Expert Report for the UK Covid-19 Public Inquiry

Module 3 – The impact of the Covid-19 pandemic on the healthcare systems of the UK

Infection prevention and control: the challenges of protecting everyone in healthcare settings from the threat of Covid-19

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Author statement

"We confirm that this is our own work and that the facts stated in the report are within our own knowledge. We understand our duty to provide independent evidence and have complied with that duty. We confirm that we have made clear which facts and matters referred to in this report are within our own knowledge and which are not. Those that are within our own knowledge we confirm to be true. The opinions we have expressed represent our true and complete professional opinions on the matters to which they refer."

Dr Gee Yen Shin, Professor Dinah Gould, and Dr Ben Warne

8th August 2024

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Preamble

Dr Gee Yen Shin, Director of Infection Prevention and Control, UCLH NHS Foundation Trust, London

Gee Yen is a Consultant Virologist at University College Hospitals NHS Foundation Trust, a position he has held since 2018. He is also the Health Services Laboratories (HSL) consultant specialty lead for virology. HSL is a public:private partnership between The Doctors' Laboratory, a private pathology company and UCLH NHS Foundation Trust and the Royal Free NHS Trust.

During the pandemic, Gee Yen was interim Director of Infection Prevention and Control (DIPC) intermittently throughout 2020, then continuously from January 2021. He was appointed DIPC substantially in November 2021. He was a member of the North Central London (NCL) Integrated Care System (ICS) DIPC Forum throughout the pandemic.

As DIPC and virologist he was heavily involved in many aspects of the COVID response of UCLH and NCL ICS partners including acute and community NHS Trusts.

Gee Yen is a member of the UK Advisory Committee on Dangerous Pathogens (ACDP) as an appointed member. ACDP is an independent expert panel advising various Government Departments such as the Department of Health and Social Care on emerging infectious Diseases. ACDP was not the lead Governmental expert committee for the Covid pandemic. Consequently, it had a limited role during the pandemic. ACDP advised on specific aspects such as laboratory safety when handling SARS-CoV-2 specimens.

Gee Yen worked for Public Health England (PHE) with Public Health Laboratory London as regional virologist for London between 2013-2018. In this role he worked with public health colleagues to tackle several significant community viral outbreaks in London.

He is a co-author of various Covid papers, including papers on nosocomial transmission.

No roles or appointments with NHS England, United Kingdom Health Security Agency (UKHSA), nor its predecessor, PHE during the pandemic or since.

No other conflicts of interest to declare.

Professor Dinah Gould BSc (Hons) PhD RN RNT FRCN

Professor Dinah Gould is a registered nurse and nurse educator with many years of experience of healthcare in different clinical settings.

Dinah developed a particular interest in education while working as an infection prevention and control nurse in one of the major London NHS trusts, later moving into full-time higher education. For many years Dinah taught the scientific aspects of the curriculum to undergraduate nurses and other health professionals and worked alongside student nurses during clinical placements. During this time, she undertook a PhD exploring how hand hygiene, use of personal protective equipment (PPE) and 'sharps' (e.g. injection needles, scalpels, razors) are handled and disposed of by staff

working in different clinical settings. Dinah's later research examined how infection prevention and control is taught during undergraduate programmes and to health professionals throughout continuing professional development.

Since 2019 Dinah has undertaken freelance research and consultancy, leading projects related to the isolation of patients with infection, mitigating the effects of skin damage caused by frequent hand hygiene and reducing the risks of infection when procedures requiring asepsis are undertaken.

Dinah has expertise in how evidence to support healthcare is created and put into practice and the methods used to analyse and synthesise this information to formulate clinical guidelines. She belongs to the Cochrane Effective Practice and Organisation of Care Group (EPOC) and the World Health Organisation's Technical Advisory Group for Hand Hygiene.

Dinah was made a Fellow of the Royal College of Nursing in 2020 for her contribution to infection prevention and nursing education. She holds an honorary chair at City, University of London and is a consultant to the Royal College of Nursing. She teaches infection prevention and the principles of evidence-based practice in various universities and for the Royal College of Nursing infection prevention and control course.

During the pandemic Dinah was commissioned by the Royal College of Nursing to undertake independent reviews of guidelines to prevent and control Covid-19 and other infections in healthcare settings.

No other conflicts of interest to declare.

Dr Ben Warne PhD MRCP DTM&H

Dr Ben Warne is a consultant in infectious diseases and general medicine at Cambridge University Hospitals NHS Foundation Trust. He trained as a registrar in infectious diseases from 2015 to 2024, and has recently finished a post as an academic clinical lecturer in infectious diseases in the Department of Medicine at the University of Cambridge.

From 2017-2021, Ben was a clinical research fellow in the Department of Medicine, University of Cambridge, using pathogen genomics to study common infectious diseases of public health significance, including antibiotic-resistant bacteria, influenza and SARS-CoV-2. This has included collaborations with teams from the Covid-19 Genomics UK Consortium (COG-UK), Public Health England, and the Wellcome Sanger Institute.

In his clinical capacity, Ben has direct experience of caring for patients with Covid-19. He was involved in the response of Cambridge University Hospitals during the first wave of the Covid-19 pandemic, producing data on viral transmission and writing local reports and guidelines. Ben provided evidence to the Hospital Onset Covid-19 Working Group of SAGE in 2020. During the 2020-21 academic year, he was the clinical lead for the University of Cambridge Asymptomatic Covid-19 Screening Programme. As a result of this work, Ben is the co-author of 12 academic papers related to Covid-19.

No other conflicts of interest to declare.

Introduction

Scope of report

This report is an independent review of the infection prevention and control (IPC) challenges faced by NHS hospitals across the UK during the Covid-19 pandemic in the period January 2020 – June 2022 (the "relevant period"). The scale, nature and duration of the threat posed by Covid-19, then a novel disease, was unprecedented in the history of the NHS. We have been instructed to look at a number of key aspects of the NHS pandemic response from an IPC perspective. We have considered what happened in the NHS in the relevant period and documented the IPC response, as guided by evolving scientific knowledge and national IPC guidelines. We have described IPC challenges faced by the NHS as the pandemic evolved.

Structure of report

Our report is structured in specific topic sections, including background setting and basic IPC definitions. We then address specific areas of the IPC response to the pandemic. In broad terms, we have critically examined: the nature of IPC in the NHS in the relevant period; IPC measures taken to protect patients and staff in NHS hospitals such as personal protective equipment, the evolution of Covid-19 guidelines in the relevant period; patient and staff testing; surveillance and epidemiology of Covid-19 in NHS hospitals; the sources of Covid-19 outbreaks; visiting policies; challenges in implementing IPC measures; and the state of IPC education and training in the NHS.

We conclude our report with conclusions and recommendations for future pandemic preparedness from an IPC viewpoint.

Methodology

We have addressed areas of NHS pandemic response as instructed by the UK Covid-19 Inquiry, through narrative reviews of relevant medical and scientific literature, published guidelines, other publicly available documents, and records made available to us from the Inquiry itself. We have included some additional material reflecting constructive Core Participant feedback at drafting stage. We divided the work according to our professional and academic backgrounds, strengths and interests. We have provided our expert opinion where we have been asked by the Inquiry, and also in the conclusions and recommendations section.

National coverage and relevance

We have endeavoured to write a report reflecting the experience, challenges and operational as well as policy responses from all nations of the UK, including the Devolved Administrations. However, as our professional experience is limited to England (DG, GYS, BW) and Wales (DG), this inevitably means we have much greater familiarity with the pandemic response, including national policy and guidelines, for England and Wales. When selecting and referring to published literature relevant to this report, we were geographically neutral. We have endeavoured to use terminology which is common to all nations of the UK. Where we could not find relevant data for the Devolved Administrations (DAs), we have stated this in the report.

Overlap with Professor Beggs' report for the UK COVID-19 Inquiry

There is some overlap with the expert report provided to the inquiry by Professor Clive Beggs. His report covers areas of his expertise in physics, particle physics, engineering, and ventilation, in far greater detail and depth than we ever could. For example, one cannot overestimate the impact of the NHS estate, especially older NHS estate, on IPC risks in "peacetime" as well as during a pandemic. Our section on the IPC risks associated with an ageing NHS estate is therefore relatively brief, but is covered in more detail in the report from Prof. Beggs. The two reports should be seen as complementary to each other.

Limitations and caveats

- Broadly speaking our expertise covers IPC, IPC nursing, education and training, infectious diseases, emerging infectious diseases, public health virology (managing viral outbreaks in the community, surveillance) and medical virology. We have only written about matters within our collective experience and expertise.
- We were tasked with writing an independent report on the IPC challenges and response faced by the NHS across the UK during the pandemic. Inevitably, our professional experience and knowledge is focused on our own NHS hospitals/organisations during the pandemic, with some local knowledge of neighbouring NHS hospitals. In England, there is a move to NHS organisations working as "Integrated Care Systems (ICS)", such as North Central London ICS, which includes several NHS Trusts.
- None of us have ever worked in Northern Ireland or Scotland. This means we are unfamiliar with the workings of the NHS in these DAs. We are very open about this and state this limitation plainly at the beginning of this report.
- In preparing the report, each of us has found it easier in general to find pandemic-related documentation for England, in the limited time available. So, if there appears to be any bias to reporting on events in England, for example, it is related to our professional experience and the ease of availability for relevant materials online. It does not reflect any bias against any DA. We anticipate that the majority of IPC considerations, challenges, and solutions, would be broadly applicable across the DAs.
- Even within England, for example, there is no way the authors of this report can know of every challenge, incident or operational innovation in every NHS hospital in the UK. Whilst drafting this report, we have endeavoured to reflect these uncertainties by referring to the possibility of regional variations. Our report reflects our own experiences in the relevant period, what we learned through our national and regional professional networks, informal networks with our peers, and the published literature.
- For the avoidance of doubt, we have primarily considered the IPC challenges and response in secondary care within the NHS during the pandemic. This reflects the expertise of the authors and our instructions from the inquiry, but also the predominance of data, guidance, and academic publications that largely focus on secondary care.

1. Background

- 1.1. The Covid-19 pandemic led to rapidly evolving, wholesale changes in the practice and application of infection prevention and control (IPC) in NHS hospitals. The dramatic changes to IPC practices in NHS hospitals were necessitated by the speed and scale of the unfolding pandemic. The many changes to the way IPC was practised were necessary to protect NHS healthcare workers, patients, healthcare students and visitors from this new and serious viral infection.
- 1.2. The threat of a pandemic, probably viral, has been recognised by the UK and the NHS for decades. However, in retrospect, the pre-2020 planning assumptions and pandemic flu exercises did not adequately prepare the NHS for what was experienced in the Covid-19 pandemic 2020-23.
- 1.3. National IPC guidelines evolved as knowledge of the causative virus, Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) evolved. Yet, SARS-CoV-2 proved to be an even more challenging threat than was first thought for a number of reasons. These include the fact that SARS-CoV-2 evolved throughout the pandemic, and the discovery that asymptomatic transmission was common and a challenging phenomenon to manage.

Few anticipated the ability of SARS-CoV-2 to mutate and evolve so frequently. New variants of concern (VOC) have been identified on a number of occasions, each differing from the previous in various ways such as transmissibility and disease severity. The emergence of new VOCs was often linked to a resurgence of Covid-19 infections in the community and consequently in healthcare settings.

1.4. Whilst good IPC practices have always been an essential feature of safe clinical care in the NHS, the pandemic brought all aspects of IPC to the forefront of the NHS response nationally. This report will provide an overview of the IPC challenges posed by the new virus and how the NHS responded.

The context: respiratory infections as a perennial challenge for the NHS

(Lead author: GYS)

1.5. Prior to, and since the onset of the Covid-19 pandemic, the NHS has faced the threat of winter seasonal viral infections, the most important of which are Respiratory Syncytial Virus (RSV) and influenza virus, commonly known as the flu. Broadly speaking, there are two types of flu which infect humans, flu A and flu B. Flu B typically has less severe symptoms, and flu A is the type which has caused all influenza pandemics in recent history, as well as the majority of cases in seasonal waves. The typical seasonal pattern of respiratory infections is a wave of RSV in infants and children in late autumn and early winter, usually declining by December. Usually starting in December, we would see flu A appear and increase for the next couple of months before declining. This is often followed by a wave of flu B, a couple of months after flu A.

1.6. The intensity of the winter flu epidemics is highly variable from year to year. **Figure 1** below shows the total number of reported cases of each main influenza subtype from the 2009 pandemic to 2024. The cases are reported from tests of symptomatic patients, most of whom are tested in 'sentinel' laboratories serving selected hospitals across England, although some tests from primary care are also included. This variation in cases is influenced by multiple factors. For example, the success or otherwise of the annual national UK influenza immunisation campaign which targets adults over 65 years of age, people with chronic medical conditions and health and social care workers. This seasonal campaign is usually launched in September, ahead of the flu season. School-age children are also offered flu immunisation, with a different type of vaccine, the live attenuated influenza vaccine (LAIV). Before the Covid-19 pandemic, there were no licensed RSV vaccines in the UK.

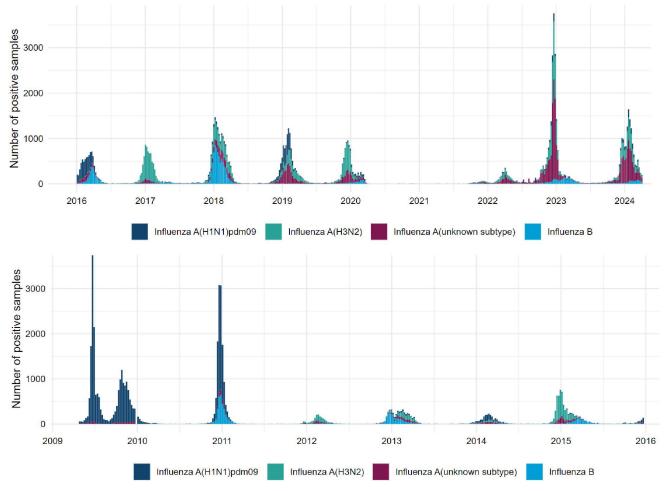
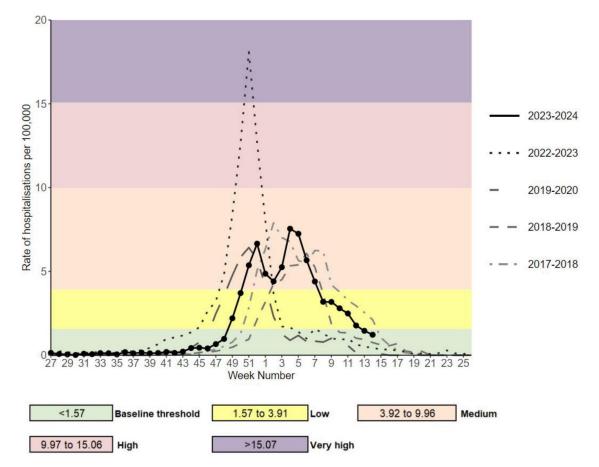


Figure 1: Weekly number of confirmed influenza cases by subtype, Respiratory Datamart, England, 2010 to 2024. Source: (UKHSA, 2024)

1.7. Other factors influencing the number of respiratory virus cases include the weather, the extent of social mixing between groups, and mutation of the pathogen. During winter 2020/2021, non-pharmaceutical interventions intended to control Covid-19 transmission

led to a temporary, but near-complete suppression of influenza cases. Flu returned in 2022/2023, with one of the largest winter waves seen in recent years, leading to a correspondingly large number of people in hospital with influenza. Comparisons of the number of hospitalisations of several influenza seasons are shown in **Figure 2**. Very similar seasonal trends are seen in Scotland, Wales and Northern Ireland.

1.8. Respiratory Syncytial Virus (RSV) is a common, seasonal respiratory virus which affects infants and children every winter. Li et al published a substantial review of the burden of disease due to RSV internationally in children under 5 years of age. This illustrated that RSV is a global health problem, including in high-income countries like the UK, but there is a substantial health burden in low- and middle-income countries (Li et al, 2022).



- Figure 2: Weekly influenza hospital admission rates per 100,000 local population. England. Week number is counted from the first week in January. Each line on the graph represents one influenza season. Source: SARI Watch sentinel surveillance, via (UKHSA, 2024)
- 1.9. RSV is a major respiratory virus, leading to large, predictable increases in NHS emergency department attendances and hospitalisations, placing pressure on acute paediatric services every winter. Furthermore, RSV is increasingly recognised as a pathogen in older adults. Van Tam et al have recently reviewed evidence of the morbidity and mortality due to RSV in older adults (Van Tam et al, 2022). In short, RSV is a

significant clinical and IPC challenge for the NHS every winter. The burden, and seasonal variation, in RSV hospitalisations in children is shown in **Figure 3**.

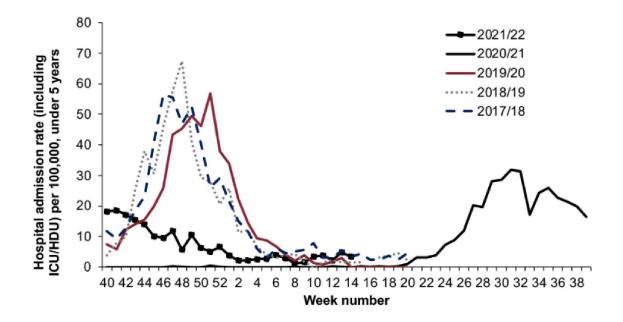


Figure 3:Rate of RSV hospitalisation in under 5-year-olds per 100,000 trust catchment population by week of admission and season, sentinel data from acute NHS trusts, England (UKHSA 2024)

- 1.10. Other respiratory viruses that contribute to seasonal pressures in the NHS each winter include parainfluenza, human metapneumovirus, rhinovirus, seasonal coronaviruses such as OC-43, and adenovirus (UKHSA, 2024). Whilst these viruses can cause considerable morbidity and some have been demonstrated to transmit within hospitals, severe illness is less common than for influenza, Covid-19 and RSV. Consequently, some of these viruses, such as rhinovirus, are not typically the direct targets of IPC interventions.
- 1.11. One other respiratory pathogen of note from an IPC perspective is tuberculosis, commonly known as TB. TB is caused by a bacterium called *Mycobacterium tuberculosis*. TB is a chronic infection which is not seasonal. It tends to be concentrated in larger UK cities with ethnically diverse demographics. For symptomatic patients with TB chest infection, also known as pulmonary TB, respirators are recommended for all healthcare staff entering the patient's room (see paragraphs 1.46 to 1.72).
- 1.12. The regular IPC challenges of RSV, flu and TB meant that the NHS had experience of IPC countermeasures prior to the Covid-19 pandemic, including respiratory PPE, isolation of infectious patients, cohorting and outbreak management.
- 1.13. Respiratory pathogens, be they viruses or bacteria, posed a seasonal infection prevention and control (IPC) challenge for the NHS and other healthcare providers across the UK

long before the Covid-19 pandemic. These predictable winter challenges will persist for the foreseeable future.

Basic IPC definitions

(Lead author: DG)

- 1.14. The WHO defines IPC as a 'practical, evidence-based approach preventing patients and health workers from being harmed by avoidable infections' (WHO, 2024b).
- 1.15. IPC is central to the work of all health professionals. All frontline staff need to know how to protect patients, everybody visiting premises where healthcare is delivered and themselves from infection. To do this, all health professionals need to understand the fundamental principles underpinning IPC and have the skills to apply them in clinical situations. All health professionals need to know how infection is spread and to undertake key IPC activities (e.g. hand hygiene, use of PPE, handling and disposing of 'sharps' such as used needles). The precise information and skills needed depend on the occupational group to which the health professional belongs, the clinical setting, and the nature of their work. For example, health professionals working in critical care units need to have the knowledge and skills to protect patients from the risks of infection associated with having multiple invasive devices (e.g. intravascular lines, urinary catheters, endotracheal tubes). Nurses working in community clinics need to be able to dress chronic wounds while maintaining asepsis. This can be a challenging undertaking in premises where the facilities can be quite basic, or in patients' homes. Managers responsible for overseeing the work of frontline workers need to know about IPC to ensure that staff have the required knowledge and skills to prevent infection and are putting them into practice.
- 1.16. The term '**source control**' means preventing the spread of infection from an individual who is known, or suspected to be, a potential source of infection. It refers to the IPC strategies put in place to prevent infection from the affected person being spread to other people. For a patient known or suspected to have a respiratory infection, source control could mean:
 - Single room isolation or cohorting in a ward or bay with other known or potentially infected patients who have/might have the same infection
 - Isolation of an infectious healthcare worker at home until they are no longer infectious and can return to work safely
 - Decontamination of the room/ward/bay
 - Decontamination of the equipment used for that patient
 - Use of a surgical mask by symptomatic or even asymptomatic people to reduce the number of potentially infectious respiratory particles that are emitted.
 - Moving a patient with a designated "High Consequence Infectious Disease" (HCID) (see paragraphs 2.4 to 2.10 and 6.2 to 6.9) to a designated HCID centre,

with specialist staff and strict engineering controls such as negative pressure rooms

- Good hand hygiene practices by all staff looking after the source patient, especially after doffing (removing) PPE.
- 1.17. The term '**personal protection**', in contrast to source control, involves the strategies taken by the individual to protect themselves from IPC risks during routine dealings with other people. In the case of Covid-19 and other respiratory pathogens, personal protection means the use of respirators, gloves and other protective clothing (see paragraphs 1.43 to 1.79), as well as hand hygiene.

The IPC team

(Lead author: DG)

- 1.18. Specialist IPC teams are employed in most countries, including all four countries of the UK. Their work is to advise on the prevention, surveillance, investigation and control of infection throughout the healthcare organisation (NHS Borders, 2013). The IPC team includes microbiology consultants and junior doctors, clinical nurse specialists, nurses who undertake and coordinate surveillance of infection, and antimicrobial pharmacists. The wider IPC team will also include staff with expertise in the built environment, epidemiologists, occupational health specialists and other personnel (list not exhaustive). In the UK there is no guidance on the number of IPC team members per bed/patient or the composition of IPC teams.
- 1.19. Most members of the IPC team are nurses. In large organisations they are likely to take responsibility for specific clinical settings (e.g. acute services, community-based services, children's services). The way the work of IPC teams is organised and how they spend their time varies. Some NHS hospitals employ large IPC teams with some post-holders designated to specific roles (e.g. education/teaching, surveillance and audit). In some health provider organisations, IPC services are outsourced to other organisations.
- 1.20. IPC link nurse schemes have been established in many NHS organisations (Royal College of Nursing, 2021). Link nurses are members of the regular nursing team who act as ambassadors for IPC within their own ward or department. Responsibilities and training are variable. Typical IPC link nurse activities include assisting with the uptake of IPC interventions, helping to conduct surveillance and audit and reporting local IPC issues to the IPC team.
- 1.21. Arrangements for the leadership of IPC teams differ across the four countries of the UK:
 - In England the Director of Infection Prevention and Control (DIPC) provides strategic leadership and oversight for all IPC matters in the NHS Trust. The DIPC advises the Board of Directors of the NHS hospital on all issues relating to IPC and is responsible for ensuring that effective systems and processes are in place.
 - In Scotland the leader of the IPC team is the Infection Control Manager (ICM).

- In Wales leadership for IPC is usually undertaken by a senior nurse with expertise in IPC. The DIPC and equivalents in Wales and Scotland report to the most senior nurse in the organisation and to the Board and are responsible for communicating information to the rest of the IPC team.
- We could not locate any publicly available information on IPC team leadership for Northern Ireland.
- 1.22. The IPC team plays a vital role creating and maintaining a safe environment for patients, everybody visiting premises where healthcare is delivered and staff. It is important to note that whilst all NHS hospitals have an IPC team, IPC is the responsibility of everyone working in the hospital. Specific activities include:
 - Supporting the development of local IPC guidelines. These are based on legislation such as the Health and Safety at Work Act 1974 (UK Legislation, 1974), the Control of Substances Hazardous to Health Regulations (UK Legislation, 2002) the PPE at Work Regulations 1992 and on international and national guidance (Health and Safety Executive, 2022). International guidance comes from the WHO. National guidance has been provided by the National Infection Prevention and Control Manual (NIPCM) in all four countries of the UK since 2022.
 - In England, IPC guidelines should also be consistent with the Health and Social care Act 2008 (Department of Health and Social Care, 2015)
 - Providing education and training, delivered formally (e.g. as part of induction training at the start of employment, mandatory updates) and informally when visiting clinical areas. The IPC team provides education and training for all employees involved in healthcare. These include staff who are on a professional register and those who are unregistered. Unregistered staff include (not exclusively) healthcare assistants, support workers, porters, cleaning and catering staff.
 - Monitoring IPC practices and standards through audit.
 - Supporting frontline staff and managers with the implementation of IPC guidelines.
 - Liaising with occupational health departments, to ensure that staff receive appropriate advice regarding infection and other healthcare-related risks at work (e.g. needlestick injury).
 - Undertaking routine surveillance of key infections (e.g. methicillin-resistant *Staphylococcus aureus* MRSA, *Clostridium difficile*). In England, for example, this includes reporting healthcare associated infections of key organisms to UKHSA.
 - Investigating and managing clusters of infections and outbreaks.
 - Providing advice and support during the management of high-risk situations (e.g. admission of a patient with a HCID classification).
 - Creating and maintaining communication between wards, departments and managers in hospital and community settings, the medical microbiology department and committees (e.g. infection control committee; senior management team).

- Working with NHS estates and facilities department colleagues to, for example, ensure the hospital estate is clean, well ventilated, and has safe hot and cold water systems.
- Supporting good antimicrobial stewardship (AMS) in the hospital for example by supporting the hospital antimicrobial stewardship committee and working hospital antimicrobial pharmacists.
- Ensuring that legal requirements for health and safety impinging on IPC are acted on. In England these would include for example, the Health and Social Care Act 2008: code of practice on the prevention and control of infections. The Act stipulates the policies that are required and reinforces the importance of IPC within governance structures (UK Government, 2022).
- 1.23. There is some variation in the precise responsibilities and operating systems adopted by IPC teams in the four nations (NHS Scotland, 2024). Variations may also occur between the way that IPC teams operate in the same country

Pathogen characteristics of most relevance to IPC

(Lead author: BW)

- 1.24. Different pathogens require different IPC considerations. A number of factors related to the pathogen itself inform when IPC measures are used, and which measures are most appropriate (NHS England, 2022). This section will define these to help inform the rest of the report. One of the key factors is the **route of transmission** of the infection, otherwise known as the "mode" of transmission. There are a number of routes by which infection can spread, such as:
 - contact either directly touching an individual carrying that pathogen, or contact with the contaminated environment (known as "fomite" transmission),
 - the spread of infectious particles in the air, for example pathogens that are inhaled and infect the airways and lungs (see Prof Beggs' report INQ000474276 parts 1 and 2 for a full discussion of the spectrum of respiratory particle sizes and the historical dichotomy between droplets (>5 μm) and aerosols (<5 μm)),
 - sexually transmitted or blood-borne, for example through contact with blood or contaminated body fluids,
 - food and/or water-borne, and
 - by insect vectors, such as mosquitoes.
- 1.25. IPC interventions often aim to prevent infection by targeting this route of transmission. For example, for patients affected by pathogens that are spread by contact and associated with hospital transmission, such as MRSA or *Clostridium difficile*, IPC measures include

PPE that provides a physical barrier between an individual and the patient or environment, such as single use gloves and plastic aprons. By contrast, respiratory viruses such as SARS-CoV-2 can be spread by multiple routes, including routes in the air, as well as contact (this is outlined in the expert report provided by Prof Beggs INQ000474276, para 15-18). PPE for respiratory viruses therefore includes a face covering, in addition to gloves and apron. Different types of PPE are detailed below. The types of face coverings commonly referred to as PPE are typically fluid resistant surgical masks (FRSM) or respirators, although the classification of FRSMs as PPE is controversial and discussed in paragraph 1.43. The routes of transmission of SARS-CoV-2 have generated considerable controversy, with conflicting views of scientists, clinicians, and other groups on the nature and relative importance of different routes, and even the correct terminology used to describe them (WHO, 2024a); these are explored in this report and in the expert report of Prof Clive Beggs (INQ000474276).

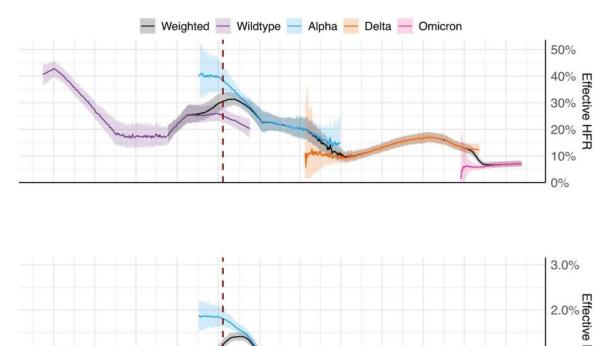
- 1.26. Another measure which informs risk assessment in IPC is transmissibility: how easily the infection can spread from an infected individual to a susceptible individual. Transmissibility is commonly expressed as the **reproduction number** (R), which became a common part of news updates during the Covid pandemic. The basic reproduction number (R_0) is an estimate of the number of uninfected people who would be infected if exposed to a pathogen after its introduction to a completely susceptible group of people. for example at the start of a pandemic (Leung, 2021). For example, for measles (which is considered highly transmissible), the R_0 is estimated as being 12-18 (Guerra et al. 2017). For respiratory viruses, the R_0 is estimated to be approximately 2.0–3.0 for SARS-CoV and the 1918 influenza pandemic, 0.9 for MERS-CoV, 1.5 for the 2009 influenza pandemic, and 3.0 for respiratory syncytial virus (RSV) (Petersen et al, 2020) (Kaler et al, 2023). Despite the more stringent recommendation for healthcare workers to wear respirators when performing all routine care for patients with the bacterial infection TB, its R_0 in countries like the UK with low incidence is significantly below 1. This means that it is less infectious than the respiratory viruses discussed in this report, even though widely acknowledged to transmit via the airborne route. The Ro for TB in many low- and middleincome countries is estimated to be much higher, and outbreaks are more common (Ma et al, 2018).
- 1.27. Estimates of the R_0 of SARS-CoV-2 early in the pandemic were around 2.5 (range 1.8– 3.6) (Petersen et al 2020), comparable to other coronaviruses and influenza. Estimates of R_0 additionally varied with different geographical regions globally, and different variants, with increased transmissibility of the delta and omicron variants in comparison to the initial pre-alpha and alpha lineages (Liu and Rocklöv, 2022). It is important to note that the R_0 value is an estimate that is ordinarily provided at a population level; the true transmissibility of a virus in a given setting, such as a hospital or ward, will depend on a range of factors, including: the innate biological properties of the pathogen; the contagiousness of the infected individual; the susceptibility of the exposed individual; the contact patterns between the infected individual and the exposed individual; and environmental factors such as ventilation (Leung 2021). In certain circumstances, one infected individual can therefore infect a far greater number of people than is suggested by the R_0 , sometimes referred to as superspreading events (see Prof Beggs' report INQ000474276, para 106-112 for further details).

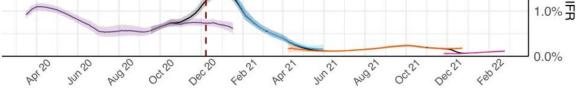
- 1.28. Other factors that influence IPC decisions include the severity of disease caused by an organism. As a generalisation, pathogens that are more likely to cause severe disease are associated with more stringent IPC measures. One of the most important and commonly used methods to assess the severity of disease is the fatality rate. There are different ways to measure fatality rate:
 - 1.28.1. The **infection fatality rate (IFR)** is the true proportion of *all individuals* infected with a pathogen who subsequently died. This can be difficult to estimate, because it relies on identifying *all* of the people infected; in practice, many individuals who are asymptomatic or minimally symptomatic, or where testing capacity is limited, often go undiagnosed. Detailed epidemiological studies that adjust for this and other important biases are needed to estimate this measure of severity; the Covid-19 infection survey from ONS, and the REACT study from Imperial College are notable examples that included asymptomatic cases. However, even before these studies were available, academics in SPI-M had estimated an IFR of approximately 1% that was accepted by SAGE on February 27 2020 (SAGE, 2020a).
 - 1.28.2. The case fatality rate (CFR) is the proportion of all confirmed cases who subsequently die. This rate is more commonly quoted in studies and public health statistics, and can be produced, for example, through comparisons of laboratory databases of positive results and registration of deaths. This enables examination of trends in fatality rates over time and geography, enabling some understanding of factors such as pathogenicity and interventions to improve clinical outcomes. However, it is subject to biases in the way that cases are identified, in particular the rates of asymptomatic and minimally symptomatic patients who would not be tested, individuals who are symptomatic but do not seek testing, availability of testing, and registration of positive results in auditable databases. This is illustrated by markedly different published global estimates of the CFR of Covid-19 in February to March 2020, ranging from 1.7%-39.0% (Horita and Fukumoto, 2023).
 - 1.28.3. The **hospitalisation fatality rate (HFR)** is the proportion of *all confirmed cases admitted to hospital* who subsequently died. Similar to the CFR, this is open to biases such as hospital testing capacity and practices.
- 1.29. The reported IFR, CFR and HFR for SARS-CoV-2 have varied over the course of the pandemic, due to a number of factors such as those above, and related to different geographical regions. The IFR is also dependent on context, varying with age, viral variant and co-morbidities. **Figure 4** uses several sources of data from England to estimate the IFR and HFR, and how they changed over time. It is notable that the authors identify factors related to healthcare that are associated with fatality rates, as well as the intrinsic properties of the virus. For example, the authors note that after declining in summer 2020, the fatality rate rose again in autumn/winter 2020/21, associated with pressure on the healthcare system:

"there was an overall higher risk of death in hospital, independently of the basic severity properties of the Alpha variant... Given there was no representative data available on hospital deaths by variant during this period to fit our model to, we cannot fully differentiate the specific contribution of variant and healthcare effects on the

increased severity. However, in an additional statistical analysis using linked patient-level records, we observed that the increase in HFR during this period was positively correlated with daily critical care bed occupancy levels, with variation across English regions"

1.30. This means that the increase in HFR during the second wave was likely to be due in part to higher bed occupancy, suggesting that large numbers of deaths in patients with Covid-19 may have been avoided if the healthcare system had been under less pressure. Other studies have reported similar findings (Kirwan et al, 2022), (ISARIC Clinical Characterisation Group et al, 2021). Other factors that impact on the fatality rate include patient age, co-morbidity, and vaccination (Kirwan et al, 2022). Deaths among patients who caught SARS-CoV-2 in hospital are explored further in paragraphs 11.18 to 11.26, and the effects of pressure on hospitals (and intensive care units in particular) are covered in Professor Summers and Dr Suntharalingam's expert report on intensive care (INQ000474255).





- Figure 4: Changes to the hospitalisation fatality ratio and infection fatality ratio over time, separated by SARS-CoV-2 variant. The black line represents the weighted average across co-circulating variants at any time. The red dashed lines refers to the start of the vaccination programme on December 8 2020. Adapted from (Perez-Guzman et al, 2023).
- 1.31. Other markers of severity of relevance to SARS-CoV-2 include the infection hospitalisation ratio (the proportion of patients infected with a pathogen that require

admission to hospital), and the proportion of hospitalised patients who require treatment in critical care units.

- 1.32. There are other features of SARS-CoV-2 that have implications for IPC measures. Over the course of the pandemic there has been increasing recognition of individuals who are either completely asymptomatic with SARS-CoV-2 infection, or experience minimal symptoms, but can still transmit the virus. The proportion of asymptomatic infections varies depending on the immune status of the individual, but a meta-analysis of studies published in 2020 estimated this figure at approximately one third of all cases in unvaccinated individuals (Oran and Topol, 2021). Higher rates of asymptomatic infection were associated with individuals who had been vaccinated (Antonelli et al, 2022). Data early in the pandemic showed that the incubation period (the time from catching the virus to developing symptoms) is 1 to 14 days, and 5 days on average (Hu et al, 2020). Individuals with SARS-CoV-2 infection are likely to be most infectious at, or around, the time that they develop symptoms. This means that patients, staff, and hospital visitors are all potentially capable of transmitting SARS-CoV-2 before they become symptomatic, if they develop substantial symptoms at all. This is the basis of asymptomatic screening of staff and patients as an IPC measure that was utilised during the pandemic that is described in more detail in section 9.
- 1.33. Additionally, the relatively long incubation period of the virus and high rates of asymptomatic infection mean that it can be difficult to identify infected staff and patients, and understand networks of transmission. This makes implementing IPC interventions to control transmission challenging. For example, in a hospital setting, there are many potential person-person interactions that patients and staff may undertake in the 5 days that form the average incubation period of the virus, often including contacts in the community and hospital setting. Establishing whether infections are acquired in the community or hospital is therefore often challenging, especially during periods of high community prevalence of Covid-19, when the likelihood of community acquired infection increases. This is discussed in more detail in section 11.
- 1.34. Finally, IPC measures may also vary dependent on setting and the care or procedures being provided. For example, IPC measures may be more stringent in areas where patients are more vulnerable to infection, such as immunocompromised individuals. They may also be adapted for procedures that are perceived as placing HCWs and/or patients at increased risk of transmission. For example, in the context of Covid-19, there has been considerable interest and debate surrounding aerosol-generating procedures being performed on patients with a respiratory infection, where different PPE has been recommended (this is discussed in detail in paragraphs 1.36 to 1.39 and 6.39 to 6.51). In practice, specific IPC measures are often determined based on a combination of: a) the pathogen that has been suspected or diagnosed as affecting an individual patient, based on what is known about that pathogen from the information above, and b) the care and procedures that the patient requires.

