to do so.

166. The ESF calls were structured conversations which covered four assessment areas and followed a framework of fifteen standard questions as follows (IT3/95 [INQ000398852]):

166.1. Safe care and treatment (Regulation 12)

166.1.1. Had risks related to infection prevention and control, including in relation to COVID-19, been assessed and managed?

166.1.2. Were there sufficient quantities of the right equipment to help the provider manage the impact of COVID-19?

166.1.3. Was the environment suitable to containing an outbreak?

166.1.4. Were systems clear and accessible to staff, service users and any visitors to the service?

166.1.5. Were medicines managed effectively?

166.1.6. Had the management of risk been affected by COVID-19?

166.2. Staffing arrangements (Regulation 12, 17 and 18)

166.2.1. Were there enough suitable staff to provide safe care and treatment in a dignified and respectful way during the Covid-19 pandemic?

166.2.2. Were there realistic and workable plans for managing staffing levels if the pandemic leads to shortfalls and emergencies?

166.3. Protection from abuse and protection of human rights (Regulation 13)

166.3.1. Were people using the service being protected from abuse, neglect and discrimination?

166.3.2. Had the provider been able to properly manage any safeguarding incidents or concerns during the pandemic?

166.4. Assurance processes, quality monitoring and business risk management (Regulation 17)

166.4.1. Had the provider been able to take action to protect the health, safety and wellbeing of staff?

166.4.2. Had the provider been able to implement effective systems to monitor and react to the overall quality and safety of care?

166.4.3. Is the provider able to support staff to raise concerns during the pandemic?

166.4.4. Had care and treatment provided to people being sufficiently recorded during the Covid-19 pandemic?

166.4.5. Had the provider been able to work effectively with system partners when care and treatment is commissioned, shared or transferred?

167. There were sector specific guidance documents for exploring the ESF questions with the different services. The guidance documents included the standard ESF questions as well as sector specific and shared support prompts and links to

potential sources of support for passing onto the providers. The prompts in the sector specific guidance documents were intended to help the inspectors frame the conversations but they were not treated as a checklist. The inspectors were expected to focus on what was important for each individual service and to discuss additional risks and issues as needed in order to fully understand the service's situation. The specific guidance documents for the healthcare sector services are exhibited as follows:

167.1. IT3/96 [INQ000398853]: Primary Medical Services – GP;

167.2. IT3/97 [INQ000398854]: Primary Medical Services – Dental Services;

167.3. IT3/98 [INQ000398855]: Primary Medical Services – Health and Justice;

167.4. IT3/99 [INQ000398856]: Primary Medical Services – Urgent Care;

167.5. IT3/100 [INQ000398486]: Primary Medical Services – Independent Healthcare;

167.6. IT3/101 [INQ000398487]: Primary Medical Services – Online Services; and

167.7. IT3/102 [INQ000398488]: Independent Health Care – Ambulance Services.

168. Inspectors used the risk levels, ESF priority rankings and their own knowledge of the services to make judgments about the order in which to make their ESF calls and prioritized those services with the highest levels of risk.

Steps Five and Six: Deciding the assessment outcome and the Summary Record

169. The outcome of an ESF call did not lead to a change in the provider's rating but would inform the ongoing assessments of the provider in relation to the level of risk present and the appropriate next steps. The ESF was used alongside other intelligence (see paragraph 173). Following the ESF call, and once the information from the ESF call had been recorded in the ESF tool, the inspector was required to complete the assessment. The ESF would automatically provide an assessment outcome of either 'Managing' or 'Needs Support' based on the answers given against the questions asked in the ESF call. The inspector may have chosen to over-rule this assessment based on what they already knew about a service.

170. ESF calls were not inspections but a targeted or focused inspection could be considered by exception where we had serious concerns (IT3/94 [INQ000398851]).

Examples of when an inspection might be appropriate included where there were serious concerns relating to:

170.1. Abuse;

170.2. Breaches of human rights;

170.3. Neglect;

170.4. Standards of care and treatment; and/or

170.5. Lack of engagement and refusal to engage.

171. Where we had serious concerns about actual or possible avoidable significant harm, abuse, and breaches of human rights we assessed the risks involved using a separate process. Between May and July 2020 the "decision to assess process" (IT3/107 [INQ000398492]) was used to guide decisions to undertake focused or targeted inspections in instances where we had serious concerns. The decision to assess process was premised on the fact that during the Covid-19 pandemic there were heightened risks across all providers but that the option of inspection was not readily available and therefore should be reserved for the most serious cases.

172. The decision to assess process followed three steps:

172.1. Ongoing monitoring: Existing processes for ongoing monitoring continued to apply except in relation to reviewing intelligence products such as Insight (a dashboard of data created by our Intelligence team for each provider which was used to support and inform our pre-pandemic approach to inspections).

172.2. Reviewing inherent risk: Consideration of the extent of inherent risk and the likelihood that any inherent risk was a potential risk to safety (i.e do the risks make the threat to safety more "remote", "possible" or "probable"?). The "indications of elevated risk" were categorized under the following four headings:

172.2.1. Indications of a closed culture;

172.2.2. Inherent risk of service type or population;

172.2.3. Weak or inconsistent leadership; and

172.2.4. Provider track record against regulations.

172.3. Decide which ESF assessments to prioritise: The Risk Tool indicated a risk level (low, medium, high, very high) and therefore determined an assessment priority. However the inspector may have chosen to over-rule this assessment based on what they already knew about a service. In making prioritization decisions, inspectors considered the following:

172.3.1. Their review of the inherent risk of each provider (from step 2 above);

172.3.2. Any recent incidents of information which had come to light; and

172.3.3. Anything else they knew about the provider which could influence risk.

173. If we received intelligence or information of serious concern at Step 1, a shortened process would be triggered in terms of which:

173.1. Review of the intelligence or information of concern (in place of stage 2 above): The impact of the concern was considered and weighed against the likelihood that the concern was a potential risk to safety to determine the level of seriousness.

173.2. In cases of extreme risk, the inspector could skip the ESF assessment (step 3 above) and move directly to scheduling a management review meeting ("MRM").

173.3. Responding to extreme risk: A MRM would be held to decide the appropriate next steps such as conducting a targeted or focused inspection.

174. The decision to assess process document explained that while the specific justification for an inspection was decided on case by case basis, there were three broad principles that would apply when deciding whether to inspect and where one of these was suspected or evident, an urgent MRM would be triggered to decide the best course of action. These three broad principles are:

174.1. Lack of response: For example, the provider was not responsive to contact. All attempts to contact the provider including Covid-19 specific routes such as the ASC provider survey had failed. This could indicate a complete failure of care.

174.2. Abuse of willful neglect: For example, if CQC received reports of abuse or wilful neglect of people using the service.

174.3. Provider unable to cope: For example, following the completion of the Covid-19 assessment process, CQC had reason to believe that the provider was not coping and was unable to manage risk.

175. The decision to assess document (IT3/107 [INQ000398492]) was replaced with the 'Principles and Triggers for crossing the threshold during lockdown easing' document in July 2020 (IT3/93 [INQ000398850]). This set out a high-level description of what governed our decisions to remotely assess and/or inspect providers during the pandemic and reflected the current approach at that time, as the nation was coming out of the first lockdown. It was agreed that the following ten principles would guide the decision to conduct an on-site assessment and/or inspection:

175.1. We will increase the use of on-site assessments and inspections as the prevalence of Covid-19 decreases;

175.2. We will not return to "previous business as usual (e.g inspection frequencies)";

175.3. We will minimize additional burdens on providers at this time recognising the pressure placed on them due to the pandemic;

175.4. We will continue to put people who use services at the centre of what we do, taking necessary action to protect them and gathering their views where this is appropriate;

175.5. We will assess only the aspects of care that we need to, being clear on the scope of our assessment and proportionate to the risk presented;

175.6. Where activity can take place remotely, it will;

175.7. Site visits will only take place when essential and time on site will be kept to a minimum;

175.8. We will take all necessary precautions to safeguard our staff, people who use services, providers and their staff from infection control and prevention risks;

175.9. We will aim for cross-sector consistency and collaboration where possible;

175.10. We will re-establish a programme of regular, planned inspections with a methodology adapted for Covid-19 as soon as it is safe to do so.

176. The "triggers" page clarified that:

"*Inspectors will continue to use all existing sources of information and our standard risk assessment processes to come to their decisions about the risk level of each provider and therefore what the appropriate regulatory action should be. The key change is that we can now cross the threshold where services exhibit a level of risk lover than "extreme".*

The information we use to inform risk will vary slightly be sector, but may include: Risk tool and ESF conversations; Whistleblowing; Safeguarding; 'Give Feedback on Care'; Inspection history; Enforcement activity; Notifications (including deaths and serious injury); Information from other organisations (e.g LA, CCG, Coroner); indicators of closed culture; inherent risks of particular service types and groups of people receiving care; Insight dashboards; Complaints etc.

Options for regulatory action include:
Crossing the threshold; desk-based assessment; continued/increased monitoring; phone calls; sharing and discussions with other agencies; requesting evidence and assurances from the provider; enforcement etc."

Roll-Out, Operation and Implementation of the ESF

177. During the relevant period we identified, through ESF calls, that approximately 250 providers in the healthcare sectors (not including Adult Social Care providers) needed support. Of those identified as needing support, 41 were inspected within a 6-month period following their ESF conversation. If the details of these inspections are required by the Inquiry we will of course provide them where available.

178. On 20 April 2020, in advance of the roll out of the ESF for all sectors, we provided an internal update to CQC inspection teams and colleagues which confirmed that the ESF was being finalised, and that the guidance shared would support colleagues to make decisions about assessments and inspections during the pandemic (IT3/475

[INQ000469888]). Three Deputy Chief Inspectors (one per sector) were named as leads on how the ESF process would be applied in their respective sectors.

179. On 1 May 2020 we published an article on our website officially launching the ESF and indicating that it would be rolled out across all sectors but that it was initially being used with ASC providers (IT3/476 [INQ000469889]) and (IT3/106 [INQ000466428]). From 4 May 2020 we began rolling out the ESF: initially in Adult Social Care, then: GPs (18 May 2020); Health and Justice services (29 May 2020); Independent Learning Disability and Autism services, Independent Dialysis services and Independent Ambulance services (5 June 2020); and Independent Doctors and Slimming Clinics (8 June 2020).

180. On 17 June 2020 we published an article on our website regarding "why raising concerns about care [was] more important than ever" for regulation during the pandemic. We stated that while routine inspections had been paused, we had continued to inspect in response to risk concerns raised and that services had remained subject to close monitoring using a range of intelligence sources, including the ESF (IT3/91 [INQ000398848]). In the article we indicated that the ESF tool would be adapted as the pandemic evolved and the impact on the health and social care systems changed.

181. It was in this context that the move from using the "decision to assess" process to the "Principles and Triggers for crossing the threshold during lockdown easing" process as explained above was made. The evolution of the ESF process and tool is reflected in the three versions of the "Guidance: The Covid-19 Emergency Support Framework" documents exhibited as (IT3/470 [INQ000469883]; IT3/471 [INQ000469884]; IT3/94 [INQ000398851]).

182. The ESF also enabled us to have structured conversations with NHS trusts specifically about infection prevention and control (IT3/92 [INQ000398849]).

183. Part of the development of our regulatory approach included undertaking IPC focused inspections from August 2020, these are described in greater detail later on

in this statement where we directly address the rationale and methodology for IPC inspections. The IPC BAF framework tool used the ESF software for the capturing and assessment of information. (IT3/103 [INQ000398489]; IT3/104 [INQ000398490]; IT3/105 [INQ000398491])

Transitional Regulatory Approach (TRA)

184. With the risks relating to Covid-19 still present, we continued to adapt our existing methodologies to work within this environment, whilst being clear that our focus would continue to be on services where we had concerns about care and taking appropriate action as necessary. Rather than returning to a fixed timetable of inspections we continued to balance the need to hear people's experiences and accurately assess quality where risk was identified against minimising the risk of spreading the virus and not adding unnecessary pressure to the health and care system. On-site inspections were a valuable tool and we continued to use them proportionately.

185. Our Transitional Regulatory Approach (TRA) built on the work done through the development of the ESF to include: consideration of more areas where quality needed to improve; and targeting safety, people's access to services, and leadership.

186. Like the ESF, the TRA was not an inspection methodology but rather a cross-sector structured approach for gathering and recording intelligence and using this information to support us in assessing risk (IT3/92 [INQ000398849] and IT3/108 [INQ000398493]). The TRA developed our regulatory approach in a number of ways, including: making greater and better use of monitoring, intelligence and data to maintain an accurate view of quality; piloting new ways of gathering information outside of physical inspections; taking a more dynamic and risk-based approach to inspection frequencies; strengthening the role of relationship management; and drawing a clearer link between monitoring activity and what we look for on inspection.

187. We made use of a range of information sources to support our monitoring, including the work undertaken as part of our Provider Collaboration Reviews (PCRs), and

information gathered through our routine ongoing monitoring. The PCRs are described in detail below. As well as information on individual services, we also used information that we held about local systems, building on the work as part of the PCRs to understand where there are barriers to good care and to target our activity to help break these down.

188. After a review of the monitoring information and using the streamlined set of KLOEs, we made a judgement. If we were confident that our review indicated that there weren't any risks to people who used the service then we would take no further action at that point, and let providers know the outcome.

189. Where the outcome of our monitoring activity led to us inspecting a service, we used our existing inspection methodologies, adapted to work with the environment we were in. This meant that across all the health and care sectors we regulate, we would still look at any or all the KLOEs on inspection, to ensure people were receiving safe, high-quality care. However, as our inspections were more targeted and focused around areas of risk, we did not always cover all aspects of our five key questions and our KLOEs. As a result, our inspections did not always lead to a change in rating for a service.

190. Following further development work we launched and rolled out our TRA in stages, starting with ASC and Dentistry on 6 October 2020 [IT3/92 [INQ000398849]]. Next all NHS Trusts and three types of Independent Hospitals (Ambulances, Learning Disability and Autism, and Dialysis services) on 12 October 2020, GPs, Independent Doctors, Slimming Clinics, Urgent Care, and Out-of-hours services on 19 October 2020, and other Independent Health and NHS core services on 2 November 2020 (IT3/108 [INQ000398493]). We continued to iterate this process on the basis of feedback (IT3/109 [INQ000398494]).

Transitional Monitoring Activity and Application (TMA)

191. Building on the lessons we had learned through the ESF we developed concurrently a more comprehensive digital application, the Transitional Monitoring Activity and Application (TMA), as a tool to support the roll out and iteration of the TRA. This

offered structured questions and prompts in the same manner as the ESF, and used further sources of intelligence and improved modelling to produce risk prioritisation scores to help inspectors corroborate their own assessments of the safety of services. The TMA would also provide a consistent place to store monitoring information and offer a consistent cross-sector method of monitoring (IT3/110 [INQ000398495]).

192. We engaged with key stakeholders during the development of the TMA to assist with the formulation and testing of the questions and prompts. The experiences of those receiving care, their families and carers continued to be central to our approach to monitoring. In this process of engagement we worked with CQC's Experts by Experience, Healthwatch England, and other organisations that help us capture the voices of people who use services.

193. A five-point scoring system was used to assess risk from very low to very high. This took into consideration the inspector's professional judgement of the risks across the topics covered by the engagement conversation, as well as the provider's awareness of the risks and issues, and their track record and capacity to recognise, respond to, and learn from relevant events. Scores of 'very high' or 'high' in any KLOE meant that there were serious risks or issues and the TMA prompted a further regulatory response to be initiated. Where a service was banded as 'very high priority' they received an on-site inspection, and those banded as 'high priority' were triaged to identify if an inspection was appropriate.

194. Where 'high' or 'very high' risk was identified the process was signed off by an Inspection Manager, and where there were concerns about actual or avoidable potential harm, abuse, and breaches of human rights, held an MRM to decide the next step, for example inspection or enforcement processes.

195. Where we needed to carry out a regulatory response such as enforcement, we used existing CQC processes in line with the sector scheme of delegation and the MRM to consider this (IT3/111 [INQ000398496]; IT3/112 [INQ000398497]; IT3/113 [INQ000398498]; IT3/114 [INQ000398499]; IT3/115 [INQ000398500]).

196. TMA engagement calls were undertaken by consent. In the event that a provider refused to engage with a TMA call, a MRM was held to determine how best to respond, including whether it was appropriate to request relevant information under section 64 of the 2008 Act.

197. Improving on the ESF, the new TMA also helped to identify improved practice and changes in the quality of care. We also undertook our own evaluation of the TMA in early 2021 (March/April 2021) with colleagues from across the organisation identifying positive feedback as well as areas for learning and improvement.

Monitoring Approach 2021/22 and the Direct Monitoring Activity (June 2021-)

198. From June 2021 we began to introduce our expanded monitoring approach to improve how we monitor services and to build capacity to inspect where higher risk is identified (IT3/116 [INQ000398501]). This included a new process to prioritise services for regulatory activity using the data we held, and placing them into three separate Regulatory Activity Bands, as well as the introduction of Direct Monitoring Activity (DMA) calls. Banding applied to most service types which we regulate. This has not applied to NHS Trusts due to the well-established relationship management already in place, and the focused risk work undertaken for high-priority areas such as IPC, and Urgent and Emergency Care.

199. DMA calls are structured conversations with providers and are an opportunity to explore any risks to service quality and the trusts actions in response to those risks, the process of sharing feedback, and whether there is a need for further regulatory activity or enforcement processes.

200. From July 2021, we did a monthly review of the information we held on most of the services we regulate to help us to prioritise our activity (IT3/117 [INQ000398502]). This involved publishing a statement on our website for lower risk (band one) services which indicated to providers and the public that we had not found any evidence that told us we need to re-assess the rating or quality of care at that time.

Although these statements were refreshed monthly, we continued to monitor services and took urgent action if we received information about a serious risk.

201. Where our review indicated that there may be higher risk (band two) we undertook additional checks such as gathering people's experiences of care and contacting the provider for a call (otherwise known as Direct Monitoring Activity) or to request evidence. If, following the necessary monitoring activity, we were satisfactorily assured the service would be eligible to have a public statement published in the next monthly information review. If not, we will record this information to inform any future monitoring. For services where we consider there to be very high risk (band three) we will prioritise these services for an inspection.

202. Risk was categorised in accordance with the scales set out in guidance (IT3/116 [INQ000398501]). In general, the occurrence or demonstration of a high probability of major harm was classified as very high risk; whilst an indication that major harm is possible, moderate harm is probable, or disproportionate restrictions of liberty or breaches of human rights are probable are indications of high risk. The relevant definitions are set out in the guidance referenced above.

203. If, following further monitoring activity such as a DMA call, further action was required, colleagues would undertake an MRM as needed. Where any KLOE is scored as 'very high' we would hold an MRM with system partners such as the police and the local authority within 24 hours of this being identified. For 'high risk' classifications we would arrange an MRM to plan next steps within two working days.

204. In August 2021 we shared an update with providers and the public on the changes we were making to how we would assess quality and update ratings going forwards (IT3/118 [INQ000398503]). These changes were designed to help us work towards our ambition to be a more dynamic, proportionate and flexible regulator in line with our new strategy from 2021.

Provider Collaboration Reviews

205. To help providers of health and social care services learn from the experience of responding to Covid-19 around the country, CQC carried out rapid reviews of how providers were working collaboratively in local areas between July 2020 and November 2021. These Provider Collaboration Reviews (PCRs) looked at how health and social care providers across Integrated Care Systems (ICS) or Sustainability and Transformation Partnerships (STPs) were working together in local areas with the aim of helping providers learn from each other's experience of responding to the pandemic (IT3/119 [INQ000398504]; IT3/120 [INQ000398505]; IT3/121 [INQ000398506]; IT3/122 [INQ000398507]; IT3/123 [INQ000398508]; IT3/124 [INQ000398509]). Using our powers under section 48 of the 2008 Act we mobilised teams to carry out in-depth reviews around specific themes.

206. This built on work we had previously undertaken with a series of 26 Local System Reviews through 2017 and 2018, under the Secretary of State's section 48 powers (IT3/125 [INQ000398510]; IT3/126 [INQ000398511]; IT3/127 [INQ000398512]; IT3/128 [INQ000398513]; IT3/129 [INQ000398514]). We looked specifically at how people move between health and social care, including delayed transfers of care, with a particular focus on people over 65 years old. The reviews did not include mental health services or specialist commissioning but, through case tracking, looked at the experiences of people living with dementia as they move through the system. The reviews also included commissioning across the interface of health and social care and an assessment of the governance in place for the management of resources. We published our findings for individual local areas and overall, online (IT3/130 [INQ000398515]).

207. The PCRs looked at data held by CQC together with information held by local inspection teams; necessitated conversations, focus groups and workshops with providers structured around the KLOEs; and gathered views from people who used services using the Healthwatch network. We also surveyed system partners, gathered statistical and engagement data relating to published reports, and reviewed literature relating to regulatory approaches in systems.

208. The PCRs covered the following five topics in phases and the findings were published to our website:

208.1. Care for older people (September 2020) (IT3/131 [INQ000235474])

208.1.1. The first phase looked to understand how care providers had collaborated to improve care for older people, who were most at risk of Covid-19.

208.2. Urgent and emergency care (March 2021) (IT3/132 [INQ000398516])

208.2.1. The second phase looked at urgent and emergency care in 8 areas of England in October 2020 to understand whether people were getting the right care at the right time and in the right place, and how collaboration across local areas had made a difference.

208.3. Cancer care services and pathways (July 2021) (IT3/133 [INQ000398517])

208.3.1. Phase 3 looked at cancer care in 8 areas of England in March and April 2021 to understand whether people were getting the right care at the right time and in the right place, and how collaboration across local areas had made a difference.

208.4. Services for people who live with a learning disability in the community (July 2021) (IT3/134 [INQ000398518])

208.4.1. This phase looked at the care and support for people with a learning disability in 7 areas of England in March 2021.

208.5. Mental Health care for children and young people (November 2021) (IT3/135 [INQ000398519]).

208.5.1. This report looked at mental health care of children and young people in 7 areas of England in June and July 2021.

209. We took the decision to pause the ongoing fieldwork element of these reviews twice due to pressures on the system caused by the pandemic. Once in November 2020 until early January 2021 and again in January 2021 to March 2021 (IT3/136 [INQ000398520]; IT3/137 [INQ000398521]).

210. We also undertook internal evaluation work around what had worked well and what could be improved upon in the PCRs to inform future iterations of work to review local health and care systems (IT3/123 [INQ000398508]).

COVID Insight Reports

211. During the relevant period, we identified that it would be beneficial for us to collate and share the data and insights we were gathering from several different sources with providers and system partners at a national and local level.

212. We decided to do this through our monthly Covid Insight Reports, designed so that we could share a contextualised and data-driven narrative about what was happening across health and social care, in light of the pandemic. We included information from internal sources including regulatory data, submissions to our 'Give Feedback on Care' portal, responses to surveys undertaken and themes and trends from website activity. We had both 'soft' information from our ongoing contact with providers looking at the problems they faced and 'hard' information on death rates from our collection of notifications data. We also included data from various external sources in this report such as ONS, PHE and NHSE. We started publishing these on our website in May 2020 and continued until January 2022. (IT3/138 [INQ000235471]; IT3/139 [INQ000235472]; IT3/140 [INQ000235473]; IT3/131 [INQ000235474]; IT3/141 [INQ000235462]; IT3/142 [INQ000235475]; IT3/143 [INQ000235476]; IT3/144 [INQ000235477]; IT3/145 [INQ000235478]; IT3/146 [INQ000235479]; IT3/147 [INQ000235480]; IT3/148 [INQ000235481]; IT3/149 [INQ000235482]; IT3/150 [INQ000235483] and IT3/151 [INQ000235484])

213. We determined the themes and content of these reports. Prior to finalisation and publication we sighted DHSC on the content, in line with our information sharing agreement, giving them the opportunity to review each report and provide us with any comments in advance of publication. In this way we continued to operate as an independent organisation whilst maintaining our accountability to Parliament and ensuring DHSC had the opportunity to consider any steps the government might choose to take in response to our reports to support their response to the pandemic.

214. The reports were principally published on our website and highlighted to the health and care sector through our Provider Bulletins and they were shared with national bodies such as NHSE. The content and format of the reports slightly evolved over

time when we incorporated statistical analysis, local and national context, findings from thematic reviews and learning across a number of key aspects of the sector's Covid-19 response. A number of the relevant Covid Insight Report Issues are referenced throughout this statement.

CQC's New Regulatory Strategy

215. In January 2020, CQC had six Directorates:
    215.1. hospitals (including ambulances and mental health);
    215.2. primary medical services and integrated care (including dentists, health and justice);
    215.3. adult social care (ASC).
    215.4. Strategy and Intelligence;
    215.5. Digital; and
    215.6. Regulatory Customer and Corporate Operations (RCCO).

216. In March 2020 the Strategy and Intelligence and Digital directorates were restructured and renamed as Engagement, Policy and Strategy, and Digital and Intelligence. After recruiting a team member to our new role of Executive Director of Operations, who joined us in August 2021, we began further restructuring to deliver our new regulatory approach. Our strategy is outlined on our website (IT3/152 [INQ000235465]).

217. In early 2021 we undertook a public consultation on our new strategy and on changes for more flexible and responsive regulation (IT3/153 [INQ000398522]). We took our experience of regulation both prior to and during the Covid-19 pandemic into account in developing this new approach. Our strategy was built on four themes: people and communities; smarter regulation; safety through learning; and accelerating improvement. To support a more flexible and responsive regulation we proposed a number of changes to our approach including moving away from comprehensive on-site inspections as the main way of assessing quality in services and instead using wider sources of evidence, tools and techniques to assess quality (IT3/154 [INQ000398523]).

218. On 24 March 2021 we wrote to registered providers to update on our regulatory approach (IT3/155 [INQ000398524]). In the letter we outlined a series of specific approaches to the different sectors we regulate. Since suspending routine inspection activity we had continued to undertake inspection activity where there were serious risks to people's safety or where it supported the health and care system's response to the pandemic. This was with the intention of taking an active role in encouraging and supporting system-wide recovery and beginning to roll out our future approach to regulation based on recent consultations.

219. We were clear that, utilising the tools we had developed over the preceding year, we would continue to respond to risk, but also that following on from the public consultations we would be delivering change and improvement across CQC in line with our ambition to regulate in a more dynamic and flexible way.

220. We set out a series of specific approaches we would be taking to elements of the Hospitals and Primary Care sectors, including: NHS and independent hospitals; mental health providers; prioritising cosmetic surgery, independent ambulance providers as well as those services where closed cultures may exist; IPC inspections; Mental Health Act visits; focused activity in emergency and maternity departments; joint working with HMIP and Ofsted on secure settings and children's services; Independent and NHS primary care, out-of-hours and 111 services; previously unrated services; and focused activity with Oral health services.

221. The strategy was launched on 27 May 2021 making clear our ambitions and commencing joint working with people who use services, health and social care providers and professionals and other partners to develop our future regulatory approach (IT3/156 [INQ000398525]). Over the summer and autumn of 2021 we continued to develop how we would implement this strategy and how this would change our approach to regulation.

Winter 2021/22

222. We wrote again to providers on 10 December 2021 to update on the regulatory approach we would take over the winter months, taking account of the increased

pressure on the health and care system, particularly compounded by the emerging Covid-19 variants (IT3/155 [INQ000398524]). We emphasised that we would not be returning to routine frequency-based inspections during this period but would continue taking our risk-based approach. We would also be continuing our ongoing monitoring of services and adapting our approach to specific sectors.

223. In awareness of circumstances where re-rating services can support providers to deliver more capacity across the system and address wider pressures that they were facing, we continued to monitor services to identify those that may have improved and where inspection and re-rating may be possible.

224. On 13 December 2021 we further updated that, in response to new data on the spread of the Omicron variant, we would be postponing on-site inspection activity in acute hospitals, ambulance services and general practice for the next three weeks with immediate effect (except in cases where we have evidence of risk to life, or the immediate risk of serious harm to people) (IT3/157 [INQ000398526]). We continued risk-based inspection activity in adult social care, mental health, independent health and dentists. We re-affirmed this position on 21 December 2021 (IT3/158 [INQ000398527]).

Changes in 2022

224.1. On 27 January 2022 we wrote to providers to further update on changes to our regulatory approach which would take effect from 1 February 2022 (IT3/159 [INQ000398528]). With consideration to the situation, including the easing of Covid-19 restrictions across the UK, we had reviewed our approach and in addition to ongoing monitoring, we planned to inspect in three situations:

224.2. Firstly, where there was evidence of risk of harm (across all sectors) including those inspections previously postponed.

224.3. Secondly, where we could support increasing capacity in the system.

224.4. And thirdly, where focusing on urgent and emergency care would help us to understand the pressures, where local or national support was needed, and where we could share good practice to drive improvement.

225. Following a period of engagement with providers, people who use services and stakeholders, we published an update on our website in July 2022 sharing information about our developing work on our new approach to regulation and the Single Assessment Framework (IT3/160 [INQ000398529]). This work remains ongoing, and we plan to begin rolling this out towards the end of this year (IT3/161 [INQ000398530]).

226. Whilst quality ratings and the five key questions will remain central to our approach to regulation, we are replacing our existing KLOEs and prompts with new 'quality statements'. These will reduce the duplication in our four current separate assessment frameworks and allow us to focus on specific topic areas under each key question. Our assessments across all types of services at all levels will be based on this Single Assessment Framework. Assessments of local authorities and integrated care systems will use a subset of the quality statements.

227. The evidence we will collect will fall into six categories:
    227.1. people's experiences;
    227.2. feedback from staff and leaders;
    227.3. observations of care;
    227.4. feedback from partners;
    227.5. processes; and
    227.6. outcomes of care.

228. For each quality statement we will state which evidence we will always need to collect and look at, although this may vary by the type of service under assessment. It may also depend on the level at which we are assessing, for example a newly registered service.

Ensuring safe care at Private hospitals

229. There was no difference in the way that CQC carried out its regulatory obligations in respect of ensuring that safe care was delivered to patients at both private and public hospitals during the Covid-19 pandemic. However, in respect of private hospitals specifically, there were additional factors to take into account when considering the

issue of how to get staff on site quickly, whilst ensuring that they were able to provide safe care to patients.

230. Ordinarily, medical practitioners working in private hospitals are engaged with the hospital via a well-recognised process of the granting of practising privileges. Practising privileges are a well-established system of checks and agreements used to enable medical practitioners to practice in private hospitals without being directly employed by the hospital. This offers practitioners protection under the provider's registration and they fall under the specific exemption outlined in Schedule 2, paragraph 3 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 in terms of the regulation of "regulated activities".

231. In March 2020 DHSC and the Independent Healthcare Provider Network approached CQC seeking assistance with the communication to providers and practitioners in the independent sector regarding the fast tracking of the process for the granting of practising privileges (IT3/432 [INQ000466434]; IT3/433 [INQ000466435]; IT3/434 [INQ000466436] and IT3/435 [INQ000466437]; IT3/436 [INQ000466438]; IT3/437 [INQ000466439]; IT3/438 [INQ000466440]). This request was made pursuant to NHSE's announcement of the partnership agreement between the NHS and the Independent Sector (IS) intended to make hospital facilities and staff within the IS available for the admission and treatment of NHS patients (the NHS Covid-19 collaboration contract). CQC was asked to issue explicit guidance to the providers included in the NHS Covid-19 collaboration contract urgently as many of them had already started admitting patients at several of their locations. The guidance needed to cover what steps should be followed by providers to ensure that there was a consistent approach for granting interim practising privileges. This represented a departure from our usual regulatory role in terms of which we would not ordinarily issue such prescriptive guidance. We agreed to issue the guidance as we recognised the need to find a balance between ensuring patient safety while a reasonable and pragmatic solution was reached urgently.

232. On 27 March 2020 we issued a letter to independent health providers and NHS trusts setting out interim guidance for the fast-tracking of interim practising privileges

(IT3/439 [INQ000466441]). The interim fast-track process for the granting of practising privileges meant that consultants could start work immediately in hospitals where they did not have practising privileges already. The interim process required consultants to give the registered manager of the IS hospital a declaration. This provided a temporary assurance framework for private hospital providers to use to ensure necessary pre-employment checks for medical practitioners were undertaken, so that practising privileges could be granted. This, in turn, enabled medical practitioners to work in (i.e. use) the private hospital facilities to carry out NHS funded care on behalf of NHS Trusts. The interim guidance only applied to providers that were included in the NHS Covid-19 collaboration contract.

233. As regulator, we are unable to comment on the practical effect of the fast-track process for the granting of practising privileges as CQC does not monitor the length of time involved in the granting of practising privileges.

234. In response to the Inquiry's specific questions set out in the Rule 9 Request we have provided examples throughout this statement of some of the instances where we adapted our regulatory response to continue monitoring and ensure safety throughout the pandemic. These examples include our work in relation to the 'Inpatient experience during the coronavirus (COVID-19) pandemic' survey; IPC; DNACPR; discharge of patients from hospitals to care homes; regulation of the Nightingale hospitals; assessment of GP services as well as the various reviews, lessons learned exercises and State of Care Reports. Below are some additional examples of where we adapted our regulatory approach and where we focused on specific services during the pandemic to continue monitoring and ensure safety which have not been covered elsewhere.

Changes to Mental Health Act Visits

235. Following our decision to pause routine inspection activity and take a revised approach to regulation, our view was that, given our unique role in supporting those people detained under the MHA, visits should be continued wherever possible. However, we moved routine visits to a digitally enabled format, including remotely monitoring mental health wards through contact with staff, patients, carers and

advocates, virtual tours of wards, remote SOAD assessments and electronic certification by SOADs. Throughout the pandemic, where we had specific and urgent concerns, we engaged with services and continued to carry out on-site visits (IT3/162 [INQ000398531]).

236. The Coronavirus Act 2020, introduced in March 2020, included amendments to the MHA in response to difficulties in providing face to face support. These easements included increasing the amount of time patients could be detained in hospital and allowed decisions to be made without calling upon a CQC SOAD.

237. Our Principal SOAD and MHA teams engaged with DHSC and system partners such as NHSEI, setting out our concerns around the impact these changes could have on a patient's treatment and the reduced protection for human rights (IT3/163 [INQ000398532]). We worked with these partners to develop an approach which would take account of the circumstances of the pandemic, without losing necessary oversight of the care of people under the MHA (IT3/164 [INQ000398533]; IT3/165 [INQ000398534]; IT3/166 [INQ000398535]; IT3/167 [INQ000398536]; IT3/168 [INQ000398537]; IT3/169 [INQ000398538]; IT3/170 [INQ000398540]).

238. We adapted our approach to these responsibilities to take account of the prevailing situation, utilising digital tools to support our approach without making use of the MHA easements in the Coronavirus Act. On 30 September 2020 it was announced that the easements would be removed from the Coronavirus Act (IT3/162 [INQ000398531]).

239. In March 2020 we discussed visiting duties within the UK National Preventive Mechanism (NPMs), and through our UK NPM we coordinated with international NPMs (IT3/162 [INQ000398531]). The UK NPM is made up of 21 statutory bodies, coordinated by HM Inspectorate of Prisons, that independently monitor places of detention (IT3/171 [INQ000398541]). The UK NPM receives technical assistance from the UN Subcommittee on Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (SPT) and the UK Government must account

for the NPM's ability to perform its functions to the SPT and other UN bodies. On 20 March 2020 the SPT issued a statement of principles which included that:

"*…monitoring by independent bodies, including National Preventive Mechanisms (NPMs) and the CPT, remains an essential safeguard against ill-treatment. States should continue to guarantee access for monitoring bodies to all places of detention, including places where persons are kept in quarantine. All monitoring bodies should, however, take every precaution to observe the 'do no harm' principle, in particular when dealing with older persons and persons with pre-existing medical conditions.*" (IT3/172 [INQ000398542])

240. From 18 March 2020 we moved our SOAD service to remote assessments. We suspended MHA on-site activity on 24 March 2020, in view of the national lockdown (IT3/162 [INQ000398531]). From 6 April 2020 we began identifying and reviewing services that required monitoring, through information gathering and contacting services remotely. We reinstated MHA monitoring digitally from 8 April 2020 and we began using the new remote method to continue our monitoring with individual mental health wards – speaking to staff, patients, carers and advocates online and by telephone (IT3/173 [INQ000398543]; IT3/174 [INQ000398544]).

241. Where we believed there were risks of harm, ill-treatment or human rights breaches for people detained in services then, with oversight from the Chief Inspector, we carried out additional activity which may have included a site visit to a service.

242. From 11 May 2020 we began prioritising inpatient complaints, to ensure that during the pandemic we were focussing on protecting the human rights of the most vulnerable people, redirecting them to our MHA Reviewers to seek immediate resolution (IT3/162 [INQ000398531]). These interventions provided an opportunity for MHA Reviewers to identify services for remote monitoring activity where a serious concern or high number of concerns had been raised.

243. Our teams collected data remotely from a range of sources, and where we identified risks of harm, ill-treatment, or human rights breaches we carried out additional activity, which could include on-site MHA visits.

244. This remote-led approach continued through 2020 and 2021, with routine on-site MHA visits restarting in July 2021, and direct SOAD visits restarting in February 2022 (IT3/175 [INQ000398545]; IT3/170 [INQ000398540]). Some elements of the remote review methodology were retained in a blended approach, in particular, continuing to contact carers and advocates outside of the physical visit. We have found that these contacts increased in remote reviews and provided a more well-rounded picture of services.

Regulation of Services for People with a Learning Disability and Autistic People

245. In November 2018, the Secretary of State for Health and Social Care commissioned CQC to carry out an urgent review of the use of restraint, seclusion and segregation in services such as hospitals and care homes for people with a mental health condition, a learning disability or autistic people. The initial findings were published in our interim report in May 2019 (IT3/176 [INQ000398546]) which is summarised as follows:

245.1. The interim report presents our initial findings on the use of long-term segregation on mental health wards for children and young people and wards for people with a learning disability and/or autism. It draws on the return from an information request sent to 89 registered providers of these services and the experiences of 39 people who were in segregation and who we visited.

245.2. Our conclusion from the review as recorded in the interim report was that the system of care, which incorporated national bodies, providers and commissioners, had failed people whose care pathways had ended with them being segregated in a hospital and that the system was therefore not fit for purpose.

245.3. Based on our initial findings we made the following five recommendations for immediate action:

245.3.1. Over the next 12 months there should be an independent and an in-depth review of the care provided to, and the discharge plan for, each person who is in segregation on a ward for children and young people or on a ward for people with a learning disability

and/or autism. Those undertaking these reviews should have the necessary experience and might include people with lived experience and/or advocates.

245.3.2. An expert group, that includes clinicians, people with lived experience and academics, should be convened to consider what would be the key features of a better system of care for this specific group of people (that is those with a learning disability whose behaviour is so challenging that they are, or are at risk of, being cared for in segregation). This group should include experts from other countries that have a better and/or different approach to the care for people with complex problems and behaviours that challenge.

245.3.3. Urgent consideration should be given to how the system of safeguards can be strengthened, including the role of advocates and commissioners, and what additional safeguards might be needed to better identify closed and punitive cultures of care, or hospitals in which such a culture might develop.

245.3.4. All parties involved in providing, commissioning or assuring the quality of care of people in segregation, or people at risk of being segregated, should explicitly consider the implications for the person's human rights. This is likely to lead to both better care and better outcomes from care.

245.3.5. Informed by these interim findings, and the future work of the review, CQC should review and revise its approach to regulating and monitoring hospitals that use segregation.

246. On 24 March 2020 we published an article on our website 'Impact of COVID-19 on restraint, segregation and seclusion review and Right Support, Right Care, Right Culture' in which we indicated that our ability to engage with stakeholders and complete the review was limited due to the pandemic and we would therefore be delaying publication of the final report until later in the year (IT3/177 [INQ000398547).

247. Between 10 April 2020 and 15 May 2020 we completed a targeted piece of analysis, supported by the Office for National Statistics (ONS), to better understand the impact of Covid-19 on people with a learning disability and autistic people specifically focusing on how the number of deaths during the period compared to the number of deaths in 2019. The analysis looked at all deaths notified to CQC in the period from providers registered with CQC who provided care to people with a learning disability and/or autism (including providers of adult social care, independent hospitals and in the community), and where the person who died was indicated to have a learning disability on the death notification form. The results of the analysis were published on 2 June 2020 (IT3/178 [INQ000235420]) and can be summarised as follows:

247.1. Between 10 April and 15 May 2020, the number of deaths of people with a learning disability and/or autism who were receiving care from services which provide support for people with a learning disability and/or autism was 386.

247.2. For the same period in 2019, the number of deaths in the sector was 165 people, therefore indicating a 134% increase in the number of death notifications for people with a learning disability and/or autism in 2020.

247.3. Of the 386 people who died in the sector between 10 April and 15 May 2020, 206 deaths were as a result of suspected and/or confirmed Covid-19 as notified by the provider.

247.4. Overall, in 2020 the number of care home 'beds' registered with CQC to provide specialist learning disability and/or autism care, excluding care to older people or those with dementia, was 30 912. In 2019 that figure was 32 217

248. The final report into the use of restraint, seclusion and segregation 'Out of sight – who cares?' was published in October 2020 (IT3/179 [INQ000398548]). This concluded that the system of care for people with multiple needs was not fit for purpose and we made 17 recommendations to support system changes. Whilst the bulk of the review was undertaken prior to the Covid-19 pandemic, the final report does state that the pandemic led to increased concerns as many people were unable to access the care they needed, it caused delays to people leaving hospital,

restricted people's movements thereby restricting or stopping families from visiting loved ones and increased the risk of closed cultures developing.

249. On 8 October 2020 we updated our "Registering the right support" statutory guidance to make how we regulate providers who support autistic people and/or people with a learning disability clearer (IT3/440 [INQ000466442]). The guidance was renamed to "Right support, right care, right culture" (RSRCRC) and outlined the three key factors that we expected providers to consider if they care for autistic people and/or people with a learning disability as follows:
    249.1. Right support: the model of care and setting should maximise people's choice, control and independence.
    249.2. Right care: care should be person-centred and promote people's dignity, privacy and human rights.
    249.3. Right culture: the ethos, values and behaviours of leaders and care staff should ensure people using services lead confident, inclusive and empowered lives. (IT3/441 [INQ000466443])

250. In April and May 2021 we undertook a number of pilot inspections of services for people with a learning disability and autism to trial out our guidance on our enhanced inspection approach and the tools developed since the 'Out of sight – who cares?' report.

251. To further explore people's experiences and how services were working together for people with a learning disability during Covid-19, we carried out a PCR across seven local areas in England. The review was covered in June 2021 in our Covid-19 Insight Report 'Issue 11: Focus on our work to support people with a learning disability' (IT3/147 [INQ000235480]) and the results were published on 21 July 2021 in the 'Care for people with a learning disability living in the community during the pandemic' PCR (IT3/134 [INQ000398518]).

252. In December 2021 we published a report which commented on the progress following publication of our 'Out of sight – who cares?' report and highlighted the main areas where further work was still needed (IT3/180 [INQ000398550]). This was

based on an assessment of progress made by key stakeholders using published data and findings from our ongoing regulatory and inspection work, including our pilot inspections of the hospitals providing services to people with learning disabilities and autistic people. The report also considered the impact of the Covid-19 pandemic, highlighting that the inequalities already experienced by people with mental ill health, people with learning disabilities and autistic people had become even more evident as people's routines were altered, support was not always possible and access to services was limited.

253. In February 2022 we formally launched the Supported Living Improvement Coalition, an action group which brings together people with experience of supported living services, their relatives and representatives, care providers, charities, and local authorities among others. We set up this coalition in response to concerns about the variation in people's experience of supported living services. The group is structured so that people can tell their stories to a range of stakeholders who can work with them to identify, resolve, and embed the improvements that are needed. With leadership and support from across social care, the Coalition aimed to achieve greater safety and quality of supported living options for people with a learning disability, autistic people and people with mental ill health and drive improved outcomes for them. Our role as the convening organisation came to an end on 6 December 2022 however the coalition has continued its work through two sub-groups: Supporting People Well and Housing Matters.

254. In March 2022 we published a further progress report (IT3/181 [INQ000398551]) outlining the progress made on the recommendations in our 'Out of sight- who cares?' report. We identified that more action was needed to ensure people with a learning disability, autistic people and people with mental ill health get the right care at the right time. The report was informed by our regulatory and inspection work, nationally published data, and data and insight from engagement with an array of stakeholders. In particular we found that there are still too many people in hospital, that once in hospital they often stayed too long, did not always experience therapeutic care and were still subject to restrictive interventions. Whilst not the focus of the report, it took account of the impact of the pandemic on aspects of services.

We found that some of the recommendations made in our 'Out of sight – who cares?' report had not been achieved and that some of the recommendations had been partially achieved.

254.1. The following recommendations had not been achieved:

254.1.1. Recommendation 1: people have a home and the right support in place;

254.1.2. Recommendation 2: people have the right community services commissioned;

254.1.3. Recommendation 3: people have the right support to avoid crisis;

254.1.4. Recommendation 4: people have their rights understood;

254.1.5. Recommendation 5: people have the right support in hospital;

254.1.6. Recommendation 7: people have skilled staff to support them;

254.1.7. Recommendation 8: people have bespoke services;

254.1.8. Recommendation 11: people who experience restrictive interventions have these reported to CQC;

254.1.9. Recommendation 13: people who are segregated in hospital experience good quality regular independent reviews;

254.1.10. Recommendation 14: people have meaningful Care (Education) and Treatment Reviews because providers and commissioners are accountable;

254.1.11. Recommendation 15: all people in segregation in hospital are recognised through updating the definition of long-term segregation

254.1.12. Recommendation 16: people see a reduction in the use of restrictive interventions; and

254.1.13. Recommendation 17: people in children's and adult social care services experiencing restrictive interventions would have these reported to regulators.

254.2. The following recommendations had been partly achieved:

254.2.1. Recommendation 6: improving how CQC regulates services for people with a learning disability and autistic people;

254.2.2. Recommendation 9: recording data to improve local services;

254.2.3. Recommendation 10: people's experiences of person-centered care; and

254.2.4. Recommendation 12: people who experience restrictive interventions have regular oversight by commissioners.

255. On 25 March 2022 we published an update in respect of Recommendation 6 (outlined above at paragraph 254.2.1) (IT3/442 INQ000466444]). We reported that CQC had taken the following steps to improve how we regulated services for people with a learning disability which led to more enforcement action where services were not meeting people's needs:

255.1. We developed a new enhanced approach to improve the way that we look at hospital and adult social care services for people with a learning disability and autistic people. This includes ensuring inspectors focus on specific areas that are particularly relevant to people with a learning disability and autistic people such as communication and engagement; their individual health needs; out of area placements; access to advocacy; and the use of restrictive practices.

255.2. In order to put people's experiences at the centre of our new approach, and to make sure that services are operating in line with our "Right support, right care, right culture" guidance we:

255.2.1. Reviewed and updated our guidance for inspectors;

255.2.2. Spent more time on site to observe practice and to enable us to identify signs of potential closed cultures;

255.2.3. Spent more time speaking to more people in the service (and their families and carers), supported by new communication tools such as the Quality of Life tool and talking mats;

255.2.4. Increased our contact with commissioners and professionals who may visit a service to get their views on the service;

255.2.5. Increased the range of tools, guidance and experts to support our inspection teams; and

255.2.6. Visited services unannounced and out of hours, often going back to a service to see what care is like at different times of the day.

255.3. We started to look at the level of training that staff working in these services were receiving to ensure that it was of an appropriate standard;

255.4. Increased focus on inspecting hospitals and care homes where there was the highest risk that people may not be safe or their rights may not be respected; and

255.5. Began developing our approach to monitor and report on the length of time that both children and adults are on waiting lists for a diagnosis of autism.

256. The update also describes the steps taken by CQC to improve how we look at services for people with a learning disability and/or autistic people.

257. In May 2022 we updated our "Draft Quality of Life Framework" and the associated "Quality of Life Tool" which was developed to help address the recommendations made in the 'Out of Sight – Who Cares?' report and in order to address the recommendations from Glynis Murphy's first report into the regulation of Whorlton Hall (IT3/443 [INQ000466445]). The draft quality of life framework provides a structured and logical set of questions our inspectors might ask, and that service providers should be asking themselves, to help us understand whether the service is meeting the needs and aspirations of the people it is supporting. The primary purpose of the Quality of Life tool is to improve CQC's ability to consistently identify and take appropriate regulatory action in services that fail or are failing to meet the needs, aspirations and skills development of people with a learning disability and/or autistic people. The tool is used by inspectors of specialist services for people with a learning disability and autistic people and helps them to identify areas to explore as they assess quality of care and safety. The Quality of Life tool is geared towards outcomes focused care and is used to understand people's experience of care and quality of life. After an inspection, the tool is used to review the evidence and to put together the inspection report. The Quality of Life tool has not replaced our methodology for assessing and evaluating the performance of registered providers, it is used to supplement and inform the existing KLOEs with it's focus being on person centered support which complements our new enhanced approach to inspection.

258. In May 2022 we also updated our RSRCRC statutory guidance again. There were no substantial changes made to the statutory guidance itself but there were changes made to the supporting case studies. The May 2022 version of the RSRCRC statutory guidance is exhibited as (IT3/441 [INQ000466443]).