Categorising IPC interventions

(Lead author: BW)

- 1.35. **Standard infection control precautions (SICPs)** are defined by the National Infection Prevention and Control Manual (see section 4) as "the basic infection prevention and control measures necessary to reduce the risk of transmitting infectious agents from both recognised and unrecognised sources of infection. These include the patient, blood and bodily fluids, non-intact skin or mucous membranes and any equipment or items in the care environment that could have become contaminated. As indicated in NHS guidance, these should be used by all staff, in all care settings, at all times for all patients".
- 1.36. SICPs include:
 - assessing all patients for the risk of infection
 - regular hand hygiene
 - catching coughs and sneezes with a paper tissue and disposing of them safely before cleansing one's hands ("respiratory hygiene")
 - regular cleaning of surfaces, equipment, clothing and bed linen
 - safe management of blood and other bodily fluids
 - safe disposal of waste
- 1.37. As an example, hand hygiene is essential to prevent and control infection in all settings where healthcare is delivered. The World Health Organisation (WHO) has developed extensive guidelines to promote hand hygiene internationally (WHO 2009). According to the WHO, hands should be cleansed i). before touching a patient; ii). before undertaking a clean or aseptic procedure; iii). after exposure to blood or any other body fluid; iv). after touching a patient; and v). after touching equipment or other objects in the environment immediately surrounding the patient. Alcohol-based handrubs and gels are recommended for routine hand hygiene unless hands are visibly soiled. Throughout the pandemic the WHO emphasised the importance of hand hygiene to prevent and control the spread of Covid-19.
- 1.38. **Transmission Based Precautions (TBPs)**, by contrast, are defined as specific measures that are required when caring for patients with known or suspected infection. TBPs are categorised based on the route of transmission of a pathogen. In this report we will discuss the SICPs and TBPs that are most relevant to the management of Covid-19, with a particular focus on PPE and respirators (also known as Respiratory Protective Equipment or RPE).

Aerosol generating procedures

(Lead author: BW)

- 1.39. Infections of the respiratory tract have, historically, been considered to spread either by "aerosol" or by "droplet" transmission. Aerosols are "Very small particles... that may contain infectious agents. They can remain in the air for extended periods of time and can be carried over long distances by air currents" (NHS England, 2024c). By contrast, droplets are larger particles that fall more rapidly to the ground, do not remain in the air for long periods, and therefore can only travel short distances. The exact definition of aerosols and droplets, including the size of the particles and those that can be aerosolised, is debated (see expert report from Prof Beggs INQ000474276, para 110-114).
- 1.40. Aerosol generating procedures (AGPs) are medical procedures that can result in the release of aerosols from the respiratory tract (NHS England, 2024c). The criteria for inclusion as an AGP are a high risk of aerosol generation and increased risk of transmission (from patients with a known or suspected respiratory infection). The relative importance of aerosolisation as a route of transmission for SARS-CoV-2 and other respiratory viruses has been debated, and is outlined in section 6. Prior to 2020, there was a general consensus in published guidelines in the UK and internationally that the risk of exposure of the virus to respiratory pathogens of HCWs either performing, or in the vicinity of, AGPs was increased in comparison to standard care procedures. However, the list of procedures that were considered an AGP varied between guidelines, and the evidence base behind this list has been debated (see paragraphs 6.39 to 6.51).
- 1.41. The current NIPCM (in all four nations) includes the following list of medical procedures that are considered to be aerosol generating and associated with an increased risk of respiratory transmission:
 - awake* bronchoscopy (including awake intubation, where a tube is inserted into the patient's windpipe)
 - awake* ear, nose, and throat (ENT) airway procedures that involve respiratory suctioning
 - awake* upper gastro-intestinal endoscopy
 - dental procedures (using high speed or high frequency devices, for example ultrasonic scalers/high speed drills)
 - induction of sputum
 - respiratory tract suctioning
 - surgery or post-mortem procedures (like high speed cutting / drilling) likely to produce aerosol from the respiratory tract (upper or lower) or sinuses
 - tracheostomy procedures (insertion or removal).

*Awake refers to patients who are sedated, but conscious

1.42. For respiratory viruses, including SARS-CoV-2, IPC guidance has been different for AGPs in comparison to other aspects of care. In particular, UK IPC guidance on Covid-19 has consistently recommended the use of respirators for HCWs caring for infected patients who are undergoing AGPs but has, in general, recommended surgical masks for routine care (see section 5). We note here that in England, a significant number of NHS hospitals have adapted IPC guidance to recommend respirators for routine care for all confirmed cases of Covid-19, regardless of whether an AGP is carried out or not (Lawton et al, 2022). Some additional procedures were included early in the pandemic and subsequently removed following reviews of the available evidence, including non-invasive ventilation and high flow nasal oxygen (NIHR AERATOR team, 2022). Various professional bodies and other stakeholders made recommendations early in the pandemic for the evaluation and/or inclusion of other procedures in the list of AGPs requiring respirators, including cardiopulmonary resuscitation (INQ000251651), the use of nasogastric feeding tubes, nebulisers, swallowing assessments, and chest physiotherapy (AGP Alliance, 2020), (Royal College of Speech and Language Therapists COVID-19 Advisory Group, 2020), (INQ000347822). These are discussed further in section 6, paragraphs 6.36 to 6.46.

Risk assessment

Lead author: DG

- 1.43. Risk assessment is defined as the process used to identify workplace hazards, how they might cause harm and what steps should be taken to minimise harm. It has a place in legislation and regulations, though this is not our area of expertise and the witness statement from HSE (INQ000347822) explains these aspects further. Risk assessment also has a place in IPC guidelines and clinical practice. Five steps are recommended by the British Safety Council to manage risk in workplaces generally (British Safety Council, 2024). Examples of each step relevant to frontline healthcare IPC are outlined below:
 - a) Identify hazards. For IPC, this will mean knowing which suspected or confirmed infection(s) a patient has, and knowing which patient care tasks need to take place that might pose a risk of transmission to staff, patients or visitors. These tasks might include invasive surgical procedures that break the skin barrier, or close contact with a patient, such as when helping with personal care like personal hygiene, that might lead to breathing in air carrying pathogens.
 - **b)** Assess the risks. Both the nature and the scale of the risk need to be determined:
 - Theoretically, susceptible patients or staff in the same room as an infectious patient for a set period of time would be at a certain percentage risk of being infected. A 0% or 100% chance of the harmful event happening is unusual, so the risk will likely be somewhere in between. The more infectious

the pathogen being released, or the longer the susceptible people stay within reach of the pathogen, the higher the risk. However, it's often not possible to do this quantitatively for the specific conditions of the risk being assessed in a particular setting. Detailed epidemiological studies are needed to accurately assess the risk, though they often give an average risk that may not be generalisable to the wide variety of settings seen in healthcare. Modelling evidence that simulates the processes of particle movement and infection transmission can also help quantify and understand risks. These methods will not be readily available to the frontline clinician, though they are available to those writing guidelines.

- As well as the chance of the event happening, risk assessment needs to take account of the severity of the harm that would result. For a hospital-acquired infection, the infection fatality rate (see paragraph 1.25.1) shows that mortality is an important harm to consider, as well as the risk of Long Covid or other complications.
- Values and norms are also important in assessing risk. Healthcare professionals are used to taking their patient's needs and preferences into account, and risk assessment for IPC does implicitly or explicitly assess what is an acceptable level of risk to the patient, their loved ones, the healthcare professional themselves, their colleagues, and society. This will need to be weighed up with other important but not easily comparable outcomes, like comfort, loneliness, and risk of other health outcomes not related to the infection.

c) Control the risks

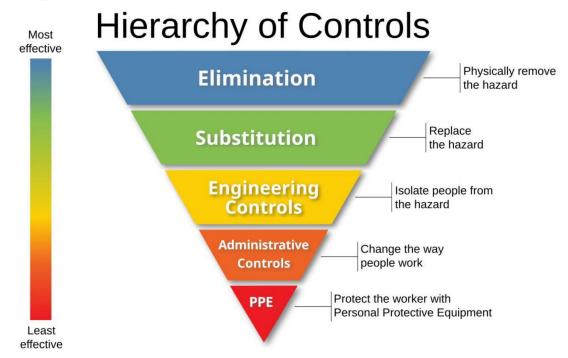
- Those tasked with performing a risk assessment will have several interventions available to reduce the risk, which will vary in effectiveness. However, similar to assessing the risk, it may not be clear to a frontline professional exactly how effective these countermeasures are in their specific context. Measures put in place might include moving a patient to a single room to isolate them, wearing PPE, and avoiding unnecessary invasive procedures that confer a risk of infection. The "hierarchy of controls" introduced below is a tool promoted for use by healthcare professionals to assist application of IPC measures. The risk of side effects (see, for example, paragraphs 7.1 to 7.13) of the control measures will also need to be considered alongside the risks assessed in the previous step.
- d) Record findings this is an important part of risk assessment, as it permits communication of the risk to other staff, management and potentially investigators when things go wrong, or researchers studying the risk. There is an important burden in doing this though, and many clinical staff resent the time spent filling out risk assessment forms and not performing other important competing tasks, as in any other industry.

e) Review the controls – risks change over time, and IPC is no different. A patient may develop new symptoms that could suggest an infection and an increase in risk to staff and other patients. The risk assessment would then need to be reviewed, and new control actions potentially taken.

Risk assessments are covered further in section 4 of this report on developing guidelines (paragraphs 4.28 to 4.31)

Hierarchy of controls

1.44. The Hierarchy of Controls is an approach used to identify safeguards to eliminate or reduce workplace hazards (NIOSH, 2024). Risk controls are described as being ranked from the highest level to the lowest and least reliable protection as illustrated on the diagram below:



1.45. The Hierarchy of Controls is a conceptual model to understand risk and how it may be mitigated. It originated in the US but its use is now advocated in health and safety and IPC in the UK. The Health and Safety Executive suggests that the Hierarchy of Controls should be used in conjunction with risk assessment (Health and Safety Executive, 2024b). PPE is described as the least effective action that can be taken to protect health workers. It is referred to as *'The last resort to protect against risks'*. This interpretation is simplistic however. In his witness statement INQ000412890 Stephen Powis argues (paragraph 338) that although PPE occupies the lowest level of the Hierarchy it is still a significant method of reducing infection risks for patients and staff during an outbreak caused by an infectious virus. It may be possible and desirable to put in place more than one tier in the Hierarchy when risk exists/is suspected. Isolation, changing ways of working, and use of PPE may all be feasible and desirable to deal with the same risk.

Personal protective equipment (PPE)

Surgical masks

- 1.46. Fluid-resistant surgical masks (FRSM) are also known more simply as medical masks or surgical masks. The technical specification of those routinely used in the NHS is a "Type IIR", with the R denoting their fluid resistance.
- 1.47. Surgical masks are regulated as Class I medical devices under the UK Medical Device Regulations 2002, and must be CE marked, meaning that the manufacturer has checked that it meets these regulations. (HSE statement of Richard Brunt, INQ000347822 para 247-250 and 260). They are designed to protect the patient/other staff, not the wearer, so are regulated differently to PPE, which is regulated more stringently under the PPE at Work Regulations 1992. However, surgical masks are often erroneously referred to in some official guidance documents, scientific literature, and the press as PPE.
- 1.48. Surgical masks are used in several clinical settings, either for source control or personal protection:
 - In operating theatres, to prevent spread of infection from staff performing procedures to protect patients and theatre staff. Although the evidence for this use case is limited, it is a very widespread practice in the NHS and internationally (Da Zhou et al, 2015), (Burdick and Maibach, 2021).
 - Potentially confusingly, in theatres, FRSMs may also serve as PPE, as they protect e.g. the surgeon's nose and mouth from body fluid exposures like blood from the patient, which carries the risk of exposure to blood-borne viruses such as HIV.
 - By healthcare workers looking after patients with RSV, flu and other common respiratory viruses, to protect the healthcare workers.
 - By healthcare workers looking after highly immunocompromised patients (e.g. bone marrow transplant patients) who are very vulnerable to infections, to protect the patients.



Figure 5: Example of a typical fluid resistant surgical mask

Respirators

- 1.49. Respirators are designed to prevent the inhalation of microscopic particles, including those containing pathogens, thereby reducing the risk of infection to the wearer. Before the pandemic, NHS patient-facing staff in certain areas of our hospitals would have had intermittent experience of using the respirators. There are several types, outlined below. They are often referred to in guidance documents as Respiratory Protective Equipment (RPE). The clinical areas where respirators would most likely have been used include:
 - respiratory medicine wards
 - infectious diseases wards

both of which could be expected to treat TB patients fairly frequently, depending on local arrangements and incidence. To a lesser extent, the following areas also may have had some experience with respirators:

• emergency departments (also known as Accident and Emergency)

- acute medical wards
- acute paediatric wards
- critical care units, both adult intensive care units (ICU) and paediatric intensive care units (PICU)
- operating theatres

In other words, only staff working in certain areas of acute hospitals would be familiar or proficient in the use of respirators before the Covid-19 pandemic.

Filtering face piece (FFP) respirators

- 1.50. There are three standards of Filtering Face Piece respirator (FFP): FFP1, FFP2 and FFP3 in order of filtering efficiency and thus level of protection. The classification of FFP is defined by European standard EN 149.
- 1.51. FFP1 masks are intended for use in industries like construction, carpentry and agriculture where the work environment may be dusty and/or contaminated by mould spores. These masks are also referred to as "nuisance dust masks", by the Health and Safety executive, for example (Health and Safety Executive, 2024a). FFP1 masks are not intended to be used in healthcare settings.
- 1.52. FFP2 masks are broadly equivalent to N95 masks. In the UK, national guidelines recommended FFP3 respirators and not FFP2/N95. This type of respirator is designed to reduce the exposure of the wearer to respiratory particles by 95% when properly fit tested compared to no mask. We are aware of some discussions around using FFP2 masks when there was a risk of local FFP3 respirators supplies being disrupted and/or exhausted, but we have no knowledge of this contingency being enacted at any scale during the relevant period. There is a review article looking at the effectiveness of N95/FFP2 respirators in protecting healthcare workers against Covid-19 infection versus FRSM, which, surprisingly found no significant difference in protective efficacy against Covid-19 infection (Kunstler, 2022). However, this review of 21 published studies was subject to several limitations, including most studies included being observational, rather than randomised controlled trials (Kunstler, 2022).
- 1.53. Filtering Face Piece type 3 (FFP3) is the most stringent standard of respiratory PPE, which can take the form of a FFP3 face mask. FFP3 respirators are designed to protect the user against 99% of respiratory particles when properly fit tested, and were primarily manufactured for non-healthcare settings, such as the building industry. For users who cannot wear a FFP3 respirator (for example, because they fail the fit-testing (see "Respirator fit-testing") of all available FFP3 respirators), a powered air purifying respirator is an option.
- 1.54. FFP3 masks can be non-valved, or valved. Valved masks may be more comfortable for users because they facilitate exhaled air to be breathed out form the mask. In general, valved masks were not preferred from an IPC perspective, because they allow unfiltered,

exhaled air to be expelled into the environment by the user (healthcare worker). Therefore, if the healthcare worker had asymptomatic Covid-19 infection, for example, they would pose an infection risk to other people in the vicinity in hospital.

- 1.55. There are many different manufacturers of FFP3 respirators; they differ in design, size and shape. There were two main types of respirator, single use i.e. disposable (Figure 6) and reusable (Figure 7) FFP3 respirators. The single use respirator was the most prevalent in the NHS throughout the pandemic. Reusable respirators had the advantage of potentially easing pressure on limited disposable respirator supplies.
- 1.56. Use cases of FFP3 masks in healthcare settings include:
 - 1.56.1. For healthcare workers looking after patients with suspected or known infections with airborne transmission such as TB.
 - 1.56.2. For a comprehensive review of face mask PPE types in the pandemic era, see (Das et al, 2021).



Figure 6: Example of a typical, non-valved single use FFP3 respirator used in the NHS.



Figure 7: Example of a typical reusable respirator mask used in the NHS.

Respirator fit-testing

- 1.57. Each model of respirator comes in a fixed size and shape; the faces of healthcare workers do not. In order for respirators to provide effective particle filtration, they must fit the user's face snugly. There must be a tight seal between the mask and the user's face, otherwise unfiltered, potentially contaminated air can leak through.
- 1.58. Therefore, before a healthcare worker can safely use a specific type/size of respirator, they must undergo a process called fit-testing. This is done to provide objective evidence that the particular type and size of respirator fits each healthcare worker tightly, with a good seal. There are two main types of respirator fit-testing: qualitative and quantitative. Both types need trained staff to conduct the test on others.
- 1.59. Qualitative respirator fit-testing typically involves the user putting on ("donning") a respirator, most often an FFP3 respirator, and seeing if they can detect the odour of an artificial scent placed near the mask by the fit-tester. The scent could be bitter or sweet. If they cannot detect the scent, then it is inferred that the respirator has provided the protection it is designed to deliver.
- 1.60. One important limitation of the qualitative method is if the user had impaired or absent sense of smell, anosmia. Ironically, anosmia became recognised as a relatively common symptom of Covid-19. This was usually of acute onset, but recovery of the sense of smell was variable and could take several weeks (Ahmed et al, 2022).

- 1.61. On the other hand, if the user can detect the artificial scent, then it is inferred this is due to an ill-fitting respirator and the chemical has reached the user's nose by an air-leak. A different type, or size of respirator would then be tried, until the user passed this test.
- 1.62. It was common for healthcare workers to have to try more than one type/size of respirator to find one which fits correctly.
- 1.63. Quantitative respirator fit-testing is more technical and needs specialised equipment. There are different types of quantitative fit-testing. One method involves the detection of particles in the environment around the user & within the respirator, by way of invasive monitoring. Based on a small number of studies, the quantitative fit-testing method may be better at detecting leaks (Regli et al, 2021).
- 1.64. The quantitative method of fit-testing requires more specialist equipment, which, to the best of our knowledge, most NHS hospitals did not have at the outset of the pandemic. There were/are companies which can conduct quantitative respirator fit testing and some NHS hospitals outsourced fit testing to these companies. A description of methodology and some images are available in this report by Xu and colleagues (Xu et al, 2023).
- 1.65. The results of the fit-testing must be carefully recorded for each healthcare worker, so that they know which type and size they need to work safely with Covid-19 patients. This is also important from the NHS hospital's perspective, as it provides evidence that they have taken reasonable steps as an employer to ensure their staff have appropriate respiratory PPE to face Covid-19.
- 1.66. This is an unavoidably laborious and time-consuming process, taking typically 15 to 20 minutes per individual for a quantitative fit test. This needs to be repeated if existing supplies of fit-test respirators are disrupted and are replaced with alternative mask types (as occurred early in the pandemic as supply chains were being secured), and periodic updates (for example every 2 years). However, it is vitally important in keeping frontline NHS staff safe from healthcare-associated (nosocomial) Covid-19 infection.
- 1.67. The Health and Safety Executive (HSE) has issued "Guidance on respiratory protective equipment fit testing" describing employers' obligations, training requirements, testing methods etc. It states that whilst it is not compulsory to follow this HSE guidance on respirator fit testing, by doing so, employers would be "doing enough to comply with the law" (Health and Safety Executive, 2019).
- 1.68. To the best of our knowledge, during the pandemic, NHS staff who needed to use respirators were fit tested for specific respirators. They would not generally be allowed to use respirators or work in environments where these respirators were required without evidence of passing the respirator fit test. However, on the ground practice in the challenging and evolving circumstances of the pandemic, this was not always the case, and we are aware of evidence submitted to the Inquiry that fit checking was, temporarily, used in place of fit testing in some trusts.

Respirator fit-check / user seal check

- 1.69. Once a suitable respirator has been identified for each healthcare worker, it is important to check that there is a satisfactory seal when the mask is donned. This is a simple safety check to ensure the mass has been donned correctly. This is explained on the US Centres for Disease Control webpage under "User Seal Checks" (CDC, 2021).
- 1.70. A respirator fit-check should be performed each and every time a new respirator is donned. Without this fit-check, the user is not assured the RPE will provide adequate protection.

Powered air-purifying hoods

- 1.71. To be effective, respirators need to achieve a tight-fit to the user's face, hence the need for fit-testing. Not all clinical staff could find a suitable size and shape of disposable respirator after fit-testing.
- 1.72. Some staff had beards for religious reasons and could not shave these. It is impossible to achieve a satisfactory FFP3, half-face or full-face respirator seal in the presence of a beard. The beard allows leakage of air between the mask and the face and prevents an effective seal.
- 1.73. Staff who could not find a suitably-sized FFP3 mask during fit-testing procedures, and those who had a beard for religious reasons could use powered hoods, also known as powered air-purifying respirators (PAPR) instead. For these healthcare workers, such hoods were the only viable respiratory PPE option. This was understood before the pandemic, but a very large number of NHS staff would fail their first fit test for a variety of reasons, and it may not have been understood in advance of the pandemic how much of an issue this would become.
- 1.74. There are many different models of powered hoods on the market. They are of different designs and degrees of complexity. The powered hoods all encompass the user's head, resting on the user's shoulders.
- 1.75. These hoods have a mechanical element as they incorporate self-contained filtering and ventilation functions, with a power source. These hoods are powered by rechargeable batteries. Compared to non-powered respirators, these hoods are complex pieces of medical equipment, which need maintenance to remain effective. Further issues with PAPR hoods are noted in paragraphs 7.12 to 7.15 and 12.15 to 12.18.



Figure 8: Example of a typical powered air-purifying hood used in the NHS.



Figure 9: Second example of a typical, powered air-purifying hood used in the NHS.

Other elements of PPE

- 1.76. PPE for managing Covid-19 patients was not confined to respiratory PPE. Linked to the risk of large droplet spread and infection transmission via direct physical touch or contaminated surfaces (see paragraphs 90-105 of Professor Beggs' report INQ000474276), other PPE was required. The PPE ensemble included:
 - Non-sterile, single use i.e. disposable gloves (sterile gloves are used for surgery and other invasive procedures, mainly to protect the patient rather than the healthcare worker)
 - Face protection such as a full-face transparent visor, to protect healthcare workers from splashes of body fluids from patients (unless wearing a full-face respirator)
 - Eye protection such as reusable safety glasses or goggles, to protect healthcare workers eyes from splashes of body fluids
 - Single-use fluid-repellent gown (if the risk of body fluid exposure was substantial)
 - Single use plastic aprons (not fully fluid-repellent).
- 1.77. Donning (putting on) and doffing (removing) of the various elements of PPE required training, time and space. Training for doffing of contaminated PPE was especially important for staff safety. PPE is doffed in a specific order to minimise the risk to the staff member. Hand hygiene is important when PPE is used. Discarded face-masks, respirators and gowns/aprons are likely to be contaminated and hands should be disinfected after disposal. Hand hygiene is important after gloves have been worn. Gloves are not impermeable to tiny virus particles. Gloves may also split or tear and hands can be contaminated when gloves are removed.

Scope and scale of PPE use

- 1.78. The above-described PPE was used by some or all frontline NHS staff managing suspected or confirmed Covid-19 cases, with official recommendations changing during the pandemic, see section 5 of this report. To some extent, this is standard IPC practice in the sense that in a hospital setting, the recommended PPE is tailored to the infectious agent. With new, emerging infections, the recommended PPE may change over time as knowledge of the pathogen characteristics listed in paragraphs 1.21 to 1.31 changes, such as route of transmission and transmissibility.
- 1.79. The scale of the Covid-19 pandemic meant that, unlike the pre-pandemic situation, most frontline NHS staff in acute hospitals would have used this level of PPE for most of the pandemic. This was a massive change in PPE and IPC culture for the NHS workforce. Rather than the exception, this kind of PPE became the norm for many NHS healthcare workers.

- 1.80. The implications of this extended to the logistical effort needed to maintain adequate supplies of all the elements of PPE, not just face masks. This logistical effort had to be maintained throughout the pandemic, across the NHS.
- 1.81. One consequence of this massive increase in PPE usage was the problem of increased production of waste. All the discarded PPE, which was assumed to be infectious, had to be safely collected and removed daily.
- 1.82. Another change brought about by the pandemic was the use of FRSM by non-clinical staff on the wards (such as caterers) and staff working in non-clinical areas e.g. offices. As national lockdowns ended and restrictions eased, staff based in non-clinical areas who previously exclusively worked from home started to return to the workplace.
- 1.83. For those who did return to the workplace, surgical face masks were recommended, in addition to social distancing. This was an entirely new way of working. These staff also needed supplies of surgical masks.

2. Overview of the threat to NHS clinical staff and inpatients from Covid-19

(Lead author: GYS)

- 2.1. In the early phases of the pandemic, many reports indicated significant morbidity and high case fatality rate, as well as clear evidence of human-to-human transmission, including in hospital settings. In the first quarter of 2020, all emerging reports from China and the growing list of countries with confirmed cases reinforced the picture of a novel Coronavirus, causing significant morbidity and mortality, with human-to-human transmission in the community and in hospitals.
- 2.2. The threat to the international community, the societies and healthcare systems of member states was clear early on. This led to the World Health Organisation (WHO) declaring Covid-19 a public health emergency of international concern on January 30 2020 and subsequently a pandemic on March 11 2020 (Eurosurveillance editorial team, 2020), (WHO, 2020c). As the WHO said at the time, they did not make these declarations lightly. They were made due to the rapid international spread of Covid-19 and the evidence of hospitalisations, intensive care unit (ICU) admissions and deaths from this novel infection, particularly in China, which had had the most cases.
- 2.3. By the time the WHO had declared Covid-19 to be a global pandemic on March 11, the virus had reached every continent except Antarctica, and caused 118,319 confirmed infections and 4,292 deaths (WHO, 2020b).
- 2.4. We could see from media reports from around the world, and the emerging literature on infection fatality rate and R_0 (see paragraphs 1.23 to 1.25), that Covid-19 was a serious communicable disease. Early estimates of IFR were quoted as 1% (CI 0.4-4.0%) on February 10 2020 in a report produced by Imperial University. SAGE planning assumptions were initially based on a CFR of 2-3% on February 11 2020, and revised to an IFR of 1% on February 27 2020.
- 2.5. These early observations of severe disease and mortality linked to the novel Coronavirus were reflected in the final, internationally agreed name for the causative virus: Severe Acute Respiratory Syndrome Coronavirus Type 2 (SARS-CoV-2). The name conveyed the threat posed by this novel Coronavirus quite literally.
- 2.6. In January 2020, Covid-19 was designated as a high consequence infectious disease (HCID) in the UK. As previously described, this implied a high risk to human health including risk of death. The IPC measures were commensurate with this HCID classification. Based on emerging reports from countries which had reported cases of Covid-19, the new virus was perceived to be a serious threat to life. Covid-19 was clearly causing many hospitalisations, including intensive care unit (ICU) admissions and unfortunately, deaths.
- 2.7. HCIDs are further classified as either contact or airborne HCIDs. Contact HCIDs are transmitted by contact with the patient's body fluids. Examples of contact HCIDs include

Ebola virus and Lassa fever. Airborne HCIDs are transmitted via the respiratory route as well as by contact route. Examples include MERS-CoV and avian influenzas e,g. H5N1 and H7N9.

- 2.8. The defining features of an HCID include (verbatim) (UK Government, 2023a):
 - an acute infectious disease
 - typically has a high case fatality rate
 - may not have effective prophylaxis or treatment
 - often difficult to recognise and detect rapidly
 - ability to spread within communities and in healthcare settings
 - requires an enhanced individual, population and system response to ensure it is managed safely, effectively and efficiently
- 2.9. At the time Covid-19 was classified as an HCID in the UK, it satisfied all these criteria. This classification reflects the consensus view amongst the leadership of the NHS and each of the public health agencies of the Four Nations at that time that Covid-19 posed a risk to public health, patients and healthcare workers in the UK.
- 2.10. In light of the high infectious risks posed by HCIDs, the UK established a network of HCID centres, equipped and trained to safely manage either contact or airborne HCIDs in 2015. A list of HCID units can be found at the above reference.
- 2.11. The concept behind the HCID network was to allow the UK to safely manage a small number of cases of HCIDs which were and still are expected to be mostly imported from abroad and limited in number. For example, since 1980, the UK has only had 11 confirmed cases of Lassa Fever, a contact HCID. Lassa fever has an animal (rodent) reservoir and is endemic in Guinea, Liberia, Nigeria and Sierra Leone (UK Government, 2023b). Generally speaking, HCIDs are expected to be seen infrequently in the UK.
- 2.12. The HCID network was not designed to manage large epidemics with widespread community transmission in the UK, nor indeed, a pandemic. A pandemic, by its very nature, would require committing beds, staff and resources across all the healthcare systems of the UK due to the sheer volume of cases of whichever pathogen is causing the pandemic.
- 2.13. Evidence of Covid-19's potential to cause hospital outbreaks and infect healthcare workers in the inpatient hospital settings was reported internationally as Covid-19 spread across the globe. Various reports of outbreaks and nosocomial transmission from multiple hospitals in 2020 was reviewed by Abbas and colleagues (Abbas et al, 2021b). Whilst this review acknowledged limitations in knowledge about the transmission of Covid at the time, it is clear that Covid-19 was causing nosocomial infections to patients and healthcare workers in hospitals in many countries. The authors made an important point

that it is difficult to be certain whether Covid-19 in a healthcare worker was acquired in hospital or in the community.

- 2.14. During the pandemic, especially in 2020, most frontline NHS healthcare workers would have looked after Covid-19 patients and many will not have had experience with a dangerous emerging pathogen that spreads easily within hospitals. This lack of experience, with PPE requirements and other IPC practices, may have put them at greater risk of acquiring the infection. These risks did not fall equally see paragraphs for 11.27 to 11.32 for detail on which staff were at highest risk.
- 2.15. For most of 2020, NHS hospital staff managed Covid-19 patients without the protection of Covid-19 vaccines. The first Covid-19 vaccine manufactured by Pfizer/BioNTech, was given regulatory approval by the Medicines and Healthcare Products Regulatory Agency (MHRA) on December 2 2020 (UK Government, 2020). It would take months to deploy this vaccine across the large NHS workforce nationally. Although relevant to this module, a detailed discussion of Covid-19 vaccines is, we believe out of scope of Module 3. Nevertheless, the history of Covid-19 vaccine roll-out to NHS staff and patients is a highly relevant consideration when describing the threat faced by the NHS from Covid-19 in our hospitals. The arrival of effective Covid-19 vaccines at scale considerably reduced the risk to NHS staff throughout 2021 and beyond.
- 2.16. Hospital inpatients were also at risk of nosocomial Covid-19. However, unlike healthcare workers, inpatients could not routinely be asked to wear complex PPE as they had their own medical problems, serious enough to need admission. FRSM face masks could be offered to inpatients, but are uncomfortable to wear effectively for the whole day, apart from when they were eating or drinking. FRSM was never designed for such prolonged use, nor, strictly speaking, are they PPE as previously described.
- 2.17. There may have been significant variation across the NHS in terms of usage of FRSM or RPE for patients with and without Covid-19. In broad terms, respirator supplies were sometimes limited and the resources for FFP3 fit-testing a constraint. This made offering such respirators to inpatients impractical in many hospitals.

3. Infection Prevention and Control Guidelines in the Four Nations

(Lead author: DG)

- 3.1. This section describes arrangements for IPC and the guidelines in place in each of the four countries of the UK before and after the pandemic.
- 3.2. IPC guidelines in the UK changed during the pandemic. Further changes have since been introduced.
- 3.3. Scotland had a National Infection Prevention and Control Manual (NIPCM) first published on January 13 2012 (NHS National Services Scotland, 2024c). Recommendations were based on literature reviews conducted with SIGN methods. The NIPCM was aimed at frontline health workers. Initially the content was not comprehensive. Recommendations were limited to standard IPCs. They addressed (not exhaustively): need for risk assessment on specific occasions; hand hygiene; and respiratory and cough hygiene. In 2014 the NIPCM in Scotland was extended to cover transmission-based precautions. It was further updated in 2016 to cover healthcare incidents and outbreaks. Health Improvement Scotland publishes IPC standards and health providers in Scotland are inspected against these.
- 3.4. The NIPCM was adopted throughout Wales in 2018, replacing its previous IPC advice introduced in 2012.
- 3.5. Before the pandemic, England used guidelines produced by PHE, professional societies (e.g. Healthcare Infection Society, Infection Prevention Society) and professional bodies (e.g. Royal College of Nursing). Examples of these guidelines include epic3, developed jointly by the Healthcare Infection Society and Infection Prevention Society (Loveday et al, 2014). Specific guidance was provided by the Department of Health, for example, for ventilation in healthcare premises by the Department of Health (see Prof Beggs' report INQ000474276). Many of these older guidelines are no longer accessible online. Before the pandemic NHS England did not publish IPC guidance, but it did provide input into policy considerations to support organisations that were responsible for generating such advice. During the pandemic it went on to assume a greater role, working with partner organisations such as PHE/UKHSA to help assess what IPC measures should be put in place. NHS England also provided practical input into PHE decisions regarding how PPE should be used in healthcare settings.
- 3.6. Need for a national IPC resource to collate all these various guidelines was recognised by the professional nursing organisations (Royal College of Nursing, 2017).
- 3.7. In her witness statement **INQ000421939**, paragraph 83) Dr Lisa Richie provides a narrative account of how the NIPCM was first created and implemented in Scotland in 2013. Wales adopted an NIPCM in 2018. The rationale behind this move is not disclosed by the witness statement. When Dr Richie took up post in NHS England in April 2020, a national manual did not exist in England and there was no national English IPC team.

Instead, the UK IPC Cell depended on evidence generated by the NIPCM in Scotland. Dr Richie goes on to write that '*By spring* 2022 *NHS England had published a NIPCM. On* 27.5.2022, the UKHSA archived the Covid-19 UK IPC guidance and replaced it with specific advice which complemented the NIPCM.' In paragraph 85 Dr Richie further states that 'The overarching IPC principles used to inform the pandemic response were drawn from the NHS Scotland NIPCM and supporting systematic reviews.' Events that took place in Northern Ireland related to uptake of NIPCM guidance were not disclosed.

- 3.8. When England adopted the NIPCM in April 2022 it was adapted to support compliance with the ten criteria stipulated in the Health and Social Care Act (2008) and the Code of Practice to prevent and control infections (UK Legislation, 2008) (UK Government, 2022). The current NIPCM is available on the NHS England website.
- 3.9. The Public Agency in Northern Ireland updated its IPC manual in 2023. It replaced guidelines that had been in place since 2008. The new website is called the Northern Ireland Regional Infection Prevention and Control Manual (NIIPCM). Its information and resources are based on the NIPCM.
- 3.10. The UK IPC guidelines published by UKHSA applied in all four nations until October 20 2020, when Scotland published and implemented the Scottish Covid-19 guidelines. These guidelines were generated in conjunction with Scottish stakeholders and were overseen by the Scottish Government Covid-19 Nosocomial Review Group.
- 3.11. There does not appear to have been much consultation with stakeholders before introducing the NIPCM in England, Wales or Northern Ireland. No feedback appears to have been obtained from those using it. One of the authors of this report (DG) worked in Wales at the time the NIPCM was introduced. At this time, she was a member of the Infection Prevention Society Welsh Branch and the Healthcare Infection Society and liaised regularly with senior IPC staff in most of the Health Boards. DG does not recall any discussion about the NIPCM, nor any reference to it in the nursing publications (Nursing Times, Nursing Standard) which seek to keep practising nurses abreast of advances in clinical practice. This is in contrast to discussion about the introduction of other guidance to support IPC (Aseptic Non-Touch Technique) and new IPC technologies (e.g. ICNET) from this time.
- 3.12. In Scotland, letters from the Chief Nursing Officer released when the NIPCM was first launched state that its recommendations for standard IPC precautions should replace existing guidance (Scottish Government, 2012). These letters are brief and provide no detail on how this should be achieved at frontline healthcare. Outside Scotland there does not seem to have been any discussion about the way that recommendations would fit with existing guidelines or with guidelines issued by the professional bodies. Some of these additional guidelines are still accessible (Coia et al, 2013), (Loveday, et al 2014). There is nothing to prevent health professionals referring to them.
- 3.13. The NIPCM was last updated (as at the time of writing, June 2024) in February 2024.
- 3.14. The regulatory bodies for healthcare play an important role ensuring that adequate standards for IPC are in place. This means that compliance with the guidance is open to

inspection by the Care Quality Commission in England, the Healthcare Inspectorate in Wales, the Care Inspectorate in Scotland and the Regulation and Quality Improvement Authority in Northern Ireland. Information relating to compliance is given on the NIPCM website for each country. The wording is different for each.

- The webpages of the NIPCM on the NHS England website (https://www.england.nhs.uk/national-infection-prevention-and-control-manualnipcm-for-england/) state that the NIPCM ' Should be adopted as mandatory guidance in NHS settings or settings where NHS services are delivered, and the principles should be applied in all care settings'.
- The webpages of the NIPCM in Scotland presents a disclaimer: 'When an organisation, for example health and care setting, uses products or adopts practices that differ from those stated in this National Infection Prevention and Control Manual, that individual organisation is responsible for ensuring safe systems of work including the completion of a risk assessment approved through local governance procedures' (https://www.nipcm.scot.nhs.uk).
- The webpages for the NICPM in Wales state that 'The National Infection Prevention and Control Manual (NIPCM) and Care Home Infection Prevention and Control Manual (CH IPCM) are considered best practice in all health and care settings. It should be adopted for all infection prevention and control practices and procedures'.
- In Northern Ireland the webpages state: 'Healthcare organisations <u>may</u> adopt this advice and guidance in Health and Social Care Trusts, Primary Care, Private Clinics and Voluntary sectors, Independent sectors, Care Homes, and Hospices to achieve IPC standardisation across all healthcare providers and professional groups' (<u>https://www.niinfectioncontrolmanual.net</u>).
- 3.15. From the above extracts it is apparent that expectations of compliance with the NIPCM differ slightly in the four countries of the UK. In England they are mandatory. In Scotland there is scope for deviation if supported by risk assessment. In Wales the NIPCM recommendations are considered good practice. In Northern Ireland a degree of choice appears to exist concerning use of the NIPCM. We are not of the opinion that use of the measures contained in the NIPCM should be mandatory across all four nations. It is hard to see how uptake could be mandated as much depends on time, resources, informing health workers about the NIPCM and winning their 'hearts and minds' to promote compliance. Furthermore, the NIPCM needs updating. The distinction between airborne and droplet precautions as part of transmission-based precautions, discussed in section 6, is out of date. There is no evidence that mandating IPC recommendations has any influence on compliance. On a day-to-day basis, compliance will depend on the accuracy of auditing.
- 3.16. During the pandemic in the UK, guidance on IPC practices was additionally provided by three sources:
 - 3.16.1. *The UK IPC cell.* Established in January 2020, its membership included senior IPC representatives from Public Health England, Public Health Wales, NHS Scotland

(ARHAI Scotland), Public Health Agency Northern Ireland, the ambulance service, and NHS England/Improvement. The majority of UK national guidance on IPC specific to Covid-19 was drafted by this group, and published by PHE/UKHSA. It took on a more prominent role from PHE in drafting IPC guidance from mid-2020. It had three aims:

- review international guidance and the published literature (national and international) to assess the learning and scientific evidence base to inform improvements in IPC practice, specifically the prevention of transmission and management of Covid-19 in NHS settings
- receive recommendations/ outputs from the Hospital Onset Covid-19 Infection (HOCI) Working Group including other SAGE subgroups and other expert groups e.g. New and Emerging Respiratory Threats Advisory Group (NERVTAG), and consider for inclusion in operational guidance
- advise on updates and revisions to IPC operational guidance ensuring alignment with the phase of the pandemic
- 3.16.2. Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland is a clinical service providing national expertise for IPC, antimicrobial resistance and healthcare associated infection (HAI) for Scotland. The group produced rapid literature reviews assessing IPC measures for the management of Covid-19 in health and care settings (NHS National Services Scotland, 2024a). This was a major source of information for the IPC cell.
- 3.16.3. *The Hospital Onset Covid Working Group (HOCWG)* was initially established as a sub-group of SAGE in April 2020 to provide scientific advice on minimising the transmission of Covid-19 within hospital settings. As Wave 1 subsided, HOCWG transitioned to the NHSE Hospital Onset Covid-19 Infection (HOCI) group in August 2020. HOCI was set up to be an operationally focused oversight group, with four nations representation, supporting implementation of good IPC practice. There were other groups within each of the devolved administrations who performed comparable roles.

Summary

3.17. During the pandemic the NIPCM applied in Scotland and Wales. Throughout the pandemic IPC guidance in England was provided by PHE and from April 21 2021 by the UKHSA. In Northern Ireland the NIPCM was adopted in 2023. Expectations of compliance differ slightly across the four countries.

4. Developing guidelines to prevent and control infection

(Lead author: DG)

- 4.1. This section will explain:
 - The nature and purpose of guidelines in healthcare.
 - How guidelines are developed.
 - Differences in the processes used to develop full-scale, traditional guidelines and the rapid review guidelines developed for use in emergency situations such as pandemics.
 - The processes used to generate rapid review guidelines throughout the pandemic.

The nature and purpose of guidelines in healthcare

- 4.2. Guidelines are widely used in healthcare. Their purpose is to help health professionals provide high quality care. As far as possible, guidelines are supposed to be based on evidence. The best available evidence should be drawn upon. Using evidence encourages the uptake of treatments that are known to be beneficial. It discourages the uptake of treatments for which proof of effectiveness does not exist or where evidence is poor. Evidence-based practice is an important way of avoiding the wasteful use of resources and helps to contain the costs of healthcare, as well as improving outcomes for patients. Putting evidence-based guidelines in place and making sure they are acted on helps to make sure that all patients have access to care of the same standard (Sackett and Rosenberg, 1995).
- 4.3. Assessing whether guidelines are effective in public health interventions such as IPC is challenging, however. The most persuasive outcome would be evidence of reduction in infection rates. A linear relationship between an intervention and infection rates is seldom possible to demonstrate because there are so many confounding factors including time, resources and compliance. Instead, audit is frequently used to demonstrate that a guideline is in place and that it is being complied with. Compliance is therefore taken as a proxy measure of effectiveness.
- 4.4. As well as guidelines, clinical recommendations are sometimes issued in manuals. In lay terms there is a distinction between a guideline and a manual. A guideline is described as a general rule, principle or advice that may have to be adapted to meet specific need. In clinical practice a guideline would usually be taken to indicate best practice. A manual is described as a list of practical instructions based on a step by step approach. Creation of a manual can be used to implement best practice guidelines. The use of a manual seems to offer a more mechanistic approach to implementing recommendations for IPC. To some extent, IPC specialists use the terms 'guidelines' and 'manual' interchangeably, however. The WHO has published criteria for developing IPC manuals (WHO, 2018). The WHO criteria state that '*The manual is not intended to be a prescriptive list of 'must do's'*. *Instead, it provides a stepwise approach to implementation based on the evidence and experience of what has worked in a number of settings and introduces examples and ideas from health care facilities around the world which can be used by IPC leads/focal*

persons and teams within health care facilities.' The WHO advocates a step-wise approach to implementing a new IPC programme, a clear summary of its core components, identification of barriers and practical solutions to uptake and the importance of 'winning hearts and minds' when an IPC manual is introduced. The phrase 'winning hearts and minds' is used to describe the 'convincing narrative' that must be put in place to secure the 'emotional and intellectual process' of motivating health workers to accept new practices.

- 4.5. Evidence to support guidelines comes from the findings of clinical trials and other types of research (e.g. cohort studies, case study series). Traditionally, randomised controlled trials have been considered to provide 'gold standard' evidence (Sackett and Rosenberg, 1995). The findings of other types of research are not considered to be as strong because they do not provide as much confidence in whether an intervention causes an intended effect (causality). Randomised controlled trials were originally developed to evaluate the effectiveness of pharmacological treatments. They do not always translate smoothly into public health interventions that apply to groups of people rather than to individuals. There are practical difficulties. For example, double blinding is one of the key features of a randomised controlled trial. Double blinding means that neither the patient or researcher knows whether an individual is receiving the novel drug or has been given a placebo instead. If a patient or researcher knew who was receiving treatment this might prejudice their judgement concerning outcomes. Public health interventions often involve the introduction of a new procedure or behaviour change e.g. educational intervention for health workers, introduction of a guideline that changes ways of working. These actions require co-operation from the people involved and cannot be concealed from them.
- 4.6. Professional groups view evidence differently. Medical staff tend to be interested in how evidence has been generated and value evidence derived from the findings of randomised controlled trials. Nurses appear to be more interested in how evidence can be used to support practice. They appear to place less emphasis on how it is generated than doctors (Kyratsis et al, 2012).
- 4.7. There is no shortage of IPC guidelines internationally, and at national level in the UK and other countries. Some IPC guidelines are generic. They are intended to be applied by all health professionals in all situations, such as SICPs (see paragraph 1.32) (WHO, 2024b).
- 4.8. Transmission Based Precautions (TBPs) are defined as specific measures that are required when caring for patients with known or suspected infection. TBPs are categorised according to the supposed route of transmission of a pathogen (see paragraph 1.21). TBPs are defined by the WHO as 'the measures that should be taken for patients who are known or suspected to be infected or colonised with transmissible or epidemiologically significant pathogens' (WHO, 2022). TBPs need to be undertaken in addition to standard precautions. Three different categories exist. The category put in place depends on whether the patient has an infection that is thought to be spread by: "contact" (hands and contaminated surfaces); "droplets"; or the "airborne route".
- 4.9. International IPC guidelines are generated by the WHO and other organisations including Cochrane and the Centers for Disease Control and Prevention (CDC) in the United States (US). In the UK IPC guidelines from the National Infection Prevention and Control Manual

(NIPCM) are now in place for all four nations. Other UK organisations that have produced IPC guidelines are:

- Public Health England (PHE) and later UKHSA
- Public Health Wales
- Antimicrobial Resistance and Healthcare Associated Infection Scotland (ARHAI Scotland).
- National Institute for Health and Care Excellence (NICE)
- Professional bodies and societies, e.g. Healthcare Infection Society, Infection Prevention Society
- 4.10. Information on the NIPCM websites for each nation of the UK states that the NIPCM guidelines are evidence-based and generated through the findings of systematic reviews. Each of the four countries in the UK has its own website for the NIPCM.
- 4.11. The guidelines produced prior to the introduction of the NIPCM were all created at different times using different methodologies. There is overlap in the information presented in all these guidelines. In some cases, pre-existing guidelines have been incorporated into new ones. For example, the epic3 guidelines (Loveday et al, 2014) jointly produced by the Infection Prevention Society and Healthcare Infection Society drew on pre-existing work from the Healthcare Infection Control Practices Advisory Committee (HICPAC) in the US. HICPAC undertakes literature reviews to inform guidelines produced by the US Centers for Disease Control (CDC). Reluctance to relinquish 'evidence' from pre-existing guidelines may be a feature of the discipline of IPC. In her witness statement to module 2 of this Inquiry (INQ000236261) Catherine Noakes, whose background is in bioengineering, observed that from her experience of working with IPC experts during the pandemic, traditional views about IPC appear to be firmly ingrained and hard to change. Disentangling the origins of all the sources of evidence included in the many IPC guidelines, and the relationship of the different IPC guidelines to one another would be a challenging undertaking and appears never to have been attempted.
- 4.12. ARHAI Scotland creates IPC guidelines, and was one of many sources of outputs used to inform IPC during the pandemic. Other sources include outputs from SAGE, international guidelines (e.g. WHO, Centers for Disease Control, ECDC), NERVTAG, and primary sources of UK epidemiological data. In the UK, NICE and Public Health England/UK Health Security Agency have created guidance for specific aspects of the management of infection and Covid-19. Of these organisations, only ARHAI Scotland has direct input to the NIPCM guidelines.
- 4.13. NICE processes and PHE/UKHSA processes are discussed in this document because they are transparent and provide a comparator to the less transparent guideline development approaches taken by ARHAI Scotland, which was a major source of information for the IPC Cell throughout the pandemic.
- 4.14. In his witness statement (INQ000412890) Stephen Powis expresses a hope that in the event of another pandemic, NICE would be able to adapt their standard guidance

procedures so that NHS England does not have to make such a major contribution to this work. He also points out (paragraph 341) that in England the Secretary of State for Health and Social Care has a legal duty to provide published information and advice relating to specific infectious pathogens. The Dept of Health and Social Security in England publishes national policy documents and initiatives to tackle healthcare associated infections which is complimented by NICE quality assurance standards as well as by pathogen specific advice from Public Health England. Paragraph 342 of Powis' statement informs us that PHE/UKHSA enacts the Secretary of State for Health's duty to publish guidance on specific pathogens in England, including Covid 19 and this informs the practice guidance outlined in the NIPCM.

- 4.15. There are key differences in the way that NICE, PHE/UKHSA and ARHAI Scotland generate guidelines. NICE and PHE/UKHSA processes are clearly explained and described in detail on the NICE website and in individual PHE/UKHSA reviews. ARHAI Scotland uses an older guideline-development methodology than that used by NICE and UKHSA, and many other organisations. ARHAI Scotland adopts the methodology developed by the Scottish Intercollegiate Guidelines Network (SIGN). However, the exact guideline development process used by ARHAI are unclear. They are not clearly described on its website. NICE provides a range of resources to help users implement its guidelines. ARHAI Scotland provides links to a variety to posters and other educational and materials aimed primarily at frontline workers. The ARHAI Scotland IPC guidelines are developed in conjunction with a Development Methodology Document (NHS National Services Scotland, 2024b). Formerly there were claims that 'Recommendations for practice are based on living systematic reviews' and that updating is ongoing in light of the most recent scientific evidence. When this link was used on August 6 2024 a message appeared to reveal that 'changes to the methodology are currently being piloted with the IPC Working Groups to increase transparency and improve rigour of development of the NIPCM. Following approval by the ARHAI Scotland IPC Oversight and Advisory Group, the development process will be updated. It is anticipated that review of the development process will be complete by December.'
- 4.16. There is no requirement for the use of ARHAI Scotland guidance in the NIPCMs used in the other three nations of the UK.
- 4.17. There are differences, too, in the way that NICE and ARHAI Scotland are commissioned. NICE develops guidelines in response to Government request in England, and they apply in England. Uptake in Wales, Scotland and Northern Ireland depends on the decisions taken by their respective governments. In England, development of the NIPCM no longer adopts ARHAI review and guideline methodology. A NIPCM is now used in all four countries of the UK and to inform the standards that the healthcare regulatory bodies expect to be met in each of the four countries of the UK.
- 4.18. The scope of IPC guidelines developed by NICE and ARHAI Scotland are different. NICE has developed quality IPC standards for key areas of practice. These include IPC guidance for patients receiving healthcare in primary, community and secondary care settings, for surgical site infection, and for healthcare-associated infection in hospitals and secondary care services (NICE, 2014), (NICE 2013), (NICE, 2016). ARHAI Scotland covers a much broader range of IPC issues.

- 4.19. The WHO provides very specific recommendations for how guidelines should be generated during an emergency such as an unidentified, prospective pandemic (WHO, 2014b). According to these international standards, guideline development should take place in two stages. First, one or more reviews of the literature is undertaken to obtain the required evidence. These are called systematic literature reviews. They are conducted in a series of pre-determined steps, adopting a strict methodology. Next the evidence from the reviews is evaluated and used to formulate recommendations. Transparency is essential throughout both stages. This is to ensure that all potential stakeholders can see what information was used in the systematic literature review and how decisions about each of the recommendations was reached.
- 4.20. Guideline development is time-consuming. It is not unusual for systematic literature reviewing to take 12-24 months. Commitment is needed from a range of people with different backgrounds able to offer complementary expertise. They include individuals with:
 - Technical expertise
 - Subject specialists
 - Stakeholders able to offer different perspectives

Stakeholders can include:

- Patients
- Patients' families
- Members of advocacy groups
- Healthcare professionals responsible for putting the guidelines into place
- Healthcare commissioners and providers
- Members of the public
- Members of professional societies
- Trade unions

Limitations of guidelines and barriers to implementation

- 4.21. Guidelines are important to support practice but they have limitations. Guidelines are only of practical use if they are translated into practice. Uptake may not occur, or be suboptimal, because:
 - Health professionals do not trust the recommendations, or the processes used to compile the guidelines: in other words '*the narrative is not convincing*' enough to '*win hearts and minds*' of staff in WHO parlance.
 - Health professionals lack the time and resources to put the guidelines in place.
 - The guidelines do not capture every eventuality that might be encountered in clinical practice e.g. introduction of new equipment or a new way of working, especially important during a pandemic.

- The guidelines are not clearly presented and do not present complete, "stand-alone" information.
- 4.22. For the above reasons, it is not feasible to enforce guidelines strictly. It is also important to remember that the advice contained in guidelines generally reflects best practice, but what is 'best' in one situation many not necessarily be best in another. To provide an extreme example: it is best practice to cleanse hands before direct patient contact but in the event of a life-threatening emergency (e.g. cardiac arrest) few would argue that hand hygiene before touching the patient would be the greatest priority.
- 4.23. Successful uptake depends on staff at the frontline believing in the guidelines, having enough time, the right equipment and the necessary training and opportunities to put the recommendations in place. If these conditions are not met, health professionals tend to improvise, develop their own alternative way of doing things or simply do not comply. In an interview study conducted in 2020 health professionals reported fears that they were unable to comply with IPC guidelines for Covid-19 because PPE was running out or had never been available in some clinical settings. Health professionals claimed that the frequently changing guidelines were causing confusion and mistrust. Problems were compounded by the discomfort of wearing PPE, the physical barriers created between health professional and patient and difficulties communicating with patients (Hoernke et al 2021).
- 4.24. The challenges of staff compliance with IPC guidelines reported during the pandemic are not new. Long before the pandemic problems were reported, for example, in relation to hand hygiene (Erasmus et al, 2010), use of gloves (Wilson et al, 2017), the isolation of infectious patients (Purssell et al, 2020), and the ability to undertake procedures aseptically outside operating theatres (Gould et al, 2021).
- 4.25. Hand hygiene is regularly audited in the UK and most other countries based on WHO recommendations dating from 2009 (WHO, 2009). Although campaigns can increase the frequency of hand hygiene short-term, compliance is very hard to sustain (Gould et al, 2017). The fragmented nature of nursing work means that hand hygiene opportunities are lost as the nurse moves rapidly between patients or is called away to tasks competing for priority. These might include attending to distressed patients and responding to crises (e.g. preventing falls and other accidents). Nurses and doctors report lack of time to undertake hand hygiene in emergency situations (Jeanes et al, 2018b). Some clinical procedures are so complicated that it is impossible for clinicians or experienced IPC nurses to decide at which precise points during a clinical procedure hands should be cleansed (Jeanes et al, 2018a).
- 4.26. There are many other practical difficulties that can prevent implementation of guidelines. In the UK, lack of single room accommodation means that infectious and potentially infectious patients are frequently admitted to beds in open ward areas. Delays receiving laboratory reports can also result in an infectious patient not being placed in isolation.
- 4.27. Nurse tutors responsible for teaching pre-registration undergraduate nurses the principles underpinning asepsis do not always appear to understand these principles themselves, frequently experience lack of the correct facilities to teach them in relation to clinical

procedures and do not believe that it is possible to maintain asepsis outside the tightly controlled conditions of the operating theatre (Hawker et al, 2023).

- 4.28. A second challenge is that no guideline, no matter how well constructed, can cover all eventualities. Healthcare is dynamic. New clinical equipment and procedures are introduced, and existing procedures are changed or adopted in different types of clinical settings. Procedures once undertaken only in a fully equipped operating theatre may now be undertaken in satellite settings with lower grade facilities. Staff in these settings may not always have had the most up-to-date training or know how to adapt. Health professionals need to be able to modify guidelines safely. It is not always easy to predict what could go wrong.
- 4.29. Guidelines are only useful if they are complete and explicitly state the action that should be taken in a specific circumstance at a particular point in time. Health professionals, short of time, will not take kindly to recommendations that direct them to another source. Unfortunately, this is a common occurrence with electronic documents as it is easy to provide an electronic link to other web-based materials.
- 4.30. Guidelines that instruct the user to take an additional action or decision are equally unlikely to meet health professionals' needs. This is another common feature of IPC guidance. All too frequently users are instructed to make a "**risk assessment**", defined above in paragraph 1.40. However, risk assessment can be easier said than done. It involves the health professional making several difficult clinical judgements, some of which will be in tension with each other.
- 4.31. If a health professional had been able to undertake clinical decision-making in the first place, they would not have needed to consult the guideline. For example, health professionals need precise information about the use of respirators when undertaking AGPs. Instruction to base the clinical action on risk assessment would not be perceived as helpful, especially in a highly stressful situation such as a pandemic.
- 4.32. The five-step approach of identifying hazards, assessing risks, controlling risks, recording findings, then reviewing controls recommended by the British Safety Council (paragraph 1.40) is endorsed by the Health and Safety Executive (Health and Safety Executive, 2024c). The information supplied by both these bodies on how to actually conduct risk assessments appears to be targeted at employers responsible for writing formal risk assessment documents to meet organisational needs. Neither addresses the requirements of individual healthcare workers although the need to undertake risk assessment before embarking on clinical procedures is frequently reiterated in IPC guidelines and manuals. For example, the National Infection Prevention and Control Manual (NIPCM) for England states: 'Patients must be promptly assessed for infection risk on arrival at the care area, e.g. inpatient/outpatient/care home, (if possible, prior to accepting a patient from another care area) and should be continuously reviewed throughout their stay. This assessment should influence placement decisions in accordance with clinical/care need(s).' In her witness statement (INQ000421939 paragraph 63) Dr Lisa Richie states that the UK IPC guidance and the NIPCM in England has 'risk assessment at its core' and that risk assessment should be underpinned by the Hierarchy of Controls. Risk assessment should include assessment of the environment

and the clinical procedure about to be conducted when decisions about the appropriate type of PPE are made (Stephen Powis **INQ0004128** Powis does not, however, indicate who should undertake this risk assessment or now they should do it. Presumably it must be the frontline health professional rather than an IPC specialist.

- 4.33. The NIPCM (England) does not explain in detail how the risk assessment should be conducted. The link supplied on the NHS England NIPCM website does not take the reader to this information despite the label 'patient placement literature review.' The challenge of undertaking risk assessment as applied to clinical decision-making when selecting RPE or PPE prior to performing an aerosol generating procedure is described by Dr Barry Jones in his witness statement INQ000273913 (paragraph 193). Dr Jones points out that health professionals are hampered because they are unable to detect virus particles in the air through any of the human senses (sight, smell) and there is no means of quantifying the numbers of virions suspended in the air. In her witness statement INQ000421939, Dr Richie admits that gaps in knowledge of the Hierarchy of Controls emerged during the pandemic.
- 4.34. IPC and IPC guidelines are important to the lay public and patients can be actively involved in this aspect of their care (Wyer et al, 2015), (Agreli et al, 2019). Before the pandemic, patients and members of the public knew about the risks of infection in hospital. Awareness had been raised by media reports of MRSA and other healthcare-associated infections in the 2000s. This anxiety is refuelled by periodic reporting of infections which are sometimes described as 'deadly' or 'dangerous'. Patients and their representatives can be highly vocal if they believe that they do not have access to safe and effective care. This includes arrangements for IPC and the necessary support from health provider organisations to ensure that these are put in place (Doll and Pierce, 2022).
- 4.35. When guidelines are developed, the systematic literature review(s) and steps taken to formulate the recommendations must adopt a clear, pre-determined methodology. This is to make sure that all the most relevant, up-to-date information is included. It is considered good practice for two teams to be involved. One team reviews the literature. A second, separate team formulates the recommendations.
- 4.36. A structured approach is advocated when formulating guideline recommendations. Ideally it should involve the use of an evidence-to-decision-framework. The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) (Schünemann et al, 2013) is the most widely used framework. GRADE identifies four levels of evidence: very low; low; moderate; and high. These are referred to as certainty of the evidence. Certainty is not the only factor that GRADE considers when formulating a guideline recommendation, however. Other key factors take into account: whether the recommendation is likely to be accepted by those who will have to use it; how straightforward it will be to put in place; the necessary resources; the number of people likely to benefit; and the likelihood of benefit outweighing any possible harm. The evidence underpinning a recommendation can be upgraded or downgraded by considering these key additional factors. Evidence derived from a rigorous study (e.g. a randomised controlled trial) might be downgraded because it would result in a recommendation that would be unacceptable to large numbers of stakeholders or too

difficult to put in place. Evidence derived from weaker research might be upgraded because a recommendation derived from it would be readily acceptable, benefit large numbers of people and not prove expensive or challenging to implement. The processes used to make these decisions must be clearly documented to ensure transparency. If transparency is lacking, stakeholders are unlikely to trust the recommendation. We acknowledge that applying GRADE can be difficult because it does not apply as well as to public health interventions such as IPC as it does to pharmacological interventions. This point is also made by Professor Beggs in paragraph 212 of his expert report INQ000474276). However, the use of GRADE does provide an audit trail demonstrating how recommendations were systematically derived from the underpinning systematic literature reviews.

- 4.37. No matter how rigorously undertaken, systematic literature reviews may not yield the required evidence. Sometimes, despite exhaustive searching, the review team is unable to locate any evidence to develop recommendations or only weak evidence. In this situation, guideline recommendations are based on the opinions of people who have specific knowledge or expertise in the topic. The evidence underpinning most IPC guidelines is weak or does not exist because it would be too difficult to undertake a controlled trial for practical or ethical reasons. For example, hand hygiene has long been considered essential to all IPC programmes. A randomised controlled trial in which health professionals were deliberately instructed not to cleanse hands after patient contact in order to explore the impact on infection rates would not be acceptable to staff or patients and would not be granted approval by an ethics committee. When little or no robust evidence exists, recommendations are based on expert opinion (Mitchell et al, 2020). For many guidelines, it is not clear how experts have been selected or what specific expertise they offer. This reduces transparency of the guideline development process and the trust likely to be placed in it.
- 4.38. The presentation of a guideline is important. Teams developing guidelines need to present each recommendation clearly and succinctly to enable health professionals to grasp the action they need to take quickly and accurately or to reach a decision. Each recommendation should be "stand alone." It should not send the user through a series of webpages trying to locate the specific information they need or demand further action, e.g. risk assessment.
- 4.39. Guideline development is time-consuming and difficult in an emergency such as a pandemic when information is needed as soon as possible. In this situation, full systematic literature reviews are replaced by rapid reviews containing whatever information is available at the time. Guidelines for conducting rapid reviews and generating emergency recommendations from them have been developed by the WHO (Tricco et al, 2017), Cochrane (Garrity et al, 2021) and the McMaster Grade Centers in the US (Morgan et al, 2018). The information given in all sources is much the same. They all state that rapid reviews should never be regarded as replacements for full scale systematic literature reviews and suggest timescales for updating. Three months is given as the arbitrary cutoff when an update should be generated and in the case of WHO, need for a six-month interim report is stated. Although it is not stated explicitly in these documents, the timescales were probably meant to be indicative rather than to be

regarded as edicts set in stone. Once an electronic search of the literature has been set up, it could simply be run again whenever deemed necessary and as often as required.

- 4.40. Rapid reviews are not considered as replacements for full systematic reviews because they involve taking shortcuts to generate the information quickly (Tricco et al, 2017), (Polisena et al, 2015), (Garrity et al, 2021). Shortcuts could include one or more of the following:
 - Searching fewer databases
 - Using fewer search terms
 - Language restrictions to the searches
 - Excluding the grey literature or pre-print literature. Grey literature is information not in the public domain, such as internal reports. Special search engines are necessary to search the grey literature.
 - Not undertaking hand searching to identify material that might not have been picked up during electronic searches. Hand searching means laboriously going through the reference lists of papers already included in the review and high-yield journals likely to publish similar papers.
 - Selection of the included papers and critique undertaken by one reviewer only. When full systematic reviews are undertaken it is usual for at least two reviewers to select and critique the papers to be included. They are supposed to work independently of one another to avoid influencing each other's judgements. When agreement cannot be reached on whether to include a paper or its quality, third party arbitration is given by another member of the research team.
 - Using pre-existing guidelines that address a similar issue, for example in the case of Covid-19, pre-existing guidelines for influenza, MERS or SARS.
- 4.41. The above list does not suggest that these shortcuts have been recommended or are endorsed. Sensible use of a shortcut is likely to depend on the situation. For example, applying language restrictions when conducting literature reviews might not matter in the case of Covid-19, where the most relevant publications were in English. By contrast, restriction of databases is very likely to have mattered because during the pandemic many publications appeared in journals not likely to have been picked up in databases dedicated to healthcare. In their rapid reviews, Public Health England/the UK Health Security Agency are careful to include disclaimers pointing out the disadvantages of rapid reviews. These disclaimers warn readers that the use of accelerated methods may result in a review that includes sources not representative of the whole body of publicly available evidence, that the review will have undergone internal but not independent critique, and that the findings should only be considered valid on the date stated on the review.
- 4.42. Taking shortcuts increases the risk of bias in the conclusions drawn from a rapid review. Bias is the systematic influence of irrelevant or unrelated factors that could influence the

findings of research and could lead to the wrong conclusions being drawn. In the case of literature reviews to support guidelines, bias could result in the creation of inappropriate recommendations. If health professionals do not know how decisions about guideline recommendations have been reached, the guidelines will not be seen to be credible. As a result, health professionals and patients may not feel confident that they are effective.

- 4.43. The shortcuts taken when a rapid review is conducted will be different depending on the team undertaking it and the resources and amount of time available. Some rapid reviews are more rapid and less rigorous than others. Lack of any internationally agreed blueprint for how a rapid review should be undertaken means that it is very important to describe the exact processes used and the shortcuts taken in a particular case. Unless the methods used to undertake the rapid review are explicitly stated, the findings will not be transparent and are not likely to be trusted by stakeholders.
- 4.44. During the pandemic, excluding work not yet officially published was a major risk. Research and publication were proceeding at unprecedented rates. A huge volume of new papers appeared swiftly, often in preprint form before they had been subjected to the usual peer review process normally employed to improve quality. As a result, it was necessary to identify, evaluate and synthesise information much faster than usual. This shortcut could have resulted loss of key information, inaccuracies and bias.
- 4.45. NICE, ARHAI Scotland, and Public Health England/UK Health Security Agency undertake rapid reviews to generate guidelines. They use different methodologies. NICE rapid review methodology is transparent and clearly described on its website. NICE states the specific shortcuts that are employed to conduct a given rapid review and explains why they have been taken. For example, where NICE has not used a formal risk of bias assessment or omitted use of GRADE, this information is provided. The PHE/UKHSA rapid reviews also use clearly described methods. These reviews contain disclaimers stating these limitations. ARHAI Scotland uses SIGN methodology to generate its rapid reviews. This methodology is not clearly described on its website and, as described in paragraph 4.15, its Development Methodology webpage is currently unavailable. SIGN compiled an online manual describing how it conducts rapid reviews dated April 2021. From this it can be inferred that the manual appeared after the ARHAI Scotland rapid reviews began to be generated.
- 4.46. Throughout the pandemic, ARHAI Scotland released a series of rapid reviews to prevent and control Covid-19. The first rapid review appeared on April 6 2020. An updated version appeared approximately every month until April 7 2022. According to NHS National Service Scotland (NSS) (in its response to a draft of this report), the ARHAI Scotland rapid reviews were generated in response to stakeholders in Scotland. The identity of these stakeholders was not identified. NSS states that the purpose of the rapid reviews was not 'to offer the basis of guideline recommendations'. However, the authors of this report note that recommendations do appear throughout the ARHAI Scotland rapid reviews, albeit somewhat 'buried' in the text.
- 4.47. Issues with the ARHAI rapid reviews relate to the methods used to compile them, consequent risk of bias and the trust that health professionals and other stakeholders could place in the recommendations. These points are addressed in greater detail below.

- The ARHAI Scotland rapid reviews drew heavily on guidelines targeted at influenza, SARS and MERS. This was inevitable early in the pandemic when little information was specifically available for Covid-19 but continued until well into the pandemic. For example, in Version 12 of the ARHAI Scotland rapid reviews (INQ00189376), published on 12.3.2021, information related to SARS and MERS continued to be quoted. The use of indirect information relating to another pathogen has the potential to result in inaccuracies and inappropriate guideline recommendations.
- Existing guidelines were used to inform the ARHAI Scotland guidelines. For example, Version 12, dated March 12 2021 (INQ000189376) continues to draw on recommendations in the epic3 guidelines (Loveday et al 2014) which specifically exclude outbreak situations. Within Version 12 references continued to be made to ECDC guidance for Covid19 dated April 2020, Health Protection Scotland dated April 2020 and Public Health England dated March 2020 among others.
- GRADE was not demonstrably in use in any of the ARHAI Scotland rapid reviews. The word 'certainty' occasionally appears, as in 'certainty of the evidence'.
- The way that stakeholders were involved is not provided in the review documents. From the information given, the reader is unable to deduce that the perspectives of health professionals (expected to put the ARHAI Scotland recommendations into practice) were explored. There is no evidence that the opinions of patients who had been, or might be, exposed to use of the recommendations and their impact on care were considered.
- Very little information was given about the team responsible for compiling the rapid reviews and their recommendations. As a result, stakeholders would not know whether the full range of required expertise had been covered in the guideline.
- Little information was available about the quality control processes used by the review and guideline development team or the arrangements for undertaking and updating each version. It was apparent that on many occasions, papers were selected and critiqued by a sole reviewer. Although this is an acknowledged approach when rapid reviews are conducted, it is known to be associated with loss of rigour (Polisena et al, 2015), (Garrity et al 2021).
- Only two databases were searched (Medline, Embase). This restriction resulted in loss of key information. For example, Version 11 dated February 5 2021 does not mention relevant work by Fennelly (Fennelly, 2020); Hamilton (Hamilton et al, 2021); Marr et al (Marr et al, 2019); Milton (Milton et al, 2013); Noakes (Noakes et al, 2006); or Tang (Tang et al, 2021) although their research focused on the transmission of respiratory viruses. These key research outputs are selected exemplars that could have been used to inform the guidelines at this point in time but were not.
- All types of evidence were considered and received equal weight (e.g. randomised and non-randomised trials), literature reviews adopting different methodologies (e.g. systematic reviews with and without meta-analysis) and single and multiple-centre studies. The level of evidence underpinning each recommendation was not stated.

- Restrictions were placed on the search terms used to identify the works to be included. In Version 11 dated February 5 2021 search terms were identified but only in an appendix. None of these search terms was likely to have resulted in the retrieval of papers in the disciplines of mathematics, the physical sciences or engineering although research teams working in these areas were conducting important work relating to the possible modes of transmission of the virus at the time with implications for IPC.
- Although hand searching was mentioned, no details were provided.
- The needs of staff employed in different types of hospitals and acute settings do not appear to have been considered.
- 4.48. In summary, little detail was provided about the processes used by ARHAI Scotland to search the literature, select the included works, or critique them, resulting in lack of the '*convincing narrative*' that the WHO suggests is central to IPC compliance with IPC guidelines and manuals. Details of the methodology were not well described. This situation is very likely to have contributed to health professionals' lack of trust in the recommendations. Lack of trust was expressed by health professionals themselves and their representative bodies (BMA, 2021).
- 4.49. The above problems were compounded by the presentation of the ARHAI rapid reviews and recommendations:
 - It is not easy to determine how each succeeding ARHAI Scotland rapid review had been updated from its predecessor. A summary of key changes would have been invaluable to users responsible for implementing the recommendations in their organisation.
 - The ARHAI Scotland rapid reviews and recommendations were not produced in a succinct, user-friendly, 'stand-alone' format. Users were very frequently referred to other sources via electronic links. They were often led back to the UKHSA guidelines, while links in the UKHSA guidelines took them back to ARHAI Scotland. This was frustrating and wasted time.
- 4.50. Professor Clive Beggs' expert report (INQ000474276) sums up the research undertaken throughout the pandemic from March 2020 demonstrating major changes in thinking related to the spread of virus particles, specifically for SARS-CoV-2. These changes had major implications for the type of precautions that should have been recommended for health professionals caring for patients infected/suspected to be infected with Covid-19, especially for PPE and RPE. Table 1 below indicates that the advice provided by ARHAI Scotland did not reflect these changes as the pandemic progressed, and knowledge and thinking advanced.

Table 1: Assorted ARHAI summaries of evidence and recommendations.

Table 1 refers to advice in selected ARHAI Scotland rapid reviews only. Regrettably the other ARHAI Scotland rapid reviews were not accessible at the time of writing.

Version/date	Summary of evidence	Recommendation
Version 8 5.11.20	Transmission is thought to occur via droplets and by direct and indirect spread No clear evidence of airborne transmission	 PPE: fluid resistant IIR surgical face mask for staff in direct patient contact and may be worn by those not in direct patient contact or at risk of spraying/splashing All patients and visitors should wear face coverings Eye/face protection should be worn if spraying/splashing or contact with body fluids is anticipated FFP3 respirators should be worn when undertaking AGPs in amber/red pathways
Version 9 4.12.20	Transmission is thought to occur via droplets and by direct and indirect spread No clear evidence of airborne transmission	 PPE: fluid resistant IIR surgical face mask for staff in direct patient contact and may be worn by those not in direct patient contact or at risk of spraying/splashing All patients and visitors should wear face coverings Eye/face protection should be worn if spraying/splashing or contact with body fluids is anticipated FFP3 respirators should be worn when undertaking AGPs in high/medium pathways
Version 12 12.3.21	No clear evidence of traditional 'long range' airborne transmission Droplet precautions when within 2m of a Covid-19 patient and during direct patient care	 PPE: fluid resistant IIR surgical face mask FFP3 respirator when conducting AGPs on high-risk pathways Health workers may choose to wear FFP3 instead of fluid resistant IIR surgical face mask when caring for patients on lower-risk pathways Eye/face protection should be worn if spraying/splashing or contact with body fluids is anticipated

Version/date	Summary of evidence	Recommendation
Version 15 11.6.21	No clear evidence of traditional 'long range' airborne transmission	PPE: fluid resistant IIR surgical face mask FFP3 respirator when conducting AGPs on high/medium-risk pathways
	Droplet precautions when within 2m of a Covid-19 patient and during direct patient	Health workers may choose to wear FFP3 instead of fluid resistant IIR surgical face mask when caring for patients on lower-risk pathways
	care	Eye/face protection should be worn if spraying/splashing or contact with body fluids is anticipated
Version 16 16.7.21	No clear evidence of traditional 'long range' airborne transmission	PPE: fluid resistant IIR surgical face mask
		FFP3 respirator when conducting AGPs on high/medium-risk pathways
	Droplet precautions when within 2m of a Covid-19 patient and during direct patient care	Health workers may choose to wear FFP3 instead of fluid resistant IIR surgical face mask when caring for patients on lower-risk pathways
		Eye/face protection should be worn if spraying/splashing or contact with body fluids is anticipated
Version 21 9.12.21	No clear evidence of traditional 'long	PPE: fluid resistant IIR surgical face mask
	range' airborne transmission	FFP3 respirator when conducting AGPs
	Droplet precautions when within 2m of a Covid-19 patient and during direct patient care	Use of FFP3 respirator should be 'considered' when numbers of infected patients are too high for single room segregation to be possible
		Eye/face protection should be worn if spraying/splashing or contact with body fluids is anticipated

4.51. Beggs points out that the NHS IPC guidelines: 'place great emphasis on the use of FFP3 respirator masks to mitigate the risk of aerosol transmission when HCWs perform socalled AGPs. However, in comparison, much less attention is paid to the risks posed by natural respiratory aerosols exhaled by patients, HCWs and visitors, despite the fact that these aerosols vastly outnumber those produced by AGPs, and potentially pose a greater infection risk. The much higher risk of infection associated simply by occupying the same indoor space as that occupied by somebody who is infected suggests that routine use of RPE would have offered a higher degree of protection.