259. In August 2022 we introduced a new routine registration condition applicable for certain providers who plan to carry out specific regulated activities (personal care, accommodation for persons who require nursing or personal care and/or assessment or medical treatment of persons detained under the MHA) (IT3/444 [INQ000466446]). Before 1 September 2022, when applying to register with CQC, a provider needed to notify us if they planned to provide specialist services for people with a learning disability and/or autistic people. We would then assess their application against our RSRCRC guidance to ensure that their planned model of care was in line with national policy and best practice. The change imposed in August 2022 had the effect that from 1 September 2022 those providers who inform us that they do not intend to provide a service for people with a learning disability and/or autistic people will be asked to agree to CQC imposing a routine condition on their registration. The condition has the effect that the provider must not provide a specialist service at the specified location to people with a learning disability and/or autistic people. If in the future the provider does wish to provide these specialist services, they will need to apply to have this condition removed from their registration and we will assess whether their proposed changes align with our RSRCRC guidance.

260. In November 2022 we published the 'Who I am matters' report on the experiences of being in hospital for people with a learning disability and autistic people (IT3/182 [INQ000398552]). The work done for this report formed part of our work to transform the way we regulate services for people with a learning disability and autistic people. During February and March 2022 we visited eight hospitals in England, utilising questions tailored in consultation with people with lived experience of learning disabilities and autism, as well as their families and carers. We conducted interviews, focus groups, observations, and an in-depth review of the care of sixteen people. Our report looked at: access to care, communication, care and treatment in hospital,

protected characteristics and equality of care; and workforce skills and development. We found that although there were pockets of good practice, people with a learning disability and autistic people are still not being given the quality of care and treatment they have a right to expect when they go to hospital. We also found that there were still restrictions in place due to the pandemic and some hospitals were experiencing an increase in Covid-19 related admissions.

261. Since the end of the pandemic, CQC has continued taking steps to drive change and improve the standards of care for people with a learning disability and autistic people. This work extends beyond the relevant period being investigated by the Inquiry in this Module but if the details of this work are required by the Inquiry they will of course be provided.

E. Patients' experiences

CQC's 'Inpatient experience during the coronavirus (COVID-19) pandemic' Report

262. The decision to undertake the 'Inpatient experience during the coronavirus (COVID-19) pandemic' survey was an internal CQC decision. The final report was published on 6 November 2020 (IT3/183 [INQ000235488])

263. Ipsos MORI were commissioned by CQC to capture information about the experiences of people admitted to an NHS hospital in England for inpatient care during March, April and May 2020. While the focus of the survey was on patients with Covid-19 (on admission or diagnosed during their stay), the survey also included patients in hospital for non-Covid reasons.

264. The report defines adult inpatient services as those that provide care to people who stay in hospital for one night or more, for tests, medical treatment or surgery, either as a result of an unplanned admission (for example via an emergency department or an urgent treatment centre) or pre-planned elective treatment.

265. NHS Digital identified the number of all patients, aged 16 or over at the time of their stay, who had been discharged from an acute or specialist hospital between 1 April 2020 and 31 May 2020. 350,207 eligible patients were identified. A random sample

of these eligible patients was selected, with the aim of achieving equal numbers of interviews with inpatients in each Sustainability and Transformation Partnership (STP) / Integrated Care System (CS) in England. More patients who had tested positive for Covid-19 than non-Covid patients were selected to ensure robust sub-group analysis. The final number of patients to whom letters were sent was 24,249.

266. The questionnaire was designed by Ipsos MORI in collaboration with CQC and other relevant stakeholders (IT3/184 [INQ000398554]) and was based on the Adult Inpatient Questionnaire used within the NHS Patient Survey Programme. Where feasible, questions were aligned with the Adult Inpatient Survey 2020 (carried out by NHS Patient Surveys) in order to allow comparisons with future inpatient surveys and the 2019 adult inpatient survey, where possible. We have set out below the ten sections in the questionnaire and an example question from each section:

    266.1. Admission to Hospital – Was your hospital stay during March, April or May 2020 planned in advance or an emergency?

    266.2. The Accident & Emergency Department (A&E) – While you were in the A&E Department, how much information about your condition or treatment was given to you?

    266.3. Covid-19 – When you were admitted to hospital, had your symptoms already been confirmed by a positive Covid-19 test result?

    266.4. The Hospital and Ward – When you were in hospital, how safe or unsafe did you feel from the risk of catching Covid-19?

    266.5. Staff – When you asked staff questions about your care or treatment, did you get answers you could understand?

    266.6. Your Care & Treatment – To what extent did staff looking after you involve you in decisions about your care or treatment?

    266.7. Communications – There were restrictions on visitors in hospital during the pandemic. Were you able to keep in touch with your friends and family during your stay?

    266.8. Leaving Hospital – Did hospital staff take your family or home situation into account when planning for you to leave hospital?

266.9. Overall – Overall, do you feel you were treated with respect and dignity while you were in the hospital?

266.10. About You – Do you have any of the following physical or mental health conditions, disabilities or illnesses that have lasted or are expected to last 12 months or more?

267. The survey used a mixed methods approach combining online and telephone modes. There was an initial postal mailing to all selected patients inviting them to take part online via a URL link (using a unique survey number and online password). A few days later, those who had provided a mobile phone number were sent a reminder text message. A second letter was then sent 5-7 days after the initial mailing, again inviting them to take part online but also indicating they would be receiving a telephone call in the next few days or inviting them to contact the telephone team directly. Again this was followed by a text reminder to those with mobile numbers. Nine days after the initial letter was sent the telephone team started to contact patients by telephone.

268. All fieldwork (online and telephone) was carried out between 14 August and 9 September 2020. In total, of the 24,249 patients identified in the random sample, 10,336 took part in the survey.

269. The results for each STP/ICS were weighted by gender and age group to reflect the profile of the population supplied by NHS Digital. Percentage figures were rounded to the nearest whole number and statistical tests were carried out on the data to determine whether there were any statistical differences between patients with Covid-19 and those who did not have the virus.

270. The report findings were categorised under the following key themes:

270.1. person centred care;

270.2. meeting patients' fundamental needs;

270.3. infection prevention and control;

270.4. staff and communications;

270.5. patient discharge from hospital;

270.6. overall experience; and

270.7. the experience of different groups of patients.

Person-centred care

271. A number of questions in the survey asked patients about their experience of making choices about their care and also the information made available to them to enable them to make well-informed choices.

272. Overall, views on person-centred care were good. The majority of patients said that staff looking after them involved them in decisions about their care and treatment 'a great deal' or a 'fair amount'. Covid-19 patients were significantly less positive about involvement in decisions about their care and treatment. Similarly, Covid-19 patients who wanted to take part in decisions about leaving hospital were less likely to say that staff involved them 'a great deal' or a 'fair amount'.

273. Patients were positive about the information they received in relation to their condition and treatment, both while in A&E (for those admitted via this route) and generally during their stay. However, views were slightly less positive about information provided while in A&E. Covid-19 patients were significantly less positive about the information they received either during their time in A&E or during the remainder of their stay.

274. Patients generally reported receiving the emotional support they needed, the majority saying they 'always' received enough emotional support during their stay. Covid-19 patients were less positive about the emotional support they received. Most patients said they 'always' had confidence in the staff treating them, but again Covid-19 patients were slightly less positive than those without a Covid-19 diagnosis.

Meeting patients' fundamental needs

275. Patients have broader needs than only those related to their treatment and condition; for example NICE highlights the importance of nutrition and pain management as being essential requirements of good care.

276. Patients reported that their fundamental needs were largely met during the period covered by the survey. Most patients reported that they got enough to drink while in hospital, with no differences between Covid-19 and non-Covid patients. However, results relating to medicine were slightly less positive, particularly among Covid-19 patients. The majority of patients needing their own medicine while in hospital were able to take it, but fewer Covid-19 patients said they could 'always' take their medicine compared to those patients without a Covid diagnosis.

Infection prevention and control

277. The survey captured views on general cleanliness in hospital, but also infection control measures and perceived safety from contracting Covid-19 while in hospital. Patients who were in hospital during the period covered by the survey reported high levels of cleanliness and visible infection control measures. Despite this, a minority of patients were concerned about catching Covid-19 during their inpatient stay.

278. During the months covered by the survey, hospitals were still admitting patients for reasons other than Covid-19. Over four in five patients said they felt 'safe' from the risk of catching Covid-19 while in hospital. Eight per cent felt 'unsafe', and this increased to 17% among patients who went on to receive a Covid-19 diagnosis while in hospital.

Staff and communications

279. The survey looked at whether patients were able to get the attention they needed from staff, as well as focusing on a number of issues with staff communication. It also asked about the impact of personal protective equipment (PPE) such as face shields and masks on communication. Patients were also asked about their experiences of communicating with their family and friends.

280. Overall, patients reported feeling able to get attention from staff when needed and reported generally positive experiences of communication during their stay. However, a minority of patients reported not always being able to understand information provided to them by staff and said their ability to understand staff was sometimes hindered by PPE. While most patients were able to keep in touch with

their friends and family, a small proportion said they did not receive the help they needed to do so.

281. Covid-19 patients were significantly less likely to say they could always get help from a member of staff when needed, and significantly less positive than non-Covid patients as to whether they 'always' understood answers given to them by staff.

282. Covid-19 patients reported PPE having a greater impact on communication compared with those patients without a Covid-19 diagnosis (70% of Covid-19 patients said they were 'always' able to understand staff wearing PPE, whereas 74% of patients without a Covid-19 diagnosis said that they were 'always' able to understand staff wearing PPE). Certain groups of patients found communicating with staff who were wearing PPE especially difficult. People aged 85 and over were less likely to always understand what they were being told, as were people with dementia or Alzheimer's, patients who were deaf or hard of hearing, and autistic people or those with a learning disability.

283. Covid-19 patients were also significantly less likely to say they were able to keep in touch with friends and family as much as they wanted to, compared to those non-Covid patients. Older patients were more likely to say they were not able to keep in touch with family and friends.

Patient discharge from hospital

284. The survey showed that experiences of discharge were less positive than other aspects of patients' stay in hospital. Significant minorities reported that their home situation was not taken into account when leaving hospital, they were not given information on who to contact should they become worried, and they were not given information on the medicine they needed to take. Around one in four reported that they did not receive the post-discharge care and support they felt would have been useful. Across every one of these measures, Covid-19 patients reported poorer experiences.

Overall experience

285. The survey showed some positive results across many areas, but with points of concern such as discharge from hospital. It was important to ask patients how they found the experience of adult inpatient services overall. Respondents were asked to provide a score for their overall experience from '0 – I had a poor experience' to '10 – I had a very good experience'. 57% gave a score of 9 or 10. Patients in hospital with a Covid-19 diagnosis were more negative than those admitted for other reasons.

Experiences of different groups of patients

286. In terms of patient demographics, across all areas of the survey, the following groups consistently reported poorer experiences of care:
    286.1. younger patients;
    286.2. women;
    286.3. people with dementia, Alzheimer's, mental health or neurological conditions;
    286.4. patients who had Covid-19; and
    286.5. people who were admitted to hospital via A&E.

287. Some questions in the 'Inpatient experience during the Coronavirus (Covid-19) pandemic' report were based on the 'Adult inpatient survey' 2020 questionnaire, and some of these were also included in previous inpatient surveys.

288. Comparisons of the findings of the 'Inpatient experience during the coronavirus (COVID-19) pandemic' survey with other surveys conducted by CQC or our contractors (before or during the relevant period) need to be treated with caution because of differences in how the surveys were run, the weighting that has been applied to the data and other aspects of the methodologies that were different. Paragraphs 289 to 292 below are based on comparisons between the 2020 Covid Inpatient Report, and the 2019 and 2018 Adult Inpatient Surveys.

289. The results suggest that patients who were in hospital during the period covered by the 'Inpatient experience during the coronavirus (COVID-19) pandemic' survey were more likely than patients in previous years (patients surveyed for the 2018 and 2019

Adult Inpatient Surveys) to rate the level of emotional support and their overall experience positively. There were no differences in relation to information about their treatment and the discharge process.

290. Patients reported better experiences during the period covered by the 'Inpatient experience during the coronavirus (COVID-19) pandemic' survey in terms of getting enough support from hospital staff during their stay, and also far more likely to say they were 'always' able to take any medicines they brought with them to hospital when needed.

291. Overall ratings of care were more positive, with more saying they were treated with respect and dignity while they were in hospital during the pandemic and more rating their overall experience as either 9 or 10 (largely due to the higher proportion rating their experience as 10 during the pandemic).

292. On the five other measures where questions were the same as in previous surveys there were no meaningful differences in the experience of patients during the pandemic compared with 2019 and 2018.

293. Full details of the comparisons are set out in Appendix C of the Covid-19 survey.

294. The 'Inpatient experience during the coronavirus (Covid-19) pandemic' report includes in Appendix D reports that were conducted by outside organisations and referenced within our findings as follows:
    294.1. The Health Foundation Covid-19 Survey – A report of survey findings, June 2020 (IT3/185 [INQ000398555])
    294.2. Academy of Medical Royal Colleges, COVID-19. Effects on health from nonCOVID-19 conditions and moving forward to deliver healthcare for all, May 2020 (IT3/186 [INQ000369651])

295. In addition, as part of our annual State of Care reports we also utilised the surveys and reports of other organisations to guide and support our findings.
    295.1. State of Care 2019/20 (IT3/187 [INQ000235495])

295.1.1. GP Patient Survey – National Report 2020 (IT3/188 [INQ000398564])

295.1.2. Healthwatch England: COVID-19: What people are telling us about their care: (IT3/189 [INQ000398559])

295.1.3. Healthwatch – 'The Doctor will zoom you now: getting the most out of the virtual health and care experience' June-July 2020 (IT3/190 [INQ000366252])

295.2. State of Care 2020/21 (IT3/191 [INQ000235497])

295.2.1. Age UK: Research showing just how badly the pandemic was impacting older people (IT3/192 [INQ000176634])

295.2.2. GP Patient Survey – National Report 2021 (IT3/193 [INQ000398564])

295.2.3. Healthwatch: 590 people's stories of leaving hospital during COVID-19 (IT3/194 [INQ000366255])

295.2.4. Healthwatch England: GP access during COVID-19 – A review of our evidence: April 2019-December 2020 (IT3/195 [INQ000366256])

295.2.5. Healthwatch England: Locked out: Digitally excluded people's experiences of remote GP appointments (IT3/196 [INQ000366258])

295.2.6. Healthwatch England: What are people telling us: July to September 2020 (IT3/197 [INQ000366254])

295.3. State of Care 2021/22 (IT3/198 [INQ000398569])

295.3.1. King's Fund: Public satisfaction with the NHS and social care in 2021: Results from the British Social Attitudes survey (IT3/199 [INQ000398570])

295.3.2. GP Patient Survey – National Report 2022 (IT3/200 [INQ000398572])

295.3.3. Healthwatch England: What are people's experiences of urgent and emergency care? (IT3/201 [INQ000398573])

296. The report does not make any recommendations and only presents the results and analysis of the survey responses.

F. Infection prevention and control ("IPC")

IPC Focused Inspections

297. All providers of services that we regulate need to ensure that they have effective Infection Prevention and Control (IPC) measures in place in order to meet the requirements under Regulations 12 (relating to safe care and treatment) and 15 (relating to premises and equipment) of the Health & Social Care Act 2008 (Regulated Activities) Regulations 2014. This was particularly relevant in the health sector during the Covid-19 pandemic because of the risk of nosocomial infection.

298. During the pandemic we recognised, as regulator, that a focus on effective IPC measures was more important than ever to ensure that providers could keep people safe. IPC was already a feature of our comprehensive inspection methodology, but as a result of the pandemic we undertook a range of activities focusing directly on IPC across the health and social care sectors which are set out below. We have set out earlier in this statement the reasoning behind our decision to stop all routine scheduled inspection activity and move to a risk-based approach from 16 March 2020.

299. On 20 April 2020 we received an email from Sue Tranka, Deputy Chief Nursing Officer for Patient Safety and Innovation at NHSEI (IT3/203 [INQ000398575]; IT3/204 [INQ000398576]; IT3/205 [INQ000398577]; IT3/206 [INQ000398578]; IT3/207 [INQ000398579]; IT3/208 [INQ000398580]; IT3/209 [INQ000398581]; IT3/210 [INQ000398583]) with some draft guidance for NHS trusts, commissioned by SAGE, for the review of nosocomial infection and transmission in acute hospitals. At our request NHSE had also agreed to publish an assurance document covering IPC for trust boards which was, at that time, under development. We received the draft IPC Board Assurance Framework (BAF) tool on 23 April 2020 (IT3/211 [INQ000398584] and IT3/212 [INQ000384605]) and collaborated with NHSE in connection with how trusts would complete the framework, whether completion would be mandatory and how to define the key lines of enquiry to help set the standard expected of the trusts. The purpose of the IPC BAF tool was to support all healthcare providers to carry out a self-assessment of their internal arrangements

for effective IPC measures and to ensure their compliance with PHE Covid-19 IPC guidance.

300. On 30 April 2020 (IT3/213 [INQ000398586]) the Hospitals Directorate Senior Leadership Team (SLT) met to agree what CQC's role and response would be in relation to the IPC BAF tool (IT3/214 [INQ000088563]) which had been developed by NHSE. It was agreed that, given the importance of IPC in the context of the pandemic, we needed to review the IPC self-assessments by trust boards at the earliest opportunity to help inform the effectiveness of our regulatory response.

301. NHSEI published the IPC BAF tool at the beginning of May 2020. Whilst not mandatory, trusts were encouraged to complete it. The publication and use of the IPC BAF tool enabled us to engage with NHS providers and to undertake a comprehensive review of how individual trusts assured their boards that they had effective IPC controls and procedures in place.

302. In the summer of 2020, our inspectors held conversations with NHS trust leaders to discuss the IPC BAF tool during which we considered their completed self-assessments together with any supporting evidence and at the same time work was undertaken to adapt CQC's Emergency Support Framework (ESF) to include conversations about the IPC BAF tool [IT3/103 [INQ000398489]; IT3/104 [INQ000398490]; IT3/105 [INQ000398491]]. Trust responses were reviewed regionally by the hospital directorate teams and then at a national panel with representatives from across the regions, together with our Intelligence and Strategy colleagues. As a result, we developed an understanding of the progress that trusts were making to identify elements of good IPC practice as well as areas which were more challenging, as set out in the document 'Outputs from the Infection Prevention and Control Board Assurance Framework Assessments' [IT3/242 [INQ000398618]].

303. Examples of good IPC practice were:

    303.1. Some trusts had used the fundamentals of the Board Assurance Framework to develop assurance tools for local clinical areas to assess

themselves and other organisations had sought external validation of their systems and processes.

303.2. The majority of trusts had systems in place to manage and monitor the prevention and control of infection. Many organisations had introduced some type of champion or 'buddy' approach to support staff, for example to ensure the correct use of PPE or adherence to handwashing.

303.3. Increasing cleaning schedules and employing additional cleaning staff was a common theme across trusts. Hospitals developed zonal areas and pathways through premises to improve the flow of patients, visitors and staff and to reduce cross-contamination where possible.

303.4. Some organisations replaced antimicrobial ward rounds with virtual ones, and in some cases identified the need for additional consultant microbiologists.

303.5. The majority of trusts provided a range of information to patients, visitors, staff and other contractors on their premises, and ensured that their websites were kept updated. Some employed guides and buddies to assist visitors and some used technology to help patients and relatives communicate.

303.6. Patients were being screened on admission and at specific intervals post-admission. Trusts implemented restricted visiting to reduce the risk of cross-infection. Hospitals were zoned to reduce the risk of cross-infection and patients were cohorted where possible.

303.7. Trusts provided training to staff, including contractors, about discharging their responsibilities around IPC. The use of agency or temporary staff was reduced where possible and organisations placed numerous information displays around buildings to inform and keep the flow of people as effective as possible.

303.8. Some trusts had adequate isolation facilities and patient cohorting took place to reduce the risk of cross-infection.

303.9. Trusts with in-house laboratory services tended to have fewer issues accessing services and Covid-19 test results.

303.10. Organisations had IPC policies in place and the majority had also developed additional Covid-specific information.

303.11. The majority of staff had access to occupational health services and trusts provided staff-testing arrangements. Some trusts provided additional support such as listening services or wellbeing rooms. Some occupational health services offered additional health assessments for staff to assess for underlying conditions in relation to Covid-19.

304. Areas where IPC practice was found to be more challenging:

304.1. Some trusts took a long time to present the Board Assurance Framework to their board, meaning that even if the trust had been working on issues identified, the board would not have had the chance to formally review it. For some trusts (particularly mental health trusts) the board assessment of IPC was either incomplete or missing.

304.2. Some mental health trusts did not have systems in place to manage and monitor IPC, for example a lack of a consistent or comprehensive systems to identify people who had an infection or were at risk of developing one.

304.3. There was some suspension of cleaning audits during April and May 2020, and a number of trusts had challenges due to the age of the estate and the lack of isolation facilities.

304.4. Some trusts suspended antimicrobial audits, and a number of mental health trusts were unable to assure themselves of their antimicrobial stewardship.

304.5. In respect of information on infections there was a notable gap in different formats being available to service users, their visitors and any person concerned with providing further support or care.

304.6. Some trusts implemented staff temperature screening but this did not appear to be universal.

304.7. Some trusts had problems with the fit of FFP3 masks, particularly for people with smaller faces.

304.8. Many trusts did not have adequate isolation facilities, usually due to the age and/or design of the estate.

304.9. There was variation both in access to the number of Covid-19 tests available in a 24-hour period and the turnaround time of tests. A small number of mental health trusts indicated they did not have access to timely laboratory services.

304.10. A minority of trusts retained their pre-pandemic guidance on individual care to help prevent and control infection, and a small number had to revise their existing IPC guidance as it was deemed out of date irrespective of the pandemic.

304.11. A small minority of mental health trusts reported they did not have access to a suitable occupational health scheme for their employees. Some trusts reported that it had been challenging to keep good levels of segregation of staff at work.

305. During the early stages of the pandemic we developed strong links with NHSEI and from July 2020 we were given access to their nosocomial infections data from across the country, which was refreshed on a weekly basis (IT3/215 [INQ000398588] and IT3/216 [INQ000398589]). We used this, together with other intelligence we had in our regular interactions with trusts and our assessment of priorities for regulatory intervention in specific trusts.

306. On 18 August 2020 CQC's Hospitals Directorate SLT met to discuss a proposal for conducting an additional programme of specifically IPC focused inspections (IT3/217 [INQ000398590]). The proposal was prepared using the knowledge that we had gained through our engagement with trusts during the IPC BAF conversations, NHSE'I's nosocomial infection data, local intelligence and the fact that our scheduled inspection programme remained suspended. The proposal presented two options in terms of the method and approach for the IPC inspections:

306.1. Option one was to undertake focused responsive inspections where there was an identified risk based on ESF IPC responses, national nosocomial infection data and local intelligence led by regional teams.

306.2. Option two was to establish a programme of inspections of those providers where there was an identified risk based on ESF IPC responses, national nosocomial infection data and local intelligence, as well as a sample of providers where there were no concerns about risk but in terms of which we had identified innovative practice which may have had a positive influence on IPC.

307. On 20 August 2020 the proposal was considered at a meeting of CQC's Sector Policy Oversight Group (IT3/218 [INQ000398591]). It was agreed that there was a need to carry out a programme of responsive inspections focusing on IPC where there were concerns. The rationale for undertaking inspections where there were no concerns about risk was so that we could understand how the IPC measures in place at those organisations had a positive influence on the prevention and control of infection. This approach would also mirror the approach already taken in the ASC directorate where a programme of IPC inspections had already commenced. Therefore the decision was taken to move forward with option two.

308. In August 2020, due to IPC concerns (outlined below), we undertook IPC-focused inspections at The Hillingdon Hospital and William Harvey Hospital. We subsequently published reports of our findings, which are set out below. (IT3/219 [INQ000398592]; IT3/220 [INQ000398594])

William Harvey Hospital

309. We had received some concerns from staff, stakeholders and members of the public relating to IPC at the William Harvey Hospital and wrote to the trust on 17 July 2020 requesting additional information relating to assurance of effective oversight of IPC, including the trust's Board Assurance Framework and associated checklist (IT3/445 [INQ000466447]). On 22 July 2020 we wrote to the trust's chief nurse setting out our specific concerns around IPC, which included (IT3/446 [INQ000466448]):
    - 309.1. A lack of hand gel in the endoscopy area of the outpatients department and a lack of signage in relation to hand hygiene;
    - 309.2. Staff booking in patients in the emergency department were touching PPE that they handed to patients without cleaning their hands between booking and handing out the PPE;
    - 309.3. Changing rooms used by theatre staff were not being cleaned routinely; and
    - 309.4. The general standard of cleaning in the emergency department, for example sinks and toilets being cleaned within toilet areas, but not the rest of the environment.