- 4.52. In his expert report Beggs additionally presents evidence from the Royal Society: "the weight of evidence from all studies suggests that wearing masks, wearing higher quality masks (respirators), and mask mandates generally reduced the transmission of SARS-CoV-2 infection." (Walport, 2023) Having said this, they added the important caveat that most studies in the review were observational and could have suffered from greater levels of confounding than experimental studies.
- 4.53. We acknowledge that Scotland developed its own IPC guidance in October 2020 and therefore have a separate timeline to that of NHS England.
- 4.54. Shortcomings in the work of ARHAI Scotland were identified in an independent review commissioned by the Royal College of Nursing (RCN) on behalf of its membership in February 2021. The RCN report looked at the then most recent version of the ARHAI Scotland review (Version 11, dated February 5 2021). The RCN report did not attempt to track changes in the development of the ARHAI Scotland guideline recommendations over time. The RCN Report concluded that the methodologies underpinning the rapid literature review and guideline development processes being used by ARHAI Scotland did not meet the standards for rapid reviews and emergency guideline development required by the WHO and other international organisations. The guidelines were not created transparently and were likely to contain a high risk of bias.
- 4.55. The RCN review was published on March 7 2021 (Gould and Purssell, 2021)). Similar concerns about the guidance were also being expressed by other professional bodies in the UK at this time, notably by the British Medical Association, the Royal College of Physicians (INQ000257930) and by the various organisations representing paramedical workers (INQ000130586). Comparison of international guidelines reported at this time demonstrated conflicting findings. Most guidelines advised the use of respirators when undertaking AGPs. Advice for the use of face coverings varied (Birgand et al, 2020) (Thomas et al, 2020).
- 4.56. A rebuttal of the Royal College of Nursing report was published in April 2021 (NHS National Services Scotland, 2021). ARHAI Scotland stated that the Royal College of Nursing report *"incorrectly assumes the UK IPC guidance is based on this ARHAI rapid review"*. The rebuttal also stated that the 'RCN report incorrectly asserts that Scotland's NIPCM is based on a rapid review methodology'. The origin of this statement is unclear, as the RCN report never mentioned the NIPCM. ARHAI emphasised the role played by other groups, notably NERVTAG, in advising the Government about IPC precautions in the rebuttal. As acknowledged throughout this document, we are alive to the many and varied sources of information available to support IPC in pandemic and non-pandemic situations.
 - The RCN commissioned the report in response to concerns expressed by its membership in relation to the ARHAI rapid review recommendations and the PHE/UKHSA advice which was largely drawn from them. The RCN membership was not complaining about advice from NERVTAG or from any other group.
 - NERVTAG is not routinely responsible for undertaking systematic reviews or developing guidelines. NERVTAG is an '*expert committee of the Department of*

Health and Social Care (DHSC), which <u>advises</u> (author underlining) the Chief Medical Officer (CMO) and, through the CMO, ministers, DHSC and other government departments. NERVTAG provides scientific risk assessment and mitigation advice on the threat posed by new and emerging respiratory viruses and on options for their management.' In fact, only a few NERVTAG guidelines existed for the RCN membership to express concern about and the same drawbacks would apply. When reviews and guidance have been provided by NERVTAG, they are based on the methodology provided by Health Protection Scotland. For example, the NERVTAG consensus statement on cardiopulmonary resuscitation (CPR) published in response to Government request on 24th April 2020 (Killingley, 2020) clearly stated that it was based on Health Protection Scotland methodology and gave a link to the Health Protection Scotland methodology approach. On 6.8.2024 this link was broken (N.B. this NERVTAG consensus statement has now been rescinded).

- In his witness statement (INQ000412890) Stephen Powis provides a timeline of how guidance from Public Health England was agreed by NERVTAG, SAGE and the IPC Cell (see, for example, paragraph 379). From this document it is evident that none of these bodies undertook regular systematic or rapid reviews of their own.
- Throughout the pandemic NERVTAG provided expert opinion to SAGE and the IPC Cell. The expert witness statement issued by Susan Hopkins, CMO at the UKSHA
 INQ000410867 provides insight into the way that NERVTAG opinion was used or not used by Government throughout the pandemic. Uptake or the decision not to act on NERVTAG advice was taken according to the opinion of SAGE and the UK IPC Cell at the time.
- Expert opinion is not the same as evidence and should be used with caution in the development of guideline recommendations (Schünemann et al, 2019). Where expert opinion is the origin of part of a guideline, this should be clearly indicated to users of the guideline.
- 4.57. In the relatively small number of cases where NERVTAG has undertaken evidence reviews they were based on the work of Health Protection Scotland. Consequently, they are likely to have contained the same limitations as the ARHAI Scotland reviews. NERVTAG was responsible for reviews on cardiopulmonary resuscitation and AGP (Killingley, 2020) (see paragraph 6.44).
- 4.58. PHE/UKHSA publishes rapid reviews that do meet the WHO guidelines for generating rapid reviews. Many of these were created to provide specific guidance for aspects of Covid-19 management. Selected examples are Covid 19: the effectiveness of face-coverings to reduce transmission (UK Health Security Agency, 2020), Covid 19: Transmission from the deceased (UK Health Security Agency, 2021a) and Covid 19: non-pharmacological interventions to reduce transmission (UK Health Security Agency, 2023a). While many of these rapid reviews have been generated post-pandemic, they provide useful blueprints of how to conduct clinically useful information synthesis. They

are well-presented, 'stand-alone documents' based on methodology that is clearly described.

4.59. Despite the rebuttal, the authors maintain that the RCN report has made some points that may be valuable when devising a strategy to draw up evidence in future emergency situations. A number of pitfalls were identified. With forethought these could be avoided or at least reduced in future pandemics.

Summary

4.60. Guideline development is a time-consuming process. It is not practical in an emergency such as a pandemic, when information is needed as soon as possible. It is accepted that in this situation, full systematic literature reviews must be replaced by rapid reviews of the information available at the time. There is no single accepted way of undertaking a rapid review and the shortcuts taken could bias the review findings and recommendations drawn from them. In this situation patients and health professionals could be placed at risk of infection or unnecessary practices might be introduced. Transparency is essential so that users of the guideline can decide whether bias is present. Lack of transparency can result in the guideline failing to 'meet the hearts and minds' of those meant to be using it (WHO, 2018). The rapid reviews undertaken by ARHAI Scotland, and guidelines drawn from them and used to underpin advice from PHE/UKSHA, was not necessarily trusted by health workers and professional groups, resulting in significant confusion and anxiety. PHE/UK has subsequently published its own rapid reviews. These are well-presented, 'stand-alone documents' based on methodology that is clearly described.

5. Timeline of the most important changes in IPC guidelines

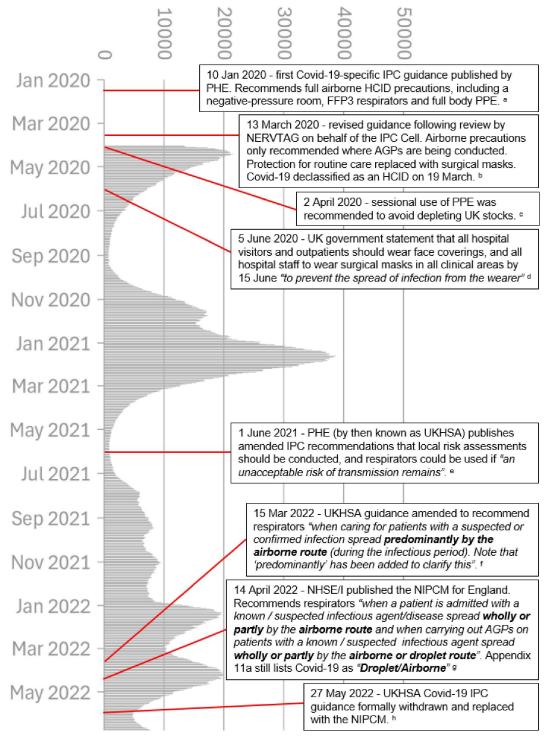


Figure 10: Timeline of key changes in IPC guidance in England. Emphasis added. Number of Covid-19 inpatients at the time is shown for context (data for April 2020 onwards from (Our World in Data, 2024)). Timelines varied in the devolved administrations. Detailed timelines of IPC guidance produced by the IPC cell and/or by PHE/UKHSA are in statements from Stephen Powis (INQ000412890 §374-419) and Susan Hopkins (INQ000410867 §288-371).

Footnotes from figure 10:

- a. INQ000101202
- b. INQ000325314
- c. INQ000348325 and INQ000410867 paragraphs 316 to 318
- d. INQ000339234
- e. INQ000271659_0005
- f. INQ000348420_0005 section 2
- g. INQ000410867 paragraph 367, and INQ000348463_0031 and 0048
- h. INQ000257936

Acronyms in figure 10, defined elsewhere in the report:

- AGPs Aerosol-Generating Procedures
- FFP3 Filtering Face Piece 3 respirator mask
- IPC Infection Prevention and Control
- HCID High-Consequence Infectious Disease
- NERVTAG New and Emerging Respiratory Virus Threats Advisory Group
- NIPCM National Infection Prevention and Control Manual
- PHE Public Health England
- PPE Personal Protective Equipment
- UKHSA UK Health Security Agency

6. Summary of shifts in scientific evidence relevant to clinical guidelines over time

- 6.1. This section will review key changes in the scientific evidence base underpinning our understanding of Covid-19 as they pertain to IPC guidance, with a particular focus on PPE:
 - Initial classification as a of Covid-19 as a high consequence infectious disease (HCID)
 - Declassification as a HCID
 - The controversies of recommendations for the use of respirators versus FRSM in the care of patients with Covid-19
 - The debate around aerosol generating procedures

Classification as a High-Consequence Infectious Disease

- 6.2. The definitions and criteria for assigning a HCID In the UK is outlined in paragraphs 2.6 to 2.12. Decisions on which pathogens to include in the list of HCIDs are taken by the four nations public health HCID group with advisory input, in particular from the Advisory Committee on Dangerous Pathogens (ACDP). The list of HCIDs currently (as of June 2024) comprises 18 diseases: 8 contact HCIDs (including viral haemorrhagic fevers such as Lassa fever and Ebola virus disease), and 10 "airborne" HCIDs (including 4 subtypes of avian influenza, and disease caused by the coronaviruses MERS-CoV and SARS-CoV-1).
- 6.3. The designation of a pathogen as a HCID has important implications for clinical management:
 - 6.3.1. There is a national Imported Fever Service, staffed by infection specialists and available at all times throughout the year, who can provide specialist advice and access to diagnostics to HCWs managing suspected HCIDs (UK Health Security Agency, 2014).
 - 6.3.2. There is specific IPC guidance for HCIDs that falls outside the scope of other guidance in the UK.
 - 6.3.3. All cases of laboratory confirmed HCIDs in England are transferred to a designated HCID treatment centre. As of January 2020, there were 4 treatment centres in the UK based in London (Royal Free), Newcastle, Liverpool, and Sheffield. In total these 4 units comprised 14 airborne HCID beds between them (Susan Hopkins statement INQ000410867 para 266).

- 6.4. The WHO was informed of cases of pneumonia of unknown microbial aetiology associated with Wuhan City, Hubei Province, China on 31 December 2019. A WHO statement on 09 January 2020 confirmed that a novel coronavirus has been identified as the cause. In early January 2020, that novel coronavirus was designated as an interim airborne HCID by the 4 Nations Public Health Agencies, a recommendation which was supported by NERVTAG as a "precautionary measure". The decision to add Covid-19 as an HCID was based on the above criteria and available information from Wuhan early in the pandemic indicating that it may have a high case fatality rate, and high rate of hospitalisation (transcript of UK Covid-19 Inquiry module 2 evidence of Professor Sir Jonathan Van-Tam, November 22 2023, p.216). The initial cases of Covid-19 identified in the UK in January and early February 2020 were therefore managed according to the HCID guidance above.
- 6.5. The first UK IPC guidance on managing the novel coronavirus was published by PHE on January 10 2020 (INQ000101202). In the absence of further information specific to this coronavirus, being less than 2 weeks since the first cases were reported to WHO, this was based on pre-existing documents developed by PHE for MERS (Susan Hopkins statement INQ000410867 paragraph 290c). This included a stipulation for FFP3 respirators to be worn by all HCWs in the same room as possible and confirmed cases of the novel coronavirus (INQ00022734).

HCID declassification

- 6.6. The very limited bed capacity of the UK's HCID network was soon exceeded. The next step was to utilise the capacity of the UK's infectious diseases units, totalling approximately 500 beds, which could provide specialist clinical infectious disease input and infection control procedures, though not necessarily to the same level as the four HCID centres. This capacity was exceeded by early March 2020 (UK Health Security Agency, 2023b). Covid-19 was removed from the list of HCIDs in the UK on March 19 2020 (see **figure 10**). The decision was taken by the UK public health bodies following a review from infectious diseases experts on March 16 2020, on the basis that "more information is available about mortality rates (low overall), and there is now greater clinical awareness and a specific and sensitive laboratory test, the availability of which continues to increase." This decision was supported by the ACDP and NERVTAG (transcript of UK Covid-19 Inquiry module 2 evidence of Professor Sir Jonathan Van-Tam, November 22 2023, p.227).
- 6.7. This declassification meant that cases of Covid-19 were no longer formally managed solely by HCID treatment centres, and could be managed at other hospital sites; however, by this date nearly 2000 patients had been admitted to hospital in the UK, far in excess of the capacity of the country's HCID network, or indeed the capacity of its specialist infectious diseases beds. It also meant that the previous HCID guidance on PPE no longer applied and was replaced by guidelines produced by the Four Nations IPC cell on March 13 2020. This guidance was based on that produced for pandemic influenza (as opposed to MERS-CoV, as was the basis for the HCID guidance).

- 6.8. As outlined to the inquiry by Peter Horby, chair of NERVTAG, during module 2, the declassification of Covid-19 as a HCID was likely sensible: "the purpose of the classification is to mitigate the risk of transmission... that only makes sense as a measure if there's not already widespread transmission of the virus. Once you have the virus in the community, then those measures make a lot less sense. In fact, they're counterproductive, because they inhibit your ability to manage patients and to do laboratory diagnostics".
- 6.9. Although decisions about the declassification of Covid-19 as a HCID and the guidance for adopting surgical masks instead of respirators for routine patient care appear to have been taken at the same time, it is not clear whether or not those decisions were directly related (transcript of UK Covid-19 Inquiry module 2 evidence of Professor Sir Jonathan Van-Tam, November 22 2023, p.226). It is the view of the authors of this report that the two issues are separate: at the point at which the decision was taken, it was entirely possible to declassify Covid-19 as a HCID and retain the need for enhanced PPE measures if considered appropriate.

Controversies surrounding the transmission routes of SARS-CoV-2 and the implications for PPE

- 6.10. As outlined in paragraph 1.21, in IPC guidance prior to the pandemic the major routes of transmission of respiratory pathogens through the air have largely been dichotomised into those spread by aerosolised particles (≤5 µm), and those by droplet particles (>5 µm). This has major implications for the type of PPE included in IPC guidance, as surgical masks were (and continue to be) recommended as the face covering for pathogens that are spread by droplets (including most endemic respiratory viruses, such as influenza and RSV), whereas respirators were recommended for pathogens that are spread by aerosolised particles (including tuberculosis and measles; see paragraph 1.46). However, there has been disagreement in the scientific and medical communities, and a changing evidence base during the course of the pandemic, related to:
 - Whether the simple size threshold of 5µm is accurate when considering which particles are aerosolised
 - Which medical procedures are at increased risk of generating aerosols (AGPs)
 - Whether aerosolised particles can be produced in the absence of AGPs (for example through talking, coughing, sneezing, and singing)
 - What is the contribution of aerosol transmission for Covid-19 in comparison to other routes in a hospital setting
 - How the above relates to implications for IPC guidance
- 6.11. Prior to the pandemic there was considerable controversy over the scientific basis of the definition of aerosolised versus droplet particles, and their relevance to the transmission of respiratory pathogens. This is detailed in the expert report from Prof Clive Beggs

(INQ000474276, para 113-127). Much of the evidence base for the route of transmission of respiratory viruses was based on studies of influenza. This evidence base is also reviewed in the expert report from Prof Clive Beggs (para 159-176). Like SARS-COV-2, influenza had been presumed to be spread predominantly via droplets rather than aerosols. However, Prof Beggs challenges this concept based on evidence produced both before and after the start of the Covid-19 pandemic.

- 6.12. Guidance on IPC issues in the NHS for pandemic influenza were provided by the Pandemic Flu Team, published in 2007 and updated in 2009 (Department of Health, 2009). These recommendations were based on the assumption that influenza transmission was predominantly via droplet spread, with increased risk from AGPs. They therefore recommended FRSM for routine clinical care, and respirators for AGPs.
- 6.13. However, even at this time, there was a difference in expert opinion on the efficacy of FRSMs in protection against influenza viruses. A study conducted by the Health and Safety Executive published in 2008 concluded that "*surgical masks provide around a 6-fold reduction in exposure. Live viruses could be detected in the air behind all surgical masks tested. By contrast, properly fitted respirators could provide at least a 100-fold reduction.*" (Health and Safety Executive, 2008)
- 6.14. Considerations on PPE for HCWs in the event of an influenza pandemic were discussed by the NERVTAG sub-committee on the pandemic influenza facemasks and respirators stockpile in 2016 (INQ000130548). While acknowledging the "thin" evidence base, at this time it was agreed that respirator use was not fully supported "by the evidence base for either transmission or respirator effectiveness". They also considered the challenges posed by the logistics of fit testing and training. It was agreed that respirators would be recommended for ICUs and HDUs classed as AGP "hot spots", but would otherwise only be recommended in ward areas when AGPs were being performed. FRSMs could be used for the majority of clinical care on normal wards, community, ambulance and social care settings. This guidance is comparable to that provided in national PPE guidance in March 2020, including the concept of AGP hot spots which, to the best of our knowledge, had not been recommended in other settings previously. The same report notes that respirators would be needed for all HCWs caring for patients with MERS-CoV, citing the high case fatality rate and occurrences of HCW transmission. However, the committee were of the view that the "virus does not have pandemic potential". Of note, The Healthcare Infection Society Working Group on Respiratory and Facial Protection recommended the use of respirators for the routine care of patients with SARS coronavirus, but FRSMs for the endemic coronaviruses, in a review published in 2013 (Coia et al, 2013).
- 6.15. A timeline summary of key scientific publications providing evidence that SARS-CoV-2 can be spread by aerosol transmission is provided in the expert witness statement from Prof Clive Beggs (INQ000474276, table 2). At the point that respirators were no longer recommended for routine care of patients with Covid-19 in the UK on March 13 2020, there were already two publications demonstrating high levels of SARS-CoV-2 RNA in the air from studies in China, suggesting that aerosol transmission may be occurring. By the end of the first wave in July 2020, this assertion was supported by further papers from various countries and settings demonstrating that: SARS-CoV-2 could survive for long

periods in the air in hospital settings; that it could transmit distances of up to 8m; aerosol transmission was likely based on epidemiological studies of outbreaks in community settings. The likelihood of aerosol transmission was also supported by experts from around the world who had reviewed the available evidence and concluded that the virus spreads in the air. This led to a letter published in the journal Clinical Infectious Diseases and signed by 239 scientists asking "the medical community and… the relevant national and international bodies to recognize the potential for airborne spread of COVID-19." (Morawska and Milton, 2020)

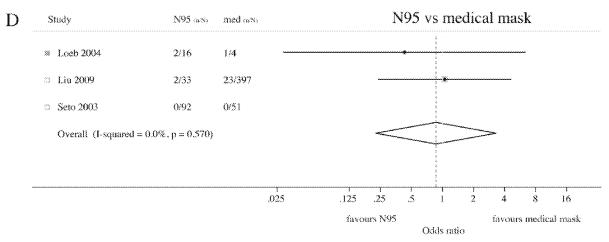
- 6.16. The initial IPC guidance for the novel coronavirus produced by PHE in January 2020 was derived from existing PHE guidance on MERS-CoV, which recommended the use of respirators for all HCWs entering the room of a patient with suspected or confirmed MERS-CoV (INQ000022734). Revised PHE guidance published on March 13 2020 (issued jointly by Department of Health and Social Care (DHSC), Public Health Wales (PHW), Public Health Agency (PHA) Northern Ireland, Health Protection Scotland (HPS) and Public Health England, based on recommendations from NERVTAG) recommended the use of surgical masks rather than respirators for HCWs caring for patients with Covid-19 on general wards. The cited rationale for this recommendation was:
 - "The transmission of COVID-19 is thought to occur mainly through respiratory droplets generated by coughing and sneezing, and through contact with contaminated surfaces. The predominant modes of transmission are assumed to be droplet and contact."
 - *"For SARS-CoV, evidence suggests that use of both respirators and surgical face masks offer a similar level of protection, both associated with up to an 80% reduction in risk of infection."*
- 6.17. The reference supporting this second statement was a systematic review and metaanalysis of studies to assess the protective effect of facemasks and respirators against respiratory infections among HCWs, published in 2017 (Offeddu et al, 2017). The specific analyses in this paper for SARS-CoV were based solely on observational studies, many of which provided insufficient detail on the PPE used to make a comparison of efficacy. A key figure from the publication summarises the results of this meta-analysis as a series of Forrest plots, which demonstrate:

A) any unspecified form of PPE significantly reduced the odds of SARS-CoV infection in comparison to no PPE (analysis of 16 observational studies)

B and C) medical masks and N95 respirators respectively significantly reduced the odds of SARS-CoV infection by around 80% in comparison to no PPE (analysis of 5 observational studies)

C) N95 respirators significantly reduced the odds of SARS-CoV infection in comparison to no PPE (analysis of 5 observational studies)

D) there was no statistically significant difference between N95 respirators and surgical masks (analysis of 2 observational studies) – shown in **figure 11** below.



- Figure 11: Meta-analysis from 2017 of two observational studies comparing the protective effect of N95 (equivalent to FFP2) respirators with medical masks (also known as surgical masks). Results from a third study are not included in the summary effect due to zero infections occurring. Adapted from (Offeddu et al, 2017)
- However, this final observation is based on only two observational studies of unclear quality, with a very limited number of HCWs in each comparison, and wide statistical confidence intervals. This raises concern for the low quality of evidence and, in turn, for the conclusions drawn. The authors clearly state that "*the existing evidence is sparse and findings are inconsistent within and across studies*". Other analyses of randomised control trials (RCTs) of medical masks versus respirators in the same paper showed that respirators were superior at preventing both symptomatic respiratory illnesses and confirmed viral respiratory infections for a range of respiratory viruses (including RSV, parainfluenza, and seasonal coronaviruses). However, they were not superior in a specific analysis of cases of influenza.
- 6.18. A revised version of PHE's main IPC guidance document "COVID-19: Guidance for infection prevention and control in healthcare settings. Version 1.1" published on March 27 2020 changes the wording of the evidence for the recommendation of surgical masks, outlining a more cautious appraisal of the Offeddu meta-analysis by stating that the "evidence base is sparse and indications (and compliance) for mask/respirator use in these studies varied" (INQ000251675_0008).
- 6.19. The first publicly available "Rapid review of the literature: assessing the infection prevention and management of COVID-19 in health and care settings", written by ARHAI and provided to the Four Nations IPC Cell, was published on April 3 2020. The process by which these reviews were produced is discussed in section 4 of our report. This first rapid review examined the evidence for the use of respirators in comparison to surgical masks (INQ000189371). It references the Offeddu et al systematic review, and again was critical of the quality of the data, commenting: "*The existing evidence base in the review was sparse and indications (and compliance) for mask/respirator use varied between the included studies*". The paper also references two observational studies of HCWs exposed to SARS-CoV-1. The first, (Seto et al 2003), asked infected and non-infected HCWs to retrospectively assess their compliance with PPE at times of caring for SARS patients. They found no cases in HCWs who reported consistent compliance with either surgical masks or respirators, and concluded that droplet precautions alone would be adequate to

prevent infection. However, the study is at high risk of recall bias, and its conclusions are based on only 13 HCW infections. The second study (Teleman et al, 2004) found that the use of respirators was protective for SARS-CoV infection, but there was no comparison with surgical masks. The ARHAI review notes that both studies are at risk of bias and confounding, as the use of PPE was self-reported.

- 6.20. A subsequent meta-analysis, focused on randomised control trials of respirators versus face masks but specifically reviewing infections with influenza, also found no statistically significant difference in protection of respirators and surgical masks (Long et al, 2020). However, there was an overlap in the trials included in this meta-analysis and that performed by Offeddu et al, leading to similar criticisms related to sample size and study bias that limit interpretation. Closer inspection of the analyses showed a trend in favour of respirators over surgical masks in many cases, even though these were not statistically significant. This analysis was used to support the UK's stance on the use of surgical masks for care of Covid-19 patients by the UK-based Centre for Evidence-Based Medicine on March 30 2020 (Greenhalgh et al, 2020).
- 6.21. The change in UK guidance in recommending surgical masks in place of respirators as the standard of care for patients with Covid-19 in general wards was consistent with contemporary WHO guidance (WHO, 2020a). However, guidance produced in other countries during the first pandemic wave (including China, Australia, the Centers for Disease Control and Prevention in the USA, and the European Centre for Disease Control) continued to recommend respirators (Thomas et al, 2020) (although Australia moved to surgical masks at a later date (ARHAI Scotland, 2022b), before returning to recommending respirators for all routine care of suspected or confirmed Covid-19 patients again (Australian Government, 2022)). An ECDC technical report (ECDC, 2020) published on March 12 2020 (the day before UK recommendations changed to surgical masks for routine care), states that "Although airborne transmission is not considered the principal transmission route, we recommend a cautious approach because of possible transmission through aerosols". For HCWs in contact with a confirmed or suspected case of Covid-19, they recommended PPE for contact, droplet and airborne transmission of pathogens, including respirators. A revised report on March 31 2020 takes into consideration potential shortages of PPE, and acknowledges the uncertainty surrounding the potential routes of transmission, but retains a preference for respirators: "The relative role of droplet, fomite and aerosol transmission for SARS-CoV-2, the protection provided by the different components of personal protective equipment (PPE) and the transmissibility of the virus at different stages of the disease remain unclear... With the exception of AGPs, it is unclear whether facial filtering piece (FFP) respirators (class 2 or 3) provide better protection than surgical masks against other coronaviruses and respiratory viruses such as influenza...Therefore, in the event of widespread community transmission leading to shortages of PPE, a rational approach would necessitate prioritising use of FFP2/3 respirators for care activities involving a higher perceived risk of transmission, such as during AGPs or in intensive care." The PPE guidance changed at this point stating that HCWs in contact with a suspected or confirmed Covid-19 case "should wear a surgical mask or, if available an FFP2 respirator tested for fitting". A further revision in July 2020 reverted to stating that a respirator should be used first line in this setting, with surgical masks used only in the event of respirator shortage.

- 6.22. As outlined in Prof Beggs' expert witness statement (INQ000474276 para 129-132), the question of whether SARS-CoV-2 could be spread by airborne transmission was considered on multiple occasions by NERVTAG, SAGE, and other groups advising on matters pertaining to IPC. Beggs describes the "*Covid-19 is not airborne' to Covid-19 is airborne' change that occurred in the scientific narrative*": initially, the major route of transmission was considered droplet spread, with a role for fomite and direct contact; this changed with the incrementally growing evidence base for aerosol transmission over the course of the pandemic. This shift in scientific evidence was known to those involved in guideline development, as reflected in witness statements from Susan Hopkins (PHE/UKHSA) and Catherine Noakes (SAGE EMG).
- 6.23. In July 2020, the role of aerosol transmission in Covid-19 was considered in a paper prepared by NERVTAG and the Environmental and Modelling Group, and presented to SAGE on July 23 2020 (INQ000212029). The authors state that this review was prompted by WHO guidance updates earlier that month that "in poorly ventilated spaces, transmission through an airborne route cannot be ruled out", and note that the WHO update itself may have been prompted by the previously mentioned letter signed by 239 scientists and published in Clinical Infectious Diseases (Morawska and Milton, 2020). The authors of the report to SAGE acknowledge the possibility of aerosol transmission of SARS-CoV-2, including in an indoor environment more than 2m from an infected person, and that this may play a role in superspreading events. The report includes evidence from a range of studies, including laboratory and animal studies, clinical settings, outbreak investigations and modelling studies, including some of the papers referenced by Prof Beggs. The wider use of respirators was considered, but not recommended: "Fit-tested FFP3 respirators provide a higher level of protection to the wearer against aerosol transmission. However the evidence that aerosol transmission is significant compared to other routes is not sufficiently strong to recommend that these are used in locations other than high risk clinical areas where aerosol generating procedures take place."
- 6.24. With the advent of the Alpha variant in December 2020, PHE members of the Four Nations IPC Cell advocated for a more precautionary approach to PPE for HCWs. They recommended sessional use of respirators for suspected and confirmed Covid-19 cases in non-AGP settings. However, the final consensus view of the IPC cell at that time was that there was no evidence that the alpha variant was transmitted by a different route, and that there was therefore no need to change the PPE recommendations (UK IPC Cell position statement on new variant INQ000348368) (Susan Hopkins statement INQ000410867 paras 325-326) (Lisa Ritchie statement INQ000421939 para 172). In making this statement, the IPC cell refer to supporting statements from the WHO, SAGE (INQ000212029), and the ARHAI rapid literature reviews.
- 6.25. As discussed in section 4, the rapid reviews of the scientific evidence produced by ARHAI, that formed a key contribution to the IPC Cell's national guidance, made little change over the course of the pandemic in their assessment of the risk of aerosolisation outside of the context of AGPs. In their final publication in April 2022, they conclude that there is *"limited evidence of traditional 'long range' airborne transmission"* and that *"there is no clear evidence from `in the field' studies that respirators offer any additional protection against coronaviruses"* (INQ000300661). However, there was a change in the

recommendation regarding PPE as of version 12 of the guidance published in March 2021, which states that "*Health workers may choose to wear FFP3 instead of fluid resistant IIR surgical face mask when caring for patients on lower-risk pathways*". While acknowledging that HCWs may want to increase the level of protection provided by PPE, this falls short of a full recommendation.

- 6.26. A paper titled "Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2", written by members of the Hospital Onset Covid-19 Working Group and Environmental Modelling Groups, was presented at SAGE on March 25 2021 (INQ000075022). This acknowledges the increasing evidence base for aerosol transmission. It advocates for measures to reduce the risk of transmission through source control (wearing of FRSM by patients and staff) and improved ventilation. However, "*if an unacceptable risk of transmission remains after rigorous application of the hierarchy of control it may be necessary to consider the extended use of RPE for patient care in specific situations*". The report recommends considering local risk assessment based on a variety of factors, including the likelihood of interaction with an infectious Covid-19 patient, the duration and proximity of exposure, the application of other IPC measures, likely adherence to fit testing and respirators, eye protection, ventilation, and overcrowding. However, the report also recognises the practical implications, including the "need to be accompanied by training, supply chain management, face-fit testing, monitoring and management oversight".
- 6.27. PHE convened an expert Respiratory Evidence Panel (REP) in February 2021 to critically assess the evidence behind SARS-CoV-2 transmission to inform their guidance and recommendations. In May 2021 they concluded that (statement at (UK Health Security Agency, 2021b), full evidence review at (INQ000348256):
 - 6.27.1. Airborne transmission beyond 2 metres was possible and that contributory factors to airborne transmission of SARS-CoV-2 include poorly ventilated indoor settings, prolonged exposure and activities that may generate more aerosols
 - 6.27.2. certain variants of concern (VOCs) were likely to have increased transmissibility, although the magnitude of reported increase varies by geographic region, modelling approach, relative transmissibility of concurrent circulating strains and current control measures in place
 - 6.27.3. the evidence to date suggests that the modes of transmission of VOCs has not changed compared to other variants, so it is expected that the same infection prevention and control measures should be appropriate, including ventilation, hand hygiene, face coverings and, in high-risk settings, respiratory personal protective equipment PPE
 - 6.27.4. epidemiological evidence (usually of low or very low certainty) from SARS-CoV-2 and other respiratory viruses suggests that, in healthcare settings, N95 respirators (or equivalent) may be more effective than surgical masks in reducing the risk of infection in the mask wearer

- 6.27.5. evidence, mainly from laboratory studies, suggests that face coverings should be well-fitted and cover the mouth and nose to increase effectiveness (as fit is a limiting factor in the overall mask protective efficiency independently of the filtration efficiency of its fabric)
- 6.27.6. there is a need for improved training (in health and care settings) and public health messaging (in community settings) on mask fitting (and quality in the community)
- 6.28. Based on the report from the REP, in May 2021 PHE produced a position paper recommending a more precautionary approach for HCWs caring for patients with suspected or confirmed Covid-19 in poorly ventilated areas, and that they should wear respirators as part of sessional use. In May 2021 the PHE position paper and REP paper were reviewed by the Four Nations IPC cell, who concluded that no change in guidance was necessary. However, in June 2021, national guidance produced by the IPC cell and published through UKHSA, made the recommendation that local risk assessments should be conducted, and respirators for routine clinical care could be used if "*an unacceptable risk of transmission remains*" following the application of the hierarchy of controls (paragraphs 1.41 to 1.42).
- 6.29. Concern regarding national guidance was raised by a number of professional bodies and other stakeholders. A summary of results of a member's survey from the Royal College of Physicians in May 2020 stated "much needs to be done to restore confidence in the scientific basis of the guidance" (Royal College of Physicians, 2020). In November 2020, a report from the National Audit Office highlighted concerns from NHS representative groups interviewed about PPE, commenting that "Clinicians lost confidence, fearing that guidance was changed because PPE was unavailable" (National Audit Office, 2020). In June 2021, a joint letter from the Royal College of Nursing, Unite the Union, GMB, Royal College of Speech and Language Therapists, British Dietetic Association, College of Paramedics, British Association for Parenteral and Enteral Nutrition, Fresh Air NHS and MedSupplyDriveUK was sent to parliament raising concerns that the provision of PPE was inadequate (British Association for Parenteral and Enteral Nutrition, 2021). In particular, they referenced the growing scientific evidence for airborne transmission, but an ongoing lack of provision of, and recommendation for, the use of respirators in routine care of Covid-19 patients. While they acknowledge contemporary updates to national guidance for respirators based on a risk assessment, they contended that: "the remainder of the guidance is unchanged so any assessment based on that guidance will still favour surgical masks for non–Aerosol Generating Procedure situations.... It is also clear that risk assessment is not realistic or practical for many situations that are unpredictable and where time is a critical factor e.g., when paramedics respond to an emergency call... In cases such as these, healthcare professionals cannot know how many people may be present, have COVID or suspected COVID, are vaccinated and whether they are unable to reduce risks in the care setting." The same letter was critical of a "serious lack of engagement with wider stakeholders and representatives of the health and care sector" and a "lack of clarity about who is responsible for determining IPC and PPE guidance".
- 6.30. The UK's IPC guidance, in particular the failure to acknowledge the airborne transmission of SARS-CoV-2, was also criticised by the British Medical Association (BMA 2022), and the Covid-19 Airborne Protection Alliance (Covid Airborne Protection Alliance, 2022).

- 6.31. However, there was also some support for national guidance in relation to HCW PPE. In August 2021, a review of the literature and recommendations for preventing SARS-CoV-2 acquisition, compiled by a Working Party (of infectious diseases/microbiology clinicians, academic IPC experts, systematic reviewers, and a lay representative) on behalf of the British Infection Association, Healthcare Infection Society, Infection Prevention Society, and Royal College of Pathologists, considered that while droplet transmission was probable, airborne transmission was only possible in some circumstances (e.g. AGPs). They concluded that "transmission most often occurs following close contact, especially where PPE is not worn... Even in these cases, transmission usually occurs during AGPs." They specifically recommend that respirators are not used unless carrying out AGPs. However, the evidence quoted in the paper includes seven studies which considered the possibility of airborne versus droplet transmission, four of which concluded that "airborne transmission was likely". It is therefore unclear how the authors reached the above conclusions. Also, the systematic review only contained papers up until May 11 2020, with additional papers published after this date considered in an ad hoc manner. The recommendation for surgical masks over respirators is based on their interpretation of the evidence that droplet spread was the predominant form of transmission; the only direct evidence referenced that face masks are non-inferior was the Long et al systematic review of face masks for influenza referenced above.
- 6.32. Changes to international guidance in 2021 were considered in the ARHAI rapid reviews (INQ000300661). They noted that recommendations to conduct local risk assessments in the consideration of respiratory PPE were present in both WHO and Australian guidance. In October 2021, WHO published an annexe to their IPC guidance that included a conditional recommendation stating that "respirators can be used instead of surgical masks based on HCW values and preferences about having the highest perceived protection possible to prevent SARS-CoV-2 infection". However, the ARHAI rapid review noted that this was based on expert opinion by the guidance development group having rated the certainty of the evidence base very low. Canadian guidance was updated in December 2021 to recommend the use of respirators for direct care of patients with confirmed/suspected Covid-19. Irish guidance was also updated to extend the use of respirators for all routine patient care. Again, the contemporaneous ARHAI review noted that there was no evidence or rationale provided as the basis for these changes.
- 6.33. In November 2022 the REP produced a paper updated with new evidence, but drawing a similar conclusion to previously, that: "*Epidemiological evidence (usually of low or very low certainty) from SARS-CoV-2 and other coronaviruses suggests that, in healthcare settings, N95 respirators (or equivalent) may be more effective than surgical masks in reducing the risk of infection in the mask wearer (low confidence).*"
- 6.34. On review of the evidence, the authors share the view that SARS-CoV-2 can be transmitted through the airborne route, and that acts including coughing, talking and breathing produce a sufficient aerosol to warrant the routine use of respirators while caring for patients with suspected or confirmed Covid-19. However, there is clear variability in the quality of this evidence, and in the way that it has been interpreted to produce IPC guidelines both within the UK and overseas. The relative contribution of each of the possible routes of transmission of SARS-CoV-2 (larger or smaller respiratory)

particles through the air, direct contact, via fomites) remains unclear (See Prof Beggs' report findings INQ000474276). Also, there clearly remains some disagreement in interpretation of the evidence base. For example, in her witness statement to this inquiry, Lisa Ritchie states "*My view regarding the evidence that aerosol transmission is significant compared to other routes is that this is not sufficiently strong to recommend that FFP3 respirators are routinely used in locations other than high risk clinical areas where AGPs take place. However, local risk assessments were recommended in the IPC guidance, and if deemed appropriate (residual risk), healthcare workers should have been provided with FFP3 respirators."*

- 6.35. While the weight of evidence at the time of writing (July 2024) is considerable, there remains a limited amount of high-quality trial evidence of the superiority of respirators over surgical masks in clinical settings. Observational studies have been published that demonstrate a benefit of respirators over surgical masks. For example, Ferris et al estimate that the risk of HCW Covid-19 infections from ward settings in one UK teaching hospital was reduced by 52-100% following the change from surgical masks to respirators for routine care of Covid-19 patients (Ferris et al 2021). While suggestive, the findings are limited by a simple "before and after" study design that is open to bias and confounding. Nevertheless, the authors are aware of a number of hospitals in England that routinely use respirators for routine care of patients with Covid-19.
- 6.36. It remains unclear to the authors from the limited information available in the public domain as to the rationale for the decision taken in March 2020 to move to surgical masks rather than respirators.
- 6.37. In addition, while respirators are likely to be effective at reducing the risk of HCW acquisition of SARS-CoV-2, it is unclear how much their widespread availability and implementation throughout the pandemic would have reduced the number of cases of Covid-19 in healthcare workers. This is due to:
 - The complexity of transmission networks involving HCWs in hospital settings, including transmission from individuals who were not known to have Covid (including other HCWs and pre-symptomatic/asymptomatic patients). This is explored in further detail in section 11.
 - Other factors involved in effective use of PPE that extend beyond the availability of respirators, including fit testing capacity (discussed in section 7), time and space for donning and doffing in routine clinical care, and the necessary training and education that is required (discussed in sections 10 and 12).
 - Variable compliance regarding the use of respirators. This is discussed in section 7.