310. The trust provided documentation on 24 July 2020 and responded to the specific IPC concerns in a letter dated 28 July 2020 (IT3/447 [INQ000466449]).

311. In addition to these concerns, there was uncertainty as to the identity of the lead executive on IPC which we learned during our Board Assurance Framework call with the trust in June 2020. We arranged a second call with the trust on 29 July 2020 where we established that the trust had limited assurance on IPC through its audit and governance structures and its compliance procedures. The Board Assurance Framework had still not been completed or sent to the trust's board. On 3 August 2020 we issued a warning notice under S29A of the 2008 Act to the trust. We carried out an IPC focused inspection at William Harvey Hospital (the trust's primary site) on 11 August 2020. Following the inspection we issued a Notice of Decision under section 31 of the 2008 Act on 20 August 2020.

The Hillingdon Hospital

312. On 2 July 2020 the Hillingdon Hospitals NHS Foundation Trust declared a Covid-19 outbreak affecting staff in a single clinical area at Hillingdon Hospital and resulting in a number of staff having to self-isolate. On 30 June 2020 a staff study day had been held in the trust Education Centre lecture theatre and concerns were raised about alleged lack of social distancing. During the time of the outbreak Hillingdon Hospital was closed to emergency admissions. We undertook a focused inspection on 4 and 5 August 2020 looking at infection prevention and control generally and in relation to Covid-19. Following this inspection we issued the trust with a Notice of Decision under Section 31 HCSA 2008 on 7 August 2020.

313. In September 2020 we published 'Covid-19 Insight - Issue 4' which included a review of IPC in acute hospitals (IT3/131 [INQ000235474]). We analysed the outcomes of the ESF calls between our inspectors and all acute and specialist trusts. These calls discussed each trust's Board Assurance Framework to identify how the trust was assuring itself of good IPC across 11 key areas. Broadly, the trusts said they had "high assurance across all the areas" indicating that most trusts assured themselves that they were managing IPC systems and mitigating risks. However, there were

some examples of where the systems and procedures for the management and monitoring of IPC were ineffective, as follows:

313.1. Robust audits not always taking place during the peak of the pandemic, including audits of PPE, waste disposal and the screening of other healthcare-associated infections. Where audits were taking place, there were a few examples of trusts not being able to show any learning from them.

313.2. Oversight of IPC training varied between trusts, meaning that some trusts could not always be assured that staff had been adequately trained in IPC procedures. Non-clinical and non-ward staff were not always provided with Covid-19 specific training or guidance. In one example, the Trust was unaware of the IPC training or guidance that contractors had received or whether any had been provided at all.

313.3. Some trusts had challenges that limited their ability to isolate and cohort Covid-19 positive patients. Insufficient side room capacity was commonly reported, particularly for trusts with older estates, as was limited ventilation. Trusts that were able to provide assurance, despite an older estate, had carried out robust risk assessments and put mitigation plans in place, for example using pop-up isolation facilities, repurposing other areas of the hospital for covid-19 patients and adding doors to the entrance of bays. challenges in isolating and cohorting Covid-19 positive patients.

314. On 22 October 2020 an updated IPC Inspection Proposal (IT3/221 [INQ000398595]) was presented to the Hospitals Senior Leadership Team, setting out the proposed approach to undertaking onsite inspections to assess IPC measures in place at NHS trusts.

315. In the updated proposal it was noted that the conversations we had been having with trusts regarding their IPC BAF assessments during July and August 2020 had informed our understanding of how they had assured themselves as part of the board assurance processes. Whilst the majority of these calls had resulted in CQC agreeing that the trusts had the right level of assurance in place, there were some where we did not agree that they had adequate assurance. In addition to this, there

had been a sharing of NHSE data on nosocomial infections on a weekly basis which had allowed further local discussions to take place with trusts who were reporting high levels of nosocomial infections.

316. The proposal set out the intended pilot approach which was to undertake up to 20 inspections, using a modified Well-Led framework specifically considering IPC issues. In the proposal it was suggested that a selection of trusts should be inspected, including both those with challenging IPC arrangements as well as those that were high performing. It was recognised in the proposal that the output of the IPC BAF calls made earlier in 2020 was outdated and therefore could not be relied upon to make decisions on which trusts to inspect due to the passage of time. Therefore CQC had started developing a data set that would help us to identify where the risks were, and this would include levels of nosocomial infection.

317. The inspections would take place in two parts:
    317.1. first, an assessment of our current knowledge of the trust from an IPC perspective, a request for limited additional information and then calls with key trust staff; and
    317.2. secondly, a short site-based inspection to test and explore the information that had been gathered.

318. At the meeting on 22 October 2020 the Hospitals SLT discussed how the updated proposal linked in with the other Key Question inspection standards and agreed that they needed to fit together and not take place as separate inspections where there are wider concerns (IT3/222 [INQ000398596]).

319. At the Hospitals SLT meeting on 19 November 2020 the Infection Prevention and Control Inspection Proposals – Paper Two (IT3/223 [INQ000398597] and IT3/224 [INQ000398598]) was presented to update the Hospitals SLT on the approach to IPC inspections. The paper set out further details of the proposed approach to undertake the 20 IPC inspections indicating that two pilot inspections were planned to take place in early December 2020 and the remaining inspections in Quarter 4 of 2020/21. It was proposed that the inspections would not result in a rating but should

concerns be identified then the inspection would be completed and an MRM undertaken to determine the appropriate response. It was proposed that there would be a national panel to have oversight and review national data and to work with regional colleagues to agree which trusts would be inspected.

320. At the meeting on 19 November 2020 (IT3/225 [INQ000398599]) the Hospitals SLT agreed that the two pilot inspections take place in early December, although the first on-site inspections did not begin until January 2021.

321. As part of the process for planning which trusts would be inspected under the IPC programme, a series of 'Super Management Review Meetings[10]' were convened to review the risks for all trusts within a region and determine inspection priorities. The rationale for carrying out each inspection was sent for approval to the Chief Inspector of Hospitals before any inspection took place and we exhibit three examples of those rationales (IT3/226 [INQ000398600]; IT3/227 [INQ000398601]; IT3/228 [INQ000398602]). Focused inspections were only to be carried out where there was no other appropriate mechanism to address concerns, such as through our ongoing monitoring of each trust.

322. The first of these IPC-focused inspections was carried out on 19 January 2021 and the last inspection concluded on 5 May 2021. These inspections were risk-based and looked at how Trust leadership, strategy, culture, governance, risk and performance management, information management, engagement and learning processes translated into robust IPC practice at clinical level and in public areas of the hospital. The Inspection Reports were published between March and July 2021. (IT3/229 [INQ000398603]; IT3/230 [INQ000398605]; IT3/231 [INQ000398606]; IT3/232 [INQ000398607]; IT3/233 [INQ000398608]; IT3/234 [INQ000398609]; IT3/235 [INQ000398610]; IT3/236 [INQ000398611]; IT3/237 [INQ000398612]; IT3/238 [INQ000398613]; IT3/239 [INQ000398614]; IT3/240 [INQ000398616]; IT3/241 [INQ000398617])

[10] A Management Review Meeting that related to multiple locations or a whole region, rather than a standard MRM which just related to a specific issue.

323. The hospitals we selected for inspection were chosen using intelligence drawn from CQC's partner organisations such as NHSE and HSIB as well as reviews of relevant qualitative and quantitative data held by CQC.

324. In addition to nosocomial rates, some of the factors taken into account when assessing which Trusts to inspect included: whistleblowing concerns being raised; performance for rates of other healthcare acquired infections (for example, Clostridium difficile, MRSA); reporting of incidents of cross infection; history of compliance with Regulations; and information provided by the Trust during engagement calls. Some of the inspections were carried out as a result of an outbreak or outbreaks of hospital-transmitted Covid-19 infections.

325. During July and August 2020 (IT3/242 [INQ000398618]) we assessed all NHS acute, mental health, community trusts (both standalone and combined) and ambulance trusts using the adapted Emergency Support Framework, which included questions about the IPC Board Assurance Framework. We carried out 190 calls to NHS trusts to discuss their Board Assurance Framework, 140 of which were to acute and specialist trusts, and the remaining 50 were to mental health and community trusts.

326. For primary care providers we used the ESF to enable monitoring and engagement conversations with those providers. The ESF calls had four assessment areas, the first of which was 'Safe care and treatment' which included questions about whether infection risks to people using the service were being thoroughly assessed and managed. The other assessment areas were 'Staffing arrangements', 'Protection from abuse' and 'Assurance processes, monitoring and risk management.' We developed a guidance document to assist inspectors in having those conversations (IT3/243 [INQ000398619]).

327. In relation to the assessment of IPC specifically, as part of the 'Safe care and treatment' assessment area we would review whether the service was managing to keep up to date with current IPC methods; what challenges the service had faced; and how it ensured that the necessary IPC controls were in place. Consideration would be given, for example (and where relevant), to whether the service had

implemented changes to IPC practice in line with guidance, dissemination of guidance to staff, and whether their IPC measures were suitable for the way in which they were delivering services.

328. There were additional guidance documents for ESF conversations within the following sectors:
    328.1. Adult Social care
    328.2. Independent ambulance services
    328.3. Dialysis services
    328.4. Learning disability and autism services
    328.5. Dentists
    328.6. Health & Justice
    328.7. Children's Homes
    328.8. Urgent Care
    328.9. Independent Healthcare
    328.10. Online Services

329. With this approach CQC aimed to strike the right balance between protecting people using services and not wanting to place any additional pressure on providers at this time. This was kept under constant review and CQC also liaised with other bodies at a local level, including Clinical Commissioning Groups (CCGs), to maintain oversight, share concerns and monitor any developing risks.

330. As is explained above, CQC's routine inspections were suspended from March 2020 and we moved to a risk-based approach to inspections. IPC was already a feature of our comprehensive inspection methodology and throughout the pandemic we continued to assess IPC, where appropriate, in inspections, including those that were undertaken outside of the IPC-focused inspection programme.

331. As set out above the Health Assessment Framework applied to all health services covered and inspected by the Hospitals Directorate. This framework required Inspectors to review IPC practice under the "Safe" key question and to look at two KLOEs: How do systems, processes and practices keep people safe and

safeguarded from abuse? How are standards of cleanliness and hygiene maintained, and are there reliable systems in place to prevent and protect people from a healthcare-associated infection?

332. Alongside the Health Assessment Framework, CQC had a number of different Core Service[11] frameworks which set out in more detail what these key lines of enquiry and prompts meant for particular services across Acute, Ambulance, Community Health and Mental Health sectors. Within each sector there are a number of core services: for example within the Acute sector there are eight core services (Urgent & Emergency Services, Medical care, Surgery, Critical Care, Maternity, Services for children & young people, End of Life care and Outpatients) with each core service having its own inspection framework. The Core Inspection Framework in each case considers the Key Lines of Enquiry including, where applicable, IPC measures under 'how do systems, processes and practices keep people safe and safeguarded from abuse.' Within that KLOE is sector specific guidance relating particularly to the core service that inspectors can consider as part of the inspection process.

333. The methodology we used for the IPC focused inspections is set out in the 'Inspection Framework: Infection Prevention and Control Focused Inspections' document (IT3/244 [INQ000398620]) which was published in November 2020, and revised in December 2020, February and March 2021. This framework supported the IPC inspection planning, preparation and information gathering, but made it clear that inspectors should use their judgement to target IPC prompts and sample questions to gather evidence relevant to the service that they were inspecting. Each inspection team included a member with a background in IPC or a Specialist Advisor in IPC.

334. The methodology used during the inspections was built around information gained during the IPC board assurance conversations, information received about nosocomial infections, Covid-19 rates within trusts and our routine engagement

[11] Core services are the ones that most providers deliver, and are typically services that people use the most, or in some cases, the ones that may carry the greatest risk.

calls. There was a desktop stage involving review of the documentation available and planning telephone calls with key individuals at the trust, such as the Director of IPC or IPC lead and other senior management team members. This would be followed by a very short-notice or unannounced on-site inspection. Consideration would be given to which areas of the hospital to inspect and whether it was appropriate to attend areas with high levels of aerosol activity.

335. The Inspection Framework then set out KLOEs. As these were Well-Led[12] focused inspections, the approach could be tailored to relevant areas of concern by the inspector and therefore not all KLOEs needed to be covered in an IPC inspection. The KLOEs covered the following areas:

335.1. Whether the Trust had the leadership capacity and capability to consider high-quality, sustainable care.

335.2. Was there a clear vision and credible strategy to deliver high-quality, sustainable care to people and robust plans to deliver it.

335.3. Did the Trust have a culture of high-quality, sustainable care.

335.4. Were there clear responsibilities, roles and systems of accountability to support good governance and management.

335.5. Were there clear and effective processes for managing risks, issues and performance.

335.6. Was appropriate and accurate information being effectively processed, challenged and acted upon.

335.7. Were the people who used services, the public, staff and external partners engaged and involved to support high-quality, sustainable services.

335.8. Were there robust systems and processes in place for learning, continuous improvement and innovation?

336. These generic key lines were then given specific IPC prompts for inspectors to consider during the inspection. In total there were 44 IPC-specific prompts set out in the Framework.

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[12] By 'Well-Led' we mean that the leadership, management and governance of the organization assures the delivery of high-quality and person-centred care, supports learning and innovation, and promotes an open and fair culture.

337. Positive tests for Covid-19 were not used as a marker of the quality of IPC measures. There were many variables that influenced the rates of positive tests within a service and therefore positive tests amongst staff and inpatients could not be relied upon as a standalone indicator of poor IPC practice.

338. However, data shared by NHSE on nosocomial infection rates was one of the sources relied upon by CQC when considering whether to conduct an IPC inspection at a particular trust. As part of the Inspection Framework, the suggested documentary evidence to consider included:

338.1. staff absences (including due to Covid-19);

338.2. testing of staff (including how testing was managed, the test results and the percentage of staff who are self-isolating in the service in question);

338.3. staff risk assessment and Covid-19 testing protocols; and

338.4. latest nosocomial data.

339. As regulator, it is our view that it is beyond the scope of our role to address issues of public health and we do not consider that we have the appropriate expertise as an organisation to address the reasons behind the variation in incidence of hospital-acquired Covid-19 between different Trusts during the relevant period.

G. CQC's Do not attempt cardiopulmonary resuscitation (DNACPR) Report

340. In March 2021, we published a thematic report entitled 'Protect, respect, connect: Decisions about living and dying well during COVID-19' (IT3/245 [INQ000235492]). Our report provides findings and recommendations arising from our review, undertaken pursuant to a request by the Rt Hon Nadine Dorries MP in her capacity as Minister of State for Patient Safety, Suicide Prevention and Mental Health in terms of section 48 of the 2008 Act[13] and commissioned by DHSC in October 2020. The review was conducted between November 2020 and January 2021 and looked at

[13] Pursuant to section 48 Health and Social Care Act 2008, we may conduct any special review or investigation, but must do so if the Secretary of State so requests.

how DNACPR decisions[14] were being made in the context of advance care planning across all types of health and care sectors, including care homes, primary care settings and hospitals. As requested, we have set out below a timeline of our key interactions with DHSC and others, together with an explanation of the approach taken and findings reached.

341. We welcomed the request from the Minister for this review as DNACPR had been an area of concern for us for some time. Shortly before the Covid-19 pandemic there had been widespread concerns that, as part of advance care planning, DNACPR decisions were being made without involving people, their families and/or carers and that blanket decisions were being applied to groups of people.

342. In November 2019 DHSC contacted CQC seeking contribution to the Minister of State for Care's response to the 2018 Learning Disabilities Mortality Review (LeDeR) annual Report, published in May 2019, specifically regarding the recommendation that CQC conduct a review of "Do Not Attempt CPR Orders and Treatment Escalation Personal Plans" relating to people with learning disabilities (IT3/448 [INQ000466450]). On 23 January 2020 CQC provided the requested update to DHSC indicating that:

"CQC acknowledges the importance of the findings of the 2018 LeDeR annual report published in May 2019 – and welcomed the recommendation made for CQC around reviewing provider's DNACPR orders and Treatment Escalation Personal Plans (TEPP) for people with learning disabilities during inspection. CQC's current inspection approach prompts inspectors to review records relevant to a person's care and treatment, including DNACPR and TEPP's where applicable. Where shortfalls in the quality and safety of care are identified, CQC will take appropriate regulatory action to encourage and ensure action is taken by providers to meet the requirements of legislation and improve care. CQC is reviewing its current relevant inspector guidance with a view to updating and expanding the guidance available,

[14] A 'Do Not Attempt Cardio Pulmonary Resuscitation' (DNACPR) decision is an instruction not to attempt cardiopulmonary resuscitation. They are designed to protect people from unnecessary suffering by receiving CPR that they do not want, that will not work, or where the harm outweighs the benefits.

and promoting its particular importance for people with a learning disability. CQC Action: By October 2020" (IT3/449 [INQ000466451]).

343. This work was put on hold until the work on the Section 48 review was completed in case there was learning from the review that needed to be incorporated into any revised guidance.

344. In March 2020 we became aware of concerns (raised via the National Care Forum) around DNACPRs and advance care planning. On 27 March 2020 Richard Kelly (Deputy Director for Adult Social Care: Covid-19 Policy at DHSC) notified CQC of a "really worrying local case" where GPs were "telling local care homes to put all residents on DNARs". The issue had been reported to DHSC by the National Care Forum on 26 March 2020. DHSC approached CQC for assistance with getting the correct messaging out to the relevant providers and GP practices (IT3/450 [INQ000466452]).

345. On 27 March 2020 NHSEI also alerted CQC, RCGP and GPC to the issue and indicated that an agreed position needed to be reached and communicated urgently (IT3/451 [INQ000466453]; IT3/452 [INQ000466454]).

346. It was important that appropriate messaging was sent to GP practices and care providers urgently and so, on 30 March 2020, we issued a joint statement, together with the BMA, CPA (representing its members) and the RCGP, to adult social care providers and GP practices stating the importance of advance care planning based on the needs of the individual (IT3/253 [INQ000235489]). It sought to remind all providers that it was unacceptable for advance care plans, with or without DNACPR, to be applied to groups of people of any description. The joint statement was also endorsed by NHSEI who were unable to authorise the use of their logo by the publication date but indicated that they were happy for CQC "to publish with the logos you get, we will then share/cascade if that's ok" (IT3/254 [INQ000398629]).

347. Additionally, from March 2020 to September 2020, we had seen an increase in Give Feedback on Care submissions that related to DNACPR. The majority of this

feedback raised concerns about DNACPR orders that had been put in place without consulting with the person or their family. Often the evidence we received was about an individual, but there were some examples where DNACPR orders were placed on numerous people routinely. As detailed in pages 8-10 of our interim report (referred to below) we were also aware of other organisations' concerns around the use of DNACPR orders during the early stages of the pandemic.

348. We saw this review as an opportunity to accelerate best practice around treatment escalation plans, advance care planning and personalised care planning. In carrying out this review we had two primary aims, to investigate the scale of this issue to understand why it was happening, and to use our evidence to make actionable recommendations that would begin to deliver real change. To carry out this review effectively and meaningfully, we knew we would need a multi-faceted approach that could bring in the views of stakeholders as well as capturing the voices of those who were receiving care, or their families and loved ones.

349. On 29 September 2020, Rosie Benneyworth (Chief Inspector of Primary Medical Services) and I met with William Vineall regarding a proposed review to be conducted under section 48 of the 2008 Act. During the meeting we were informed that an announcement would be made in the House of Lords the following day (IT3/247 [INQ000398622]).

350. On 1 October 2020, a question was raised by Baroness Browning in the House of Lords asking the Government what assessment they had made of the use of Do Not Resuscitate notices in hospitals and nursing homes since March 2020. Lord Bethell (Parliamentary Under-Secretary of State, DHSC) stated that the Minister for Patient Safety and Mental Health would be writing to CQC requesting that we investigate and report on DNACPR issues. (IT3/248 [INQ000339272]).

351. On 6 October 2020, we had an initial meeting with DHSC colleagues to discuss the proposed review in more depth. The meeting was attended by representatives from DHSC's Health Ethics team and their CQC Sponsorship team. DHSC advised that the reason for the review had arisen due to multiple reports of blanket DNACPR

decisions being issued. It had coincided with Parliament returning and heightened interest in both the House of Commons and House of Lords on this issue. DHSC also advised that it had received a pre-action protocol letter looking to instigate a judicial review. We indicated that we could expand the scope of the review requested to also look for examples where DNACPRs were being used in a good way. DHSC asked us to provide some options and timescales, and to share our work undertaken up to that point on the issue together with an engagement plan so that terms of reference could then be agreed. (IT3/249 [INQ000398624]).

352. On 7 October 2020, the Rt Hon Nadine Dorries MP wrote to us in her capacity as Minister of State for Patient Safety, Suicide Prevention and Mental Health to request that we conduct a special review, under section 48 of the 2008 Act, of DNACPR decisions taken during the pandemic in the context of advance care planning. The letter referenced concerns around the blanket application of DNACPR decisions and that DHSC was committed to ensuring that DNACPR policy and best practice guidance was understood and followed. We were asked to look at 'all key sectors', including care homes, primary care and hospitals, exploring implementation of best practice DNACPR guidance. The special review was to start with immediate effect. (IT3/250 [INQ000235490])

353. We met again with DHSC on 9 October 2020 where we introduced the options and remit for the thematic review and discussed approaching it through both a person-centred approach and online information gathering; and assured them that we would be mindful of local Covid-19 escalation levels when planning face to face activity. We discussed the cost of undertaking the review and timescales for the delivery of the interim and final reports. It was agreed that CQC would formally respond to the Minister's letter of 7 October 2020 (including our proposed approach and budget requirement), and DHSC would share with us a list of MPs and Peers who had expressed an interest in the topic and a list of Parliamentary Questions raised on the topic since September 2020. (IT3/251 [INQ000398627])

354. On 23 October 2020 I wrote to Ms Dorries responding to her letter of 7 October 2020 setting out our intended scope and approach and timelines for the review as well as

the estimated delivery costs (IT3/453 [INQ000466455] and IT3/454 [INQ000466456]).

355. On 29 October 2020 I wrote to Ms Dorries again to provide an update on the estimated cost of the review (IT3/455 [INQ000466457] and IT3/456 [INQ000466458]).

356. On 2 November 2020 I received Ms Dorries' response to my letters of 23 and 29 October 2020 wherein she confirmed that DHSC was content with the timing, approach and costs relating to the review (IT3/457 [INQ000466459]).

357. As a result of our interactions with DHSC in October 2020, we immediately began conversations with key partners, including Disability Rights UK, Compassion in Dying, Mencap, the BMA, RCGP and the CPA, among others. Although the review was our responsibility, we wanted to give our stakeholders the opportunity to help us shape it, taking into consideration the questions they wanted to ask. We undertook a series of scoping meetings with several key partners. Stakeholders welcomed the review and demonstrated strong support for our work.

358. All aspects of our review were guided by our assessment framework, which was developed in consultation with these stakeholders. We focused on assessment of the following areas:

    358.1. Putting people at the centre: How were providers and systems putting people at the centre of their care in approaches to DNACPR decisions to protect human rights, protect people from discrimination and meet people's individual needs? What were people's experiences from the start of the pandemic?

    358.2. Shared vision, values, governance and leadership: How did providers and the system work in partnership to influence and agree a shared approach for the use of DNACPR decisions to protect human rights, give equal access to care and treatment and prevent avoidable deaths? What were the enablers and barriers for the appropriate use of DNACPR?

358.3. Workforce capacity and capability: How were providers and the system working together to ensure that clinicians, professionals and workers involved in the use of DNACPR had the right knowledge, skills and tools to deliver personalised approaches to DNACPR in line with the relevant legislation, and how were staff and people supported to raise concerns in order to improve care?

359. The methodology used included:

359.1. Review of literature, guidance and evidence: We wanted to understand what was already known about the use of DNACPR before the pandemic and what impact the use of DNACPR had on people's experiences during the pandemic. This included understanding best practice in approaches to thinking about future care and treatment if a person was to become seriously ill or approaching the end of their life.

359.2. Engagement with external stakeholders and experts: To ensure that the views of interested parties, and in particular the views of people affected by the use of DNACPR during the pandemic, influenced and shaped the scope of the review from the outset, we held initial conversations with nearly 50 stakeholders who had a specific interest in the scope of the review. These included organisations that represented or advocated on behalf of the public, family carers, care providers, and care professionals. Many of these organisations and individuals continued to provide their expertise and insight through our Expert Advisory Group which influenced the scope, approach and the recommendations in our final report.