Aerosol generating procedures

- 6.38. IPC guidance for SARS-CoV-2 throughout the pandemic has recommended the use of respirators for HCWs engaged in AGPs, which were considered to produce a higher risk of transmission than standard care (see paragraphs 1.36 to 1.39). However, the procedures that are considered AGPs, and the evidence base behind this assignation, have changed over the course of the pandemic.
- 6.39. The list of AGPs in the initial IPC guidance for the novel coronavirus produced by PHE in January 2020 was originally derived from guidance produced by WHO in 2007 and updated in 2014 (WHO, 2014a). The foundation for the WHO guidance was that certain procedures were associated with higher rates of SARS transmission, and that these procedures also had a theoretical risk of producing aerosols. The updated WHO guidance was based on a systematic review of procedures and their associated risk of pathogen transmission (Tran et al, 2012). In total, 10 observational studies were included in their review, all conducted on SARS-CoV-1. The procedures reported to present an increased risk of transmission included tracheal intubation (based on 8 studies), non-invasive ventilation (2 studies), tracheotomy (1 study) and manual ventilation before intubation of body fluids, bronchoscopy, nebulizer treatment, administration of O2, high flow O2, manipulation of O2 mask or BiPAP mask, defibrillation, chest compressions, insertion of nasogastric tube, and collection of sputum were not significant."
- 6.40. However, both the Tran et al systematic review and the WHO guidance from 2014 note that the quality of evidence for the studies on which the review was based were "very low quality" based on the GRADE evaluation framework. They acknowledge a "significant research gap" regarding the epidemiology of respiratory pathogen transmission from patients to HCWs during AGPs. Some of the limitations include: the overall small size of the cohorts studied; a reliance on retrospective self-reporting by HCWs; a lack of clarity on which aspect of a multi-step procedure placed the HCW at risk; potential alternative sources of HCW infection, for example from other procedures or aspects of patient care; not assessing compliance with PPE; unclear generalisability to pathogens other than SARS-CoV.
- 6.41. There has been little scientific consensus on which procedures are aerosol generating. A rapid review published early in the pandemic attempted to address how guidance documents and academic publications published before April 2020 had classified procedures as being AGPs or non-AGPs (Jackson et al, 2020). It identified a wider range of procedure groups considered AGPs than the WHO guidance above, including autopsy, surgery/postmortem procedures with high-speed devices, intubation and extubation procedures, bronchoscopy, sputum induction, manual ventilation, airway suctioning, cardiopulmonary resuscitation, tracheostomy and tracheostomy procedures, non-invasive ventilation, high-flow oxygen therapy, breaking closed ventilation systems, nebulised or aerosol therapy, and high frequency oscillatory ventilation. The authors note disagreements between sources on some procedure groups, including oral and dental procedures, upper gastrointestinal endoscopy, naso-gastric tube insertion, thoracic surgery and procedures, and nasopharyngeal and oropharyngeal swabbing. However,

this review did not re-analyse the data underlying the list of AGPs stated in each guideline, which they note were "*developed with varying degrees of scholarly rigour, and they were sometimes based on one another or based on common sources.*" The authors also acknowledge the increasing evidence base for coughing as a source of aerosolisation, which would have "profound" implications for PPE, "*especially since coughing is a common symptom of COVID-19*".

- 6.42. An international scoping report compiled by the Independent High Risk AGP Panel published in July 2021 (but prepared several months prior), highlighted a *"clear lack of consensus among countries regarding what is considered a high-risk AGP"*. The authors stated that this reflects the "sparse evidence landscape", and lack of standardised methods, and that the variation may be attributable to a reliance on expert opinion in the absence of evidence (Public Health England, 2021b). However, the list of AGPs in the UK was broader than most other countries (including lists compiled by the WHO and ECDC). Two exceptions, nebulisation and cardiopulmonary resuscitation (CPR), were present on the AGP lists of 5 or more countries but not on the UK list currently. Both were previously considered by the UK IPC cell, which concluded that they do not currently have a strong evidence base linking them with increased risk of infection transmission.
- 6.43. CPR is one example of conflicting guidance between the IPC cell and other professional organisations in the UK:
 - 6.43.1. Guidance on CPR is provided by the Resuscitation Council UK (RCUK). In a statement published on March 4 2020 and updated in April 2020, RCUK recommended that, in a cardiac arrest setting, *"Full Aerosol Generating Procedure (AGP) Personal Protective Equipment (PPE) must be worn by all members of the resuscitation/emergency team before entering the room… No chest compressions or airway procedures… should be undertaken without full AGP PPE"*.
 - 6.43.2. NERVTAG released a statement on CPR as an AGP on April 24 2020 (INQ000257933), based on work performed by Health Protection Scotland, that "The scientific evidence base is extremely weak and heavily confounded by an inability to separate out specific procedures performed as part of CPR, e.g. chest compression, defibrillation, manual ventilation and intubation." (Killingley, 2020) They refer to the Tran et al systematic review discussed above as the best available evidence that chest compressions and defibrillation were not significantly associated with an increased risk of SARS infection. As a result of this review, PHE did not add CPR to the list of AGPs in the UK.
 - 6.43.3. The RCUK's president subsequently raised concerns that CPR was not included in the list of AGPs provided in national guidance, stating that "*The absence of high quality evidence for this should not be interpreted as the absence of risk*", and that the difference between the RCUK and (PHE) guidance had caused "significant confusion" (Iacobucci, 2020). Anecdotal reports were made of variations in practice between hospitals in the UK, with some recommending the use of AGP-level PPE for all patients in cardiac arrest irrespective of the likelihood of Covid-19, while others used different cardiac arrest protocols depending on whether the patient was on a Covid or non-Covid ward (Thorne and Ainsworth, 2020).

- 6.43.4. An RCUK review of evidence in August 2022 cited the increasing evidence base for aerosol transmission of SARS-CoV-2, and continued to recommend "AGP PPE" (including respirators) when performing chest compressions on patients with suspected or confirmed Covid-19 in healthcare settings (Resuscitation Council UK, 2022).
- 6.44. There has been criticism of the UK's guidance on AGPs from other stakeholders. This is demonstrated in the witness statement of Dr Barry Jones (INQ000273913), chair of the Covid-19 Airborne Transmission Alliance (CATA). CATA's membership originates from the creation of the Aerosol Generating Procedures Alliance (AGPA) in August 2020, and would later include a range of professional associations representing a number of medical specialties, nurses, allied health professionals, and infection and respiratory specialists. AGPA, and subsequently CATA, were critical of the decision to move to FRSMs for routine care of patients with Covid-19, and of the official list of designated AGPs in national IPC guidance, on the basis of evidence that aerosols are produced by activities including coughing, talking and breathing. The statement from Dr Jones provides CATA's position on the evidence base for airborne transmission of SARS-CoV-2, the potential risks of the UK's IPC and PPE guidance to HCWs, and the role that AGPA/CATA and its members have played in advocating for changes to guidance.
- 6.45. Partly as a response to the concerns raised by professional organisations, the Independent High Risk AGP Panel, a group of IPC experts, reviewed medical procedures that did not meet the WHO definition for high risk AGP recommendations in late 2020, and published their findings on January 11 2021 (Public Health England, 2021b). The procedures included in the review were: nasogastric tube insertion, cardiopulmonary exercise and lung function tests, spirometry, swallowing assessment, nas(o)endoscopy and suction in the context of airway clearance (not associated with intubation or mechanical ventilation). It concluded that the available evidence was not currently robust enough to demonstrate that these procedures generate significantly more aerosols than other types of care, or that exposure to the aerosols results in infection. The authors were cautious to exclude the possibility of transmission from these procedures: "*Given the limited range and poor quality of the evidence, with many studies underpowered or vulnerable to bias and confounding, it is not possible to distinguish the absence of risk from the absence of evidence.*" However, the authors did not advise that any of these procedures be added to the existing UK AGP list.
- 6.46. Studies were conducted during the pandemic that have improved the evidence base surrounding AGPs. A series of publications from the UK-based AERosolisation And Transmission Of SARS-CoV-2 in Healthcare Settings (AERATOR) study aimed to investigate the amount and type of aerosol generated when medical procedures are performed, and how infectious this aerosol is. The potential AGPs studied included:
 - 6.46.1. Continuous positive airway pressure (CPAP) and high flow nasal oxygen (HFNO) (Hamilton et al, 2022). Healthy volunteers were recruited to breathe, speak and cough in ultra clean operating theatres, followed by using CPAP and HFNO. Aerosol emission was measured using two different methods. In addition, hospitalised patients with Covid-19 had cough recorded using the same methodology on the infectious diseases ward. They found that coughing was

associated with the highest aerosol emissions of any recorded activity. CPAP produced less aerosol than breathing, speaking and coughing. Aerosol emission from the respiratory tract does not appear to be increased by HFNO.

- 6.46.2. Tracheal intubation and extubation (Brown et al, 2021). Aerosol emission was measured in relation to patients undergoing procedures requiring general anaesthesia with tracheal intubation in an operating theatre. Tracheal intubation produced very low quantities of aerosolised particles. Tracheal extubation, particularly when the patient coughed, produced a detectable aerosol which was 15-fold greater than intubation but 35-fold less than a volitional cough.
- 6.46.3. Facemask ventilation. Aerosol emission was measured from patients during normal breathing in comparison to when receiving face mask ventilation in an operating theatre. The aerosol concentration detected during facemask ventilation was considerably lower than that of normal breathing and coughing.
- 6.47. Additional studies were conducted on a wider range of therapies and oxygen delivery devices. Wilson et al measured aerosol generation from 10 healthy volunteers (Wilson et al, 2021). In comparison to quiet breathing, particle counts increased 34.6-fold during talking and 370.8-fold during coughing. By contrast, high-flow nasal oxygen increased particle counts 2.3-fold during quiet breathing. Non-invasive ventilation with quiet breathing increased counts by 2.6-fold to 7.8-fold.
- 6.48. A rapid review of AGPs, conducted on behalf of the UK IPC cell by an expert panel including members of the AERATOR study group, was published in June 2022 (NIHR AERATOR team, 2022 (INQ000130583)). The review included 37 studies, including those above, and critically appraised the evidence related to the UK's list of AGPs. Based on this evidence they recommended that: intubation and extubation, manual facemask ventilation, non-invasive ventilation and HFNO be removed from the UK's AGP list; that dental, sinus, upper respiratory tract and ENT procedures, and upper gastrointestinal endoscopy remain on the UK AGP list; there was insufficient evidence to make recommendations on tracheostomy insertion and bronchoscopy, and no studies that examined high frequency oscillatory ventilation (HFOV), induction of sputum using nebulised saline, respiratory tract suctioning, or post-mortem procedures.
- 6.49. The authors of this review note a number of limitations of the underlying studies (including the risks of bias and confounding, varied methods and outcomes, and the predominant study of patients not infected with a respiratory virus). They also acknowledge the limitations of rapid review methodology, as discussed in section 4 of this report. However, their recommendations are referenced in the current NIPCM, including the removal of the procedures listed above.

6.50. In the discussion of the review, the authors note that:

"For many of the reviewed procedures, the aerosol generated by natural respiratory activities exceeded that produced by the actual procedure, often by more than an order of magnitude. It is further apparent that the source of the detected aerosol in several of the AGPs that do generate increased aerosol (such as, upper gastro-intenstinal [sic] endoscopy) is predominantly from the patient's own respiratory activities (i.e., coughing) rather than from the actual procedure."

7. Adverse effects of PPE and challenges with frontline implementation

(Lead author: GYS)

Adverse effects of masks

- 7.1. The use, especially the prolonged use, of respirators and surgical masks had potential adverse effects. FFP3 masks, whilst necessary to protect healthcare workers from Covid and other infections, are uncomfortable. This is especially true with prolonged, daily use.
- 7.2. Adverse effects of respirators included increased fatigue and lower exercise tolerance. The filtering element of FFP3s limits breathing compared to working without a mask. The FFP3 mask is a physical barrier to breathing in and out freely. In short, breathing with FFP3 masks requires more effort and more energy.
- 7.3. Even simple FRSM limit breathing, albeit to a lesser extent. It is generally more comfortable for NHS staff, or anyone, to not wear a mask at all.
- 7.4. The discomfort and local irritation caused by prolonged mask wearing have been reviewed and summarised by (Greenhalgh et al, 2024). Pressure from the mask could result in local irritation to the skin and eyes and contact dermatitis. Headaches were also frequently reported.
- 7.5. As FFP3 masks usage became more widespread during the pandemic, there were reports of facial pressure ulcers on healthcare staff. This was particularly noted on the bridge of the nose, where a piece of flexible metal was incorporated in the mask design, to allow a tight fit (Kwasnicki et al, 2022). Pressure-related skin injuries were noted elsewhere on healthcare workers' faces, such as their cheeks.
- 7.6. A pressure ulcer has differing degrees of severity but is an injury to the tissues due to prolonged pressure on specific areas, in this case the nose. In the worst cases, the skin and underlying tissues can break down and is then at risk of infection. This is a painful and disfiguring condition. The problem was exacerbated because sessional use of PPE had been recommended during the first wave. This meant that mask wearing continued for an entire shift, for up to 12 hours.
- 7.7. In the early stages of the pandemic, when Covid-19 was classified as a HCID, the recommended PPE included:
 - FFP3 masks
 - Eye protection such as goggles or safety glasses and/or full-face visors
 - Fluid-repellent gown
 - Disposable non-sterile gloves

- 7.8. This combination of PPE would be uncomfortable if used for prolonged periods. The fluidrepellent gown is not breathable, and is similar to wearing a full-body waterproof coat. Reports of dehydration amongst staff were common, as this PPE led to the wearer feeling hot and it made staff sweat and therefore lose fluids. The dehydration of staff in full Covid-19 PPE, for example in the intensive care unit (ICU) setting was measurable by loss of weight (Rojo-Rojo et al, 2022). Dehydration is undesirable in general. For healthcare workers looking after sick Covid-19 patients, the dehydration would only add to the sense of fatigue and stress.
- 7.9. The best countermeasure would be to drink plenty of fluids at work, as often as possible. However, given the complexity of the PPE, donning and doffing is a complicated and time-consuming ritual, so it would not be easy to take regular hydration breaks and maintain continuity of care. We know of anecdotal evidence from some NHS Trusts in England that in practice, shifts in areas where Covid-19 PPE was required were broken up into 2-hour blocks, with another team relieving the previous one. This was a pragmatic measure to reduce dehydration and fatigue of ward staff.
- 7.10. A study by Dovey et al. conducted in 2020 looked at the health effects of Covid-19 related PPE ensembles (face mask; facial visor; gloves, plastic apron +/- fluid resistant gown). Although the samples size of NHS staff was limited (n=224), we believe the findings are typical and resonate with our experiences in our own hospitals. In summary, respondents found that wearing the PPE ensemble led to physical and cognitive impairment manifested as increased fatigue, headaches and decision making/problem solving performance declined. The conclusion was that the wearing of this PPE, especially for prolonged periods, was associated with risk of heat stress (Davey et al, 2021).
- 7.11. Non-sterile disposable gloves are manufactured from nitrile, polyvinyl chloride or latex. Prolonged use can result in dermatitis which can be severe (Royal College of Nursing report 2022). Allergy is possible to the glove material or to the powder used in some brands to encourage ease of donning. Dermatitis resulting from prolonged glove use exacerbates the skin damage caused by frequently cleansing hands throughout long shifts.

Adverse effects of respiratory hoods

- 7.12. As noted in paragraphs 1.68 to 1.72 above, the filtered, powered hoods (PAPR) were essentially helmets, covering the head and neck. They are bulky and some designs are rigid and/or heavy, often associated with boxed power supply, which adds to the weight. The built-in ventilation system may be noisy. The noise from the mechanical element of the PAPR, and the hood/helmet would make verbal communication difficult.
- 7.13. The deleterious impact of PAPR on user hearing and communication was studied by Weiss et al, using a human-sized laboratory model with precise audiometric measurement data. Whilst acknowledging the protective efficacy of PAPRs, the authors raise concerns about the potential risks of reduced verbal communication in acute healthcare settings, where good and timely communication between team members is essential (Weiss et al, 2021).

- 7.14. PAPR should be cleaned after each use, as per local IPC guidelines and/or in line with PAPR manufacturer's instructions. There is evidence, that even after use of IPC-approved PAPR cleaning procedures with disinfectant wipes by staff familiar with PAPRs, there is a risk of microbial contamination by bacteria and fungi. PAPRs are complicated and expensive pieces of equipment with many components. Although in a 2021 British study by Chakladar et al. found only commensal (normally occurring on human skin) bacteria and environmental mould, the study shows how difficult it is to thoroughly disinfect PAPR. Reassuringly, they did not detect SARS-CoV-2 RNA by PCR (Chakladar et al, 2021).
- 7.15. In summary, the PAPR respiratory hoods, whilst necessary to protect certain staff from the risk of nosocomial Covid-19 infection, are uncomfortable and impair communication between staff. In addition, even when cleaned with disinfectant wipes, PAPRs may carry a risk of harbouring contaminating bacteria and fungi.

Challenges faced in the implementation of fit-testing for respirators

- 7.16. Early in the pandemic, Covid-19 was classified as a high consequence infectious disease.
- 7.17. When the pandemic hit the UK and the scale of the challenge became clear, most if not all acute NHS hospitals began targeted FFP3 respirator fit-testing. Areas thought most likely to see and look after Covid-19 included Emergency Departments, acute medical wards, infectious diseases wards, critical care units (intensive care units and high-dependency units) and staff in these areas were prioritised for FFP3 fit-testing initially. However, as the first wave of Covid-19 hit in the first half of 2020, the volume of Covid-19 hospitalisations necessitated a much wider roll-out of FFP3 fit-testing for many patient-facing NHS staff. This was a sea-change from the pre-pandemic situation of fit-testing only for staff in a few specific areas only.
- 7.18. For many NHS staff, this was their first experience of the use of respirators and fit-testing. At an already stressful time, the need to be fit-tested was another unfamiliar complexity for thousands of NHS staff.
- 7.19. Many patient-facing NHS staff who worked in the NHS during the 2009-2010 Influenza A (H1N1) pdm09 "Swine Flu" pandemic, would have been fit-tested for respirators in 2009/10. However, this would have been a distant memory, and the fit-testing would need to be updated.
- 7.20. Apart from the steep learning curve for many NHS staff, the challenge in implementation was largely logistical.
- 7.21. Fit-testing must be delivered face-to-face, using personnel trained to perform fit-testing, with specialist equipment and potentially several different mask types. At the outset of the pandemic, staff trained to perform fit-testing were few and far between. Across the NHS, more NHS staff had to be rapidly trained to be competent Respirator fit-testers.

- 7.22. Larger NHS hospitals could have thousands of patient-facing staff and fit-testing each one was a huge undertaking. Many larger NHS hospitals are based on multiple sites, which meant that training had to be delivered on each site, stretching the limited training resources. Alternatively, if the fit-testing resource was so limited it had to be delivered in one location only, staff would have to travel to the fit-testing site. This was inefficient and took clinical staff away from their usual ward, clinic, or other place of work, just as the NHS was being stretched by the rising tide of Covid-19.
- 7.23. As in other aspects of pandemic response, there may have been areas, including devolved administrations which had better-resourced fit-testing infrastructure than other regions of the UK.
- 7.24. Another significant logistical challenge to massively scaling up PPE deployment was procurement of large quantities of respirators, almost certainly of different brands. As Covid-19 spread across the world in 2020, global demand for respirators and other PPE surged. Most, if not all, NHS hospitals would have had to procure multiple brands of respirators simply to ensure that they had sufficient supplies, let alone a sufficient variety of masks to achieve satisfactory fit-testing for their workforces' differing facial shapes and sizes. We recognise that PPE logistics varied across the UK. We understand that in some parts of the UK, PPE supply was more centralised than in others. We cannot comment with any authority on the specific PPE supply arrangements or challenges in any UK region outside of our own and understand that this will be further investigated in module 5 of the Inquiry.
- 7.25. The fit-testing of hundreds, if not thousands of clinical staff in each NHS hospital would have taken a great deal of organisation, planning and resourcing:
 - Procuring various respirators in sufficient quantity, and in continuous supply
 - Procuring fit-testing equipment and/or services, either provided in-house by NHS staff or procured from external providers such as quantitative fit-testing services.
 - Identifying qualified fit-testers
 - Training additional fit-testers
 - Purchasing fit-testing services from qualified external contractors where required
 - Identifying locations where fit-testing can be carried out
 - Establishing an appointment system for staff
 - Establishing a robust record of the fit-testing, to record which respirator type and size fit each member of staff accurately
- 7.26. Procurement and security of supply chain of PPE is not an IPC matter directly, but the safe implementation of PPE to protect NHS staff depends upon robust supplies of a range of respirator types over the duration of the pandemic.

- 7.27. The huge scale of PPE purchasing and distribution would have been challenging, albeit not for NHS hospital IPC teams. NHS procurement managers spent very significant amounts of their time on managing PPE.
- 7.28. The massive scale up of FFP3 fit-testing across the NHS revealed an unexpected finding. Existing commercially available FFP3 respirators did not fit the diverse NHS workforce well. The NHS has a diverse workforce in terms of ethnicity and gender, more diverse than the general UK population (Garratt 2024). For example, 88% of NHS nurses were female and 63% of nurses and health visitors are White, lower than the UK working population average of 80%. (as of October 2023). During the pandemic, evidence emerged that existing FFP3 respirators did not fit certain female and Black Asian Minority Ethnicity (BAME) NHS staff well (Cruz et al, 2022). This topic is also covered in the Inquiry's expert report on intensive care by Dr Suntharalingam and Prof Summers (INQ000474255) paragraphs 208 and 209.

8. Visiting guidance

(Lead author: GYS)

- 8.1. Hospital admissions are stressful events, even if elective. The ability to receive visits by family and friends is important for patients' mental health and wellbeing. Visitors can also help with essential care activities like assistance with feeding, often more effectively than staff in the hospital who may never have met the patient before, enabling healthcare staff to spend more time on other tasks. In addition, those close to the patient are often seasoned experts by experience in the patient's condition, and can significantly improve communication with healthcare staff about the person's needs and preferences.
- 8.2. For these reasons, in normal circumstances all NHS hospitals permit visiting, with arrangements like specified visiting hours. These will vary by hospital and also may vary by type of ward and the discretion of senior ward nursing staff. Maternity units will not have specified visiting hours because the mother-to-be's partner or support person will often accompany them and normal deliveries happen at any time of the day or night.
- 8.3. Some of the reasons why visiting hours are controlled is to allow patients to rest at night, to minimise noise and disruption on hospital wards and to reflect lower levels of staffing overnight. In some hospitals and wards, visiting hours may be designed to facilitate fixed ward activities like medicine dispensing rounds, which are usually led by nursing staff, and meal times for inpatients.
- 8.4. There are usually different arrangements for paediatric inpatient wards, including neonatal intensive care units. Many paediatrics wards make provision for a parent to stay with their child either in the same room, or in dedicated parental accommodation on or near the paediatric ward.
- 8.5. Therefore, the principles of controlled visiting to NHS hospitals were established prior to the pandemic. This includes also special arrangements for specific types of patients and during incidents like ward outbreaks. These principles were applied in the pandemic, although in general the restrictions were greater, due to the increased risk of hospital-acquired infections.
- 8.6. Visitor restrictions were an option in certain situations like outbreaks long before the Covid-19 pandemic. In some viral outbreaks on hospital wards, visiting restrictions could be considered by the IPC team managing the outbreak. Such restrictions are never applied lightly. Examples of infections which may warrant visitor restrictions include Flu outbreaks, norovirus outbreaks and measles outbreaks.
- 8.7. There is evidence preceding the Covid-19 pandemic that planned visitor restrictions can reduce seasonal respiratory virus transmission in certain inpatient settings like hospital neonatal intensive care units. One study looked at the effect of restricting visitors e.g. to parents of neonates only between 2007 and 2013. This encompassed the 2009-10 H1N1 "Swine Flu" pandemic of 2009-2011 (Szatkowski et al, 2019).

- 8.8. During the pandemic, NHS hospitals followed national guidance on visiting. For example, NHS Trusts in England followed visiting guidance issued by NHS England. This visiting guidance outlined general principles for visitors, for example what type of PPE they could be asked to wear. It also stipulated that visitors with Covid-19 symptoms should not visit hospital inpatients. The latest published version (version 5) was issued in June 2022 (NHS, 2022b, INQ000409940). Comparable guidance was prepared by all 4 nations, but varied in the exact advice provided and the timing that this guidance was released.
- 8.9. In order to reduce the risk of hospital acquired (nosocomial) Covid-19 infection, visiting of NHS hospital inpatients was restricted to varying degrees during the pandemic. NHS hospital visiting guidance evolved over the course of the pandemic. It also fluctuated during the pandemic in response to the variations in Covid incidence. In general, as Covid incidence increased, visitor restrictions were tightened and vice versa.
- 8.10. NHS visiting guidance was issued for specific patient groups, as the pandemic evolved. One example was NHS England visiting guidance for hospital maternity services. This made provision for the mother to have a partner or support person present during the birth of her child in hospital. Whilst this guidance supported the partner or support person to be present during delivery, it also said the support person should not attend hospital if they had Covid-19 symptoms. This guidance was first published in December 2020. The latest version (version 2) was issued in June 2022 (NHS, 2022a).
- 8.11. Ward outbreaks of Covid-19 also led to local, ward-level restrictions on visiting. This was to avoid/reduce the risk to visitors, but also to reduce the risk of further introductions of Covid from the community. However, the cessation of visiting during Covid-19 outbreaks was not absolute. For example, even in the face of a Covid-19 outbreak, visiting was permissible for patients at the end of life, at least in the latter phases of the pandemic, when mass vaccination had begun.
- 8.12. Another scenario when visiting was permitted for Covid-19 positive patients is for patients with certain conditions, such as dementia, when a familiar face of a relative helped reduce confusion and distress.
- 8.13. Even on wards without an outbreak, visiting was limited by social distancing rules, when these were in force nationally and across the NHS. In practice, this meant visiting was limited to one visitor per patient at a time. In the 2022 NHS England guidance, two visitors are permitted by the bedside of each inpatient. Individual NHS hospitals may have implemented systems to manage visiting such as an appointment system.
- 8.14. The extent and consistency with which these restrictions were, and should, be put in place across different clinical areas is unclear. We assume that most, if not all NHS hospitals followed relevant national NHS visiting guidance in the four nations. Exceptions to visiting restrictions, for example for patients who are in the last days of life, paediatric patients, or those with complex care needs, have been permitted by national visiting guidelines and were implemented with some local variation during the pandemic in the UK.

- 8.15. When national pandemic guidance required the use of surgical face masks in enclosed spaces, this was mirrored in NHS hospitals. FRSM would be the recommended PPE for visitors, regardless of whether the patient they were visiting had Covid-19 or not. The only feasible PPE for visitors is FRSM. There was no question of training visitors to wear respirators. The reasons for this included: the need to preserve FFP3 respirator supplies for NHS staff looking after Covid patients and/or at risk due to AGPs; lack of resource for FFP3 fit-testing a resource intensive and time-consuming activity, and a service already stretched by the need to fit-test large numbers of NHS staff and public acceptability of the uncomfortable, tight-fitting FFP3 masks. Masks also impede non-verbal communication between visitors and their relative or friend in hospital. The effect of this is hard to quantify.
- 8.16. One modelling study reviewing a range of interventions introduced during the first wave of the pandemic concluded that sustained visiting restrictions were likely to have reduced nosocomial transmission, but its implementation was likely of less impact than other IPC measures such as universal mask wearing and isolation of infected HCWs (Evans et al, 2024).
- 8.17. However, a number of studies have been published demonstrating the negative impact of visitor restrictions for patients, family members and loved ones, and the provision of care. The following quote, from a review published in 2021, shows the breadth of concerns raised in 17 papers across a range of health and social care settings (Hugelius et al, 2021):

"Among physical health consequences, reduced nutrition intake, decreased activities of daily living and increased physical pain and symptoms were reported. Among mental health consequences for the patient, loneliness, depressive symptoms, agitation, aggression, reduced cognitive ability and overall dissatisfaction were observed. For family members, worry, anxiety and uncertainty occurred, and they reported an increased need for information from care providers. Family members of neonatal intensive care unit patients reported less bonding with their child and family relation disturbances due to the restrictions. For care providers, visiting restrictions added the burdens of ethical dilemmas, learning new technical means to enable social interaction and an increased demand for communication with families and providing social support to both family members and patients."

- 8.18. The balance of risk and benefits of visitors to healthcare settings in the context of a pandemic is therefore complex, and for many issues will be specific to context, and potentially even individual situations. This makes overall guidance and consistency in visitor policy across the NHS challenging. A full analysis of the issues is beyond the scope of this report. However, we are aware of the importance of this issue and would strongly support further research into this area, including:
 - 8.18.1. Quantifying further the risks and benefits of visitors in specific situations, to ensure that informed decisions can be made in future pandemics.
 - 8.18.2. When visiting is deemed appropriate or essential, improving methods to reduce the risk of transmission. This could include optimal use of PPE for visitors and patients,

or other methods, such as social distancing that is adapted to the hospital environment.

8.18.3. When more stringent visiting restrictions are required, how alternatives to face to face visiting can be utilised most effectively (Moss et al, 2021). There were many examples of the use of technology for this purpose during the pandemic, locally at first and then nationally, as mentioned in NHSE visiting guidance. Inpatients could keep in touch with family and friends on smartphones and/or tablet devices, including devices purchased by NHS hospitals in some cases, with wi-fi connectivity. Whilst no substitute for face-to-face visitors, this connection by phone or video-call was beneficial to both inpatients and their loved ones. Other measures that have been used include: more frequent telephone updates from clinical teams to the patient's next of kin;

Summary

- 8.19. Visiting of hospital inpatients is an important activity from the perspective of both patients and their relatives. It has important psychosocial benefits at a stressful time. Visiting has a long history of being controlled to some degree, long before this pandemic. The Covid-19 pandemic led to varying degrees of visitor restrictions being applied across the NHS. The NHS followed national guidance issued by the relevant NHS lead agencies in each of the Four Nations of the UK e.g. NHS England. The restrictions were intended to protect both inpatients and their visitors from the risk of nosocomial Covid-19, which was circulating widely in the community for the relevant period of the Inquiry. From a visitor's perspective, NHS hospitals had large numbers of Covid-19 infected inpatients and entering NHS hospitals carried risk, which is hard to quantify and communicate.
- 8.20. Balancing the infection prevention and control risks with the need to support hospital visiting was not easy. Visiting guidance was influenced over the course of the pandemic by increasing knowledge of the virus, its transmission characteristics, community prevalence and to an extent, the UK vaccination programme. Some of the visiting restrictions were mitigated by using smartphones and tablet devices to facilitate videocalls, including for patients who did not own such devices.
- 8.21. Visiting guidance was generally liberalised over the course of the relevant period and broadly reflected loosening of public health restrictions in society as a whole. We are aware there was significant lobbying of various NHS organisations to ease visiting restrictions and this debate was sometimes played out in mass media.
- 8.22. Overall, taking into account the exceptions made for special circumstances like end-of-life care, maternity services, patients with cognitive impairment or additional care needs, and paediatrics and the fact that visiting guidance evolved to be more flexible over time, we believe a reasonable balance was struck, but with variation in local practice that contributed to differing experience. It is unlikely any iteration of visiting guidance would satisfy all relevant stakeholders who have very different priorities and responsibilities. Further research is required in this area to provide optimal guidance in future pandemics.

9. Other IPC measures

(Lead author: BW/GYS)

- 9.1. A variety of interventions were introduced into healthcare settings to reduce transmission of SARS-CoV-2. While widely implemented, there is considerable variation in the breadth and quality of the evidence underlying these measures. Based on studies up to the end of January 2021, a systematic review of IPC interventions to reduce the nosocomial transmission of SARS-CoV-2 other than PPE found no high-quality evidence for any interventions (Jafari et al, 2022). A modelling study attempting to quantify the impact of IPC interventions during the first wave of the pandemic found a paucity of evidence around a range of commonly used interventions, such as hand hygiene, or a wide degree of uncertainty around the effectiveness of other interventions, such as masking. Similarly, there is little evidence on the compliance with any of these interventions in real world settings (Evans et al, 2024). However, various guidelines, reviews, and opinion pieces have been published that support the interventions detailed below.
- 9.2. Whatever their individual contribution, it is likely that a combination of approaches was effective in reducing transmission. A modelling study from authors affiliated with UKHSA estimated that the combination of interventions used to reduce nosocomial transmission from March 2020 to July 2022 averted 400,000 infections in inpatients and 410,000 HCW infections (Evans et al, 2024). It is therefore highly likely that a combination of approaches will be needed in any future pandemic to have the maximum impact on hospital acquired infections.

Testing patients on admission and at intervals during inpatient stay

- 9.3. One of the urgent strategic responses to the pandemic was the development and deployment at scale of sensitive, accurate tests for Covid-19. The capacity for Covid testing by sensitive polymerase chain reaction (PCR) tests increased across the NHS throughout the pandemic, beginning in early 2020. The term "sensitive" as used here means a diagnostic test with a relatively low number of false negatives. PCR tests tended to be more sensitive than lateral flow tests, though this is a complex topic that is also dependent on the time during an infection when someone is tested, and also has to bear in mind the number of false positives, true positives, and true negatives.
- 9.4. PCR is an inherently sensitive laboratory diagnostic methodology, which has been in use in medical laboratories in a wide range of pathology disciplines, including virology and microbiology, for decades now. The sensitivity i.e. the ability to detect the target entity under investigation is the ability to detect the target. The higher the sensitivity, the greater the ability to detect the target, such as specific RNA sequences of SARS-CoV-2, Influenza A, RSV etc. PCR is sensitive because the polymerase chain reaction amplifies the target RNA by a series of thermal cycles and chemical reactions. After amplification of RNA (or DNA), the assay looks for its target.

- 9.5. Lateral flow tests, also known as lateral flow devices (LFD) for detection of SARS-CoV-2 viral proteins in nose and/or throat swabs. These work on similar principles to a pregnancy test and the physical format is similar. The advantages of LFDs are that they are relatively inexpensive, user-friendly (and designed to be usable by members of the public), rapid (with results in less than 30 minutes), and deployable at large scale, limited only by supplies of the LFDs. They are also most accurate at picking up the most infectious patients with the highest viral load. This made them an attractive option for many use-cases in the pandemic.
- 9.6. However, LFDs also lack sensitivity compared to PCR. The assay detects SARS-CoV-2 proteins (antigens) without any amplification. There was a huge proliferation of types (brands) of Covid-19 LFD during the pandemic. In general, LFDs are less sensitive than PCR, but the performance of different LFD test kits varies, sometimes considerably. One of the earliest systematic reviews of SARS-CoV-2 LFD performance compared to PCR was conducted by Mistry et al, 2021. This review of 24 papers on this subject revealed wide variation in sensitivity, from approximately 37% to 99% sensitivity, compared to SARS-CoV-2 PCR (Mistry et al, 2021). Opinions amongst experts do differ here, but we are of the view that LFDs are not generally appropriate for hospital IPC.
- 9.7. From an IPC perspective it was of vital importance to quickly identify Covid-19 in our patients to facilitate effective isolation of Covid patients, either alone in a single room, or together in the same hospital bay or ward. Cohorting of infected patients is not a new practice. It was also used during previous winter flu seasons and would have been necessary in NHS hospitals with limited isolation capacity. Cohorting of patients with the same infection is done to reduce the risk to other inpatients.
- 9.8. Testing is especially important where a diagnosis based on symptoms and signs alone (a "clinical diagnosis") is difficult. The most common symptoms of Covid were fever, cough and/or shortness of breath. These are typical symptoms for a respiratory viral infection like flu, or a bacterial pneumonia. However, a substantial proportion of patients present with a range of other symptoms, including gastrointestinal symptoms or headaches. This is especially true for elderly patients with Covid-19, who may just present with drowsiness and reduced mobility. The diagnostic accuracy of symptoms for Covid-19 is moderate to low and any testing strategy using symptoms as selection mechanism will result in both large numbers of missed cases and large numbers of people requiring testing (Struyf 2022). Anecdotally, we are aware that this did happen early in the pandemic, when many patients did not meet the case definition so were not tested during times of testing scarcity. They may have come to harm or passed on the infection to others as a result.
- 9.9. Making a diagnosis of Covid-19 based purely on clinical grounds, such as symptoms, was also unreliable for much of the pandemic because its symptoms of fever, cough and/or shortness of breath were common to many other respiratory viruses like influenza A or B, RSV etc. Bacterial respiratory tract infections like pneumonia due to *Streptococcus pneumoniae* may also present with a combination of fever, cough and shortness of breath.
- 9.10. There was one exception to this: anosmia, a loss of sense of smell and/or dysgeusia, a loss or reduction in sense of taste. In 2020/21, patients presenting with any combination

of fever, cough, shortness of breath plus anosmia and/or dysgeusia would be suspected to have Covid-19 infection on clinical grounds. Some patients with Covid-19 can present with sudden onset anosmia on its own. Anosmia in Covid-19 is reviewed by Karamli et al 2021 (Karamli et al, 2021).