359.3. Bespoke information collections: To help us understand the scale of the issue, we sent a voluntary information request to around 25,000 adult social care providers (including care homes, nursing homes, domiciliary care agencies, supported living schemes, Shared Lives facilities and extra care housing). While acknowledging that responsibility for making DNACPR decisions did not predominantly rest with adult social care providers, we asked them a range of questions to understand their views of the experiences of people in these settings. We asked about the number of inappropriate DNACPR decisions put in place from 17 March 2020, what

made them inappropriate and if they remained on people's records at the point of submission of the information request. With the support of voluntary sector partners, we ran surveys to ask people who used the services and their families and carers about their experiences of DNACPR decisions during the pandemic. We made sure that some communities who needed support in sharing their experiences through this survey were enabled to do so.

359.4. Fieldwork activities: We carried out fieldwork to explore how primary, secondary, social care and system partners worked together in an area including the impact of commissioning arrangements. We identified seven clinical commissioning group (CCG) areas as case studies for our review. These covered a cross-section of geographical areas and a mix of demographics so that the lessons learned would be of value to people in health and social care across the country. We focused activity at a CCG level, the level at which clinical services are planned and delivered and where population health management was used to target interventions to particular groups, in partnership with NHS organisations and local government.

360. Wherever it was possible and appropriate to do so, our fieldwork was completed virtually which also involved:

360.1. Retrospectively tracking people's journeys through care: To gain an understanding of people's experiences of care and how decisions about their care and treatment were made and communicated, we carried out an in-depth review of seven people's experiences. This involved reviewing the relevant care records and, wherever possible, speaking to the person experiencing care and their families and a range of relevant health and care professionals.

360.2. Sampling DNACPR records: We reviewed the DNACPR records of 166 people affected during the pandemic allowing us to consider a larger number of people's cases. We accessed care records through a range of care settings (acute, mental health hospitals, care homes and GP services).

360.3. Information from local advocacy groups: We spoke with local advocacy organisations that had engaged with the public and providers over the use of DNACPR decisions to share our emerging findings, ask for their feedback on these, and their thoughts on recommendations.

360.4. Interviews and focus groups with frontline staff: We held 156 interviews and focus groups with clinicians, professionals and workers from different roles and organisations involved in providing care, which included the use of DNACPR decisions, to understand practice, challenges and enablers for best practice.

360.5. Interviews with commissioners and members of the wider system: We spoke with commissioners and system leaders to explore practice across the system, collaboration and how oversight arrangements ensure best practice in DNACPR decisions.

361. Throughout November 2020 we regularly met and corresponded with DHSC colleagues to discuss and provide updates regarding the review. The timetable for the sharing of the interim and final reports with DHSC and the publication of the final report was agreed with DHSC on 19 November 2020 (IT3/458 [INQ000466460]). The draft interim report was shared with DHSC colleagues, including the CQC Sponsorship Team, on 20 November 2020 (IT3/459 [INQ000466461] and IT3/460 [INQ000466462]). DHSC provided their comments on the draft interim report to CQC on 24 November 2020 (IT3/461 [INQ000466463] and IT3/462 [INQ000466464]).

362. We sent the interim report to Nadine Dorries and our DHSC colleagues along with a cover letter on 30 November 2020 (IT3/463 [INQ000466465]; IT3/464 [INQ000466466]; IT3/465 [INQ000466467]).

363. The final copy of the interim report was sent to DHSC on 2 December 2020 (IT3/466 [INQ000466468]) and it was published on our website on 3 December 2020 (IT3/246 [INQ000235491]). On 4 December 2020 Minister Dorries' Private Secretary confirmed that she had reviewed and noted the interim report (IT3/467 [INQ000466469]).

364. We published our final report on 18 March 2021 (IT3/245 [INQ000235492]). When concluding our review we found that there needed to be a focus on three key areas:

364.1. Information, training and support

364.1.1. We found that the quality of people's experiences was greatly impacted by having the time and information they needed to talk about what care and support they wanted. People's experiences of DNACPR decisions varied.

364.1.2. We made it clear in our conclusions that best practice requires that every DNACPR decision must take account of each person's individual circumstances or wishes. While most providers we spoke with were unaware of DNACPR decisions being applied to groups of people, we heard evidence from people, their families and carers that there had been 'blanket' DNACPR decisions in place.

364.1.3. We found also that the training and support that staff received to hold these conversations was a key factor in whether they were held in a person-centred way that met people's needs and protected their human rights. Where people using services and health and care staff were not fully informed about advance care planning or given the opportunity to discuss DNACPR decisions in a person-centred way, there was a clear risk of inappropriate decision making and a risk of unsafe care or treatment. This also gave rise to concerns that people's human rights and rights under the Equality Act 2010 had not been considered or were at risk of being breached.

364.2. A consistent national approach to advance care planning

364.2.1. Our findings highlighted the need for a consistent national approach to advance care planning and DNACPR decisions, and a consistent use of accessible language, communication and guidance to enable shared understanding and information sharing among commissioners, providers and the public.

364.2.2. Across all the areas that we looked at, there were many types of advance care planning in use.

364.2.3. This lack of consistency and the problems this causes could affect the quality of care received by the person and result in missed opportunities to support them in the right way at the right time.

364.2.4. We found that the way in which health and care professionals talked about advance care planning and DNACPR decisions also varied.

364.2.5. Every service provider we looked at had taken steps to make sure that service providers were aware of the importance of taking a person-centred approach to DNACPR decisions and advance care planning. However, we found that providers had to cope with a huge amount of guidance about all aspects of the pandemic that lacked clarity and changed rapidly, leading to confusion.

364.3. Improved oversight and assurance

364.3.1. We determined that there was an urgent need for regional health and care systems, including providers, clinical commissioning groups and patient representative bodies, to improve how they assure themselves that people are experiencing personalised, compassionate care in relation to DNACPR decisions.

364.3.2. Most providers and health and care professionals told us that the individuals, their families, carers or advocates were involved in conversations about their care, including DNACPR decisions. However, poor record keeping and lack of audits meant that we could not always be assured that the individuals were being involved in conversations about DNACPR decisions, or that these were being made on individual assessments. Once DNACPR decisions were in place, it varied whether providers and local systems reviewed them. We were also concerned about whether local areas had oversight of training and support for health and care professionals to ensure they were making sound clinical decisions that were person-centred and protected people's human rights.

365. We knew it was important to keep up momentum and use our findings to make recommendations that could encourage real systemic change. Focusing on the above mentioned three key areas we recommended that:

365.1. Recommendation one: a new Ministerial Oversight Group (MOG) be set up to take an in depth look at the issues raised in our report. The group, which should include partners in health, social care, local government and voluntary and community services, should be responsible for overseeing the delivery and required changes suggested by the recommendations of this report. DHSC was identified as the lead department responsible for this.

365.2. Recommendation two: providers ensure that people and/or their representatives are included in compassionate, caring conversations about DNACPR decisions as part of advance planning. This includes making reasonable adjustments for disabled people to remove any information or communication barriers and ensuring that clinicians, professionals and workers have the necessary time to engage with people properly.

365.3. Recommendation three: health and social care systems consider diversity, inequality and mental capacity factors when planning care for the local population in partnership with local communities, including voluntary and community services. Integrated care systems were identified as the lead bodies responsible bodies for this.

365.4. Recommendation four: there are clear and consistent training, standards, guidance and tools for the current and future workforce. This needs to be in line with a national, unified approach to DNACPR decision making. Providers also need to ensure that there are training and development opportunities available for all health and care professionals. Health Education England, Skills for Care and Providers were assigned as the lead organisations for this.

365.5. Recommendation five: there is a consistent national approach to advance care planning and positive promotion of advance care planning and DNACPR decisions, as well as a more general focus on living and dying well. In addition, we recommended that there should be more widely

publicised and accessible information available via a national campaign in partnership with the voluntary sector and advocacy services. DHSC and NHSEI were identified as the lead bodies responsible for this.

365.6. Recommendation six: system partners across health and social care work together with voluntary sector organisations, advocacy services and individuals to establish and assure a national unified approach to policy, guidance and tools that support the positive implementation of DNACPR decisions. DHSC was identified as the lead department for this.

365.7. Recommendation seven: the system ensures that there is digital compatibility between providers enabling them to share real-time updates and information between professionals, services and sectors. NHSX (from 2019 to Feb 2022, NHSX had responsibility for setting national policy and developing best practice for National Health Service technology, digital and data, including data sharing and transparency, it is now part of NHSE's Transformational Directorate) and integrated care systems were assigned as the lead organisations/bodies for this.

365.8. Recommendation eight: there are comprehensive records of the decisions and conversations regarding individuals' care that support them to move around the system well. This requires providers to ensure proper standards of documentation and record keeping and sharing of information around the system.

365.9. Recommendation nine: integrated care systems need to be able to monitor and assure themselves of the quality and safety of DNACPR decisions. To do this, there needs to be a consistent dataset and insight metrics across local areas.

365.10. Recommendation ten: providers ensure that all workers understand how to speak up, feel confident to speak up and are supported and listened to when they speak up. To do this, providers must follow national guidance to foster positive learning cultures and ensure consistency and clarity of speaking up arrangements across the patient pathway. The National Guardian's Office was assigned as the lead organisation for this.

365.11. Recommendation eleven: CQC continues to seek assurance as part of our regulatory work that people are at the centre of personalised, high-quality

and safe experiences when it comes to DNACPR decisions, in a way that protects their human rights. To do this, we will ensure a continued focus on DNACPR decisions through our monitoring, assessment and inspection of all health and adult social care providers.

Overview of feedback received in relation to the recommendations of the report

366. The communication channels established with partners across the health, social care, community and voluntary sectors early in the review gave us the opportunity to gather feedback on the findings and recommendations in the final report. Prior to publication we met with representatives from organisations within the sectors to share the details of the recommendations and as appropriate seek comment thereon.

367. A series of virtual meetings were held in February and March 2021 and provided a platform for us to share our findings and recommendations and to gather feedback from organisations, including but not limited to: Resuscitation Council; Compassion in Dying; RCGP; National Care Forum; ADASS; Local Government Association; Mencap and Care England.

368. The feedback gathered during these sessions was largely positive and supportive. The partners we spoke to were keen to ensure that the messaging emphasised the importance of advanced care planning in its entirety, involved people in discussions about their care and that it should be a whole system approach. The decision to designate lead responsible bodies was welcomed as was the proposal to set up the MOG. Partners expressed some caution around the potential for headlines around this to be misconstrued. At publication we made it clear that although we found a worrying picture of poor involvement, record keeping, and a lack of oversight and scrutiny of those decisions, more work was needed to support health and care clinicians, professionals and workers in holding conversations about DNACPR decisions as part of a holistic approach to advance care planning. Additionally, the feedback received encouraged us to emphasise that when done in the right way these conversations can be a positive experience for all involved. It also highlighted

the need to capitalise on the momentum gained to ensure that conversations about advance care planning and DNACPR decisions are high on everyone's agenda.

369. Details of the draft recommendations were also shared with the lead organisations/bodies in February and March 2021 including NHSE (IT3/255 [INQ000398630] and IT3/256 [INQ000398631] and IT3/257 [INQ000398632]), Skills for Care (IT3/258 [INQ000398633]), Health Education England (IT3/259 [INQ000398634]), NGO (IT3/260 [INQ000398636]) and DHSC (IT3/261 [INQ000398637] and (IT3/272 [INQ000398649]). Comments and feedback around these were received either in writing or during discussions with the organisations concerned. Again, these discussions and the feedback enabled us to ensure that the appropriate organisations were identified as the lead bodies responsible for the recommendations and that the wording used clearly conveyed the appropriate messaging prior to publication.

370. Specifically, our discussions with NHSE and DHSC helped us to ensure that the lead bodies responsible for recommendations 6, 7 and 8 (as summarised in paragraphs 365.6; 365.7 and 365.8 above) were appropriately designated in the final report. The recommendations as set out in the report published on 18 March 2021 were accepted by all lead bodies.

371. We also met with Nadine Dorries MP and Lord Bethell on 16 March 2021 to discuss the report's findings and recommendations. During this meeting we were able to explain the importance of this piece of work and how it had led to broader conversations encouraging good practice in end-of-life care planning and ensuring that these conversations happen. We were able to provide reassurance around concerns about blanket usage, which in part led to the review, and emphasize the need for training and awareness across all sectors including the public. We discussed the role of the then proposed MOG and our willingness to be part of that.

372. Following publication of the report we continued to engage with interested parties concerning the report. Some examples include a presentation at a Parliamentary

engagement event on 24 March 2021 and a webinar aimed at bringing together Clinical Commissioning Groups on 22 April 2021.

373. Following publication of the final report we also wrote to each of the NHS CCG's involved in the review in May 2022 to thank them for their support and co-operation and to provide some additional detail from the fieldwork completed in their local area. An example of one of the letters sent is attached. (IT3/263 [INQ000398639]).

374. One key recommendation from the final report was the formation of the MOG, to oversee the delivery of the recommendations. The MOG, led by DHSC together with health and social care partners, local government, voluntary and community services and CQC, was set up in May 2021 and began to meet quarterly from June 2021. The main aim of the MOG was to ensure that conversations about end-of-life care sat firmly on the agenda across the health and care systems. Our former Chief Inspector of Primary Medical Services, Rosie Benneyworth, sat on the MOG, on invitation by Nadine Dorries MP (IT3/264 [INQ000398640]).

375. The MOG's terms of reference confirmed that it would oversee the delivery of our recommendations on DNACPR decisions (IT3/265 [INQ000339339]). The terms of reference confirmed that the group would bring together key bodies responsible for delivering the recommendations and would also report on the progress of ongoing workstreams and make decisions where necessary. The MOG was set up initially for one year with a plan that its role and membership would be reviewed by the Minister responsible for the work thereafter.

376. The MOG held its first meeting on 8 June 2021 and met quarterly throughout the remainder of the relevant period: on 20 October 2021, 9 February 2022 and 17 May 2022. Updates were provided by the lead bodies during each of these meetings.

377. The summary notes were published on the MOG gov.uk page and briefly captured the status of some of the recommendations as reported by some of the lead bodies up to that point in time. Copies of the summary notes were also distributed after the

meetings (IT3/266 [INQ000398642]; IT3/267 [INQ000398643]; IT3/268 [INQ000398644] and IT3/269 [INQ000398645]).

378. In advance of the meeting of 17 May 2022, a summary of progress document was circulated to MOG members together with a more detailed updated report combining each of the lead bodies updates. These documents were shared with MOG members only. These documents represent the latest updates that we are aware of. (IT3/270 [INQ000398647], IT3/271 [INQ000398648], IT3/262 [INQ000398638] and IT3/273 [INQ000339340]).

379. We were the lead body responsible for Recommendation 11 (as summarised in paragraph 365.11 above). Details of the update we provided to that meeting are set out in our internal briefing note attached (IT3/274 [INQ000398651]). In summary, we explained how we had ensured continued focus on DNACPR through our strategic priorities of People and Communities, Safety Through Learning and Accelerating Improvement. We set out the actions taken internally to ensure end-of-life care was included in our new assessment framework and the work undertaken with providers. We also set out details of concerns being raised with us at that time and our continued focus in this area.

380. A working group sat below the MOG, this was set up to undertake the work required to implement the recommendations. The working group met quarterly between August 2021 and April 2022. We were represented on this group by one of our Inspection Managers. Copies of the readouts from meetings 2 and 3 of the working group meetings are attached as (IT3/275 [INQ000398652] and IT3/276 [INQ000466429]).

381. The last meeting of the working group and the MOG that we were invited to and attended were held in April and May 2022 respectively. The last update received in January 2023 from DHSC indicated that a ministerial steer was awaited on whether to extend the MOG beyond the initial 12 month period set out in the terms of reference. DHSC agreed to keep us informed but no communication has since been received.

382. Although we have not been asked for any updates since the last MOG meeting, we continue to monitor our own compliance with the matters related to Recommendation 11 and the closely aligned recommendations from the Joint Committee on Human Right's Report of 13 July 2022 'Protecting human rights in care settings'. Internal quarterly updates are provided by our relevant Directorate lead to our Board and Senior Leadership team. The latest internal update provided in September 2023 indicated that a number of actions linked to these recommendations have been implemented. Specifically, the update noted the following items of delivery:

382.1. Internal Cross-Directorate End of Life Working set up and has provided internal learning on expectations of DNACPR;

382.2. Guidance for inspectors to identify risks and protect people was issued in September 2021;

382.3. DNACPR searches are now part of routine PMS inspection clinical searches;

382.4. DNACPR evidence gathering is part of Single Assessment Framework (SAF) assessments across all relevant sectors;

382.5. CQC's joint statement with BMA, Care Providers Alliance and RCGP

382.6. around individualised care planning was published in April 2021; and CQC's GP Mythbuster 105 regarding DNACPR was also published in Aug 2021. These Mythbusters are documents published on our website which aim to clear up some common myths about our inspections of GP services, independent doctors and clinics and out-of-hours services and share agreed guidance to best practice.

H. Discharge of patients from hospital to care homes

383. Below is a summary of CQC's involvement in the high-level decision-making to discharge patients from hospital. As advised by the Inquiry, we have avoided the inclusion of information about the impact of the decision on care homes as this is due to be covered in a later Module.

384. In March 2020 we became aware of the evolving situation and growing national concern that hospitals would soon reach capacity. We knew that if patients were to

be discharged back into care settings the process would need to be managed in a robust and considered manner, with checks in place to ensure that vulnerable people were kept safe and that providers were able to cope.

385. On 16 March 2020 DHSC wrote to CQC and NHSEI indicating that the Trusted Assessor Guidance needed to be updated to align with NHSEI's new policy on hospital discharge that was due to be published later that week, specifically "to amend the Trusted Assessor regime to enable very rapid hospital discharge to care homes, with acute staff acting as trusted assessors." (IT3/277 [INQ000398653]; IT3/278 [INQ000398654]; IT3/279 [INQ000398655]; IT3/280 [INQ000398657]; IT3/281 [INQ000398658]).

386. 'Trusted Assessor' schemes are a national initiative driven by the NHS designed to reduce delays when people are ready for discharge from hospital and to promote safe and timely discharges from NHS Trusts to adult social care services. The schemes are based on providers adopting assessments carried out by suitably qualified Trusted Assessors working under a formal, written agreement. Trusted assessors must have the qualifications, skills, knowledge and experience needed to carry out health and social care assessments, and to formulate plans of care on behalf of adult social care providers. Providers must be confident that Trusted Assessors understand the needs their service can meet, and that the discharges to their service they arrange will be appropriate. Trusted Assessor accountability and employment arrangements vary. They can work for local provider organisations, hospital trusts, or under collaborative arrangements. Specific employment and accountability arrangements must be set out in Trusted Assessor agreements.

387. Before the pandemic we first produced the Trusted Assessor Guidance, together with NHS England, setting out how Trusted Assessor agreements should be set up to meet people's needs and legal requirements including guidance on what should happen when adult social care services have concerns that inappropriate discharges are being made. This guidance was published on our website and is annexed as (IT3/282 [INQ000398659]).

388. NHSEI advised CQC that insofar as the current Trusted Assessor Guidance provided that the assessor must be someone who understands the needs of the individual they are assessing and the capability/capacity of the care home to receive and support their needs would still apply. However, they advised that "we will need more Trusted Assessors and quickly... to ensure we can respond to the planned changes in a way that supports the aims of the changes" and asked for our assistance in amending the wording of the guidance to provide for this (IT3/283 [INQ000398660]). We were asked specifically to provide "a simple statement...making the following points":

"1. Complete support for the principles in the new hospital discharge guidance and the Discharge to Assess model (D2A)

2. Advise all hospitals to develop trusted assessor regimes for every care home in their area, based on the D2A model

3. Aim is to support hospitals and care homes in the safe transfer of existing care home residents and new residents who need nursing/residential support but not acute hospital care, whilst D2A is current

4. Emphasising need for community based support, such as the EHCH framework, to support care homes

5. Status of existing trusted assessor guidelines during this period: suspended/ supplanted by this"

389. On 16 March 2020 our Chief Inspector for Adult Social Care, Kate Terroni, was copied into an email thread involving Ros Roughton, DHSC Director for Adult Social Care; Deputy Chief Medical Officer Jenny Harries; Matthew Winn, Chief Executive of the Cambridgeshire Community Services NHS Trust and Senior responsible officer across Bedfordshire and Luton for community health and integrated discharge; and others regarding discharge into care homes (IT3/284 [INQ000398661]). Kate provided the following advice in relation to the approach regarding "*allowing patients to be discharged into care homes who are symptomatic of Covid-19*":

"the approach would depend on the position of the home and how its staffing is affected by covid-19. You might consider keeping 'clean' and 'infected' locations separate to ensure people aren't unnecessarily being placed in services where

there is currently no other known people with the virus. It would be good if attention can still be paid to the ratings of services and that inadequate services are avoided where possible.

Important questions to ask/discussion to have in pre-discharge conversations between providers/commissioners to help assess suitability of provider/location:

- *Additional financial impact on providers*
- *How robust are the systems to prevent, detect and control the spread of infections? Consider availability of suitable PPE etc.*
- *Are there enough medicines for people at the service?*
- *Are there plans in place to ensure consistent access to and supply of medicines going forward?*
- *Has the provider taken steps to ensure the environment is as conducive as possible to containing an outbreak?*
- *Are there enough suitably skilled staff available to meet people's care or treatment needs whilst maintaining their dignity and respect?*
- *How robust are staffing contingency planning arrangements in relation to an outbreak of COVID-19?*
- *Are steps in place to manage existing risks to people?*
- *Are there systems and process in place to assess and manage new and emerging risks?*

These questions are in line with CQC's revised assessment framework."

390. On 16 March 2020 ADASS and Care England were also brought into the conversation for their views on the draft Hospital Discharge Service Requirements Guidance (IT3/285 [INQ000398662]; IT3/286 [INQ000398663]; IT3/287 [INQ000398664]). ADASS raised two concerns regarding the draft guidance, indicating that it "*only look[ed] at discharge and unless you look at capacity of the whole system – including primary, community health care, social care and the inevitable additional needs if unpaid family carers cannot function then there is serious potential to make things worse not better*"; and that it "*is ostensibly a 'systems' message – though actually it reads as a directive from NHSE to social*

care. Social care is part of the system it hasn't been co-produced... communication in this form is likely to cause chaos which is the absolute last thing we need right now for local systems." (IT3/286 [INQ000398663]). The draft Hospital Discharge Service Requirements Guidance was shared with CQC by NHSEI on 17 March 2020 (IT3/288 [INQ000398665]; IT3/287 [INQ000398664]).

391. On 17 March 2020 we provided comments and suggested amendments to the draft Trusted Assessor Guidance (IT3/290 [INQ000398668] and IT3/291 [INQ000398674]). On the same day, ADASS, Care England and the National Care Forum were brought into the conversation regarding the amendments to the Trusted Assessor Guidance (IT3/292 [INQ000398670]) and provided their comments regarding the draft (IT3/293 [INQ000398671]; IT3/294 [INQ000398672]).

392. On 18 March 2020 we provided the marked-up version of the amended Trusted Assessor Guidance to ADASS and clarified our role and position in relation to the amendments made to the guidance (IT3/295 [INQ000398673] and **IT3/291** [INQ000398674]]).

393. On 18 March 2020 we received NHSEI's letter, sent the previous day to all NHS trusts and foundation trusts, CCGs, GP practices, Primary Care Networks and providers of community health services, informing them of the NHS's next steps on its response to the pandemic (IT3/299 [INQ000398677]; IT3/300 [INQ000087317]). The letter set out the measures required of the NHS to redirect staff and resources, including:
    1. Freeing up "*30,000 (or more) of the English NHS's 100,000 general and acute beds*" by:
        ...
        a. "*Urgently discharg[ing] all hospital inpatients who are medically fit to leave...*"

394. On 18 March 2020 Kate Terroni met with NHSEI to discuss the new Hospital Discharge Service Requirements Guidance and specifically the issue of the quality of care homes (IT3/301 [INQ000398680]; IT3/302 [INQ000235327]).

395. On 19 March 2020 DHSC wrote to CQC indicating that they were intending to publish the Hospital Discharge Service Requirements Guidance which included "CQC's annex on trusted assessors" later that day and asked for CQC to supply a logo to attach to the Trusted Assessors Guidance (IT3/303 [INQ000398682]).