- 9.11. We therefore rely on diagnostics, such as PCR, to distinguish acute Covid-19 infection from other similar clinical presentations. Initially during the pandemic, there was limited capacity centred on laboratory services, with turnaround times for test results in excess of 24 hours. This posed a substantial problem for hospitals with limited isolation capacity in hospital emergency departments or wards, overcrowding in emergency department waiting areas, and the risk of patients with unknown Covid status being admitted to bays with a number of other patients while awaiting results. Modelling results estimate that placing suspected Covid-19 patients in single rooms or cohorted bays has the potential to reduce hospital-acquired infections in patients by up to 35%. (Evans et al, 2021), and is one of the most effective methods of reducing transmission to patients and HCWs (Evans et al, 2024) (see paragraphs 11.34.2 to 11.34.5 and 12.37 to 12.40 on cohorting and single rooms).
- 9.12. Therefore, once it became more widely available, the ability to test symptomatic patients in emergency departments was very welcome from a clinical and IPC perspective. It meant that Covid-19 positive patients could be prioritised for isolation into limited numbers of isolation side rooms and/or into Covid bays on hospital wards bays, or dedicated Covid wards.
- 9.13. Eventually, commercially available rapid Covid PCR tests became available, at increasing scale, with test turnaround time (TAT) of one hour, perhaps less. This capability was a game-changer for IPC and hospital bed management.
- 9.14. Unfortunately, at least initially, rapid Covid PCR test capacity was limited by national and international demand for these commercial analyser systems. In London at least, distribution of this capability was managed or co-ordinated by NHS England, at least in part.
- 9.15. For a period, there was limited supply of both the Covid PCR test machines and the test kits. This meant that in some cases, for those NHS hospitals which had delivery of the Covid PCR test machines, testing had to be explicitly rationed and highly targeted, for example by case-by-case approval from medical virologists or microbiologists.
- 9.16. Apart from speed, another advantage of some of these rapid Covid-19 PCR analysers is that they are highly automated and user-friendly, so that even relatively junior lab staff can operate them effectively, after suitable training. Some systems are also modular by design. This means that test capacity could be readily expanded in the future as supplies of this hardware and the Covid-19 test kits which are tested on these machines improved during the pandemic.
- 9.17. Another operational advantage of rapid Covid-19 PCR analysers is that because of their small size (in some cases) and user-friendliness, they lend themselves to deployment near the patient, for example in NHS Emergency Department (ED) "hot labs", which are

small labs in, or adjacent to, ED which conduct the most urgent tests, which may include urgent biochemistry and haematology tests. In large NHS hospitals on multiple sites, the ease with which these could be deployed meant these rapid Covid-19 PCR analysers could be set up in hospital sites far away from the main virology or microbiology lab, ensuring the rapid PCR test's benefits were not diluted by the delays due to sample transportation across NHS sites.

- 9.18. This clinically valuable rapid test capability came at a cost as these tests were typically more expensive than "standard" Covid PCR testing which had a TAT of up to 24 hours. The test machines (analysers) also tend to be expensive to purchase.
- 9.19. It was observed that asymptomatic patients on hospital wards would often become symptomatic and test positive after admission, either because they were incubating the infection at the time of admission, or they acquired Covid-19 on the ward. This could only partially be prevented by admission PCR testing.
- 9.20. Therefore, as hospital Covid-19 PCR test capacity increased across the NHS, it became possible to recommend routine surveillance PCR testing of asymptomatic inpatients, for example, on a weekly basis. This allowed NHS hospitals to identify asymptomatic, or mildly symptomatic cases of Covid-19, who could be infectious. These patients could then be isolated to protect other patients.
- 9.21. Similarly, patients who were initially asymptomatic but who became symptomatic for Covid-19 after admission could be tested by PCR. Ideally, symptomatic patients e.g. with fever and cough should be isolated anyway. However, when hospitals are full and isolation side rooms are scarce, a positive result allowed IPC teams to prioritise this limited resource. However, there are limitations to asymptomatic screening, including the overall financial cost, testing capacity (at expense of screening for those symptomatic or high-risk staff/patient screening), staff time collecting samples, patient costs and inconvenience, delays to medical care, and a false sense of security in the not uncommon event of a false negative result (Talbot et al, 2023)
- 9.22. A modelling study estimated that a policy of PCR testing of symptomatic patients on admission would detect 26% of hospital-acquired infections. Adding asymptomatic PCR testing on days of stay 3 and 6 increases the proportion detected to 33% (Cooper et al, 2023). More frequent testing would therefore likely increase the number of cases detected, but requires considerable testing capacity, and would still not detect all asymptomatic or presymptomatic cases.
- 9.23. In one time series analysis using real-world data from England and Scotland, stopping universal admission testing was associated with significant increases in hospital-onset SARS-CoV-2 infections relative to community-onset infections (Pak et al, 2023). There are limitations to this study, including the risk of bias and confounding factors that may have influences the result.
- 9.24. Whilst Covid-19 PCR testing at scale was of great clinical and IPC utility in NHS hospital settings, we also learned that patients could remain PCR positive for prolonged periods after the infection had resolved. Studies have shown that it is possible to detect SARS-

CoV-2 by PCR up to 135 days after symptom onset in nasopharyngeal (nose and throat) swabs from a "normal" immunocompetent patient (Leitão et al., 2021). In the UK, it has been common practice to assume patients could be Covid-19 PCR positive up to 90 days after an initial positive result.

Staff testing and its impact on hospital associated transmission

- 9.25. Routine symptomatic testing or asymptomatic screening for respiratory virus infection in healthcare workers was not performed in the UK prior to the pandemic, and neither were available at the outset of the pandemic. During March and April 2020 there was a large increase in PCR testing capacity for SARS-CoV-2 in the UK. This meant that testing became available for some NHS workers with symptoms or signs of Covid-19, and their household contacts, with national guidance published at the end of March. This enabled the isolation of individuals with confirmed infections, in line with national guidance, and a return to work for those with a negative test result.
- 9.26. Asymptomatic screening of healthcare workers was piloted at a small number of NHS hospitals in March-May 2020. They identified a prevalence of asymptomatic or minimally symptomatic infection in approximately 2-7% of those tested (Brown et al, 2020), (Rivett et al, 2020), (Treibel et al, 2020). However, to maximise the impact on reducing transmission, testing needs to be both frequent (requiring considerable testing capacity and associated cost) and with a rapid tumaround time for results (placing additional strain on testing pathways) (Hellewell et al, 2021). There was variation in asymptomatic screening availability across hospitals in the UK (including the devolved administrations) during this time, and inconsistency in the procedures in place, including the frequency of testing. A modelling study has shown that periodic testing of HCWs has a small effect on the number of hospital-acquired Covid-19 cases in patients, but reduces infection in HCWs by as much as 37%, and results in only a small proportion of staff that have been reported to be absent from work owing to suspected Covid-19 and self-isolation (Evans 2021).
- 9.27. Guidelines for the rollout of asymptomatic staff testing using lateral flow devices (LFDs) were published by the NHS in November 2020, making twice weekly screening available to all NHS staff in acute hospitals across the UK. It was subsequently made available to patient-facing primary care staff in January 2021. From April 2021, LFDs were available to everyone in the population, including HCWs.
- 9.28. Subsequent modelling of the use of twice weekly lateral flow devices demonstrated that it caused a reduction in transmission between HCWs (Evans et al, 2024). However, to the best of our knowledge there has been no comparison made between testing approaches, and therefore their relative contribution (and cost) as an IPC measure remains poorly studied.

Reducing attendance to hospital sites

- 9.29. As the Covid-19 pandemic arrived in the UK, the community prevalence of Covid-19 increased rapidly. Until Covid-19 PCR diagnostics were available at scale from approximately mid-2020, it was hard to identify Covid-19 with confidence and differentiate it from all other respiratory viruses. As more was learned about Covid-19, it became clear that asymptomatic Covid-19 or mild Covid-19 which would be easily missed existed and may be common. Yet these patients could be infectious. For these reasons, anybody entering hospital could pose an infection risk, be they asymptomatic patients, staff, visitors, students etc.
- 9.30. Therefore, it was important from an IPC perspective to minimise attendance in hospitals to those who were essential to providing clinical care, and staff who keep critical hospital services running, like catering, portering, cleaning etc. The pandemic forced many radical changes to the way the NHS conducted its business, as described below.
- 9.31. A range of approaches were taken during the pandemic to reduce traffic in healthcare facilities, through:
 - cancelling, postponing, or reducing services such as elective surgery, screening programmes, and patient follow-up (see expert reports from Professor Gale on ischaemic heart disease (INQ000494739) and Professor Bhangu and Dr Nepogodiev on colorectal cancer (INQ000474244));
 - rearranging outpatient services, for example by staggering appointments, social distancing in waiting areas, increasing the total clinic duration with spaced appointments;
 - using outpatient treatments that rely on fewer hospital visits, for example the use of oral medication over intravenous therapy ("drip") or the use of medications with a longer duration of action;
 - making greater use of remote consultations through telephone and video consultations;
 - use of home working for staff in non-patient facing roles or tasks;
 - placing restrictions on hospital visiting. Such measures were widely described and practised during the pandemic. See paragraphs 8.1 to 8.22)
 - establishing off-site Covid-19 PCR testing units, including drive-through testing stations, to facilitate pre-admission testing. This enabled patient screening without needing to come onto the hospital site.
- 9.32. Some of these interventions may have positive health, economic and environmental implications outside of pandemic settings, and should therefore be critically studied.
- 9.33. However, they also need to be balanced against the negative impact on any of these strategies, to carefully consider: 1) the broad local impact of any such policies; 2) clear

pathways for how and when these measures can be reversed, and how any negative impact on services can be re-established to pre-pandemic levels; 3) where hospital visits are necessary, that they can be made as safe as possible.

Reinstating elective clinical activity

- 9.34. In the early phase of the pandemic, for much of 2020, the NHS's priority was to cope with the tidal wave of Covid-19 patients coming in from the community, including many severely ill patients. In this early phase, many acute NHS hospitals became de facto Covid hospitals with multiple inpatient wards, including ICUs, occupied by Covid-19 patients. As discussed above, many elective operations and procedures were cancelled or postponed, leading to a growing backlog of elective surgical work.
- 9.35. This was recognised by the NHS and the Government. It was clear the NHS had to resume elective activity, whilst not putting these patients at risk of nosocomial Covid-19. A variety of strategies were implemented to separate Covid and other acute patients from non-Covid-19 elective patients e.g. cancer patients.
- 9.36. The most enduring system was to create a system of "blue and green pathways". The non-Covid elective patients would be seen in "green pathways", which kept them apart from Covid patients in "blue pathways", as much as the physical estate permitted. This included, in some cases, designating some sites of a hospital green and some blue. There may have been regional differences in nomenclature, but the principles are likely to have been similar.
- 9.37. Many larger NHS hospitals have multiple sites, which can be quite far apart, for various reasons. This kind of arrangement lent itself to the green and blue pathway model. Acute sites e.g. those where the emergency department was sited, would naturally be predominantly blue sites, with Covid-19 cases. Other sites, without the unpredictability of the acutely admitted patients from A&E, could be green, especially if they had operating theatres, endoscopy suites, radiology etc.
- 9.38. To further protect the green pathways, patients on this pathway were PCR tested a few days before their planned elective procedures. A negative PCR result meant that the procedure could go ahead. On the other hand, a positive result meant home isolation, as per national Covid guidance prevailing at the time.
- 9.39. This layer of pre-procedure PCR testing assurance was made possible by the large expansion of Covid-19 PCR testing across the NHS in the latter half of 2020 and 2021. This testing gave objective, ongoing assurance that the clean "green" elective pathways were relatively safe form an IPC perspective. The reassurance to immunocompromised patients, who were understandably worried about nosocomial Covid-19 risk, was particularly important.

- 9.40. This pre-procedure testing provided a degree of confidence in the green pathway, but it was not perfect. Unfortunately, patients could become PCR-positive and therefore were likely to be infectious in the two to three days between the Covid swab and the procedure.
- 9.41. Nevertheless, the segregation of Covid/acute and non-Covid elective patients was relatively successful in that it permitted the resumption of some elective activity e.g. for cancer-related diagnosis and treatment in a relatively safe manner.
- 9.42. We note that when NHS elective activity was being resumed, priority was given to resuming procedures for cancer-related waiting list patients as their clinical need was high. However, this was also a group of patients who were relatively immunocompromised and so at greater risk of harm from Covid-19 (Johansson et al, 2023). Therefore, appropriate IPC precautions were needed for this higher-risk population and were applied e.g. green pathways, segregation from acute/infectious patients, surveillance testing, etc.

Social distancing and use of PPE in staff-only areas

- 9.43. IPC measures were applied in staff-only areas of NHS hospitals. This was a potentially important aspect of protecting staff from nosocomial Covid-19 infections, especially before Covid-19 vaccines became widely available in 2021.
- 9.44. In principle, for much of the relevant period of the pandemic (2020-2022), social distancing was applied in NHS hospitals in both clinical and non-clinical areas. The latter included staff-only areas such as:
 - offices
 - staff rest areas
 - staff canteens / restaurants
 - postgraduate education centres
 - seminar rooms
 - lecture theatres
- 9.45. In the UK, standard social distancing measures that were widely publicised in the community were also applied to all parts of the NHS estate, both clinical and non-clinical. These exact distancing measures varied, in line with guidance provided by the devolved administrations, across the pandemic.
- 9.46. In addition, FRSM masks were recommended in non-clinical areas, although obviously this could not apply in areas where food or drink were consumed.

- 9.47. As time went on, and as the NHS workforce was protected by Covid vaccination, these measures were gradually eased, especially when the prevalence of Covid-19 waned in the community. However, when we saw new surges of Covid-19, some of these measures were reintroduced e.g. in the winter months.
- 9.48. The gradual easing of IPC measures was reflected in the conduct of meetings. Over the course of the pandemic, these moved from online only, to some face-to-face meetings in large rooms with 2 metres social distancing and masks, to social distancing without masks and finally no restrictions.
- 9.49. These changes in non-clinical areas in hospitals reflected the trends in the easing of social distancing/mask restrictions seen in wider society in the relevant period.

Bed spacing and temporary increase of isolation capacity

- 9.50. The authors are not aware of any direct evidence about the efficacy of bed spacing as an IPC measure. While one study has shown that non-respiratory transmission of SARS-CoV-2 was associated with bed distance ≤2.5m, the authors note that respiratory exposure anywhere within a bay shared by patients is a risk for transmission and that further evidence is needed (Leeman et al, 2022). Although planned to be included in a modelling study of IPC interventions to reduce transmission, bed spacing was removed from the final model due to a lack of evidence on which to base assumptions (Evans et al, 2024).
- 9.51. Isolation capacity is limited in many NHS hospitals. Temporary, portable isolation pods and tents are marketed and can expand isolation capacity, but may not always be suitable: the experience of being in a tent may be disorienting for a patient who is febrile and very sick; delivering complex nursing care within the confines of a tent can be ergonomically problematic; they are often larger than a standard patient bed space, and their use may therefore reduce overall hospital bed capacity, further exacerbating overcrowding and the risk of transmission; they come with associated additional cost.

Ventilation and air cleaning

9.52. A discussion of the importance of ventilation as an IPC measure, and methods of air cleaning, are discussed in detail in part 4 of the expert report from Professor Beggs (INQ000474276).

Protecting clinically vulnerable staff

9.53. The NHS is one of the largest employers in the UK and the world, with just over 1.3 million staff as of February 2024 according to the King's Fund (The King's Fund, 2024). The NHS workforce reflects the population it serves, in many respects, including medical conditions, both common and uncommon. The occupational health demands related to the Covid-19 pandemic were substantial for many reasons. This report is not about

occupational health (OH) per se, but it is relevant to record some important aspects of OH relevant to IPC in the NHS.

- 9.54. In response to the pandemic, the UK Chief Medical Officers classified patients with certain serious medical conditions as clinically extremely vulnerable (CEV). These patients were advised to shield at home, i.e. to stay at home as much as possible to avoid coming into contact with Covid-19. Patients on this list constituted the Shielded Patients List. The Shielded Patients List (SPL) was maintained in the UK between March 2020 and September 2021.
- 9.55. Clinically extremely vulnerable patients are those with severely weakened immune systems who were likely to develop severe Covid-19 disease and have a higher case fatality rate compared to an immunocompetent person. Examples include patients with certain cancers, haematological cancers like leukaemia, bone marrow transplant recipients and solid organ transplant recipients.
- 9.56. With such a large workforce, the NHS had some staff who fell into the CEV category and who shielded at home, whilst the SPL was in effect. Various Covid-19 risk assessment tools were developed to help clinicians risk assess their patients, for example the "QCovid" tool designed by Prof Julia Hippisley-Cox and colleagues and hosted by NHS Digital/NHS England (NHS England Digital, 2024).
- 9.57. Some NHS staff may not have fulfilled CEV criteria but were at increased risk of harm from Covid-19, for example, they could be on immunosuppressive drugs for a medical condition which put them at increased risk of harm from Covid-19.
- 9.58. NHS hospitals have a duty of care to protect their staff from harm at work. During the pandemic, this included risk of harm for clinical staff who might see patients with Covid-19. Although PPE and good IPC practices provide good protection to staff, the most vulnerable staff need special consideration. For non-clinical staff, they could work equally effectively from home with emerging teleconferencing and videoconferencing technologies and cloud-based office suites etc.
- 9.59. For clinical staff assessing and managing the risk was more challenging. For those on the SPL, the decision was simple. For those with other risk factors (such as male gender, older age, being of a "black, Asian, minority ethnic" (BAME) background with chronic diseases like diabetes, asthma etc) the decision was more complicated. These staff were at increased risk compared to staff without these characteristics.
- 9.60. A lot of work was carried out across the NHS by OH departments working with subject matter experts in virology, microbiology and IPC. This included case-by-case risk assessments for staff with risk factors, short of the CEV category. We suspect there was a lot of variation in the individual arrangements for NHS staff in different hospitals, reflecting differences in individuals and these organisations. For example, large NHS hospitals may have had more flexibility to allow vulnerable, but not CEV staff to work from home, than a smaller NHS hospital.

- 9.61. In practice, most NHS hospitals had some form of Covid-19 risk assessment during the pandemic, as advised by, for example, NHS England. This became more pressing when shielding was paused in April 2021 and eventually ended in September 2021, when CEV patients were advised to end their isolation and return to work. Guidance was issued to NHS organisations in England on how to do this, emphasising the importance of individual risk assessment (NHS England, 2021a).
- 9.62. The roll-out of Covid-19 vaccines in early 2021 reduced the risk to NHS staff, including clinically vulnerable NHS staff. Nevertheless, staff with greater Covid-19 risk would have been anxious about returning to work, which is why the individual risk assessment were so important. Reasonable adjustments for NHS staff at risk could include partial working from home, also known as hybrid working, and not working on Covid-19 wards.
- 9.63. We note from our experience of working in many NHS hospitals (in England) that NHS OH departments are often relatively small, with high staff turnover and recruitment challenges. In some cases, NHS OH services are outsourced. The state of OH in the modern NHS is far from ideal.
- 9.64. A sobering article on NHS OH experience in the pandemic opens with "…NHS OH services have been pared to the bone…" and concludes with: "We conservatively estimate that the workload in OH increased 20-fold since the pandemic" (Walker-Bone et al, 2020).
- 9.65. The unprecedented demands on NHS OH services brought about by the pandemic e.g. overseeing a massive staff vaccination programme, Covid-19 surveillance testing of most if not all staff, and the individual risk assessments would have placed unimaginable strain on this scarce resource. In some NHS hospitals, these functions were allocated to other departments, or newly created teams to deliver these specific OH functions because existing OH services simply could not cope.
- 9.66. These pressures are well-recognised, as evidenced by the publications of a comprehensive "roadmap" to improve NHS OH services in the future (NHS England, 2023). We commend these efforts to improve NHS OH services.

10. Enabling the workforce to prevent and control infection

(Lead author: DG)

- 10.1. This section outlines the arrangements for educating the NHS workforce about IPC. Nurses make up most of the IPC workforce but others contribute to IPC including (not exhaustively) medical staff, epidemiologists, healthcare scientists and those with expertise in the built environment.
- 10.2. Registered and unregistered nurses (healthcare assistants) make up the bulk of the NHS workforce and provide most of the frontline care. It is here that the risk of spreading and of contracting infection is highest. The Royal College of Nursing advocates for the pay and conditions of nurses, including for issues related to IPC. Healthcare assistants are not subject to regulation in the UK. They do not receive specific training for IPC and most of their clinical skills are learnt 'on the job' and through in-house training schemes which may differ between organisations in scope, quantity and quality. Unregistered nurses and support workers who provide health or social care under the guidance and supervision of a registered nurse, midwife, or health visitor, are eligible to join the Royal College of Nursing and use its membership services and resources even though they are not on a professional register.
- 10.3. Input on IPC is especially important for nurses. In the UK IPC is a nurse-led service and most members of the IPC team are nurses. Other professional groups contributing to healthcare look to nurses for leadership and advice about IPC (Five Year Antimicrobial Plan 2019-2024) (Department of Health and Social Care, 2019). The Nursing and Midwifery Council (NMC) is the regulatory body for nurses and midwives in the UK. Preregistration student nurses undertake the theoretical aspects of their course in a university. Clinical placements which account for fifty percent of the course, take place in the NHS and other health provider organisations (e.g. nursing homes, primary care, private hospitals). IPC must be included in all pre-registration nursing programmes. Content and teaching methods depend on the university. Opportunities to practice clinical skills depend on where student nurses undertake clinical placements and the enthusiasm of clinical mentors. Arrangements for assessment vary between universities and health provider organisations (Hawker et al, 2020). The Nursing and Midwifery Council does not provide specific details of what aspects of IPC should be included in the curriculum or when or how it should be taught and assessed. It is the personal experience of one of the authors of this report (DG), teaching undergraduate nurses in two universities in the Greater London area since 2022, that there is variation concerning what and how IPC is taught. The NIPCM was never provided in the learning resources used in these two institutions.
- 10.4. IPC input into the medical and physiotherapy curricula also appears to vary between universities and to be more comprehensive in some centres than others.
- 10.5. Education and training in relation to IPC is supposed to continue post-qualification for all health professionals. Arrangements for updating are different in England, Scotland, Wales

and Northern Ireland and vary according to clinical specialty and employer. Ancillary staff also need training and updating.

- 10.6. Before the pandemic a NIPCM was used to educate and train health professionals in Scotland. The same training was adopted in Wales in 2018. It replaced previous guidance dating from 2012. Various training resources were used in England. These had been developed by NHS England and professional bodies such as the Royal College of Nursing. Northern Ireland had its own training manual introduced in 2008. This was updated in line with the NIPCM in 2023.
- 10.7. Before the pandemic IPC was supposed to be included during the induction programme when a health worker joined an organisation and there were supposed to be mandatory annual updates for all staff regardless of whether they were on a professional register or not. Sessions were the same for all staff regardless of whether they were registered or unregistered. Knowledge was assessed by a multiple-choice guestionnaire. Emphasis was placed on hand hygiene. Other standard IPC precautions were also addressed: use of PPE (gloves, aprons/gowns and standard face coverings). In accordance with the Health and Safety Act (1974) and the Control of Substances Hazardous to Health (COSHH) Regulations (2002), all employers were, and still are, required to ensure that their staff know when and how to use the appropriate PPE. Much depended on the degree of exposure they were likely to have. Greater emphasis was placed on the use of RPE for staff in clinical settings where they would be more likely to encounter patients infected with respiratory pathogens: emergency departments; respiratory medicine wards; infectious disease units; acute paediatrics; intensive care units; and operating theatres. Healthcare providers in these settings were periodically reminded of the importance of training staff to use PPE and RPE. For example, in its guidance for influenza pandemic preparedness published on 1st April 2012, the Department of Health emphasised employers' responsibility to ensure that staff could undertake risk assessment and knew the correct techniques for donning (putting on) and doffing (removing) RPE to prevent cross-infection (NHS Health and Social Care Influenza Pandemic Preparedness and Response April 2012, Health and Safety Executive 2019) (Department of Health, 2012). Nevertheless, there was some evidence that health professionals were not fully conversant with these requirements. Difficulties selecting the most appropriate type of face covering were reported pre-pandemic (Coia et al, 2013).
- 10.8. Arrangements for IPC education and training have been updated since the pandemic. The same core topics (standard and transmission-based precautions) are included in each, but delivery varies in the different nations. Little consideration appears to have been given to the specific needs of different professional groups or the clinical procedures they undertake. Training resources must still meet the needs of qualified and unqualified staff.
- 10.9. NHS England published a new IPC Educational Framework in March 2023. Training is mandatory. Three levels (tiers) of training are described. Level depends on the role and responsibilities of the employee. Six standards have been developed within the Framework. They are supposed to be incorporated into all health and social care programmes and apply to all NHS employees. Online instruction free of charge is

available on the NHS England e-learning for health hub (eLFH). It has not been possible for us to locate any health professionals who have accessed this resource willing to provide feedback. NHS England has stated that it will commission education and training resources from other organisations. Details of how this will be achieved and of any quality control or accreditation processes are not presented in detail.

- 10.10. NHS Scotland has its own IPC Education Team. All educational resources are streamlined into the Scottish Infection Prevention and Control Education Pathway (SIPCEP). They are available free of charge to everybody employed in the health and social care sectors in Scotland, including the independent and voluntary sectors. Level of training depends on the role and responsibilities of the employee. Three levels are described depending on role and responsibilities.
- 10.11. Public Health Wales has replaced its earlier online learning resources with those used in Scotland. On the date the e-learning manual was accessed (April 26 2024) the website was under review and information was not available.
- 10.12. Educational resources in Northern Ireland are related to specific topics. Most of the resources and references relate to the NIPCM.
- 10.13. In all four countries of the UK assessment for IPC is online. The checks undertaken to ensure that assessment is taking place and the action to take if the results are suboptimal are not described in detail.
- 10.14. Uptake of education and training depends on local circumstances. IPC teams are responsible for providing input throughout their employing organisations. The way the work of these teams is organised and how they spend their time, including time devoted to education, varies. Some NHS hospitals employ large IPC teams with some post-holders specifically designated to teaching roles. These may offer a programme of events or outreach teaching sessions throughout the clinical areas. In some NHS hospitals, study days or one-day conferences are held. In other less well-resourced organisations education is more basic and might best be described as training. A great deal of emphasis is placed on hand hygiene audit and the associated feedback is often described as 'education'. This 'education' is not always welcomed by health professionals if it is delivered in front of patients and colleagues (Fuller et al, 2012).
- 10.15. IPC is a recognised nursing specialism in the UK but there is no statutory qualification or clearly identified career pathway. Newly recruited IPC nurses do not necessarily have to have statutory IPC education or training. IPC nurses come from different clinical backgrounds. This affects the knowledge and skills they bring to their new role. Many have previous experience in critical care and are likely to be well prepared. For nurses from other backgrounds, this might not always be the case. A variety of education and training courses are available at different levels, delivered in different ways. Some universities offer IPC courses. These are usually aimed at recently appointed IPC staff. They usually lead to a master's degree or credits towards a master's degree. Scope and content vary. Some IPC courses are online only with self-assessment. Others are delivered face-to-face or through a blended learning format. The Infection Prevention Society (IPS) is a registered charity that represents IPC specialists in the UK. It provides

educational resources and a national conference held annually. There is no requirement for IPC nurses to belong to the IPS and it does not offer educational preparation for aspiring or newly appointed IPC nurses leading to a statutory qualification. This situation contrasts with the highly specific arrangements for preparing the critical care nursing workforce. The Critical Care National Network Leads Forum (CC3N) oversees the preparation of critical care nurses. Its aim is to support the career development of critical care nurses and promote a sustainable model for staffing that will encourage nurse retention in the specialism. There is a well-defined training programme offered at three levels. Programmes are run collaboratively between NHS organisations and partner universities. They are competency based. Participants must pass practical and theory assessments. Cancer nursing is another well-established nursing specialism for which postgraduate nursing courses are available.

Summary

10.16. This section has demonstrated the under-provision of IPC in the pre-registration nursing curriculum. Before the pandemic opportunities for nurses and other health professionals to update their IPC knowledge and skills was variable and did not reflect the clinical setting in which they worked or the clinical procedures they undertake. Post-pandemic, arrangements for IPC updating should have improved in line with the NIPCM but there is little objective evidence of improvement so far.

11.The burden of SARS-CoV-2 transmission in hospitals

(Lead author: BW)

11.1. The transmission of SARS-CoV-2 within hospital, and the potential impact of such transmission on patients, staff and visitors, has consistently raised concerns throughout the pandemic. Although our understanding of hospital associated infections has developed substantially since January 2020, there remain considerable challenges in quantifying the number or proportion of cases that have been acquired in secondary care, and identifying all of the factors that contribute to transmission. In this section we will explain why these challenges exist and summarise what is known about hospital transmission of SARS-CoV-2. This section is predominantly focused on the spread of infection in inpatient settings, which is where the majority of published data and studies can be found. While we touch on other healthcare settings (such as outpatient secondary care, primary care, ambulance services, home visits, and so on) there is a relative paucity of data on which to base any conclusions.

Challenges in determining transmission

11.2. At the onset of the Covid-19 pandemic in the UK, data on the scale and route of transmission of any respiratory viruses in hospital settings was extremely limited. Healthcare-associated transmission was a key feature of hospitalised cases of the coronaviruses SARS-CoV-1 (24% infections were HAI) and MERS-CoV (36% of known infections, excluding HCWs), but neither virus had impacted UK health systems (Bhattacharya et al, 2021), (Zhou et al, 2020). While influenza was an increasingly recognised cause of hospital acquired infection (HAI), only a limited number of influenza outbreaks have been reported from acute hospital settings (Salgado et al, 2002), (Pollara et al, 2013), (Eibach et al, 2014), (Cunney et al, 2000). However, it has been acknowledged that combating nosocomial influenza transmission is complex and requires multidisciplinary interventions (Vanhems et al, 2016). In particular, there are challenges in the recognition and diagnosis of mild or asymptomatic influenza cases, disproportionate impact on the frail elderly, and poorly understood roles of healthcare worker (HCW) and hospital visitors in transmission networks. Asymptomatic influenza infections are common, comprising the majority of individuals infected each year (Hayward et al, 2014). However, asymptomatic infections retain the ability to transmit virus, having implications for any IPC strategies based on determining cases through symptomatic infection alone (Cohen et al, 2021). Interventions that have been used to reduce nosocomial transmission of influenza, such as staff vaccination, rapid diagnostics, and medicines such as oseltamivir for post-exposure prevention of illness and treatment of established illness, were not available to impact SARS-CoV-2 transmission at the start of the pandemic. Similarly, there was very limited data on the virology, clinical features, and pathogenicity of the virus on which to base infection control guidelines. However, the first study on Covid-19 published from Wuhan in February 2020 stated that 41% of all cases identified in patients and HCWs were HAIs, raising immediate concerns for the burden of

hospital onset infection for this novel virus (Wang et al, 2020). This is reflected in the oral evidence provided to the Inquiry by Peter Horby, chair of NERVTAG, where the potential for nosocomial transmission of SARS-CoV-2 was considered very early in the pandemic (transcript of UK Covid-19 Inquiry module 2 evidence of Professor Sir Peter Horby, October 18 2023, p.163-164).

- 11.3. Determining the location where a SARS-CoV-2 infection was acquired is challenging. The most frequently used definition of a hospital acquired infection (for other pathogens) is the development of a disease more than 48 hours after admission to hospital (Abbas et al, 2021a). This definition is commonly used in clinical practice, and is the basis for a range of surveillance and infection control studies. It is appropriate for infectious agents with short incubation periods (the time between exposure to a pathogen, and the onset of signs or symptoms), such as influenza or norovirus. However, the mean incubation period of SARS-CoV-2 infection is comparably longer, approximately 5 days (range 2-14 days) (Li et al, 2020). Therefore, patients who develop symptoms of Covid-19 on days 1 to 5 of their admission are more likely to have acquired their infection in the community than in the hospital; conversely, a proportion of patients who become symptomatic between days 6 to 14 of their admission may have acquired their infection prior to coming to hospital. This makes the conventional 48 hour definition of hospital acquired infection investigations and surveillance programmes for HA-Covid.
- 11.4. Table 2 (Bhattacharya et al, 2021) shows definitions of HAI which reflect the increasing likelihood of HAI with longer inpatient stays from admission to sample collection, up to the maximum incubation period of 14 days. Initial definitions were proposed by the SAGE Hospital-Onset Covid-19 Working Group and subsequently adopted by PHE (shown here), NHS organisations, and ECDC, with slight modifications. For example, some organisations do not include the "Community onset, suspected healthcare associated" category, if hospital admission data cannot be linked from previous admissions. Although these are the most commonly used definitions in the UK, they were not universally applied, and alternatives have been used in other settings and early studies before a standard definition was developed (Abbas et al, 2021a).

Category	Definition	
Hospital onset, definite healthcare associated (HO.HA)	Positive test from day 15 of admission until day of discharge, inclusively	

Table 2: Categories used by PHE to assign likelihood of an infection being hospital acquired

Category	Definition
Hospital onset, probable healthcare associated (HO.pHA)	Positive test from day 8 to day 14 of admission, inclusively
Hospital onset, indeterminate healthcare associated (HO.iHA)	positive test from day 3 to day 7 of admission, inclusively
Community-onset possible healthcare- associated (CO.pHA)	Positive test date ≤14 days post-discharge; if readmitted during this period, up to day 2 of admission where date of readmission is day 1
Community-onset community-acquired (CO.CA)	Positive test date <14 days pre- admission/attendance and up to day 2 of admission; no prior discharge within 14 days of admission/attendance

- 11.5. The above definitions had a number of advantages. They could be established using hospital admission dates and sample collection dates, which were readily available in electronic hospital and laboratory record systems, and therefore available to both local studies and in centralised databases that were then used to form national surveillance systems of HA-Covid from mid-2020. They could therefore be widely applied across studies over time, and their consistency enabled identification of trends in transmission over time and geographical regions. However, they also pose some limitations:
 - 11.5.1. The definition is based on the sample collection date of the first laboratory sample that tested positive for SARS-CoV-2. If there was a delay in sample collection (for clinical reasons, such as a delay in recognition of an atypical presentation of Covid-19, or practical reasons such as a shortage of staff or testing capacity), there may be a false attribution of a community acquired case as one that is hospital acquired. A single site study in the first wave of the pandemic found that 49.4% of probable or definite HAIs, based on the above criteria, were actually likely CAIs. The majority of these were delayed testing of patients presenting to hospital with respiratory symptoms and/or radiological changes consistent with pneumonia, at a time of limited testing capacity (Wake et al, 2020). The wider availability of testing as the pandemic progressed, and the increased use of asymptomatic screening of patients on presentation to hospital, would likely have reduced this false attribution.