396. On 21 March 2020 Sir Robert Francis KC, then Chair of Healthwatch England and a member of CQC's board, wrote to CQC's then Chair, Peter Wyman, raising his concerns regarding the "*ethical dilemma*" associated with the "*admission of untested hospital patients*" into care homes following the publication of the Hospital Discharge Service Requirements Guidance (IT3/304 [INQ000398683]). Mr Wyman forwarded Sir Robert's email to Kate Terroni and me on 22 March 2020, summarising the thread as follows:

> "*The central point is that there still isn't enough guidance, in my view anyway, for care home managers/owners, who are mainly using their own judgement as to what to do. While this may seem reasonable the fact that different homes are making very different rules for visiting, admissions, re-admissions and so on in circumstances that aren't obviously different suggests more guidance (from DHSC) might be helpful.*"

397. On 23 March 2020 Kate Terroni responded to Peter Wyman indicating that she had discussed the issue with Ros Roughton, DHSC on 22 March 2020 and that there was a "system conversation" taking place on 23 March 2020 "*about the impending Discharge to Assess plans and the increasing pressure care homes are likely to come under from hospitals to accept patients with little opportunity to assess themselves and for whom may have a covid-19 diagnosis*." Ms Terroni confirmed that CQC had been involved with revising our Trusted Assessor Guidance but that "*to date, the Discharge to Assess revisions ha[d] been Dept led*." Ms Terroni also indicated that the Trade Associations, ADASS and Local Authorities had all expressed concerns about how the hospital discharge policy would be implemented. Ms Terroni confirmed that DHSC agreed that there was a need for specific advice from PHE about Care Homes accepting people either with a positive covid-19

diagnosis or having had covid-19 and that CQC would "*write a short guidance to care homes*" on this (IT3/304 [INQ000398683]).

398. Following the publication of the original Government guidance on Hospital Discharge Service Requirements on 19 March 2020 [IT3/305 [INQ000087450]), DHSC contacted us on 25 March 2020 inviting us to co-sign amended guidance that had been written in collaboration across DHSC, PHE and the NHS. Our objective was to ensure that proper attention was given to the voice of care providers, and that any revised guidance was clear that providers should be involved in decisions about how they managed the care needs of any returning residents, while being ever mindful of the increasing pressure on hospital capacity. At this point in the pandemic there were issues with PPE supply, Covid testing was not widely available and asymptomatic transmission was not well understood (IT3/306 [INQ000235323] and IT3/307 [INQ000235324])

399. We raised concerns with DHSC about this guidance. At this point providers had not been appropriately engaged in shaping this directive guidance, and it did not reflect an understanding of the pressures care home providers were facing in dealing with the spread of the coronavirus.

400. We highlighted that necessary consideration needed to be taken as to occasions when a care home may not be in a position to safely accommodate a returning or new resident. In our view, the original guidance proposed by Government, and subsequent early draft additions put to us by DHSC, left providers with little or no power to challenge individual decisions if they felt an admission of an individual from a hospital back to their care setting would not support the best interests of the person or could put them or others at risk. (For instance, if staff in the care home did not have adequate PPE, or if the setting itself wasn't able to safely accommodate individuals who needed to isolate.) In order to provide safe care, providers would benefit from being informed if a person had any reason to undertake a Covid-19 test or was showing any symptoms while in hospital, to allow them to make decisions accordingly.

401. In discussion with DHSC, we worked to update the guidance with our amendments and recommendations, reflecting our ongoing conversations with providers about the evolving environments care homes were operating in, while at all times being mindful and sympathetic to the acute pressures being put upon hospitals and their capacity.

402. We also highlighted the need to involve trade associations and linked bodies, to ensure they were sighted and their views reflected. DHSC supported this by convening a call with provider bodies, and we also contacted a leading provider trade association (the CPA) to ensure they were brought into the conversation. On 26 March 2020, DHSC contacted us again with a revised version of the guidance, which was sent to provider bodies and trade associations in parallel (IT3/308 [INQ000235325]; IT3/309 [INQ000235326]; **IT3/302** [INQ000235327]; IT3/311 [INQ000235328]).

403. We only put our name to the guidance, on 27 March 2020, once we had assurances that it would offer providers the power to make their own informed decisions. By exercising our influence through the drafting process, we helped to ensure providers had a say in the discharge and admissions process, and therefore had the power to make decisions that put the needs of the individual first (IT3/312 [INQ000235329]; IT3/313 [INQ000235330]; IT3/314 [INQ000235331]; IT3/315 [INQ000235332]; IT3/316 [INQ000235333]).

404. The final version of the guidance, dated 2 April 2020 (IT3/317 [INQ000235334]), stated that people could only be discharged to care homes if certain criteria were in place:

404.1. that information from the discharging hospital included the data and results of any Covid-19 test, the date and onset of the symptoms, and a care plan for discharge from isolation;

404.2. that the care home had the ability to isolate symptomatic patients; and

404.3. that care staff had adequate PPE.

405. If these elements were not in place, we were clear with providers that they would be able to refuse an admission. We also wrote to providers to reiterate the duty on them

to continue assessing how they were keeping people safe despite Covid pressures, and the need to clearly understand and uphold the rights of the individual at all times.

406. Some care home managers contacted us to ask whether we would support their decision not to admit a patient with Covid-19 based on the absence of one of these elements. There was anxiety among some care home providers as they were feeling pressured by hospital discharge teams to accept admissions and they felt that, without our support, they were made to feel obliged to accept admissions.

407. On 20 April 2020 DHSC followed up and asked us to provide input on the issue of the necessary assessments required by providers in the context of decisions to discharge patients from hospital as outlined in the Home Care Guidance, indicating that "Without clear guidance from CQC, it is difficult for providers to feel assured" that they can meet the necessary legal requirements for any discharge assessment decisions". This area was, however, covered in the NHS's Discharge to Assess Guidance and, in almost identical form, on our website as a standalone piece (IT3/318 [INQ000235572]).

408. Further to our input into the guidance regarding admissions to care homes (detailed above), DHSC again requested our input into updated guidance drafts in May 2020. Along with some specific comments on the document itself, we also raised general concerns regarding how realistic the proposals were, particularly with regards to settings with people living with dementia or people with limited mental capacity, as well as the need to consider increased costs given the need for increased staffing levels and PPE [IT3/319 [INQ000235382] - IT3/320 [INQ000235383]).

409. One of the regular data collections we make is the NHS National Patient Survey program. There are five surveys in this program each running annually or bi-annually. In August 2020, we commissioned a one-off Covid inpatient survey to capture the experiences of patients discharged from hospital during April and May 2020. We focused our questioning on those admitted with confirmed or suspected Covid-19, as well as those admitted for unrelated reasons. Evidence and learning

from the survey was shared in a report published in November 2020. This report was published on our website IT3/183 [INQ000235488] and is further referred to in paragraph 463.5 below. The survey received feedback from 10 336 people who had received inpatient care in an NHS hospital and were discharged between 1 April and 30 May 2020. Patients with a Covid-19 diagnosis reported consistently poorer experiences than people who did not have the virus. The greatest differences in people's experiences were during discharge and knowing what would happen next with their care after leaving hospital.

410. Following this, on 15 January 2021 we were asked by DHSC to review a proposal created by NHSE entitled Care Hotels' approach: using hotel spaces to improve patient flow from hospital. We provided a range of comments including that any interim arrangement is rarely the best thing for a person leaving hospital; that the proposal assumes people will agree to this approach and there is a risk that people may choose to wait in hospital; that workforce capacity would be needed to manage such a programme; that safeguarding was paramount; and that a joined-up approach was needed. Other comments covered people's discharge from hospital in more detail. (IT3/322 [INQ000235558])

411. On 18 January 2021 we also commented on a draft letter from Matthew Winn, Director of Community Health, NHSE to CCG Accountable Officers, Local Authority Directors of Adult Social Care and System discharge leads providing comments to help ensure clarity (IT3/323 [INQ000235559] and IT3/324 [INQ000235560]). The letter was published on 20 January 2021.

I. Other concerns or issues

Nightingale Hospitals

412. Below is an outline of CQC's involvement in ensuring that safe care was delivered to patients in Nightingale hospitals. Our involvement with the Nightingale Hospitals occurred primarily during the setup phase through the provision of advice on the requirements of the regulations and through the exercise of our existing registration and ongoing monitoring functions. The details of CQC's involvement with the Nightingale Hospitals are outlined below.

Assurance Visits at Nightingale Hospitals

413. During the set-up of the Nightingale hospitals, we wanted to be assured, and, in turn, be able to assure the public, that the Nightingale hospitals were safe and that they met our fundamental standards, in terms of both the facilities and the clinical staff who would be working on site.

414. On 23 March 2020 we were contacted by NHSEI and informed that the Board of Barts Health NHS Trust had agreed to a request from NHS London that they should host the first Nightingale Hospital at the ExCeL centre. Following discussions with Vinod Diwakar, Regional Medical Director & Chief Clinical Information Officer (CCIO) at NHSEI it was agreed that Ted Baker, CQC's Chief Inspector of Hospitals at the time, would conduct an assurance visit at the site. On 30 March 2020 NHSEI circulated the Nightingale Hospital Mobilisation Review "Nightingale Assurance Model checklist" to the assurance visit attendees indicating that "after the visit a narrative report will be taken to the national incident board" and asking colleagues to indicate whether they were able to attend the visit. (IT3/325 [INQ000398686] and IT3/326 [INQ000398687])

415. The Nightingale Assurance Model checklist (IT3/326 [INQ000398687]) stipulated that the Nightingale Clinical Panel would review the mobilisation of each hospital to provide assurance to Amanda Pritchard as chair of the National Incident Response Board, as to the state of readiness of each Nightingale facility. The purpose of the assurance visits was "to walk the patient pathway and discuss with the hospital/regional team mobilising each facility". The checklist acknowledged that "the Nightingale concept [was] rapidly evolving, and the intent [was] to undertake constructive discussion and identify opportunities for learning." The checklist specifically stated that the assurance visits were not formal inspections.

416. The first assurance visit was undertaken on 31 March 2020 at the ExCeL centre led by Professor Chris Moran, Deputy National Strategic Incident Director & NCD Trauma, Covid-19, NHSEI and the attendees from CQC were: Ted Baker; Nigel

Acheson, Deputy Chief Inspector of Hospitals; Cliff Double, IR(ME)R Inspector; William Harrop-Griffiths of the Royal College of Anaesthetists; and Dr Jim Down, Intensive Care Consultant. (IT3/327 [INQ000398688]).

417. On 1 April 2020 NHSEI asked us whether we would be able to act as the radiation protection liaison team to support the national roll out of imaging services in the Nightingale hospitals. We agreed to the request as it allowed CQC to provide system support and enabled us to have some further oversight of the implementation of these services. (IT3/328 [INQ000398689]; IT3/329 [INQ000398690]; IT3/330 [INQ000398692])

418. Over the following weeks, CQC colleagues from our Hospitals Directorate Inspection Team, Registration Team and IR(ME)R Team attended assurance visits at the proposed Nightingale Hospital sites together with representatives of NHSE. The details of the assurance visits conducted are set out together with the details of the registration of each of the Nightingale hospitals in paragraphs 421 to 429.7 below.

419. The assurance visits were coordinated by NHSE and were conducted jointly by our Registration, Hospital Inspection, and IR(ME)R teams, along with NHSE. They provided the opportunity for the sharing of information and for CQC to gain an understanding of the proposed care model, a walk-through of the care pathway and for us to provide advice on the requirements of the regulations including in relation to:

    419.1. Staffing;

    419.2. Our regulatory function under IR(ME)R, with a focus on the provision of the radiology service, equipment and to ensure there was a plan in place for radiographers to receive the necessary training; and

    419.3. The suitability of the venues for ensuring that people were treated in a dignified environment with access to toilets and handwashing facilities.

420. Where we identified concerns during these visits, we raised them at the time, and we sought assurances from the relevant Trust that these matters would be addressed. Where any concerns were identified during the assurance visits

conducted at each of the respective Nightingale hospitals we have summarised the details of the concerns and the steps taken to resolve any concerns below in paragraphs 429.1 to 429.7.

Registration of Nightingale Hospitals

421. We knew it was imperative that the Nightingale hospitals were established as quickly as possible in order to relieve the strain on existing hospitals. We were clear throughout the pandemic that we had to follow the existing statutory framework for dealing with registration matters although as set out above we did adapt our existing methodologies for Covid-19 related applications where it did not impact on the exercise of our statutory duties.

422. On 25 March 2020, following the UK Government's announcement of the opening of the first Nightingale Hospital at the ExCeL centre, CQC and the South East regional team of NHS England discussed the need for some guidance around the registration of Nightingale and field hospitals (IT3/331 [INQ000398693]). As NHSEI started to prepare for the opening of additional Nightingale hospitals, members of our Registration team began drafting the "Registration information for Field Hospitals (temporary location)" document as initial guidance for the registration of Nightingale and field hospitals (IT3/332 [INQ000398694] and IT3/333 [INQ000398695]). The guidance outlined the process and factors to be taken into consideration by a Trust during "Nightingale/Field Hospital Development" and focused on: the process for registration; consideration of registration details; how to ensure that the site/location would be "Safe" and "Well-Led"; and consideration of the appropriateness of the site/location. The guidance provided a list of questions to be considered under each of these headings. On 3 April 2020 the draft guidance was provided by Joyce Frederick, Deputy Chief Inspector for Registration and Regulatory Assurance to NHSEI for their review IT3/334 [INQ000398696] and IT3/335 [INQ000398697]).

423. The NHS Trusts seeking to host the Nightingale Hospitals were:

423.1. Barts Health NHS Trust - NHS Nightingale Hospital London;

423.2. University Hospitals Birmingham NHS Foundation Trust - NHS Nightingale Hospital Birmingham;

423.3. Manchester University NHS Foundation Trust - NHS Nightingale Hospital Northwest;

423.4. North Bristol NHS Trust - NHS Nightingale Hospital Bristol;

423.5. Leeds Teaching Hospitals NHS Trust - NHS Nightingale Hospital Yorkshire and Humber;

423.6. Newcastle Hospitals NHS Foundation Trust - NHS Nightingale Hospital Northeast; and

423.7. The Royal Devon and Exeter NHS Foundation Trust - NHS Nightingale Hospital Exeter.

424. These Trusts were already registered as providers with known regulatory histories and therefore the Nightingale hospitals could either be treated as satellite sites (part of an existing location) or as new locations for registration purposes, as set out above.

425. Trusts who wished to add the Nightingale hospital as a satellite site to their registration, were able to do so by submitting an online notification together with an amended Statement of Purpose. The appointed Inspection relationship owner would then review these documents and any supporting documents provided by the Trust and our Registration Covid-19 Advisory Panel, Legal and Registration colleagues would also be made aware of the notification, as necessary. Any concerns or issues arising out of the notification would be raised with the Panel and the other relevant teams, who would advise as to the best course of action.

426. For a Trust applying to add a Nightingale hospital as a location, instead of submitting a notification and an amended Statement of Purpose, a full registration application was required. Upon submission of the application, it was assigned to a Registration Manager or Inspector to process and to determine whether it should be granted or refused and our Registration Covid19 Advisory Panel were informed. Where concerns were identified by us through the registration process at the assurance visits these were raised with the Trust, and additional evidence and assurances were sought before registration was granted. A registration report was prepared setting out the evidence considered together with the outcome of the application. Decisions

to grant the applications were ultimately made by the Deputy Chief Inspector for Registration and Regulatory Assurance.

427. By early summer 2020 we recognised that the demands on health services were changing and that some of the Nightingale Hospitals, which had intended to be temporary, were being retained to provide capacity for a possible second wave and in some cases the type of services provided at the sites were changing. On 11 June 2020 our Registration Quality and Risk Assurance Team made proposals in a paper to our Regulatory Oversight Group that the Covid-19 Registration Principles and Decision-Making Framework be amended such that the starting point for any provider proposing to deliver services at new sites apply to add the location to their registration (IT3/336 [INQ000398698] and IT3/337 [INQ000398699]). The proposed amendments were approved by the Regulatory Oversight Group on 12 June 2020 and the existing Covid-19 Registration guidance for providers was updated later that month on our website to reflect the new approach. The result of the amendments was that the Trusts which had initially sought to add the Nightingale Hospitals as satellite sites to their existing registration, rather than apply for them to be added as new locations, subsequently applied to add these as locations to their registration.

428. Initially, Barts Health NHS Trust, University Hospitals Birmingham NHS Foundation Trust, Leeds Teaching Hospitals NHS Trust and North Bristol NHS Trust elected to notify us of the relevant Nightingale hospitals by adding them as satellite sites to their registration. The registrations of these hospitals therefore preceded the updates to the Covid-19 Registration guidance described above. However, following the update of our Covid-19 Registration Guidance in June 2020, these Trusts then applied to add the sites as new locations.

429. The details of the registration of each of the Nightingale hospitals, including the dates of the respective assurance visits, any concerns identified and the steps taken are outlined below:

429.1. NHS Nightingale Hospital London: On 27 March 2020 Barts Health NHS Trust submitted a notification (IT3/338 [INQ000398700]) and amended Statement of Purpose (IT3/339 [INQ000398701]) to register the hospital at

the ExCeL centre as a satellite site. An assurance visit was conducted on 31 March 2020 as referenced in paragraph 416 above. During the assurance visit we identified some minor issues with the mobile radiation equipment and the proposed 12-hour shifts for the radiographer and assistant, particularly in the context of them wearing lead aprons. We raised these concerns with the Trust and received assurances by email and telephone. On 31 March 2020 the Trust decided to submit an add location application following internal discussions (IT3/340 [INQ000398703]; IT3/341 [INQ000398704]; IT3/342 [INQ000398705] and IT3/343 [INQ000398706]). The registration application in respect of the Nightingale Hospital at the ExCeL centre was granted on 1 April 2020 (IT3/344 [INQ000398707]). The hospital treated only 54 patients in the first wave of the pandemic and on 4 May 2020 it was placed on standby. In January 2021 it re-opened and was used to treat non-Covid-19 patients. It was formally closed in April 2021.

429.2. NHS Nightingale Hospital Birmingham: On 1 April 2020 University Hospitals Birmingham NHS Foundation Trust submitted a notification and an amended Statement of Purpose to add Nightingale hospital at the Birmingham National Exhibition Centre as a satellite site to their existing registration. At the assurance visit on 10 April 2020 several concerns were identified, including for example: the number of registered nurses compared to the number of beds did not align; the radiology pathways needed some work; the environment meant that privacy and dignity would be a challenge; the ward environment was not ideal in terms of the location of the toilet and shower facilities; there were no emergency bells which was a worry due to the acoustics being problematic; and there was no hot water at the bed side which presented concerns regarding hand washing. The main concern was regarding the reality of the hospital being able to step up to accept patients and the operation plans for this. The hospital was not used in the first wave of the Covid-19 but was later brought out of hibernation to function during the second Covid-19 surge. NHSEI reviewed and updated the operating model for the Nightingale Hospital Birmingham for the predicted second surge of Covid-19 and the hospital was down

scaled in bed numbers and the admission criteria was confined to short stay patients only. Consequently, on 5 November 2020, the Trust submitted an application to CQC to add the hospital as a new location in accordance with our updated Covid-19 Registration Guidance.. On 20 November 2020 an assurance visit was conducted where some concerns were identified including for example: missing fire signage; whether there were protected times for admission of patients into the halls from referring hospitals or for discharge to their final destination (i.e home); what system was in place for identifying patients likely to stay longer than 2-3 days; the number of resus trolleys on site; and confirmation of the start-up plan outlining the first bays to be used on Day 1. An email was sent to the Trust on 23 November 2020 outlining the concerns and seeking assurances. The Trust responded later on 23 November 2020 providing the requested assurances and the application was granted on 25 November 2020 (IT3/345 [INQ000398708]) and it was agreed that a follow-up visit would take place once the site was operational to obtain better insights into the patient experience and patient safety. The Nightingale Hospital Birmingham never admitted patients and was formally closed on 1 April 2021.

429.3. NHS Nightingale Yorkshire and Humber: On 16 April 2020 Leeds Teaching Hospitals NHS Trust submitted a notification and an amended Statement of Purpose to add the Nightingale hospital at the Harrogate Convention Centre as a satellite site to their registration. The intention of the Trust, at that stage, was to temporarily provide acute services in response to the Covid-19 pandemic from April 2020. No concerns were identified at the assurance visit undertaken on 20 April 2020 and the hospital remained on stand-by to admit patients. In June 2020, the hospital was repurposed for the provision of CT scanning for outpatients for Trusts in the Yorkshire and Humber region, to assist with the phase 2 recovery period related to Covid-19. Multiple meetings took place between CQC and the Leeds Teaching Hospitals NHS Trust around the ongoing direction and control of the hospital and on 8 August 2020 the Trust submitted an application to add the hospital as a new location at which they could carry on the regulated activity of Diagnostics and Screening. The application was granted on 14

August 2020 (IT3/346 [INQ000398709]). The Nightingale Hospital Yorkshire and Humber never admitted patients and was formally closed in March 2021.

429.4. NHS Nightingale Hospital Bristol: On 2 April 2020 North Bristol NHS Trust submitted a notification with an amended Statement of Purpose to add the Nightingale hospital at UWE Bristol Exhibition and Conference Centre as a satellite site to their registration. Several concerns, mainly in relation to the radiology equipment and policies, were identified and shared with the North Bristol NHS Trust following the assurance visit which took place on 23 April 2020. Some examples of the concerns identified include: There was a risk of repetitive strain injury and fatigue associated with the weight of the radiology equipment; the CT scanner was ill placed; and the functionally and origin of the 2 Topaz DR Units were concerning. Some of these concerns were raised with NHSE. In June 2020 the hospital entered into a functional phase of dormancy after the first peak of the pandemic passed without the need to use it. In Autumn 2020, it was decided that the hospital would be used for non-Covid-19 treatment and therefore, in October 2020, the Trust submitted an application to add the hospital as a location and for 2 Regulated Activities: Diagnostic screening procedures and Treatment of disease, disorder or injury. The application was granted on 22 October 2020 (IT3/347 [INQ000398710]). The Nightingale Hospital Bristol did not treat any Covid-19 patients and was formally closed on 31 March 2021.

429.5. NHS Nightingale Hospital Manchester: On 10 April 2020 Manchester University NHS Foundation Trust submitted a registration application in respect of the Nightingale Hospital at the Manchester Central Convention Complex. An assurance visit was conducted on 12 April 2020. The registration was granted on 15 April 2020 (IT3/348 [INQ000398711]). The Nightingale Hospital Manchester treated a small number of patients during the pandemic and was closed in March 2021.

429.6. NHS Nightingale Hospital Newcastle: On 30 April 2020Newcastle Hospitals NHS Foundation Trust submitted a registration application in respect of the Nightingale Hospital at the Centre of Excellence for Sustainable Advanced Manufacturing. An assurance visit was conducted on 30 April 2020 during

which we identified that the environment had limited support for those with dementia, learning disabilities or mental health issues. We raised this with the trust and were informed that those patients would not be accepted onto the site (although those conditions were not detailed in their exclusion criteria). The Trust advised that arrangements were in place to ensure that staff had all relevant information about people's health needs to provide continuity of care. Individual patient risks and vulnerabilities would be identified prior to the site and advance treatment plans put in place. In addition, we identified that there was no provision to offer any rehabilitation to patients prior to discharge, for example there was no therapy kitchen or stairs to access. The Trust told us that rehabilitation would be available, with the hospital supported by physiotherapy staff and occupational therapy staff from across the region and provided three possible outcomes for rehabilitation depending on patient requirements. The registration was granted on 1 May 2020 (IT3/349 [INQ000398712). The Nightingale Hospital Newcastle did not admit any patients during the pandemic but was used as a mass vaccination centre from January 2021 before it was closed on 31 March 2021.

429.7. NHS Nightingale Hospital Exeter: On 22 May 2020 the Royal Devon and Exeter NHS Foundation Trust submitted a registration application in respect of the Nightingale Hospital at the Former Homebase Store Moor Lane. An assurance visit was conducted on 3 July 2020. The registration application was granted on 23 June 2020 (IT3/350 [INQ000398714]). The Nightingale Hospital Exeter was first used to provide diagnostic tests to local people, host the delivery of a Covid-19 vaccine study and provide training to nurses. On 12 November 2020 the hospital admitted its first Covid-19 patient and over the next four months it cared for nearly 250 patients with Covid-19. The last Covid-19 patient was discharged from the hospital in March 2021 and it was then purchased by the Royal Devon University Healthcare NHS Foundation Trust on behalf of NHS organisations across Devon and the South West region to continue the site's legacy of supporting local people.

Regulation of the Nightingale Hospitals

430. Due to the exceptional nature of the circumstances surrounding the set-up, registration and regulation of the Nightingale hospitals, some of the trusts were concerned about being able to meet the regulations and looked to CQC for reassurance. On 31 March 2020 Barts Health NHS Trust asked CQC for a "letter of comfort" to cover our approach to the regulation of the Nightingale hospitals while they proceeded with the development of the Nightingale Hospital London. On 3 April 2020 CQC sent a letter to Barts Health NHS Trust to provide an explanation of the approach that we proposed to take to the discharge of its regulatory responsibilities in relation to the Nightingale Hospital London (IT3/351 [INQ000398715]; IT3/352 [INQ000398716]). In the letter we confirmed that

"...as part of our response to the Covid-19 pandemic, CQC has changed its approach to how it regulates to take account of the position in which providers find themselves during this time. This means that in looking at any departure from the fundamental standards, and what response may be appropriate, the standards of care that can be reasonably expected to be delivered by trust staff at the Nightingale would take full account of the unprecedented circumstances in which this care is being delivered...