- 11.5.2. Alternative approaches have based their assessment of hospital acquisition on symptom onset date, rather than sample collection date (Wake et al, 2020). While this may lead to more accurate categorisation, symptom onset data requires manual collection and curation, and is therefore less feasible to collect routinely and at scale, for example in national surveillance systems.
- 11.5.3. Identifying patients who had recently been in contact with healthcare services, even hospital admissions, is challenging. This is especially true if the admitting hospital was different to that from which the patient was discharged. A proportion of re-admitted patients likely acquired SARS-CoV-2 in hospital; in one single site study, 9% of all patients with Covid-19 infections had been readmitted following a hospital discharge in the incubation period of the virus (Meredith et al, 2020). National data from England in the first pandemic wave showed that community-onset possible healthcare-associated cases represented 5.1% (14,913/293,204) of all laboratory-confirmed cases in the UK (at a time when there was limited community testing), but these represent less than 1% of the estimated 3 million Covid-19 cases in this period (Bhattacharya et al, 2021).
- 11.5.4. While they provide an approximation of the most likely location of acquisition, the definition is not absolute. At an individual or outbreak level, further information is required to characterise the nature and location of any transmission events.
- 11.5.5. The definitions rely on a confirmed positive result. This is impacted by testing availability and screening criteria that changed during the course of the pandemic. Initially, only symptomatic individuals with epidemiological risk factors for Covid-19 infection were tested. In one case report from a patient presenting in February 2020, at a time of limited testing for patients deemed at low risk, a patient presented with an exacerbation of underlying lung disease but no epidemiological risk factors for SARS-CoV-2 acquisition. He was not diagnosed with Covid-19 until day 8 of his admission. A review of this case and the patient's contacts while in hospital identified a number of patients and HCWs who were exposed and subsequently developed Covid-19. (Taylor et al, 2020). Similarly, before the advent of patient screening, asymptomatic or minimally symptomatic patients would not have been tested and therefore would not have been counted towards HAI estimates.
- 11.5.6. For the purposes of datasets, diagnoses in hospital were generally based on molecular detection of viral RNA (i.e. identifying parts of the particular genetic code that are unique to that virus). These tests are highly specific, so rarely led to false positive results. They were generally considered to be very sensitive (i.e. detect the majority of cases, with few false negatives), but this rate can be influenced by a range of factors including swab type and staff training. While their use has generally been discouraged for the diagnosis of SARS-CoV-2 infection, lateral flow devices (LFDs) have been shown to have a variable, but generally reduced sensitivity compared to molecular methods; their use for screening or diagnosis is therefore likely to miss a proportion of hospital acquired infections, although the evidence for this is limited. (Dinnes et al, 2022)

- 11.5.7. The distinction between "indeterminate" and "probable" on the table above is based on patients being admitted for more than 7 days at the time of sample collection. However, the mean incubation period of the virus has repeatedly been estimated to be less than 7 days, with the omicron variant being 3.6 days in one study (Galmiche et al, 2023). This will lead to a number of cases testing positive on days 4 to 7 of their admission being falsely attributed as community-acquired, when they are more likely to have been hospital-acquired.
- 11.5.8. One modelling study using data from CO-CIN from the first wave (from the start of the pandemic up to July 31 2020), estimated that up to two thirds of all hospital-acquired Covid-19 infections would not be identified, accounting for 20,000 patients. The majority of these individuals were not identified in studies because they were discharged prior to symptom onset. The authors note that this would have led to a subsequent burden of transmission in the community. (Knight et al, 2022). They estimate that 15% of cases originally classified as community-acquired were hospital-acquired or hospital-linked.
- 11.6. Data on hospital transmission of Covid-19 is derived broadly from three sources:
 - 11.6.1. **National surveillance data.** Surveillance systems were not immediately available at the start of the pandemic, but were developed over the course of 2020. Patient surveillance combined databases of hospital admissions and positive SARS-CoV-2 laboratory test dates, to categorise patients into community or hospital onset infections according to the table above. There were different data sources and methodologies between the devolved nations, but the majority of UK hospitals were included. Data on staff absences were collected nationally in the devolved nations and via NHS digital. Such surveillance data could demonstrate overall national and regional figures and trends rapidly and at scale, but had minimal associated data on patients and staff, and could not provide detailed information on the nature and mechanism of transmission within hospital settings (Abbas et al, 2021a). One limitation is changes in asymptomatic patient and staff testing, that helps to identify community acquired pre-symptomatic infection sooner, but was introduced to varying degrees in different hospitals through the first and second wave of the pandemic.
 - 11.6.2. **Single site studies.** Initial data from the first wave was more rapidly obtained from single hospital trusts in England, where a range of studies were performed to quantify rates of HAI, and understand networks of transmission at a more granular level. Approaches included the use of traditional epidemiological methods for outbreak investigations, network analyses of patient movements, and the use of pathogen genome sequencing. Infection in healthcare workers has been studied using a combination of serological studies, and symptomatic and asymptomatic staff testing. Serological studies test the blood of individuals for the presence of antibodies (part of the body's immune response) to SARS-CoV-2; on the assumption that everyone should have had no antibodies at the start of the pandemic, HCWs that tested positive for antibodies subsequently provides evidence that they had subsequently been infected with the virus. Most studies

compile a greater depth of detail on staff and patients that cannot be performed at scale. The majority of these studies were performed in teaching hospitals in the first wave of the pandemic, so the impact of a number of changes (including widespread vaccination, the impact of therapeutics with proven benefit, the changing pathogenicity and transmissibility of SARS-CoV-2 variants, etc), are not well understood. Similarly, there was considerable homogeneity in hospitals around the UK in terms of testing capacity and, in some cases, PPE utilisation, that may impact on the generalisability of these studies.

The increasing availability of pathogen sequencing technology prior to the pandemic led to a number of genomic epidemiology studies on SARS-CoV-2, supported by the COGUK consortium (Marjanovic et al, 2022). These studies compared viral genomes from infected individuals to identify closely related isolates; when combined with traditional epidemiological methods demonstrating co-location of individuals in time and space, they can provide strong evidence supporting or refuting transmission events. However, they are limited by incomplete availability of viral sequences in some outbreaks. Similarly, there are limits to the granularity of detail available from epidemiological data on patient or staff locations (often limited to the ward or bay level), which may miss the complex movements of individuals within the hospital environment. All studies are impeded by incomplete ascertainment of cases involved in transmission networks (including asymptomatic or missed cases). Finally, while these methods can identify individuals involved in transmission, there is often uncertainty about the direction of transmission (i.e. which person transmitted or received the virus, especially in complex networks), the mechanism of transmission (i.e. whether the virus was transmitted by close contact, contaminated environment, or an intermediate), and the IPC procedures that could be used to intervene in that transmission. While genomic studies were successfully integrated into some IPC measures during the pandemic (Meredith et al, 2020), (Ramsey et al, 2022), their use in routine care is currently limited by factors including cost, availability, the required technical expertise, and the turnaround time for sequencing results (Stirrup et al, 2022).

- 11.6.3. **Multicentre cohort studies.** Large multicentre studies of Covid-19 have been performed in both patients and HCWs. These include a larger dataset of individuals on which to base more complex analyses of hospital associated infection than national surveillance systems. Their results are often more representative of the nation as a whole, but can lack the detail or flexibility of local studies, and suffer a similar range of limitations.
- 11.7. There is a clear focus in these studies on hospitalised inpatients, as opposed to other healthcare settings. There are likely multiple reasons for this, related to the challenges of IPC studies in the community in comparison to hospitals. For example:
 - 11.7.1. Identifying cases in hospital, where there is wider routine access to both clinicians (to identify infection), and diagnostics (by which to confirm it) is far more straightforward than in the community.

- 11.7.2. Data that is routinely collected in hospitals is not readily available in the community. For example, information on the dates of patient admission and discharge from hospital provide basic location information on the patient's whereabouts; this is available at a more granular (ward, even bed) level for some studies. Comparable location data is hard to identify in community settings, where the patient can move between many locations and have many human interactions that risk transmission. Confirming that transmission would have occurred in a community healthcare setting, as opposed to any of the other community settings visited by a patient, would be extremely challenging.
- 11.7.3. Inclusion of affected patients and staff into studies is more straightforward in secondary care, where patient and staff records can provide more detailed, comprehensive information over the course of an infection than the records made in community settings.
- 11.7.4. The necessary expertise to conduct these studies is also based in secondary care, where most clinical infection experts are based. Academic clinicians who straddle both university and hospital settings and often led on these studies, are also more commonly based in secondary (if not tertiary) centres.
- 11.7.5. There is a general historic bias of the IPC literature focusing on hospitals rather than community settings.
- 11.8. The risk of healthcare associated infections in the community is therefore poorly studied, and there remains a considerable gap in our understanding of the impact of Covid-19 in this context that requires further study.

Summary

11.9. In this section we have shown why it is difficult to confidently state whether a Covid-19 infection in hospitalised patients was acquired nosocomially, even using the most sophisticated scientific methods. The definitions that were developed were based on a pragmatic compromise and available information. However, they have been widely and consistently used in a range of studies that have provided a wide range of information on SARS-CoV-2 transmission in hospitals. Such approaches should be actively and rapidly considered in future pandemics.

Estimates of the number of hospital-acquired SARS-CoV-2 infections

- 11.10. The number and/or proportion of hospital acquired infections has been calculated in a number of studies with varying methodologies from data collected across the UK, throughout the pandemic. This has led to some considerable variation in the estimates provided.
- 11.11. Initial data on the rates of HAI in England were provided in a SAGE update on April 16 2020, based on a questionnaire circulated to all NHS trusts and reflecting the situation as

of April 9 2020. This showed that of all Covid-positive test results in 46 responding trusts, 8.2% were diagnosed 14 or more days post-admission, but the rates were variable across trusts (inter-quartile range 3.8% to 12.0%) (SAGE, 2020b).

- 11.12. The CO-CIN study provided an alternative source of results early in the pandemic. By April 30 2020, the study had included up to one third of hospitalised Covid-19 cases in England, Scotland and Wales (Docherty et al. 2020), and identified that approximately 9.3% cases had symptom onset at least five days after admission (SAGE, 2021). Subsequent data published from the same study including patients in the UK up to August 1 2020 showed that 11.3% (95% CI 11.1-11.6) patients with Covid-19 in 314 UK hospitals had probable or definite hospital acquired infection. This proportion increased to at least 15.8% (17.6%; 15.8–19.6) of patients with Covid-19 by the middle of May, 2020, long after the peak of admissions. Using the conservative definition of definite HAI (symptom onset at least 14 days after admission), they estimated that 6.8% (95% CI 6.7– 7.0) of all patients with Covid-19 had nosocomial infections (Read et al, 2021). A retrospective analysis of data from national surveillance systems produced by Public Health England during the first wave estimated that probable and definite hospital-onset cases represented 15.4% (15,564/100,859) of laboratory-confirmed cases among hospital patients. (Bhattacharya et al, 2021) Published data from investigations at individual hospitals quote a similar range of HAI rates.
- 11.13. A modelling study based on data from CO-CIN and national surveillance data from the start of the pandemic up to July 31 2020, estimated that although approximately 7% of hospitalised Covid-19 cases in acute hospitals in England were classified as hospital acquired, based on definition of a classification >7 days from admission to symptom onset, the actual figure is much higher. They estimated that 15,900 individuals, or 20.1% (19.2%, 20.7%) of identified Covid-19 cases in hospitals, were likely to have been hospital-acquired infections; up to 15% of cases originally classified as communityacquired were actually hospital-acquired or hospital-linked. This reflects a combination of hospital onset infections <=7 days from admissions, and re-admissions of patients who acquired Covid in hospital but were not diagnosed before discharge. The authors also note that up to two thirds of all hospital-acquired Covid-19 infections would not be identified during a hospital admission, the majority because they were discharged prior to symptom onset. (Knight et al, 2022). This would have led to a subsequent burden of transmission in the community and contributed a further 47,400 (45,000, 50,000) hospitallinked infections due to transmission from patients who were not identified in hospital being discharged into the community. However, all of the infections that were derived from hospital transmission account for less than 1% of all estimated Covid-19 cases during the same time period. (Knight et al, 2022)
- 11.14. Subsequent modelling analysis of the second wave (between June 10 2020 and February 17 2021), based on data from 145 NHS acute trusts in England combined with other national datasets, showed that a total of 16,950 and 19,355 SARS-CoV-2 infections in hospital inpatients met the criteria for definite and probable healthcare-associated infections, respectively (Cooper et al, 2023). As with the paper in the paragraph above, the authors viewed these numbers as an underestimate of the true figure and therefore adjusted these numbers based on confounding factors such as the incubation period of

the virus, length of stay and the accuracy of the diagnostic tests used. The authors estimate that, in total, between 95,000 and 167,000 inpatients acquired SARS-CoV-2 in hospitals (between 1% and 2% of all acute hospital admissions) in England over this time period. (Cooper et al, 2023)

- 11.15. Estimates of HAI rates varied by different patient populations:
 - 11.15.1. The proportion of HAI was higher in mental health and community hospitals in the first wave. The CO-CIN study showed that hospitals providing acute and general care had a lower proportion of hospital-acquired infections (9.7%; 95% CI 9.4–9.9) compared to residential community care hospitals (61.9%; 56.4–68.0) and mental health hospitals (67.5%; 60.1–75.8). (Read et al, 2021). National surveillance data in England supported this finding, with a higher proportion of laboratory-confirmed cases linked to Mental Health and Learning Disability NHS Trusts classified as probable or definite healthcare-associated (54.2%, 1253/2310) compared with NHS Acute Trusts (14.3%, 13,875/97,372). (Bhattacharya et al, 2021). However, this higher proportion likely reflects: 1) longer hospital stays for patients in these trusts; 2) the far smaller number of patients being admitted to these trusts with CA-Covid-19, such that the nosocomial patients are based on smaller overall case numbers in these trusts.
 - 11.15.2. Older patients (age ≥60 years) who had a confirmed diagnosis of Covid-19 in the first wave were more likely to have a hospital-onset probable or definite healthcare-associated infection (18.5% (12,106/65,534)) than patients under 60 years of age (5.6% (1769/31,830)). (Bhattacharya et al, 2021).
 - 11.15.3. Patients with a higher number of co-morbidities were also disproportionately affected by HAIs during the first wave. The proportions of patients with a Charlson index ≥2 ranged from 42% in CO.CA cases to 70% in HO.HA cases in NHS acute trusts in England. (Bhattacharya et al, 2021).
- 11.16. Estimates of HAI rates varied by hospital and region:
 - 11.16.1. There was marked variation in the proportion of hospital acquired infections in different individual hospitals providing acute and general care services in the first wave in the CO-CIN study. The cause of this variation was unclear. (Read et al, 2021)
 - 11.16.2. There was considerable variation across regions of England in the proportions of hospital patients classified as HO.pHA and HO.HA, from 11.2% (2427/21,770) in London to 19.3% (3173/16,427) in the North West NHS region. (Bhattacharya et al, 2021). This variation was maintained in the second wave, with the highest rates seen in the North West NHS region, and the lowest in the South West and London regions (Cooper et al, 2023).
 - 11.16.3. Hospital-onset cases during the first wave represented 5.3% of all laboratory-confirmed Covid-19 cases in England, 6.4% of all laboratory-confirmed Covid-19 cases in Scotland, and 10.5% of all laboratory-confirmed Covid-19 cases

in Wales (NHS National Services Scotland, 2020), (Public Health Wales, 2021). No data was readily available for Northern Ireland. However, this data must be interpreted with caution, as routine screening of patients in hospital was not readily available, nor was community testing. The lower proportion in England may therefore reflect differences in hospital admissions or testing strategies over the peak months.

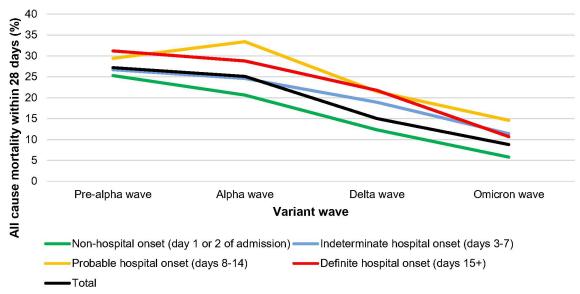
Summary

11.17. Estimates of the proportion of SARS-CoV-2 infections acquired in hospital range between 5 to 20% of all Covid-19 cases identified in acute hospitals. This number varies based on their timing in the pandemic, geography, patient population, and study methodology. It is therefore challenging to guote an exact number of people who acquired their infection in hospital in the UK. This is compounded by limited publicly available data and studies related to the delta and omicron variants, which were considered more transmissible and were circulating at times when IPC measures based in the community (such as testing and restrictions on movement) were being relaxed. However, even assuming a conservative estimate of 7% of Covid-19 cases in secondary care being hospitalacquired, given there were approximately 900,000 hospitalised cases in total across the UK up to June 22 2022 according to data from the UKHSA dashboard archive (UKHSA, 2024), this would indicate that over 60,000 were hospital acquired. This is likely an underestimate of the true number of hospital-acquired infections, which has been quoted as approximately 3 to 5-fold higher based on modelling studies. Overall, it is therefore highly likely that the true number of patients who contracted a hospital-acquired Covid-19 infection in the UK is well over 100,000.

Outcomes of patients with HA-Covid

- 11.18. Studies early in the pandemic raised concerns for poorer outcomes in cases of hospital acquired Covid-19. There were clinical concerns that patients who already required hospital admission, due to another acute illness or co-morbidity, would be more vulnerable to subsequent infection with SARS-CoV-2. However, detailed studies in this context are challenging. For example, not only is it difficult to establish whether infections were acquired in hospital, for patients who died following an infection it may be difficult to establish the relative contribution of Covid-19 to their death.
- 11.19. Initial data from the first wave in England demonstrated that patients with probable and definite hospital onset infections in NHS Acute Trusts had 41.3% (5726/13,875) 28-day Covid-related mortality, compared with 25.9% (15,620/60,233) in CO.CA cases. In patients in NHS Mental Health and Learning Disability Trusts, 28-day mortality among probable and definite hospital onset cases was 21.9% (274/1,253) (Bhattacharya et al, 2021). Higher rates in HA cohorts was, in part, attributed to their increased age and comorbidities, that were not adjusted for in the analysis.

- 11.20. In a meta-analysis of global cases published up to February 9 2021, the risk of mortality was 1.3 times greater in patients with nosocomial infection, compared to community-acquired (95% CI: 1.005 to 1.683). Immunosuppressed patients diagnosed with hospital acquired Covid-19 were twice as likely to die in hospital as those admitted with community-acquired infection (RR=2.14, 95% CI: 1.76 to 2.61). The authors identify patients with immunosuppression (specifically malignancy or previous transplantation) as a major driver for this increased risk. (Ponsford et al, 2021).
- 11.21. Subsequent analysis of national surveillance data from Scotland from March 2020 to March 2022 showed that 22.3% patients who developed probable or definite hospital onset Covid-19 died within 28 days (2,445 deaths in total, all-cause mortality). These patients were noted to be older than community acquired cases (median 82 years versus 78 years of age) and were anticipated to have a higher burden of morbidity, as they had been admitted with a separate medical condition for at least 8 days at the time of testing positive, and were therefore more likely to die from causes other than Covid-19. After adjusting for age, co-morbidity and other factors, the authors found no evidence that patients developing definite hospital onset Covid-19 are at an increased risk of death compared with other patients diagnosed with community acquired infection. Patients with probable hospital onset infection had a small but significantly higher odds of death compared with community acquired cases, which the authors attribute to differences in the patient population that could not be controlled in the analysis. (ARHAI Scotland, 2022).
- 11.22. A similar analysis from national surveillance data in Wales identified 25,263 hospitalacquired cases of Covid-19 and 5,490 (22%) deaths between February 2020 and March 2022. Adjusting for confounding, there was no increased mortality for hospital-acquired cases compared to cases admitted with Covid-19 from the community. Male sex and older age were, however, associated with increased mortality. (Rubeshkumar et al, 2023).
- 11.23. Outcomes for patients with hospital acquired Covid-19 improved over the course of the pandemic. The ARHAI Scotland study found that, after controlling for potential confounders (such as age, patient co-morbidities, and vaccination status), patients who were first diagnosed with Covid-19 in hospital had lower odds of death within 28 days in the delta wave and omicron wave compared with the pre-alpha wave (prior to 3rd January 2021). For example, the all-cause mortality for definite hospital onset infection was 31.2% for the pre-alpha wave, 21.8% for the delta wave, and 10.7% for the omicron wave. This latter figure is similar to the crude mortality rate of all patients aged 80 or over and discharged from Scottish hospitals in January 2020, where 10.6% of patients died within 30 days of their hospital admission, although the authors note that the data are not directly comparable.



- Figure 12: Covid-19 case all-cause mortality within 28 days by onset status and variant wave in Scotland overall; specimen dates up to 31 March 2022. Adapted from data produced by ARHAI, NHS Scotland (ARHAI Scotland, 2022a).
- 11.24. Similarly, Public Health Wales data (Rubeshkumar et al 2023) demonstrated that vaccination and infection in later pandemic waves were associated with lower mortality. Similar to the figures for Scotland (but using different timeframes), they quote a mortality for definite hospital onset infection of 30.7% for the first wave (up to 26th July 2020), 25.9% for the second wave (27th July 2020 to 16th May 2021), 15.5% for the third wave (17th May 2021 to 19th December 2021), and 12.2% for the fourth wave, 20th December 2021 to 31st March 2022.
- 11.25. The causes of the improved outcome over time are likely multifactorial. The ARHAI study found that inpatients who had been vaccinated with either one, two, or three/four doses had lower odds of death within 28 days compared with those who had not been vaccinated (ARHAI Scotland, 2022a). The authors also acknowledge that improvements in treatments for Covid-19 over this time period are likely to have contributed to reduced mortality rates. The reduced virulence of the virus is, similarly, likely to have contributed. The Public Health Wales study found that vaccination reduced the odds of death in hospitalised patients by 40-50% (Rubeshkumar et al, 2023).

Summary

11.26. The evidence that hospital acquired infection led to worse outcomes is inconsistent. This may reflect differences in methodology, including adjustment for confounding factors, such as age. However, there is consistent evidence that, in line with community acquired infections (Kirwan et al, 2022), the mortality from HAIs fell considerably over the course of the pandemic and that by summer 2022 mortality was comparable to that for other causes of hospital admission. Data on other patient outcomes, such as length of stay and adverse hospital events, is lacking.

The burden of Covid-19 infections in hospital healthcare workers

- 11.27. Healthcare workers provided a vital role in the delivery of treatment for patients with Covid-19. However, from the earliest reports of Covid-19 from Wuhan, high rates of infection have been noted in hospital HCWs. This causes concern for a number of reasons: the direct impact on the safety and wellbeing of staff as a result of viral infection; the indirect impact of the pandemic on other aspects of physical and mental health; resultant staff shortages; the processes and procedures placed on hospitals to provide a safe working environment for their staff. However, very little was known about the role of staff transmission in nosocomial infection of respiratory viruses prior to the pandemic.
- 11.28. Various studies have demonstrated that healthcare workers in hospitals were at increased risk of Covid-19 infection early in the pandemic. For example, a Royal Society report from 2020 estimated that at least 10% (95% confidence interval: 4-15%) of all Covid-19 infections in England were identified in patient-facing healthcare workers and resident-facing social care workers during the period from April 26 to June 7 2020 (Royal Society, 2020), (Nguyen et al, 2020). Compared with the general community, front-line health-care workers had at least a threefold increased risk of reporting a positive Covid-19 test, even after adjusting for other confounders. In comparison to the general population, during the first wave of the pandemic, patient facing HCWs were more likely to have developed antibodies to SARS-CoV-2 (Ward et al, 2021). The proportion of HCWs who developed antibodies to SARS-CoV-2, and are therefore presumed to have been infected, during the first wave of the pandemic varies between study and geographical region (Hanrath et al, 2021). In one study, the seroprevalence (i.e. the proportion of individuals that had detectable antibodies to SARS-CoV-2 and therefore prior infection with the virus) in HCWs was estimated at 24.4%, considerably higher than the 6% estimates in the general population (Shields et al, 2020). During the second wave, the SIREN study found that 12.9% (2,353/18,284) of susceptible HCWs enrolled in the study became infected with SARS-CoV-2. The authors noted regional differences in HCW risk, part of which may have been associated with higher incidence rates in the community.
- 11.29. Healthcare absences due to sickness in England are reported at a national level on a monthly basis by NHS digital. Prior to the pandemic, monthly sickness absence rates for NHS healthcare professionals generally fluctuated between 4% and 5%, with clear seasonal variation (generally lower in the summer and spring, peaking in the winter). NHS employees have been shown to have rates of sickness absence that are double that of the UK labour force as a whole (Blaaza et al, 2024). The Nuffield Trust reviewed the data on staff absences over the pandemic, focusing on absences in 2022 compared to the last pre-pandemic year, 2019 (Palmer and Rolewicz, 2023). The report found that:
 - a) Monthly sickness absence rates in 2022 were consistently higher than the highest peak in 2019. The mean reported rate for NHS staff across 2022 was 29% higher than in 2019 (5.6% v 4.3%).

- b) This equates to 27 million full time equivalent days across 2022, which the report estimates is the equivalent of approximately 74,500 full-time staff, including 20,400 nurses and 2,900 doctors.
- c) Any reported figures are likely to have been an underestimate, due to various causes of under-recording of the sickness absence rate.
- d) A separate analysis of data from NHSE estimated that 122,501 staff reported as absent from work through sickness or self-isolation at the peak across health care providers in 2022 (on January 6, during the Omicron wave) (NHS England, 2024d).
- e) Approximately one in six (18%) sickness days were reported as specifically due to Covid-19. However, there was variation in classification of staff absence days across the study period. Assessing the detailed reasons for sickness absence (which does not identify Covid-19 separately), conditions that may be attributed to Covid-19 (chest & respiratory conditions; cold, cough or flu; infectious diseases) account for much of the increased levels compared to 2019 (27% in 2022 compared to 10% in 2019).
- f) Another major contributor to staff absence was mental health, totalling 6 million days of staff absence in 2022, an increase of 26% between 2019 and 2022.
- g) Trends in peaks in absence were similar across the different regions of England, but the absolute numbers varied considerably, being highest in the North West and lowest in London. The exact reasons for this regional variation are unclear. Previous analyses of staff absences during the first wave suggested that trends followed rates in the community, with variation in regions reflecting the spread of the pandemic across England (Appleby, 2021). The South West experienced smaller increases in staff absence compared to other regions in England, and also consistently lower incidence rates of Covid-19 in the community. However, staff absences were also lower in the South West prior to the pandemic.

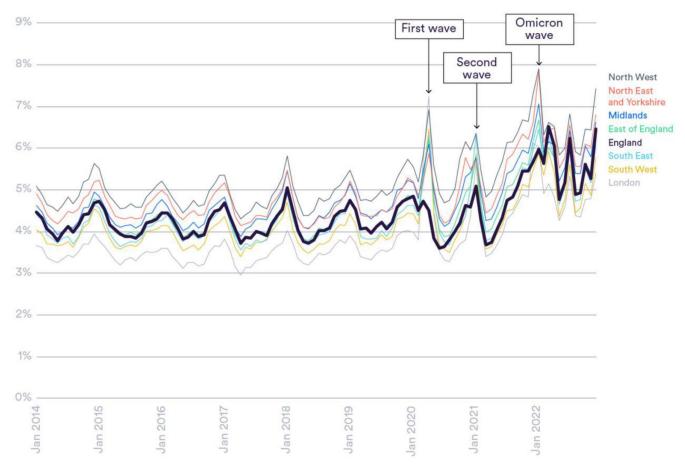


Figure 13: Trend in reported sickness absence rate in NHS organisations, 2014 to 2022 (Nuffield Trust, 2023).

- h) The report notes surges in sickness absence were also observed in published data from Wales and Scotland (the report does not specifically refer to Northern Ireland).
- All types of NHS trust (from small to large, and from acute to community) have, on average, reported a substantial increase in staff absence due to sickness. However, there was considerable variation at a provider level. Mental health and learning disabilities trusts were less affected; ambulance trusts were more severely affected, with rates rising to over 10% in some trusts across 2022.
- j) Pre-pandemic, reported sickness absence rates varied between healthcare professional groups (being generally lower in doctors, and higher in nurses, ambulance staff and allied health professionals) (Blaaza et al, 2024). Sickness absence rates increased for almost all staff groups between 2019 and 2022. However, the rise was minimal for some groups (managers, central functions, and for some categories of largely locally employed doctors) while other professions,

including ambulance staff, support to ambulance staff, and midwives, saw larger increases.

- 11.30. While the Nuffield Trust report demonstrates higher levels of staff absence in 2022, the exact reasons for this, and the relationship to the pandemic, are somewhat unclear. While a proportion of absences will have been directly related to Covid-19 infections in HCWs, the report authors highlight additional factors that influence staff absences, including job satisfaction and employee engagement, workload over previous years, effort-reward imbalance, socioeconomic status, and gender (Jones, 2020).
- 11.31. Covid-19 infections in staff led to a number of hospitalisations and deaths. As with the general population, deaths in HCWs globally were more common in males and older HCWs (Bandyopadhyay et al, 2020). Data produced by the Office for National Statistics on deaths involving Covid-19 among health workers aged 20 to 64 years in England and Wales, show that 414 deaths were registered between March 9 and December 28 2020 (ONS, 2021).

Summary

11.32. Rates of infection in HCWs are considerably higher than the general population. The pandemic has been associated with high levels of staff absence, related to waves of viral transmission in the community, but also varying by region and profession. The overall number and/or proportion of staff absences directly due to Covid-19 over the course of the pandemic are not readily quantifiable. Where absence has been attributed to Covid-19, it is not possible to reliably demonstrate at scale the proportion of Covid-19 infections in HCWs that were acquired in healthcare settings, as opposed to the community. This is explored below.

Sources of transmission

- 11.33. Sources of transmission and ongoing propagation of Covid-19 in hospital are numerous. Hospitals are complex settings with an extensive array of human-human interactions related to healthcare provision, which provide opportunities for virus transmission. The likelihood of transmission of each interaction is, in turn, influenced by a range of factors including compliance with social distancing, PPE utilisation and other IPC measures. A number of studies have illustrated some of the complex issues.
- 11.34. Transmission occurs across a range of clinical areas:
 - 11.34.1. Numerous studies provide evidence of transmission on both Covid and non-Covid wards including a range of general and specialist medical and surgical wards (Meredith et al, 2020), (Wake et al, 2020), (Lindsey et al, 2022). Transmission is uncommon on ICU (Lindsey et al, 2022). While there are some wards that appear to have repeated transmission events, this is an inconsistent finding across studies (Lindsey et al, 2022). In non-Covid wards, patients with asymptomatic, presymptomatic or atypical presentations of Covid-19 may have been admitted to

these wards and been the source of transmission, especially if there are delays in case identification. (Wake et al, 2020), (Snell et al 2022), (Illingworth et al, 2021).

- 11.34.2. Admission areas at particularly high risk of transmission include cohorting areas for patients with suspected Covid-19, awaiting results of viral testing. At times of high bed occupancy, or in estates with low availability of side rooms, patients presenting with suspected Covid-19 may be cohorted in the same clinical area while awaiting test results. During the first wave of the pandemic, rapid point of care testing was not readily available outside of trial settings. The turnaround time for test results from laboratories was ordinarily in excess of 24 hours from swab collection to result, meaning that patients may spend one or more days cohorted with other patients before definitive results could be reached. Some of these patients may have had Covid-19, while others had similar illnesses. Susceptible individuals were therefore exposed to SARS-CoV-2 by close proximity with infected patients, and seed outbreaks in subsequent wards. (Wake et al, 2020). In a modelling study, the proportion of admissions wrongly suspected of having Covid-19 on admission and therefore incorrectly cohorted with Covid-19 patients, increases the rate of nosocomial transmission (Evans et al, 2023)
- 11.34.3. A weak correlation has been identified between the cumulative rates of definite hospital onset infection and bed occupancy, reduced availability of single bedded rooms, and a reduced total volume of heated areas of hospital buildings (Cooper et al, 2023), (Evans et al, 2023). Increased single room availability, and increased heated volume per bed, is associated with a reduced incidence of healthcare associated infections in patients, but not for HCWs (Cooper et al, 2023). Reports of patient-to-patient transmission increasing during the second wave, when bed pressures were higher and there was an increased effort to maintain routine and elective services (Lindsey et al, 2022). Where studied, outbreaks were more common in wards with higher numbers of beds per bay (Lindsey et al, 2022).
- 11.34.4. Transmission has also been demonstrated in a crowded emergency department, leading to seeding and outbreaks on three wards and onward transmission in the community from discharged patients (Hare et al, 2022).
- 11.34.5. Wards where Covid-19 patients were being cared for in the same ward as patients without the infection (but cohorted in bays or side rooms) have been associated with increased rates of hospital onset infection (Price et al, 2020).
- 11.34.6. Clinical areas that shared staff, or had frequent patient or staff movement between them, have been associated with higher rates of transmission. Examples include renal wards (and potentially access to dialysis facilities) (Price et al, 2020).
- 11.34.7. Certain outpatient areas have also been identified as having higher risk of transmission. For example, multiple genomic investigations have shown transmission associated with dialysis units in the first wave of the pandemic (Meredith et al, 2020), (Li et al, 2021). Dialysis patients are at particular risk of infection, representing high risk patients for the development of infection, with individuals having frequent travel to units, as well as prolonged and regular contact

within the dialysis units themselves. Of note, these studies show transmission both within the dialysis unit (for example between patients who dialysed in the same session in closely located chairs), and on shared transport to and from the unit. However, the introduction of enhanced IC measures nationally in April 2020 led to a reduction in healthcare associated cases (Li et al, 2021).

- 11.35. The major source of hospital onset infection in patients is other admitted patients:
 - 11.35.1. Modelling studies have demonstrated that other patients act as the main source of transmission in hospital associated patient cases, either directly or via indirect spread in the environment, or HCWs as vectors (Evans et al, 2021). Patient to patient transmission events occur more commonly in shared bays. (Lindsey et al, 2022). In particular, patients who themselves acquired SARS-CoV-2 infection in hospital were the main sources of transmission to other patients. (Mo et al, 2021), (Cooper et al, 2023). In one genomic epidemiology study, 40%-50% of hospitalonset patient cases resulted in onward transmission compared to 4% of communityacquired cases (Lindsey et al 2022). The most likely explanation for this is that patients with community acquired infections, who typically present to hospital having had symptoms of Covid-19 for some days, are likely past their peak infectivity but are more likely to be effectively isolated with appropriate PPE precautions; whereas hospital acquired cases are likely to reach peak infectivity at, or just before, the time of symptom onset and are less likely to be effectively isolated. The distribution of secondary cases was very similar across first and second waves when studied, with ~50% of SARS-CoV-2 cases resulting in onward transmission in one study, where only 5-10% of all infections resulted in more than two secondary cases (Lindsey et al, 2022), (Lumley, 2021).
 - 11.35.2. Some studies have identified a small number of patients who contribute a disproportionately high burden of transmission. In one single site study, 21% of individuals were responsible for 80% of viral transmission (Illingworth et al, 2021). Of the four key patients driving transmission, all of whom had hospital-acquired Covid-19, two had a history of chronic liver disease, and two had previous haematological malignancies, one of whom was still on immunosuppressive treatment. One of these patients was confused and mobile on the ward. Another had a fever for several days before being tested for SARS-CoV-2, which had been attributed to a pre-existing community-acquired bacterial infection. The immunosuppression of these patients may dispose to prolonged shedding of virus, at higher viral loads. Confused patients may be less likely to report symptoms, and more likely to mobilise around clinical areas and have difficulty complying with IPC practices.
 - 11.35.3. The role of HCW-patient transmission is much smaller, but is likely increasingly important at times of high HCW positivity (Evans et al, 2021). Of note, many studies identified cryptic transmission, where the clear epidemiological links could not be identified between all cases, or the index case of an outbreak could not be determined. (Meredith et al, 2020), (Snell et al, 2022).

- 11.36. The source of Covid-19 infections in staff is more complicated, with roles for both hospital and community infection, from other HCWs and patients. However, the relative importance of each of these varies between studies.
 - 11.36.1. Modelling studies have shown that the risk of HCWs acquiring Covid-19 in the community versus the hospital depends on the prevalence in the community. At times of high community prevalence, community transmission is the most likely source of infection. When the community incidence rate is reduced, HCW-to-HCW transmission becomes the most likely source of transmission. (Evans et al, 2021). Conversely, there was an increasingly important role for patient-to-HCW transmission when the proportion of beds occupied by Covid-19-positive admissions was high. However, on average, the risk of HCW acquisition of infection from a patient was less than half that of acquisition in the community. (Evans et al, 2021).
 - 11.36.2. Data from several studies (Illingworth et al, 2021), (Mo et al, 2021), (Cooper et al, 2023) have demonstrated that transmission from both HCWs and patients (mostly nosocomially infected patients) were of similar importance for transmission to HCWs. In one study comparing the first and second waves, transmission between HCWs was more important than patient to staff transmission in the first wave, but reduced in the second wave. In the same study, patient to staff transmission remained constant both in terms of absolute and proportion of transmission events across the two waves, suggesting that control measures introduced during the pandemic likely reduced transmissions between healthcare workers but were insufficient to prevent increasing numbers of patient-to-patient transmissions. These control measures were, predominantly, introduced between waves and included improved HCW PPE for all patient contacts, testing all hospital admissions (and, subsequently, on day 5 of admission), testing asymptomatic staff and patients in outbreak areas, FRSM use in all areas of the hospital (Lindsey et al, 2022).
 - 11.36.3. The overall risk of a HCW acquiring infection from a patient with Covid-19 following an unprotected exposure appears to be low. A review of studies published in the first wave of the pandemic found that 1.6% of HCWs became infected following contact without PPE, or with PPE that was considered to be inadequate; this figure remained the same for HCWs who were reported to have a high-risk contact (defined in studies as prolonged, at least 10 minutes of direct contact <2m with the infected patient or being present during AGPs performed on infected patients) (Bak et al, 2021). The methodology underlying these studies is likely subject to recall bias, and the nature of the interactions studied heterogeneous. However, although the risk for each individual encounter may be low, given the high number of interactions between patients and HCWs in different clinical environments, the overall risk to HCWs of infection remains high.
 - 11.36.4. The location of HCW-HCW transmission is often related to the clinical area in which those HCWs are based, but the exact circumstances are unclear. It is the authors' view that transmission may be more likely to occur in staff break and communal areas (which are often more poorly ventilated, with lower rates of PPE

usage, for example for meals), than in clinical areas (where PPE usage is more consistent), but the data to support this are currently lacking.

- 11.36.5. Of note, a number of studies have identified a substantial proportion of asymptomatic HCW infections, individuals who may still transmit the virus. For example, 31% of staff testing positive in one study reported no prior symptoms (Valdes et al, 2021), (Cooper et al, 2022).
- 11.36.6. Transmission events in the community have been identified in a number of studies, including between HCWs who live together in shared accommodation (Meredith et al, 2020), (Illingworth et al, 2021). Household contacts with a known or possible case were a significant risk studies of HCWs based on serology and molecular testing (Eyre et al, 2020)
- 11.37. Although specific sources of transmission for HCW infection are sometimes lacking, a number of factors have been associated with positive serology or molecular testing in a number of studies conducted in the first and second wave:
 - 11.37.1. Higher rates were observed in HCWs with black or south Asian ethnicity; (Hanrath et al, 2021), (Martin et al, 2022), (Eyre et al, 2020), (Cooper et al, 2022), (Shields et al, 2020), (Valdes et al, 2021).
 - 11.37.2. Higher rates were observed in HCWs of higher social deprivation (Hanrath et al, 2021).
 - 11.37.3. Certain occupational groups had higher rates, most notably domestic services staff, nurses, and health-care assistants (Hanrath et al, 2021), (Eyre et al, 2020), (Cooper et al, 2022), (Shields et al, 2020), (Pople et al, 2022), porters, physio-, occupational and speech and language therapists. Junior medical staff had higher rates than senior medical staff. Administrative staff had the lowest proportion of any major staff group.
 - 11.37.4. Certain specialties, with the highest rates in the emergency department (Martin et al, 2022), (Eyre et al, 2020), (Pople et al 2022), haematology and oncology, trauma and orthopaedics/rheumatology (Eyre et al, 2020), and acute or general medicine (Eyre et al, 2020), (Martin et al, 2022), (Cooper et al, 2022), (Shields et al, 2020).
 - 11.37.5. Seroprevalence decreased with seniority in medical/nursing practitioners. (Martin et al, 2022).
 - 11.37.6. Anaesthetics/ICU staff members were less likely to be positive than other specialties (Martin et al, 2022), (Valdes et al, 2021), (Eyre et al, 2020), (Shields et al, 2020), (Pople et al, 2022). Suggested reasons for this include: level of PPE (FFP3 had availability in ICU from the outset; FRSM introduced at a midway point in the study in confirmed cases in non-critical care settings), training and time for PPE

donning and doffing (higher in ICU); increased exposure to patients with Covid-19 in non-critical care settings where the diagnosis was not suspected, e.g. elderly patients with delirium or diarrhoea (Eyre et al, 2020). In an air sampling study investigating the quantity of virus circulating in clinical areas, SARS-CoV-2 RNA was detected in the air of a medical ward caring for general medical patients on the majority of study days, but there was considerably less SARS-CoV-2 RNA detected in air in the ICU (Conway Morris et al, 2022).