As part of our specific response to Covid-19 we are fast-tracking the changes to your trust's registration to facilitate the stand-up of the Nightingale Hospital London. And as you know, CQC has suspended routine inspections during this period of national emergency... Only in exceptional circumstances would inspection be considered...

...In the event that concerns do arise, you can be reassured that any regulatory intervention would be considered at the most senior level... Our hope would be to avoid regulatory action, and for our senior teams to work together to identify solutions that support the provision of the best possible outcomes for patients... Save in exceptional circumstances, there will be no unannounced visits by CQC staff to the Nightingale Hospital."

431. A copy of the letter was shared with NHSEI on 3 April 2020 (IT3/353 [INQ000398717] and IT3/352 [INQ000398716]).

432. On 6 April 2020 NHSEI wrote to CQC on behalf of the Manchester University NHS Foundation Trust indicating that the Trust was looking for some assurance from CQC around our regulatory model for the Nightingale hospitals before they started admitting patients. Later that day Joyce Frederick attended a call with Sarah Corcoran, Director of Clinical Governance at Manchester University NHS Foundation Trust, to discuss the Trust's concerns in respect of meeting the regulatory standards. During the discussion Joyce mentioned the letter that CQC had sent to Barts Health NHS Trust and it was agreed, should it be needed, that CQC would look into getting a draft to the Manchester University NHS Foundation Trust (IT3/355 [INQ000398719]).

433. During the relevant period, CQC did not carry out any inspections of the Nightingale Hospitals. As explained above, most of the Nightingale Hospitals did not admit patients and those that did were not open for very long. Additionally, save in relation to the Nightingale Hospital Exeter (as set out below), we did not receive notifications in respect of any of the other Nightingale Hospitals and therefore CQC did not consider carrying inspections at any of them.

Notifications from Nightingale Hospitals under Regulation 18 of the Care Quality Registration Regulations 2009/3112

434. During the relevant period, only one of the seven Nightingale hospitals submitted notifications to CQC under Regulation 18 of the CQC Registration Regulations 2009 (IT3/468 [INQ000466470]). The Nightingale Hospital Exeter submitted four notifications pursuant to Regulation 18(2)(c) in respect of the outcome of Deprivation of Liberty Safeguards (DoLS) applications. The notifications were received on 12 January 2021; 5 March 2021 and 15 March 2021 and the details are as follows:

    434.1. 12 January 2021: A DoLS application was made on 3 January 2021 but the application was withdrawn as the patient passed away on 4 January 2021.

434.2. 5 March 2021: A DoLS application was made on 14 January 2021 but the application was withdrawn as the patient was discharged home on 26 January 2021.

434.3. 5 March 2021: A DoLS application was made on 11 January 2021 but the application was withdrawn as the patient was discharged home on 30 January 2021.

434.4. 15 March 2021: A DoLS application was made on 2 February 2021 but the application was withdrawn as the patient was discharged home on 10 February 2021.

435. As all of the notifications were withdrawn, CQC did not have to take any action in response.

Concerns raised to or by CQC during the pandemic

436. During the relevant period we received concerns in several ways. Concerns could be raised with us by members of the public or by someone working for a health or social care service via the 'contact us' section of our website (IT3/356 [INQ000398720]). Members of the public could also raise concerns about care through our Give Feedback on Care (GFC) form, accessible via our website (IT3/357 [INQ000398721]). GFC was, and still is, our priority channel through which we collect information from the public about their experiences of health and adult social care. The feedback we receive can be from any member of the public, from people working in services, people receiving care, or their relatives or advocates. Members of the public can also email or contact us if they are unable to complete the GFC form. We had, and continue to have, routine processes in place to ensure that individual GFCs and enquiries were/are reviewed by our National Customer Service Centre (NCSC) and operational teams. There was also whistleblowing guidance in place for providers and individuals who work for providers on our website to enable them to make us aware of any concerns. (IT3/358 [INQ000398722]; IT3/359 [INQ000398723])

437. From 1 March 2020 to 28 June 2022, we received approximately 138,000 comments through GFC, and 2.5 million enquiries were made to NCSC. When an enquiry was

processed by NCSC a 'True/False' field referred to as a 'CovidFlag' could be applied by the operator. The field 'CovidFlag' was a 'Y/N' checkbox which was used to indicate whether the enquiry related to Covid-19. This was also used to indicate whether the service user in question had Covid-19 at the time of writing the enquiry. Approximately 223,000 enquiries, 9.1% of the total, were flagged 'True' for the field 'CovidFlag' during this period. We did not consistently use any other tags to differentiate types or themes of Covid-19 related enquiries.

438. We used qualitative analysis methods to explore people's experiences to inform topics of focus for State of Care. Examples of qualitative analysis for State of Care include the following: free text responses of Urgent and Emergency Care survey data; GFC responses specific to the health and social care workforce between 1 April 2022 and 31 March 2023; GFC responses specific to the National Maternity Inspection Programme and peoples experiences of maternity services; analysis of notes from group discussions of the Supported Living Improvement Coalition (collected August to December 2022), inspection additional question notes (collected May and June 2022), and transcripts from interviews and focus groups with Coalition partners; analysis led by clinical fellows to explore what good workforce wellbeing looks like and what we can do to improve this. We have always collected data for the purpose of regulating individual providers, not to provide wider trend analysis within a sector. At this point in the pandemic we still had old technology systems, and any analysis beyond an individual provider required significant manual work and could not be relied upon for policy making. We have subsequently made significant investment in the way we organise and process data and can now offer insights in a much faster and more comprehensive way.

439. We have developed a project to address this, with methodologies and tools to enable routine analysis of the GFC data through the application of data science techniques with qualitative analysis methods. Successful delivery of this project will contribute to our strategic aim to become driven by people's experiences of care by: enabling the provision of regular insight from GFC to senior leaders across our organisation to support their decision making; providing insights from GFC to inform prioritisation of our activity for operational teams; providing insights about specific, high priority

issues and topics; improving responsiveness to queries about specific issues in services; reducing the length of time spent preparing relevant data for analysis; and providing insight from people's experiences available at area or service level.

440. While it is not currently possible to perform new analysis of concerns received during the relevant period, we will highlight later in this statement where this has been undertaken in relation to some specific areas that the Inquiry has asked us to address.

441. In addition to the methods discussed above, during the relevant period, we engaged and communicated with a wide range of stakeholders as part of our day-to-day functions and as part of our response to Covid-19 to receive and raise concerns relevant to our work.

442. Concerns were raised to or by CQC about the following issues:
    442.1. Shortages of oxygen, including in medical gas pipeline systems or portable bottles;
    442.2. Hospital-acquired infections and infection prevention and control, including PPE, in hospitals, primary care and ambulance services; and
    442.3. The widespread shift to remote care in general practice and the increased use of NHS 111 during the relevant period.

443. These issues are addressed below.

Concerns or issues – Oxygen

444. During the relevant period we engaged with HSIB, and we attended meetings of the National Emergency Medicine Specialist Advisor Forum, about matters related to the supply of oxygen.

445. In October 2020 we were asked by HSIB to review and comment on a draft National Learning Report on 'Oxygen safety risks during the Covid-19 response' looking into a selection of Covid-19 patient safety incidents highlighting oxygen related safety risks (IT3/360 [INQ000398725]; IT3/360a [INQ000398728]; IT3/360b

[INQ000398729]). The draft report was circulated amongst our Policy and Strategy and Pharmacy Specialist colleagues. Following consideration of the draft report we provided HSIB with comments and observations on 23 October 2020, noting several potential issues with the focus of the report based on the observations of those colleagues consulted and their knowledge of this subject. (IT3/361 [INQ000398730])

446. On 17 November 2020, HSIB advised that they would not be proceeding with the publication of the National Learning Report, stating that the stakeholders consulted had highlighted the need to understand local governance processes that relate to the use of oxygen within hospitals. They advised that the scope of the National Learning Report was limited to a review of previously published and unpublished HSIB investigations, which did not explore local governance processes. HSIB decided that without this understanding, publication of the report was not viable. HSIB shared with us a summary of concerns that emerged during the consultation period. (IT3/362 [INQ000398731])

447. On 21 January 2021 HSIB shared a draft interim bulletin on oxygen issues. (IT3/363 [INQ000398732]; IT3/363a [INQ000398734]) This was circulated internally to relevant colleagues in the PMS, Operations and Hospital Directorates for their comments. We identified the following two areas of concern relating to topics we considered had been omitted from the draft bulletin (IT3/364 [INQ000398735]):
    447.1. "The systems were designed with more port in the walls than ports system has capacity to be used…Our hospitals were designed for 1 respiratory ward not a whole hospital."; and
    447.2. "The other risk is the vulnerability of the primary pipe from the regulator panel to the main hospital. As the VIE can be some distance from the building- if that leaks or is broken then there is no plan B as one site cannot have enough cylinders to cope with the repair time. To take the hospital out take the weakest link out the primary oxygen pipe…"

448. On 28 January 2021, CQC's Deputy Director of Medicines Optimisation met with HSIB to discuss the draft bulletin and to communicate our concerns. As a result, the

interface between the estates team and the clinical team was raised internally as a key issue. IT3/365 [INQ000398736])

449. On 27 April 2021, HSIB shared a draft copy of the 'Oxygen issues during the Covid-19 Pandemic' investigation report. The draft report contained the following recommendation for CQC: "Safety recommendation R/2021/XXX: HSIB recommends that the Care Quality Commission review and adapt the CQC inspection model for NHS hospital estates to ensure greater scrutiny of estates related patient safety concerns." In correspondence with Professor Ted Baker, our former Chief Inspector of Hospitals, and Kevin Cleary, former Deputy Chief Inspector, we recognised that there was a need to develop our relationship with NHSE Estates, for them to share any concerns with us and assist us in making judgements as to the proportionality of our regulatory responses. (IT3/366 [INQ000398737]) Additionally, we provided an official response to HSIB via its feedback form on 25 May 2021 (IT3/367 [INQ000398738]; IT3/367a [INQ000398740]).

450. We received the final report and safety recommendation letter on 21 June 2021 **IT3/369a** [INQ000398744]). To assist in the formulation of our response, we met with NHS Estates in order to discuss the ways that we could work with them and gain the assurances needed (IT3/368 [INQ000398741]). We submitted our formal response to the safety recommendation on 17 September 2021 (IT3/369 [INQ000398742]; IT3/369a [INQ000398744]), a copy of which was shared with NHS Estates (IT3/370 [INQ000398746]; IT3/370a [INQ000398748]). Our formal response to the safety recommendation stated as follows:

450.1. "We welcome this report, which shines a light on an estates issue that can have a significant impact on patient safety. We are committed to working with partners, including NHS Estates, to ensure that where there are concerns about the management and governance of estates issues, we can act upon these in a timely and effective manner."

450.2. "As we develop our new regulatory model, we will ensure that the management and governance of estates issues is reflected in our trust level Well-Led framework. We will explore ways of working with NHS Estates

(and other relevant partners such as the Health and Safety Executive) that enable them to raise with us any assurance concerns they have, and provide the technical expertise to help us respond to such risks appropriately."

451. We are currently rolling out a new regulatory model and Single Assessment Framework which is comprised of 34 Quality Statements structured under five key questions. There is a Quality Statement for Safe Environments, strengthening the previous Health Assessment Framework where premises and equipment were a small part of the wider Key Line of Enquiry for Safeguarding and Protection from Abuse (IT3/371 [INQ000398749]; IT3/372 [INQ000398750]). Parallel changes to the scoring and ratings approach means that going forward we will be able to interrogate the information we have on the performance of providers and services in relation to safe environments more efficiently.

452. NHS Estates have added additional questions to the Premises Assurance Model on medical gas supplies, although for 2023 they are for consideration only. They will be mandatory from 2024. An updated and revised Health Technical Memorandum 02-01 NHS Estates guidance for medical gas pipeline systems has not yet been published by NHS Estates. (IT3/373 [INQ000398751]; IT3/374 [INQ000398752])

453. We continue to discuss options for sharing data from the NHS Premises Assurance Model (PAM) self-assessments and we are considering what may be required in the form of a Data Sharing Agreement if it relates to unpublished indicators. However, this is not prioritised for acquisition in this financial year. We have agreed to meet NHS Estates quarterly to have oversight of each other's work regarding how the NHS estates are looked at by the CQC, and how that standards set by NHS Estates can be utilised more effectively in our regulatory assessments.

454. On 11 January 2021, at the National Emergency Medicine Specialist Advisor Forum meeting attended by the Chief Inspector of Hospitals and other colleagues from the Hospitals Directorate, Engagement and one of our National Professional Advisors (NPA) for Emergency Medicine, the subject of oxygen delivery was reported as an

issue and a challenge by the various specialists in attendance (IT3/375 [INQ000398753]).

455. We did not undertake any quantitative or qualitive analysis of the data received via the routes described above in relation to the issue of oxygen supply during the relevant period. Further, it has not been possible to perform any retrospective analysis of the data for this specific subject when preparing this statement because we did not have the relevant tags in place within our Customer Relationship Manager system (CRM), the system used by our NCSC operators at the time, and due to the limitations of our current system.

Concerns – Infection Prevention and Control

456. During the relevant period, we received concerns relating to IPC and PPE in hospitals and primary care via NCSC and GFC. These concerns were published by us in the form of high-level summaries relating to IPC and PPE in some of our Covid Insight Reports and State of Care Reports published during the relevant period. Additionally, our internal Cross-Engagement Insight Reports included some anecdotal references to concerns about various IPC and PPE issues that we were alerted to via our NCSC and GFC channels.

457. Whilst we have not undertaken analysis of individual IPC related concerns received via GFC and NCSC for the duration of the relevant period, some qualitative analysis of information from complaints, GFC and whistleblowing data for the period 2 March 2020 to 2 August 2020 was performed. This analysis was completed in support of an internal working group called Covid-19 Emerging Issues Group. The group consisted of various colleagues from our Intelligence unit at the time. We developed a report by collating and analysing qualitative information that directly related to Covid-19 from information tagged by NCSC colleagues against the themes identified below to monitor what people using services, their relatives and staff were telling us in relation to Covid-19. (IT3/376 [INQ000398754])

458. These themes included: Infection Control; Management approach; Being Informed; Attitudes and concerns; Access to services; and Other. Each of these themes was

sub-categorised to provide a further level of detail related to various aspects as follows:

458.1. The theme of Infection Control was of particular significance because it contained analysis of the data related to two subcategories:

458.1.1. 'Availability of infection control: Availability of hand sanitiser/soap/washing facilities; Personal Protective Equipment (PPE), including clothing; availability of tests (staff, patient, relatives.

458.1.2. Infection and control practice: How hygiene/infection control is practiced within service; cleaning facilities, wearing PPE (if PPE is available), movement of staff between wards/services/people's homes, (self-)isolation of people with suspected symptoms (NOT staff, movement of people using the service within and outside of the service.'

458.2. The theme 'Being Informed (Information/guidance/leadership/training)', reflected the information received about: 'training in how to prevent coronavirus spreading, e.g. training in use of PPE, training infection control.'

459. The report can be filtered to show the number and percentage of Covid-19 related enquiries with information for each theme. The report can be further filtered to show the number of concerns and percentages by sector (ASC, Hospitals, PMS), by source type (complaint, complaint about provider, GFC, whistleblower), and by week, beginning from 2 March 2020 to 27 July 2020. The report also provides the number of IPC related tags applied to concerns we received by CQC region and NHSE region, which can again be further broken down into sector, source type and date. We divide England into regions for management and oversight purposes, that we apply across our work. These are: East; East Midlands; London; North East; North West; South East; South West; West Midlands; Yorkshire and Humberside. Our regional groups do not exactly align with those used by NHSE for the purposes of their own work. NHSE regions are: Midlands; North East and Yorkshire; South East; North West; East of England; London; and South West.

460. The individual enquiry details from our CRM system relating to availability of IPC products and infection control practice for the data contained in this report, including the free-text box description of the enquiry, can also be found in the Power BI report where they exist, by searching through the location ID numbers. (IT3/376 [INQ000398754])

461. The report was last updated on 7 August 2020.

462. Our Covid Insight Reports published during the relevant period also featured information about concerns raised to by us relating to hospital-acquired infections; IPC; and PPE in hospitals and primary care settings. They were designed so that we could share a contextualised and data-driven narrative about what was happening across health and social care during the pandemic.

463. We determined the themes, content, and format of these reports which evolved over time and sometimes differed from report to report. We published 15 in total. More detail on 7 of the Covid Insight Reports which refer to IPC concerns is set out below by way of example.

463.1. Issue 1 published on 1 May 2020 referenced 'The Impact on Care Providers and Staff'. In this issue we reported how access to testing was key to reducing infection and saving lives, stating a key consideration in this regard had been to improve the availability of testing for frontline social care and primary care staff. We described how concerns around testing had continued, particularly around communication, with a need for clarity about who is leading on testing and where to go for it. (IT3/138 [INQ000235471]

463.2. Issue 2 published on 15 June 2020 focused on how providers were working across systems in response to the pandemic. From our conversations with providers, we reported that one of the barriers to collaboration that stakeholders had faced was the need to share resources, including PPE, fairly and in a timely way. (IT3/139 [INQ000235472])

463.3. Issue 3 published on 15 July 2020 highlighted our news item published on our website on 17 June 2020 about the increase in NCSC calls from providers raising concerns about care, many of which related to issues with

PPE and infection control. (IT3/140 [INQ000235473]; IT3/91 [INQ000398848])

463.4. Issue 4 published on 15 September 2020 focused on IPC for acute hospitals and GP Surgeries as one of its key themes. To review IPC in acute hospitals we analysed the outcomes of the Emergency Support Framework (ESF) calls between our inspectors and all acute and specialist trusts. (IT3/131 [INQ000235474])

463.4.1. The ESF calls were analysed within the context each trust's 'Board Assurance Framework' to identify how the trust was assuring itself of good IPC. While most trusts assured themselves that they were managing IPC systems and mitigating risks, Issue 4 highlighted some examples where the systems and procedures were ineffective. We reported that PPE was a challenging area for acute hospitals. Concerns and issues included the pace of change of PPE guidance and the multitude of suppliers of PPE. In our section on GP surgeries, we highlighted some of the measures taken by GP surgeries (drawn from conversations with 43 surgeries) to understand any challenges, concerns as well as good practice. Some services had experienced difficulties in obtaining adequate stock in a timely manner, especially during the early stages of the pandemic.

463.5. Issue 5 published on 18 November 2020 provided a summary of the results of the Covid Inpatient Survey commissioned in August 2020. One of the regular data collections we make is the NHS National Patient Survey program. There are five surveys in this program each running annually or bi-annually. In August 2020, we commissioned a one-off Covid Inpatient Survey to capture the experiences of patients discharged from hospital during April and May 2020. We focused our questioning on those admitted to hospital with confirmed or suspected Covid-19, as well as those admitted for unrelated reasons. Evidence and learning from the survey was shared in a report published on our website in November 2020. The survey captured views on general cleanliness in hospital,

infection control measures and perceived safety from contracting Covid-19 while in hospital. Section 4.3 of the report focuses on IPC (IT3/321 [INQ000235488]). In Covid Insight Report 5, we further highlighted that from the Covid Inpatient Survey responses, people with Alzheimer's disease were least likely to always understand staff who were wearing PPE. Deaf people, those with a learning disability, dementia or Alzheimer's, people aged over 85 and autistic people also found it particularly difficult to understand staff when they were wearing PPE. (IT3/141 [INQ000235462])

463.6. Issue 12 published on 21 July 2021 focused on IPC in NHS Trusts as one of its key themes. Following the review of the NHS trusts' board assurance regarding IPC board during the summer of 2020 as referenced in Issue 4, we carried out 13 unannounced inspections within acute NHS services to monitor IPC. These took place between January and March 2021. The full reports for these IPC focused inspections were published on our website. We did not rate the trusts at these inspections, and all previous ratings prior to this inspection remained. Any concerns and issues we identified regarding IPC are included in the reports. (IT3/148 [INQ000235481])

463.7. Issue 13 published on 20 September 2021 focused on the recovery of NHS hospital services. In May and June 2021, we asked 73 trusts about their approaches to longer waiting lists and how they were considering people's care in a fair and equal way. Relating to IPC concerns, we reported that hospital capacity was under pressure due to social distancing, IPC, cleaning measures, use of PPE and enhanced testing especially for trusts with older estates or reduced space. (IT3/149 [INQ000235482])

464. During the relevant period we also produced Cross-Engagement Insight Reports which were shared internally. Twenty two issues were produced from April 2020 to March 2022. The reports were contributed to by a collaboration of colleagues from across our Transformation teams and Engagement Directorate. Monthly meetings were held by the Director of Engagement as a means of keeping CQC employees

informed of the plans for the upcoming reports and any initial insights and key themes noted from liaison and engagement with different stakeholders.

465. Individual teams (our Transformation, Public Engagement, Provider Engagement, Internal Engagement, and Parliamentary Governance and Stakeholder Engagement teams) collated insight from their engagement activity in the form of meetings, reports, action notes, survey results, focus group notes and webinar notes. The contents of the reports vary depending on the engagement activities undertaken and information received during the period. This includes concerns received from a wide range of stakeholders, on a wide range of Covid-19 related themes.

466. The reports were not published or shared externally. The information in the reports was used by Engagement colleagues to inform discussions and briefings with key external stakeholders and internal colleagues. Key themes and insights from the reports were also brought to our Gold Command meetings at times. Engagement teams also used the findings throughout their wider engagement work to evidence any concerns we wished to raise externally, to show how we had listened to and engaged with external stakeholders, and to help us respond to feedback and concerns.

467. Some examples of the reports which featured information related to IPC and PPE concerns in hospitals and primary care settings are included below.

468. Issues 1 to 6 released between 8 April and 20 May 2020 reported on access to and availability of PPE as a recurring concern from people who use services. A lack of consistent guidance on IPC and use of PPE was also a common theme across audiences and was reported in earlier Issues as well as Issues 12, 14 and 15 released between 30 June 2020 and 14 August 2020.

469. Concerns were regularly noted on social media channels, tagged by an internal system and reviewed by NCSC colleagues and communicated to Engagement colleagues. These social media concerns tags were reported to ET, included in Insight Reports and were communicated at Regional Escalation Groups by CQC (IT3/377 [INQ000398755]; IT3/378 [INQ00398756]; IT3/379 [INQ000398757];

IT3/380 [INQ000398759]; IT3/381 [INQ000398760]; IT3/382 [INQ000398761]; IT3/383 [INQ000398762]; IT3/384 [INQ000398763]; IT3/385 [INQ000398764]).

470. During the relevant period we stood up Cross-Sector Regional Escalation Groups situated across the country. The groups offered real-time intelligence on issues from providers at a local level, helping to build a picture of trends and risk. Information gathered here was shared with system partners, such as DHSC and Local Authorities, for national support and to help make decisions at a local level. The groups reported into a National Escalation Group.

    470.1. Issue 3 released on 29 April 2020 specifically noted a lack of PPE for independent hospitals, even though they were caring for NHS patients. In addition, we noted serious financial implications for hospitals where they were paying for PPE themselves. Staff at some mental health services were buying their own PPE products.

    470.2. Issue 4 released on 6 May 2020 noted that dementia and nursing staff had been highlighted as a particular group with unmet PPE needs across service providers. Concerns relating to IPC and hygiene levels in services were being expressed on social media by those representing people using services.

    470.3. Issue 5 released on 13 May 2020 noted that there were recurring concerns on social media regarding BAME staff access to PPE.

    470.4. Engagement colleagues started to produce quarterly Cross Engagement Reports in 2021. The first quarterly issue released on 28 May 2021 for the period January to May 2021 noted IPC as a barrier for the public, providers, and stakeholders. Providers were concerned about access to PPE, and the public shared concerns about access to services due to infection risk. (IT3/386 [INQ000398765])

471. These considerations are echoed and summarised in the State of Care Reports produced during the relevant period, which included IPC as a consistent theme as set out below:

State of Care Report for 2019/2020 IT3/187 INQ000235495]

472. In the section covering the impact of the Covid-19 pandemic on IPC our 2019/2020 State of Care Report we reported that:

472.1. The ESF had enabled our inspectors to have structured and consistent discussions with providers about the impact of Covid-19 on staff and people using services, and helped us identify where we might need to inspect or escalate concerns to partners.

472.2. We saw an increase in calls to our national contact centre from health and social care staff raising concerns about care. The biggest increase came from staff in the adult social care sector where there was a 55% increase in the number of calls made for the period 2 March 2020 to 31 May 2020 compared to the same period in 2019.

472.3. We also saw an increase in information sharing from people using services, their relatives, and staff, including through our GFOC service. IPC was the most common theme from the feedback received through our GFOC service, appearing in 44% of enquiries.

472.4. While most NHS acute and specialist trusts assured themselves that they were managing IPC well and mitigating risks, there were some examples of where the systems and procedures were ineffective. Robust audits did not always take place during the peak of the pandemic, including audits of PPE, waste disposal and the screening of other health care-associated infections. Oversight of IPC training varied between trusts, meaning some could not always be assured that staff had been adequately trained in IPC procedures. And some trusts had challenges on space that limited their ability to isolate and cohort Covid-19 positive patients.

472.5. The results of our 'Inpatient experience during the coronavirus (COVID-19) pandemic' survey showed that the observation of IPC-related practices (such as handwashing with hand sanitiser or soap, staff wearing PPE, staff disposing of gloves and plastic aprons, cleaning of surfaces and waste bins being provided) were all relatively high (90% or above in all cases). However, respondents reported seeing social distancing measures (such as markers on the floor or signage at the entrance) to a lesser extent (65%).

472.6. The results of our special programme of IPC inspections were mostly encouraging. The main areas that needed to improve were around having out-of-date IPC policies and not using PPE in the most effective way.

472.7. Our calls to a sample of GP practices showed that they generally had good PPE and cleaning procedures, procedures for social distancing and audits of IPC. Those we talked to said that one challenge had been around the clarity and effectiveness of communication around national IPC guidance – saying that messages, particularly in the early stages of the pandemic, were inconsistent and confusing

State of Care Report for 2020/2021 **IT3/191** [INQ000235497])

473. In our 2020/2021 State of Care Report we reported on the findings of the IPC inspections undertaken in hospitals and care homes for the 2020/2021 period as follows:

473.1. Care homes: Our report on 'How care homes managed infection prevention and control during the coronavirus pandemic 2020' published in November 2020 was based on a programme of 440 care home inspections in August and September 2020 that looked at IPC assurance across eight questions and found that most of the providers demonstrated that they had faced the challenges of the pandemic well.

473.2. NHS hospitals: Our July 2021 COVID-19 Insight report detailed the findings of our first nine Well-Led focused inspections in acute NHS services to monitor IPC which highlighted that good IPC practices had been implemented by most of the trusts inspected. Prior to our inspections, several trusts had seen an increase in the number of nosocomial infections particularly around December 2020 to January 2021, and had action plans and objectives to reduce them. They carried out reviews and shared learning from any outbreaks. The results from the 2020 Urgent and Emergency Care survey were among the largest year-to-year differences ever observed by NHS Patient Survey Programme surveys likely reflected enhanced IPC measures in urgent and emergency care services in response to the Covid-19 pandemic.

474. The theme of IPC also featured in the discussions at meetings of the National Emergency Medicine Specialist Advisor Forum. Particularly in the early stages of the pandemic, members of the forum anecdotally reported concerns around nosocomial infections, practicalities of segregation in Emergency Departments (ED), delays caused by infection control measures, the impact of winter pressures and bed issues on effective infection control management and the potential harm caused to medically optimised patients. (IT3/389 [INQ000398766]; IT3/390 [INQ000398768]; IT3/391 [INQ000398769]; IT3/375 [INQ000398753] and IT3/392 [INQ000398770])

Concerns – Remote care in general practice and use of 111

475. In January 2021, we issued an internal report based on a review of access to Primary Medical Services between April and December 2020. The report provided insights into people's experiences of access to these services shared with us through GFC, phone calls, and our social media channels. The report was for internal use only and was not shared externally. (IT3/393 [INQ000398771])

476. The report set out the findings of our qualitative analysis of a random sample of the concerns we had received during the review period. In the report we were able to highlight 'access to services' as a common topic amongst GFC submissions. We were also able to provide examples of access issues, together with a summary of the common themes and barriers associated with access. The report also provided an overview of the outcomes associated with poor access (where this was included in comments received and/or conversations we had) and referred to the personal impact this had. The data analysed as part of this review was limited to the experiences and concerns of those who had submitted comments to us through the channels mentioned above. As a result, it is stipulated that "This report cannot comment as to whether PMS access issues are prominent/have increased within the general population, as the analysis presented here has only considered the experiences of those who submitted comments through the previously mentioned data sources."

477. In November 2021, we commissioned research and consultancy company Traverse Ltd to carry out a survey of the experiences of adults in England who had tried,

successfully or not, to access GP services during the pandemic. The survey, which comprised 28 questions, was completed between 1 and 15 November 2020 and covered the experiences of 2087 adults in England who had tried, successfully or not, to access a GP service in the past 12 months. It was conducted using an online survey administered to members of the YouGov Plc UK panel of 1,000,000+ individuals who had agreed to take part in surveys. (IT3/394 [INQ000398772]

478. Some of the themes and findings of our 2021 PMS Access Review and the Traverse GP Access Report are also featured in our State of Care Report for 2021/2022. (**IT3/191** [INQ000235497]), as follows:

478.1. Of the 2,087 adults who responded to the Traverse GP Access survey and who did not get a GP appointment in the previous 12 months:

478.1.1. 25% didn't see or speak to anyone.

478.1.2. 25% decided to contact their practice at another time.

478.1.3. 16% attempted to self-diagnose using an internet search.

478.1.4. 10% went to A&E

478.2. In our analysis of feedback received via our Give Feedback on Care service, phone calls and social media between April and December 2020, we found that many people who contacted CQC about access to GP services told us about their inability to make an appointment. People described finding it difficult to figure out the best or 'correct' way to contact practices. When calling by phone, people told us they were often on hold or in a queue for a long time. Some people found that, when they did make a telephone appointment, the doctor did not call them during the allotted time or at all, and they had to go through the booking process again.

479. Between 2 March 2020 and 2 August 2020 our internal Covid-19 Emerging Issues Group also analysed qualitative data from complaints, GFC and whistleblowing concerns in relation to access to services and produced a report. The report provides a summary of the concerns received regarding 'access to services (systems)' and the numbers of Covid-19 related enquiries with information pertaining to 'access to treatment/care (other conditions)' and 'access to treatment/care for coronavirus'. The data can be filtered by sector, by source type (complaint, complaint about

provider, GFC, whistleblower), and by week. The report also provides the number of access to services/system related tags applied to concerns we received by CQC region and NHSE region, which can again be further broken down into sector, source type and date. (IT3/376 [INQ000398754)

480. Additionally, our Covid Insight Reports also featured information on concerns raised to and by us relating to GP access, NHS 111, and remote care services. More detail on two of the relevant Covid Insight Reports is set out below by way of example.

480.1. Issue 2 published on 15 June 2020 (IT3/139 [INQ000235472]) focused on the changing face of general practice and online primary care as one of its key themes. In our conversations with GP practices, we observed that one of the key challenges they faced during the pandemic was 'information overload'. Practices told us that they were struggling to interpret the guidance being issued from different sources that weas constantly changing or conflicting. We also reported in this issue that the working systems of GP practices had not fully reflected the rapid shift in ways of working to online/remote consultation that took place from March 2020.

480.2. Issue 4 published on 15 September 2020 (IT3/131 [INQ000235474]) reported on findings drawn from conversations we had with 43 GP surgeries to understand actions taken in response to the pandemic, as well as good practice and challenges they had faced. We reported that the changes in the way GP practices were working did not come without cost. We were told that some staff and patients felt increased levels of stress and frustration with remote care. There were also concerns that some non-urgent patients who required procedures like routine screening and immunisation were not being seen in a timely manner because they were worried about the risks of contracting Covid-19 during a visit to the surgery, or because they thought their GP lacked capacity to see them.

481. Furthermore, during the relevant period our Cross-Engagement Insight Reports consistently featured information regarding concerns relating to access to services and remote access. The long-term impacts on people and services due to an inability to access services at early stages for non-Covid related conditions was a common

concern across social media and at Regional Escalation Groups during the relevant period. This was especially felt across PMS settings and by GPs. (IT3/377 [INQ000398755]; IT3/378 [INQ000398756]; IT3/379 [INQ000398757]; IT3/382 [INQ000398761]; IT3/395 [INQ000398773]; IT3/396 [INQ000398774]; IT3/397 [INQ000398775]

482. We reported that there were specific concerns from service users around access to medicines, transport to appointments and cancer treatments. (IT3/380 [INQ000398759]) We received concerns from our Experts by Experience regarding access to information issues experienced by people who do not have access to technology or online communication channels (IT3/381 [INQ000398760]). Peer support replacing professional support and the impact on mental health was a concern across all sectors, particularly where people were not able to access the services they would usually have used prior to the pandemic. (IT3/398 [INQ000398776]; IT3/399 [INQ000398777])

483. Similar considerations and themes were echoed in the State of Care Reports published for the relevant period. **IT3/187** [INQ000235495]; **IT3/191** [INQ000235497]; IT3/198 [INQ000398569]; IT3/400 [INQ000398778])

484. Concerns relating to remote care in general practice and the use of NHS 111 also featured in the discussions at meetings of the National Emergency Medicine Specialist Advisor Forum. In the early stages of the pandemic members of the forum were positive about the assistance provided by these services. However, later in 2020 and 2021 members reported anecdotal concerns around an increasing number of patients attending EDs as a replacement for GP face-to-face appointments, patients using EDs to get a second opinion after virtual consultations with GPs, pressures on the NHS 111 service and GP's due to additional virtual triage methods and a notable increase in children presenting to ED instead of primary care services. (IT3/390 [INQ000398768]; IT3/391 [INQ000398769]; IT3/401 [INQ000398779]; IT3/402 [INQ000398780]; IT3/403 [INQ000398781]; IT3/404 [INQ000398782]; IT3/405 [INQ000398783]; IT3/25 [INQ000398625]; IT3/406 [INQ000398784];

IT3/407 [INQ000398785]; IT3/408 [INQ000398786]; IT3/409 [INQ000398787] and IT3/410 [INQ000398789]

GP Access Inspections

485. In October 2021 NHSEI, supported by DHSC, published a guide setting out their plan for improving access for patients and supporting general practice, in conjunction with the new Winter Access Fund. The guide noted that CQC had recorded a rise in the number of concerns and complaints about access to general practice. In anticipation for another challenging winter for the healthcare sector, the guide described the actions to be taken by the NHS, Government and other partner organisations to support general practice and improve access to GPs. As part of the plan to address variation and encourage good practice, specifically by "tackling unacceptable variation" the plan provided for CQC to work with NHSE to support systems and to make the required improvements across those practices which were not meeting people's reasonable needs. The plan noted that CQC was rapidly developing an inspection methodology with a particular focus on access to GP services and that "wherever appropriate, [CQC] will make unannounced inspections" (IT3/477 [INQ000391358]).

486. In November 2021 we circulated guidance to our PMS Inspection Teams (IT3/478 [INQ000469891]) setting out CQC's approach to carrying out inspections of GPs with a specific focus on access. In the guidance we indicated that CQC had committed to working with NHSEI to support systems to make required improvements by:
    486.1. Providing data about the volume of queries and concerns we had received;
    486.2. Maintaining an ongoing dialogue with CCG/ICS teams regarding practices of concern; and
    486.3. Reviewing information received from NHSEI (and from other sources) and deciding where it was appropriate to undertake inspections with a specific focus on access.

487. Between November and December 2021 CQC carried out 38 inspections with a specific focus on the management of access in GP practices. None of the inspections identified breaches of regulations or resulted in changes to ratings and some of the findings explained in a meeting with the then Parliamentary Under

Secretary of State (Minister for Patient Safety and Primary Care), Maria Caulfield MP, on 19 January 2022 were as follows (IT3/479 [INQ000469892]):

487.1. None of the inspections identified current issues with patient access to the services, the practices had recognised previous problems and taken action to manage those and improve their systems;

487.2. Practices had taken steps to ensure that patient needs were met when it came to contacting the practice or requesting an appointment;

487.3. eConsultations were identified as being in use in almost all of the locations inspected;

487.4. Some practices told the inspector of significant rises in the number of submissions they received through the eConsult system;

487.5. Staff training was specifically commented upon in a number of the reports. This included sepsis training, care signposting and the provision of templates, flow charts and protocols to ensure patients requiring urgent appointments were triaged in the correct way;

487.6. In most of the locations inspected, practices had reviewed their telephone systems and either taken remedial actions such as setting up a call centre or updated the systems with their provider;

487.7. Whilst inspectors reported practices being under pressure, this was not judged to be a specific risk to patient safety in any of the locations inspected; and

487.8. Two practices were identified as proactively ensuring access to comprehensive care, treatment and support for underserved individuals such as the homeless, asylum seekers, the travelling community and sex workers;

488. The access inspections focused on the responsive key question (KLOE R3 - Access to Treatment) to consider how appointment systems were being operated. This enabled us to identify and highlight good areas of practice and to support a broader understanding of access issues. The inspections were triggered in response to risks and/or concerns identified through a targeted intelligence review and from information received via existing routes such as GFC, whistleblowing and/or complaints or from information shared with us by CCG/ICS teams as part of their

plans to improve access. The access inspections were undertaken as a standalone activity but were not intended to replace other inspections. The inspections were usually unannounced and focused on access and were guided by a series of specific questions and prompts as follows:

488.1. Do people have timely access to appointments/treatment and was action taken to minimize the length of time people waited for care, treatment or advice?

488.2. Does the practice provide a range of appointment types to suit different needs?

488.3. Can people make appointments in a way which meets their needs?

488.4. Are there systems in place to support people who face communication barriers to access treatment?

488.5. Do people with the most urgent needs have their care and treatment prioritised?

488.6. Is there information available to support people to understand how to access services?

488.7. Are there enough staff to provide appointments and prevent staff from working excessive hours?

488.8. Are there systems in place to monitor the quality of access and make improvements?

489. On 9 December 2021 DHSC informed CQC that the UK Government had "requested the additional unannounced access inspections are paused until end January [2022]" (IT3/480 [INQ000469893]). This instruction preceded the updates communicated by CQC on our website on 10 December 2021 and 13 December 2021 as referenced in paragraphs 222 – 224 above.

490. From January 2022 the access inspection questions and prompts were incorporated into our existing inspection framework to enable us to ensure that we continued to have a comprehensive view of access, in conjunction with other aspects of general practice.

Analysis of mortality trends in people detained under the MHA 1983

491. A summary of CQC's analysis of mortality trends in people detailed under the MHA over the relevant period is outlined below.

492. During the relevant period, analysis of data received in relation to deaths of people detained under the Mental Health Act was published in our Mental Health Act Annual Report (MHA annual report) and in our Covid Insight Reports. These reports include aggregate figures on the number of notifications received pursuant to Regulation 17 of the Care Quality Commission (Registration) Regulations 2009/3112 and 2012 (Statutory Notification 17 "SN17") during the relevant period. In terms of Regulation 17, providers are required to notify us of deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983 (MHA), including where the death occurred while services were being provided in the carrying on of a regulated activity or have, or may have, resulted from the carrying on of a regulated activity (IT3/411 [INQ000398790]; IT3/412 [INQ000398791]; IT3/413 [INQ000398792]). The death of children or young people whilst under care of a service should also be notified to us as a Regulation 16 notification using the SN16 form. This information is submitted to us via notification forms and through our Provider Portal. Any registered provider with 100 locations or fewer can access the Provider Portal. (IT3/414 [INQ000398793])

493. Deaths of people under the care of mental health services may also be reported to us via the SN16 process. Regulation 16 requires that notifications by providers are made without delay so that we can take urgent follow-up action where needed.

494. We have not been able to identify any specific analysis undertaken by us that focused on this subset of data during the relevant period.

495. We report annually on deaths of detained patients in our MHA annual reports. This data is also routinely shared with the Ministerial Board of Deaths in Custody. The 2020/21 and 2021/2022 annual reports published on our website fall within scope of the relevant period and are exhibited as **IT3/175** [INQ000398545]; IT3/416 [INQ000398795]). Our 2022/23 MHA annual report is currently being drafted and it

will include data on deaths of detained patients for the later part of the relevant period. The unpublished and early draft analysis of this data has been shared with the Ministerial Board of Deaths in Custody and is now in the process of being updated in readiness for inclusion in the final report which is due to be published in December 2023.

496. Issues 1 to 13 of the published Covid Insight Reports the analysis of 'person level data', outlining the number of SN17 deaths during the pandemic. This reporting started at the beginning of the pandemic and ended in September 2021. We stopped including data for SN17 notifications after Issue 13. We have highlighted the analyses, as explained, in some of the issues by way of example.

496.1. Issue 1 (IT3/138 [INQ000235471]) includes details of the number of death notifications we received from 1 March 2020 to 8 May 2020 where mental health providers had indicated that they were suspected or confirmed to be related to Covid-19. This data includes both deaths of people who were detained in hospital and under the MHA in the community. This data is compared to the numbers of SN17 notifications received from mental health providers and non-mental health providers in previous years, up to 2016.

496.2. Issue 2 (IT3/139 [INQ000235472]) includes details of all notifications of deaths of detained patients from 1 March to 5 June 2020, broken down by age, gender and Covid-19 status where known. This was the first time that age and gender were looked at in the analysis of this data in the Covid Insight Reports.

496.3. All subsequent issues reporting on deaths of people detained under MHA (issues 3 to 13) include information regarding whether the mental health providers indicated that the deceased was suspected or confirmed to have had Covid-19. This data includes detained patients on leave of absence, or absent without leave, from hospital, and conditionally discharged patients. 'Detained patients' also includes patients subject to holding powers under sections 4, 5, 135 or 136 of the MHA, and patients recalled to hospital from a Community Treatment Order (CTO). Issues 3 to 13 also show SN17

notifications broken down by age, gender, ethnicity, place of death, learning disability and/or if the detained patients were autistic.

496.4. From Issue 3, we included data to show the total number of detained patient deaths during the period where the patient had a learning disability/autism, and whether the patient was confirmed or suspected to have had Covid-19. As with our approach to the publication of data regarding deaths of people with a learning disability and/or autistic people in other settings, we did not publish exact numbers at this level to avoid identification of individuals.

497. When compared, the data recorded in our MHA annual reports for 2020/21 and 2021/2022 is likely to differ from that shown in the various issues of our Covid Insight Reports covering the same period. Our Covid Insight Reports provided overall figures for any death notified to CQC through our MHA death notification process based on date of notification rather than date of death (as reported in the MHA annual report). In addition, notifications data may be updated over time leading to changes in overall numbers and/or the categorisation of deaths. These updates may relate to data cleaning, delays in notifying CQC of a death of a detained patient or information received through the coroners' courts. The timing and frequency of the published Covid Insight Reports together with our desire to share this information in as timely and helpful a manner as possible meant that limited data validation and data cleaning could take place in advance of publication.

498. We do not have a comprehensive view on how well different NHS trusts and other service provider organisations collaborated during the relevant period to provide both covid and non-covid care. We did not explicitly inspect this degree of collaboration.

Long Covid Clinics

499. Since 2020, the NHS has established post-Covid services across England for adults, children and young people.[15] These multidisciplinary services include physical, cognitive, and psychological assessments; diagnostic tests; and management or

[15] NHS England Website - Post-COVID syndrome (long COVID) What is Post-COVID syndrome/long COVID?

appropriate onward referral to post-Covid rehabilitation, treatment, and other support.[16] As of 1 April 2023, there are 102 organisations which provide post-Covid services for adults and 13 organisations which provide specialist paediatric post - Covid services for children and young people.[17]

500. We have not undertaken a programme of specific inspections of specialist long covid clinics. However, following a review of the list of inspections undertaken by CQC at NHS organisations between January 2020 and January 2023, we identified that we inspected 87 organisations which were listed on the NHSE website as providers of post-Covid services.[18] 75 of these NHS organisations provide post-Covid services for adults and 12 provide specialist paediatric post-Covid services for children and young people. We reviewed our inspection reports for these 87 organisations for the period January 2020 to January 2023 to identify any reference to long Covid in general and our findings are set out below.

501. The following inspection reports discuss the impact of long Covid on staffing and staff wellbeing:

501.1. Northern Lincolnshire and Goole NHS Foundation Trust: This inspection took place between 28 – 30 June and 26 – 28 July 2022. We looked at the significant impact that Covid-19 had on staffing, patient flow, ambulance pressures, increased wait times and service remodelling (IT3/417 [INQ000398796]).

501.2. Mersey Care NHS Foundation Trust: This inspection took place between 8 November 2022 and 24 January 2023. The report indicates that the Trust was considered to be an outlier for the number of staff absent with long Covid. In particular, the Trust's Ashworth site had several staff absences due to long Covid (IT3/418 [INQ000398797]).

501.3. Birmingham Women's and Children's NHS Foundation Trust: This inspection took place between June and October 2022. This report also comments on staffing issues. The Trust continued to support staff with

[16] Ibid
[17] Ibid
[18] Ibid

Covid-19, including providing individual Covid-19 risk assessments, regularly refreshed assessment and guidance and continuous support to staff members affected by long Covid (IT3/419 [INQ000398798]).

501.4. Blackpool Teaching Hospitals NHS Foundation Trust: This inspection took place between 14 September to 20 October 2021. The Trust recognised the importance of staff wellbeing and in January 2021 appointed a trainee associate psychological practitioner to provide post therapeutic input for staff, initially focusing on Covid related conditions, with a subsequent focus on PTSD (IT3/420 [INQ000398799]).

502. The following inspection reports address the findings regarding the support provided to patients with long Covid:

502.1. The Mid Yorkshire Hospitals NHS Trust: This inspection took place between 26 and 28 April 2022. The report indicates that during the pandemic, patients had access to emotional support to help deal with any trauma they might have experienced as a result of Covid-19 (IT3/421 [INQ000398800]).

502.2. Walsall Healthcare NHS Trust: This inspection took place between September and November 2022. The report notes that the Trust had structural support in place for patients with long Covid. This included virtual wards set up to help people manage Covid-19 patients at home, as well as to support those with long Covid. These wards were expanded in Walsall to include patients with respiratory conditions and Chronic Obstructive Pulmonary Disease (COPD). The virtual wards were implemented to reduce the length of time people were in hospital or prevent them from having to go in at all. The Trust also worked with others including local organisations to plan care, with increased investment in community support services, which included rapid response services, community nursing and virtual wards for covid and respiratory conditions to reduce readmission rates within the medical service (IT3/422 [INQ000398801]).

502.3. Barking, Havering and Redbridge University Hospitals NHS Trust: This inspection took place between 7 and 10 November 2022. The report notes that senior staff commented on the increase since the Covid pandemic in

patients presenting as more confused with progressed dementia, often displaying aggressive behaviour. Trust staff also commented on the increase of patients with medical complexities, presenting challenges to staff in managing complex caseloads and discharges, which impacted on the hospital flow. Plans and ongoing liaison to address these risks was ongoing (IT3/423 [INQ000398802]).

Internal and External Reviews, State of Care Reports, Lessons Learned Exercises

503. The Inquiry has asked us to provide, for the relevant period, a chronological list of any internal or external reviews, State of Care Reports, lessons learned exercises or similar, commissioned by us and which relate to any of the matters in the Provisional Outline of Scope for Module 3. In addition, we have been asked to include a summary of the conclusions and recommendations of any such reviews, reports or exercises, and whether any recommendations made as a result have been implemented.

504. The attached chronological list ("the list") (IT3/424 [INQ000398803) sets out the reviews, reports and exercises completed together with details of the findings reached and recommendations made (as appropriate) where these can be drawn from the document itself and any supporting information. The list comprises 83 entries that have some potential relevance to the Provisional Outline of Scope for Module 3. We have intentionally omitted the inclusion of any such reviews, reports or exercises that were solely focused on matters that related to Social Care in anticipation that these will be directly relevant and of interest to the Inquiry later in Module 6.

505. The list was compiled following the manual review of publications on our website as well as the work undertaken by our internal teams and directorates which was reported to the Board, the Executive Team, and the Gold and Silver Command Committees.

506. Column C of the list indicates whether the review, report or exercise was internal or external. In respect of the external reviews, reports and exercises Column C also

indicates whether they were conducted upon the request of the Secretary of State in terms of section 48 of the Health and Social Care Act 2008. We have also included details of any implementation activity undertaken to date (Column J) and recommendations (Column H) where it has been possible to do so.

507. In terms of whether CQC would seek to make any recommendations in order to improve the response of the healthcare system and its regulatory oversight in the event of a future pandemic, we confirm that we did not feel that there are any specific regulatory changes required, save for the need to always consider social care as an important part of any response by the healthcare system and to ensure that changes in one sector are in lockstep with the others.

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: 12 April 2024