- 11.37.7. Direct care of patients with Covid-19 (Eyre et al, 2020), (Cooper et al, 2022), (Pople et al, 2022). (Although it was noted that there was a higher overall number of staff acquisitions in non-Covid-19 acute medical wards compared to Covid-19 cohort wards).
- 11.37.8. Workplace exposure, with reported contact without PPE with a known or suspected Covid-19 patient (Eyre et al, 2020). Reuse of PPE or reported inadequate PPE. However, even with adequate PPE, health-care workers who cared for patients with Covid-19 remained at increased risk. (Nguyen et al, 2020).
- 11.37.9. In the second wave, the likelihood of infection was higher in HCWs under 25 years old, and those living in larger households (Pople et al, 2022).
- 11.37.10. HCW vaccination was associated with substantial reduction in transmission to patients linked to exposures in infected HCWs, and large reductions in the overall rate of infection in HCWs (Cooper et al, 2023). Increasing time to first vaccination has been strongly associated with infection, and potentially onward transmission (Pople et al, 2022). Mathematical model simulations have indicated that rates of infection during the second wave in patient facing hospital HCWs would have been 69% higher were it not for the rapid introduction of vaccination (Pople et al, 2022).
- 11.38. The role of visitors in transmission of SARS-CoV-2 in hospital remains unclear.
 - 11.38.1. Restrictions to visiting were commonly used methods during the pandemic to reduce contact within hospitals, alongside a range of other measures to reduce human-human contact (Ahmad and Osei, 2021). This was performed with the intention of reducing visitors importing the virus into the hospital and, early in the pandemic, preventing visitors from acquiring the virus in hospital. However, there is limited evidence to quantify the impact of restricted visiting on nosocomial transmission.
 - 11.38.2. Whereas national surveillance studies can be performed on centralised databases of patients and healthcare workers, no such routinely collected data exist for hospital visitors. Similarly, there are no large-scale studies that investigate the impact of visitors, and they have largely been absent from smaller studies at the hospital level. However, rates of asymptomatic or pre-symptomatic infections are well described in the general population and there is therefore likely to be a considerable risk of transmission from visitors at times of high community prevalence. There are case reports of hospital acquired infection being attributed to visitors, at a time of limited restrictions (Rhee et al, 2020). Conversely, there are

also case reports of visitors acquiring Covid-19 when attending patients in hospital (Bak et al, 2021).

Summary of the principal sources of outbreaks of hospital acquired Covid-19 in the UK

- 11.39. In summary, there are a number of potential sources of hospital acquired infection in the UK, in both patients and visitors. These can be divided into individual factors (where individuals with Covid-19 were able to transmit the virus within hospital) and environmental factors (where the hospital environment facilitated transmission).
- 11.40. Individual factors:
 - Newly admitted Covid-19 patients who could not be isolated quickly or adequately, for example when side-room isolation capacity was exceeded.
 - Newly admitted patients from the community who were asymptomatic on admission, or inter-hospital patient transfers who were asymptomatic at transfer, but who subsequently developed Covid, including with initial admission Covid PCR negative results.
 - Patients in whom the infection was not promptly diagnosed (for example due to atypical presentations, or in patients who were confused or unable to report their symptoms).
 - Patients and staff who transmitted Covid-19 before symptoms developed, or were persistently asymptomatic throughout their infection.
 - Staff who acquired Covid, with mild or unusual symptoms, but came to work (presenteeism).
 - Visitors who may have had mild or unusual symptoms and/or visitors who did not adhere to IPC guidance for visitors e.g. wearing of fluid-resistant surgical masks (FRSM).

11.41. Environmental factors:

- Hospital ward ventilation systems in older NHS hospitals which do not meet modern NHS Health technical Memoranda (HTM) or Health Building Notice (HBN) standards.
- Relative lack of isolation side room capacity, especially HEPA-filtered, negative pressure, lobbied side rooms.
- Ward designs which are open-plan and not well segmented e.g. by doors or partitions.

- Suboptimal IPC practices on hospital wards which increase the risk of nosocomial transmission e.g. poor hand hygiene practices, or poor adherence to PPE guidance
- Shared equipment between Covid and non-Covid patients e.g. blood pressure machines shared between bays
- Suboptimal cleaning of high-touch surfaces on wards e.g. door handles
- Hospital associated staff outbreaks linked to crowded and/or shared staff rest areas which were not conducive to social distancing and had many common high-touch surfaces
- Staff rest areas shared by more than one ward. Therefore, if one ward had a Covid outbreak, staff on the other ward were at increased risk through the shared staff room.

12. Other key challenges in implementation of IPC guidance in hospitals in the UK

Communications with staff on IPC measures

- 12.1. Communications with staff about the constant changes to IPC measures throughout the pandemic was a major part of the NHS response to Covid and involved a lot of work from all levels of NHS leadership, from NHS national bodies, down to hospital and ward level. Communication with staff was a vitally important activity. Reaching all staff within an NHS hospital is challenging enough in normal times, let alone in the context of a pandemic when everyone was so busy, under pressure, and potentially working outside their usual team structure. Effective dissemination of key messages was a necessary task but also a constant challenge for NHS Trusts. Busy and exhausted frontline NHS staff may simply not have had time to read e-mails, or other commonly utilised methods of communicating with staff at scale. In one study reviewing the cause of outbreaks in an NHS hospital, some of the recurring themes identified included inconsistent communication, variable implementation of infection prevention and control measures, and incomplete guidelines. (Ramsay et al, 2022)
- 12.2. It is the view of the authors that the cascading of key IPC communications at a national level, such as new guidelines, briefing notes and instructions to NHS Trusts was generally effective and improved over the course of the pandemic as processes and pathways of information cascade evolved and matured.
- 12.3. The many societal changes introduced in response to the pandemic like social distancing, lockdowns, widespread adoption of working from home (WFH) drove rapid innovation in communication methods. In the relevant period, Microsoft Teams became the standard online web platform for communication within and between NHS teams. Technology like Teams enabled communication with large numbers of staff, more than would be possible face to face. This mode of communication was a useful tool for communicating changes to IPC measures in many, if not all NHS Trusts.
- 12.4. However, we cannot know how each individual NHS Trust in the UK communicated with their staff, in terms of mechanism, frequency, and efficacy of this communication. We can describe the principles from our own experiences:
 - NHS Trust would receive information or indeed instructions relating to changes in IPC measures from UKHSA and/or NHSE (or the DA equivalent).
 - This would be discussed internally by IPC teams and Trust leadership to agree on how these new IPC guidelines would be implemented.
 - Agreed messaging would then be cascaded by e-mail, through managerial cascades, Trust intranet, online webinars, ward "huddles" at the beginning of a shift, etc.

- 12.5. One of the challenging aspects of changes to Covid-19 related guidance, including testing policy, was that these often gave little notice for the change. As many NHS Trust IPC teams will attest, new UKHSA/NHSE guidance would not infrequently be issued on a Friday afternoon, for implementation early the following week.
- 12.6. These short-notice changes to IPC and/or testing policy were challenging to implement quickly, given that internal hospitals approvals and communication plans had to be obtained and agreed very quickly. Furthermore, it was often prudent to co-ordinate response to new guidance with regional partners e.g. within Integrated Care Systems, particularly for changes affecting staff like PPE and social distancing. This was to avoid staff complaints about variation within the local NHS region and sometimes beyond. However, we appreciate that sometimes variation was necessary, because on occasion, parts of the UK had more severe Covid-19 surges than others, so they may have had stricter masks policies for non-clinical areas for example.

Adherence to PPE usage by NHS staff

- 12.7. Anecdotally, there were reports of incomplete adherence to recommended RPE by clinical staff. This would almost certainly have varied greatly across the NHS. The reasons for this were multifactorial and included: lack of training; variable quality of training; perceived lack of PPE supply in the organisation; lack of confidence in the recommended PPE; varying social pressure to adhere to PPE policy.
- 12.8. This anecdotal perception is supported by a 2020 survey of over 1,035 UK healthcare workers by Smith et al. They found self-reported adherence to PPE use to be 80%. Adherence was greater in older healthcare workers, in situations where PPE supply was good, and where PPE training was perceived to be good (Smith et al, 2022).
- 12.9. Given that adherence to PPE is influenced by knowledge of correct PPE usage and confidence in PPE, the findings of another UK healthcare worker study by Ismael et al are pertinent. This cross-sectional survey of UK healthcare workers found that knowledge and confidence in PPE in healthcare workers during the pandemic was influenced by hospital communication to staff regarding PPE policy and RPE training, and self-perceived knowledge of Covid-19 infection (Ismael et al, 2023).
- 12.10. The implications for a future pandemic are that PPE training must be of a good standard across the NHS, PPE supplies must be robust, and communication to staff about PPE policies must be effective. Improving performance in these areas should improve PPE adherence in a future pandemic.

Limited IPC resources: unwarranted variation?

12.11. Based upon our own experience of working in various NHS Trusts (in England), and having worked with NHS Trusts IPC teams in our local regions, we know there is significant variation in the IPC resources available to NHS hospitals. The Covid-19

pandemic was the most severe test of multidisciplinary IPC teams in the history of the NHS.

- 12.12. In our experience, large teaching hospitals tend to have IPC teams of adequate size and expertise in non-pandemic times. In the pandemic, even these relatively well-resourced IPC teams were stretched for a prolonged period. We can only imagine the strain felt by smaller IPC teams. In these small teams, absences e.g. due to sick leave due to Covid-19 would have a disproportionate operational impact on their NHS hospital's IPC capability.
- 12.13. The pandemic has highlighted the importance of all aspects of IPC and the risks of having IPC teams which are too small to provide surge capacity and or to be resilient under pressure. We hope these lessons will not be forgotten.

Challenges relating to the supply and distribution of PPE to NHS staff

- 12.14. The authors of this report have no personal experience of PPE supplies not arriving or being exhausted in our NHS Trusts. We are not aware of any examples of specific NHS Trusts running out of PPE at any stage of the pandemic. Some specific PPE products did run out in some areas, e.g. London, but alternative PPE (such as other brands of FFP3 respirators) were sought and supplied (National Audit Office, 2020).
- 12.15. This is testament to the work of our colleagues in our hospitals, regional and national NHS procurement teams. Unprecedented quantities of various types of PPE, not just respiratory PPE, had to be acquired from manufacturers, delivered to NHS warehouses and thence to NHS hospitals across the UK. This logistical effort had to be sustained throughout the pandemic.
- 12.16. However, we are aware of widespread concerns raised by frontline staff in health and social care regarding the availability of PPE on the frontline in the first half of 2020. A report from the National Audit Office published in 2020 included an informal survey of NHS provider organisations, who did not report PPE stocks running out. However, it also summarises member surveys conducted by the British Medical Association, the Royal College of Nursing, the Royal College of Physicians and Unison in April and May 2020, that showed that over 30% of participating members reported having insufficient PPE, even in high-risk settings where AGPs were being performed. They also reported a widespread perception of inadequate training in the use of PPE (National Audit Office, 2020). The National Audit Office report highlights methodological limitations in these studies, and that reports of inadequate PPE supplies had reduced by May 2020. However, concerns that PPE supplies were inadequate in the first wave of the pandemic have persisted, for example in a report published by the BMA in October 2023 (BMA, 2023).

British Medical Association (BMA), Royal College of Nursing (RCN), Royal College of Physicians (RCP) and Unison surveys of their members show that at least 30% of respondents experienced problems in at least one aspect of PPE availability or training

		Self-selecting respondents reporting insufficient PPE/PPE training						
		In a high-risk environment:		In an environment with possible or confirmed cases:				
		BMA¹ (%)	RCN ² (%)	RCP ³ (%)	BMA1 (%)	RCN ² (%)	RCP ³ (%)	Unison⁴ (%)
$\widehat{}$	Eye protection	-	22	-	88 (456/516)	30	39 (520/1,350)	32
	Face mask	-	-	-	62 (320/518)	27	16 (215/1,354)	32
m m	Gloves ⁵ (most available type)	15 (74/501)	4	4 (19/509)	23 (119/515)	3	2 (22/1,358)	9
4-D	Gown	43 (215/503)	30	31 (156/506)	17	-		-
	Respirator mask	54 (271/504)	27	19 (95/505)	-	-	-	-
	Not fit-tested for PPE	-	- 1	25 (125/508)	-	-	36 (384/1,063)	_
	No training on safe donning and doffing	17 (169/974)	34	-	44 (210/481)	46	-	-

Figure 14: Results of surveys of frontline healthcare professionals in April and May 2020 on PPE availability and training, summarised by the National Audit Office. Full notes and caveats are available at (National Audit Office, 2020).

- 12.17. We are aware of some hospitals utilising PPE that was acquired outside the usual NHS supply chains, for example from donations by local academic or industrial organisations. In addition to concerns regarding the availability of PPE, we are also aware of reports of variable quality of the PPE provided early in the pandemic, and of some hospitals re-using PPE outside the scope of national guidance with a view to prolonging supplies (Health and Social Care Committee, 2020) (Royal College of Physicians, 2024). However, we are not aware of any systematic studies investigating these issues, and cannot comment on why there is a reported difference of PPE availability between procurement teams and frontline healthcare workers. A full discussion of the adequacy of PPE supplies is beyond the expertise of these authors. We understand that Module 5 of the UK Covid Inquiry will examine procurement of pandemic supplies, including PPE, in detail.
- 12.18. Perhaps the most noteworthy adverse event related to PPE supply was the distribution of national Flu pandemic stockpile FFP3 respirators to NHS hospitals. The national stockpile had been built up over several years for the next pandemic. Unfortunately, many NHS hospitals reported that these masks were in poor physical condition and could not be used. For example, some of the masks had begun to partially disintegrate. This was manifested as visible deterioration of the fabric and elastic head straps of these masks.

- 12.19. These pandemic stockpile masks could not be safely used and although they were distributed to NHS hospitals, in many cases, they were not used due the physical deterioration. These degraded respirators were discarded.
- 12.20. This is a lesson for pandemic preparedness in the future. All PPE has a shelf-life and stock must be carefully managed, including for example periodic visual inspections of long-storage PPE for physical condition. The details of suitable pandemic stockpile management strategies are beyond our expertise as IPC professionals.

Logistical challenges related to respiratory hoods

- 12.21. It is worth noting here another challenge relating to the PAPR hoods. These are bulky, expensive items and need clean, dry, secure storage. In many NHS hospitals, storage space is at a premium at the best of times (personal experience). Finding suitable storage space for these filtered, powered hoods was not trivial.
- 12.22. In addition, these masks need to be cleaned after each use. We assume NHS hospitals' IPC teams, working with relevant local stakeholders, developed their own standard operating procedures (SOP) for cleaning of these specialist pieces of PPE. The PAPR manufacturers cleaning guidelines should also be followed.
- 12.23. Finally, these respiratory hoods need maintenance, not just cleaning. Although the hoods were of differing designs, they all had filters, which needed to be changed, at a frequency determined by the manufacturer. These powered hoods run on battery power and these batteries need to be recharged intermittently.
- 12.24. The maintenance requirements of these PAPR hoods were an added and unforeseen logistical burden for NHS hospitals to manage. Ideally, the maintenance for respiratory hoods should have been systematically recorded. To use these hoods over a prolonged period without such evidence of maintenance would carry a risk that they may not be effective. This could put staff at risk of infection.

IPC considerations for deceased Covid-19 patients

- 12.25. The evidence base on IPC risks of deceased patients to HCWs is relatively limited. Unfortunately, there were many in-hospital Covid-19 deaths during the pandemic, so protecting staff from any risks was an important IPC/OH consideration for NHS hospitals.
- 12.26. Body fluids from deceased Covid-19 patients could pose an infection risk to staff. The staff who would have contact with deceased Covid-19 patients include clinical staff on the wards where these patients were cared for, hospital porters and hospital mortuary staff, including histopathologists if a post mortem was carried out.

- 12.27. PHE produced a rapid review of the evidence on "COVID-19 transmission from the deceased" in 2021 (Public Health England, 2021a). This reviewed the evidence in the literature, including from published case series looking at staff working in "autopsy facilities" where autopsies (post mortem examinations) were carried out on multiple deceased Covid-19 patients. None of the studies were UK-based. In all these observational studies, staff wore robust PPE e.g. FFP3 respirators, eye protection +/- disposable gowns and, in some cases, the autopsy facility was described as having "...a ventilation system..." or "...whole room ventilation...".
- 12.28. With robust PPE ensembles as described above, these studies found no evidence of Covid-19 transmission to the autopsy facility staff.
- 12.29. Transmission risk from deceased patients was also examined by looking for evidence of SARS-CoV-2 in the bodily fluids of these patients. None of these studies were UK-based. It is clear from the 11 studies reviewed that SARS-CoV-2 was detectable by PCR in the respiratory tract, the lungs and in some cases, the eyes of the deceased.
- 12.30. HSE provides guidance on "Handling the deceased with suspected or confirmed COVID-19", which includes advice on PPE relevant to mortuary staff and pathologists (HSE, 2024). This includes enhanced PPE for autopsy procedures, which reflects the evidence form the aforementioned PHE rapid review.

The challenges of the ageing NHS estate

- 12.31. The massive scale of the pandemic and the highly infectious nature of Covid-19, initially in a population with no pre-existing immunity, exposed the inadequacy of older NHS buildings from an IPC perspective. Some NHS hospital buildings date back to the mid-19th century. Some may even be older.
- 12.32. Even early 21st century hospital buildings, depending on when they were built, will not have been suited to the challenges of Covid-19.
- 12.33. Modern day, newly built NHS hospital buildings must conform to national standards i.e. Health Technical Memoranda (HTM), including Health Building Notes (HBN). These standards evolve over time, as engineering knowledge and technology change and new threats, like Covid-19 emerge.
- 12.34. The collection of HTMs and HBN documents between them cover all aspects of hospital design and available online e.g.: (NHS England, 2024a), (NHS England, 2024b), (Department of Health, 2013), (NHS England, 2021b).
- 12.35. The NHS estate is extremely complex, with buildings of various ages, most are decades old, some are centuries old.
- 12.36. The most extreme example of an old hospital design unsuited to a pandemic is the Nightingale ward (distinct from the Nightingale hospitals used in the pandemic). These

are long, open wards, with almost no segmentation or barriers of any kind. It would be incredibly challenging to control patient-to patient spread of an airborne virus like Covid-19 or measles on such a ward.

- 12.37. Newer NHS hospital buildings, for example those designed in the last decade, should conform to the latest HBN and HTM standards and would have relatively more side rooms and isolation capacity and good ventilation with multiple air changes per hour, as per currently HBN/HTM recommendations. Most NHS hospitals suffer from a shortage of single room accommodation, especially older estates. In most other countries single room accommodation is the norm and isolation is not such a challenge. In the UK the policy initiative is to build new hospitals with at least 50% single room accommodation.
- 12.38. In contrast, older NHS hospitals tend to have limited side room isolation capacity and ventilation conforming to older and usually lower standards. Very old hospitals may rely on natural ventilation e.g. opening of windows.
- 12.39. The risks of Covid-19 transmission in older NHS estates, with limited isolation capacity and lower standards of ventilation would be greater than in a newer hospital. In simple terms, if an older hospital has less isolation capacity (side rooms) it will have to start cohorting Covid-19 patients in open bays sooner than a newer hospital with more isolation capacity. Unless there are robust physical barriers between these Covid-19 cohort bays and non-Covid bays, there is a risk of nosocomial transmission.
- 12.40. Whilst older hospital buildings can be upgraded to meet modern standards, including improved ventilation, this will obviously be expensive, and take a long time. The cost of these improvements may be prohibitive. There are no quick fixes for improving ventilation or isolation capacity on the ageing NHS estate.
- 12.41. In summary, it is harder to manage IPC risks in older NHS hospitals than newer ones built to the latest HTM and HBN standards. This is because older hospitals, unless extensively modernised, will have less good ventilation, be less spacious, may have ward designs which are permissive to nosocomial transmission and have fewer isolation side rooms.

The precautionary principle

- 12.42. We note feedback from a number of Core Participants, commenting on a previous draft of this report, lamenting the perceived inadequacy of some IPC measures, such as not recommending respirators when the evidence of airborne transmission was evolving or still a matter for debate. They urge the "precautionary principle" to be applied in future pandemics. Indeed, the term is used in the current versions of the NIPCM, in section 2.4 on FRSMs and RPE "If the hazard is unknown the clinical judgement and expertise of IPC staff is crucial and the precautionary principle should apply."
- 12.43. The precautionary principle is an approach to risk mitigation, in the face of potentially serious threats amid scientific uncertainty. The term has been used in various ways during the pandemic, by various parties (Crosby and Crosby, 2020). The authors of this report acknowledge this viewpoint.

- 12.44. In the face of a new, emerging threat of any kind, it is easy to say that one should adopt the precautionary principle and implement maximal precautions and safeguards e.g. maximal PPE. In the UK, we do in fact apply the precautionary principle when we suspect or diagnose a HCID. For example, whenever a febrile patient presents to an NHS ED with relevant travel history, symptoms and signs suggestive of the possibility of a viral haemorrhagic fever (VHF) like Ebola virus or Lassa Fever, as per ACDP guidance, highlevel PPE is recommended, as well as isolation of the patient in (ideally) a lobbied, negative-pressure, HEPA-filtered isolation side room and VHF testing undertaken.
- 12.45. It is harder to apply the precautionary principle when the threat is on a massive scale, as seen in a pandemic, partly because it risks exhausting the supplies of PPE for which the precautionary principle advocates.
- 12.46. The causative pathogen of future pandemics is likely to be classified as a HCID, at least in the early stages of global spread. At this point, the precautionary principle will very likely be applied and high levels of RPE will be recommended as a consequence. Given the increasing evidence base and methodologies developed for SARS-CoV-2, it will be possible to more rapidly acquire evidence on any new pathogen in relation to a number of IPC measures, including considerations of the appropriateness of de-escalating levels of PPE, and under which circumstances. The authors of this report strongly recommend that any guidance on de-escalating IPC measures for pathogens in the context of a future pandemic is performed carefully, transparently, engaging stakeholders and utilising the expertise and evidence from a range of disciplines. We acknowledge the possibility that future pandemics may involve pathogens for which debated areas of PPE in the context of SARS-CoV-2, such as FFP3 masks, may not be required. However, each individual pathogen, and the circumstances under which that pandemic arises, should be considered on their own merits. While we have learnt much from our experiences with Covid, as we have shown in this report, issues surrounding IPC are complex and dynamic; our response to future pandemics must be equally complex and dynamic.

13. Conclusions and recommendations

A – Personal protective equipment

- 13.1. Healthcare workers have played a critically important role in the delivery of treatment for patients with Covid-19. During the pandemic they were frequently working outside their usual areas of practice working longer hours, with more frequent shifts, often in unfamiliar clinical environments, and with unusual working practices. They were at greater risk of contracting the infection. Staff absences were more common due to a combination of direct Covid-19 infection, and increased rates of mental health concerns and other indirect effects of the pandemic.
- 13.2. Keeping health professionals free of infection is important to maintain delivery of the service. Longer term, not protecting staff from occupational health hazards is likely to promote feelings of disaffection and fuel problems of staff recruitment and retention. These are already entrenched throughout the UK, especially for nursing.
- 13.3. We do not know when the next pandemic will occur nor what pathogen will cause it. It is most likely to be a respiratory virus of zoonotic (animal) origin because, as history has shown, this is exactly the kind of pathogen with pandemic potential. We can therefore learn generic lessons from the Covid-19 pandemic in areas of IPC practice which were the most challenging for NHS IPC teams and NHS hospitals in general.

Recommendation A:

- (i) UK healthcare systems should maintain the capacity to rapidly deploy and scale up respirator fit-testing, potentially to all patient-facing clinical staff. This will require all acute NHS hospitals to maintain a small cadre of staff knowledgeable in fit-testing, who can in turn train more staff to fit-test in a future pandemic or major epidemic.
- (ii) UK healthcare systems should maintain supply lines of different brands and types of respirators to suit the different sizes and shapes of NHS staff faces. This will also improve resilience of PPE supply in the face of a future global emergency. This will not be wasted effort because respirators are also required to manage other infectious diseases which currently occur in the UK such as tuberculosis and measles, as well as occasional outbreaks of high consequence infectious diseases such as MERS-CoV and avian influenza.
- (iii) Manufacturers of respirators should be encouraged to design and manufacture respirators of a wider range of shapes and sizes, including sizes more suited to staff who: are female, of a black and minority ethnic (BAME) background, have facial hair, or are of small stature. The Medicines and Healthcare products Regulatory Agency (MHRA) and the Health and Safety Executive (HSE) should act on the difficulties experienced by female NHS staff, especially female staff from an ethnic minority background, in finding suitable respirators during the pandemic. This information should be used by these regulatory bodies when asked to approve respiratory PPE and/or investigate work-related adverse incidents relating to NHS premises and respirators.

- (iv) National stockpiles of PPE should be retained as a pandemic preparedness strategy, and they should be systematically inspected to provide assurance of continuing fitness for use. Assurance checks must account for the usable shelf life of each type of PPE. We understand that module 5 of this Inquiry will investigate the required scale of stockpiles. We support this being reviewed further due to the concerning logistical problems touched on in sections 12 and 7 of this report.
- (v) We are aware of variations in **PPE adherence** across the NHS and even within NHS organisations in terms of adherence to PPE policies. The best quality PPE will not help protect staff if they do not use it, or use it properly. We recommend that in a future pandemic or major epidemic NHS IPC training is of sufficient quality to inform HCWs of the threat posed, what PPE to use, why and when. This should be communicated efficiently and effectively. The NHS leadership across the UK should take steps to reduce unwarranted variation between NHS hospitals in PPE education and training.
- (vi) We would support further research into how to achieve good levels of PPE adherence of very large numbers of clinical staff during 'peacetime' or during a pandemic - where more stringent IPC might be required again over a long period of up to several years. Investment in high-quality research in this area will pay dividends in the long run.

B – Diagnostics and surveillance

- 13.4. Hospital acquired Covid-19 infections were common across secondary care. Overall, it is likely that the number of patients who contracted a hospital-acquired Covid-19 infection in the UK is well over 100,000. The transmission networks within hospitals are complex. Rapid case identification, including screening of asymptomatic or presymptomatic staff and patients, is of critical importance in preventing transmission.
- 13.5. The timely deployment and scale-up of appropriate diagnostics in the next pandemic will be an important aid to good IPC practices. We should not repeat the challenges of limited diagnostics early in the Covid pandemic which were initially confined to a few national reference laboratories.
- 13.6. Although the UK did scale up testing to adequate levels, thought should be given to how this can be achieved more rapidly in a future pandemic of this magnitude. Accurate and rapid diagnostics for novel (and established) pathogens is invaluable to IPC response.
- 13.7. Future national pandemic preparedness plans and exercises should address rapid development and deployment of relevant pathogen diagnostics explicitly. This planning should anticipate simultaneous global surges in demand for these diagnostic kits.
- 13.8. The possibility of asymptomatic infection being infectious was recognised relatively late. This was linked to limited PCR test capacity in the early phases of the pandemic, strengthening the argument for avoiding delays to new pathogen diagnostic capacity at scale.

13.9. One of the positive things about this pandemic was the early deployment of SARS-CoV-2 genomic (the entire gene library of the virus) studies to better understand the virus and its variants, but also genomic surveillance to help us track directly who gave the virus to whom in hospitals and the community. This will probably happen to a greater extent in the next pandemic or major epidemic and we fully support this - see also recommendation G (iii).

Recommendation B:

- (i) The UK continues to invest in the development and evaluation of diagnostics for infectious diseases, in particular point-of-care platforms, that are accurate, affordable, provide rapid results, and can be adapted quickly and rolled out at scale in the event of a novel pathogen with pandemic potential.
- (ii) Studies of **asymptomatic infection** in both patients and HCWs should be conducted as soon as any novel pathogen is identified.
- (iii) Surveillance mechanisms are established as soon as possible in future pandemics to develop and combine national datasets of positive test results and hospital admissions, to quantify and determine trends in hospital transmission. Systems developed for Covid-19, or other seasonal respiratory viruses, should be continuously refined in preparation for future pandemics, and would provide additional benefit on these other pathogens in the interim.
- (iv) Especially if testing does need to be rationed in a future outbreak, then case definitions must be kept updated, as a matter of urgency, on the basis of changing epidemiological knowledge, for example on geographical spread and newly recognised signs and symptoms.
- (v) Technology has enabled rapid PCR diagnostics for SARS-CoV-2, with results sometimes available in less than one hour. This capability will probably be available for the next pandemic pathogen. In addition, we recommend this rapid PCR capability be deployed on-site in, or near, Accident and Emergency departments as soon as practicable. This recommendation is based upon a trend, in parts of England at least, of centralisation of pathology services into large hub pathology labs.

C – Mitigating the IPC risks of the ageing NHS estate: ventilation and isolation capacity

- 13.10. Inadequate ventilation of old NHS estate was a challenge and a risk to patients and staff in the Covid pandemic. Even NHS hospitals designed as recently as the early 2000s may have suboptimal ventilation compared to hospitals designed in the last 5-10 years.
- 13.11. The capacity of most NHS hospitals to effectively isolate suspected and confirmed infections is limited by side room capacity (in both inpatient ward areas, emergency departments and other assessment areas), especially in older NHS hospitals.

Recommendation C:

- (i) Within the 6 months of the publication of the UK Covid-19 Inquiry's module 3 report, we recommend an independent review of NHS hospital ventilation to systematically review how ventilation in hospitals built to older HTM and HBN specifications can be improved. Once review findings have been published, UK Governments should produce clear action plans outlining how and when identified necessary improvements will be implemented. These plans should be supported by dedicated capital estates funding. This review could be carried out by e.g. academia or UK IPC organisations like the Healthcare Infection Society (HIS), Infection Prevention Society (IPS) or a combination of independent bodies with relevant expertise.
- (ii) We recommend that the overall NHS isolation capacity should be increased over the next 5-10 years to improve the NHS's ability to cope with infection-related winter pressures and the next novel pandemic or major epidemic to emerge. This can be achieved by increasing side room isolation capacity in older NHS hospitals during major renovations or rebuilding of existing NHS hospital buildings and/or wards. This investment in the NHS estate will be beneficial even if we do not suffer another pandemic for many years. There is always a need for isolation capacity for IPC of seasonal winter viruses like influenza and norovirus. If nothing is done to improve NHS isolation capacity, the UK will face the next pandemic with the same systemic IPC risks as we did in January 2020.
- (iii) We recommend that NHS(E) HBNs and HTMs relevant to IPC should be reviewed in light of the pandemic, if post-pandemic reviews are not already underway. We note that the current NHS HBN 00-09 "Infection Control in the built environment" was published in 2013 (Department of Health, 2013). The NHS HTM 03-01 "Specialised ventilation for healthcare premises", whilst published in June 2021, the Preface states "*This HTM was prepared prior to the COVID-19 pandemic…*". The word "pandemic" appears twice in this 213-page document (NHS England, 2021b). In our view, it would be prudent to review HTM 03-01 taking in all the lessons of the pandemic.

D – Guideline development

- 13.12. The core principles underpinning IPC are the same everywhere. A single suite of guidelines (not a step-by-step manual) supported by the best evidence available would promote uptake of beneficial interventions, discourage uptake of futile interventions, and avoid the wasteful use of resources. It is likely that IPC teams within a specific organisation would have to adapt these guidelines according to local need to some extent, which is already within their remit. We acknowledge that work is already being undertaken, notably in Scotland, to update IPC guidelines and that the methodology used to underpin guideline development is likely to be available in December 2024.
- 13.13. Guidelines are unlikely to be put in place effectively unless the health professionals who will be obliged to use them know about them and have faith in the information they contain (in WHO parlance, the guideline must provide a '*convincing narrative*' to '*meet the hearts and minds of users*'). Health professionals must believe in the processes used to

generate that evidence. Throughout the pandemic, doctors, nurses and other groups consulted their own professional bodies because they were anxious and confused about the guidance and did not perceive it to be trustworthy. Lack of compliance and improvisation were reported in relation to the use of PPE and RPE. During the pandemic some professional organisations resorted to publishing their own guidelines.

- 13.14. Guidelines must be up-to-date and reflect the most recent evidence. At present transmission-based precautions still distinguish between droplet and airborne routes of spread.
- 13.15. In the UK, three organisations have generated evidence germane to different aspects of IPC. These organisations are ARHAI Scotland, NICE and Public Health England/UK Health Security Agency. For example, throughout the pandemic NICE brought in additional resources and successfully updated its systematic reviews on pandemic Covid-19 pharmacological treatments. NICE and Public Health England/UK Health Security Agency processes are clearly described, shortcuts are clearly described when used and they are user friendly (likely to 'win the hearts and minds' of users). In comparison, the methodology used to develop ARHAI Scotland reviews and extract recommendations is less easy to follow.
- 13.16. Developing full-scale guidelines supported by full systematic reviews is not possible during emergency situations because it is a time-consuming and labour-intensive process. It is not possible to adopt full guideline development processes in emergency situations. Regularly reviewing and updating existing guidelines emergency situations requires a more agile approach that is nevertheless rigorous.
- 13.17. Rapid reviewing and rapid review guideline development are relatively new enterprises and the methods used to conduct them are evolving. Further work is needed to refine these methods because the timely availability of robust guidelines during emergencies has direct consequences for the safety of patients, staff and the public. The rapid reviews generated by Public Health England/UK Health Security Agency are a good step in this direction.
- 13.18. Guidelines frequently mention risk assessment and the Hierarchy of Controls to support clinical actions but do not explain how this should be undertaken or what it involves.

Recommendation D:

- (i) A single source of official IPC guidance should be available throughout the UK. This must set out the core elements of IPC. There should be scope for adapting the resource to meet the needs of different types of clinical settings and for different clinical procedures. The guidance must contain clear, pragmatic and scientifically sound instructions on when and how to undertake risk assessment for IPC, including airborne risk of infection.
- (ii) Official IPC guidelines should be supported by the best evidence available. The timetable for updating should be stated and the guideline should be **regularly reviewed** and updated in line with the timetable. The guidance for transmission-based precautions

should be updated as soon as possible to reflect the most recent evidence, removing the dichotomy between droplet and airborne spread. Health professionals are unlikely to welcome guidelines unless they trust them and the information that has been used to develop them and know they are up-to-date.

- (iii) The processes used to generate rapid reviews and rapid guideline development during an emergency need to be debated and improved before the next pandemic. A clear methodology needs to be created and adopted to streamline these processes. The aim will be to agree and put in place a more balanced approach to replace the lengthy processes advocated by the WHO and the ultra-fast track approach adopted in the UK during the pandemic. The rapid reviews generated by Public Health England/UK Health Security Agency could be used as a basis of what a useful rapid review might look like in future.
- (iv) Nationally agreed guidelines should be generated using the updated methodology described above. The methods used should be transparent and informed by a wider range of stakeholders. An evidence-to-decision framework should be used to draw out recommendations where possible, recognising the limitations of GRADE. The processes operated by NICE and the UK Health Security Agency are well-established and transparent. They could provide a blueprint for guideline development in future.
- (v) Each recommendation should be clearly stated. Strength of the underpinning evidence should be indicated (e.g. randomised controlled trial or observational study with stated risk of bias, expert opinion). This information will be more important to some health professionals than others. Where there is no evidence to support a guideline recommendation or only weak evidence is available, it will be necessary to draw on the experience and expertise of clinical and lay 'experts'. The protocol used to identify and recruit these experts should be stated.
- (vi) We recommend there is **more transparency around who has developed guidelines**. This will add to the credibility of the guideline and likely increase compliance.
- (vii)Once developed, information about the new guidelines should be disseminated to all stakeholders. Many avenues are available in addition to traditional routes from senior officials at national level via local and national healthcare networks. Information can be communicated to the professional bodies and societies, the regulatory bodies, patient support and charitable groups and education providers. All these groups should have played a role in development. Public relations departments can play a prominent part in the dissemination process. However, it is ultimately critical that information is **disseminated to frontline staff**; further work is required to understand the most effective mechanisms of guideline dissemination and measures of determining compliance in HCWs.
- (viii) The number of trained staff conducting evidence reviews and writing IPC guidelines should be increased and their diversity of backgrounds improved to include sufficient epidemiological, physical science, nursing, virology, microbiology, health systems management and other relevant subject matter expertise. Critical analysis of studies informing IPC is challenging work, and a multidisciplinary approach is essential.

This should be the case during peacetime, but it is especially the case during a pandemic. It is unclear how many people were involved in conducting ARHAI evidence reviews. At a time of national emergency where IPC can prevent, or fail to prevent, hundreds of thousands of hospital-acquired infections, **interpretation** of a rapidly changing evidence base must be as skilled, comprehensive, and unbiased as possible to ensure that guidance is of the highest possible quality. This requires a diverse and large team.

E – IPC training

- 13.19. Although nurses are regarded as responsible for IPC by other health professionals, preregistration nursing programmes only provide basic information about the principles of IPC. The Nursing and Midwifery Council does not clearly state how or what should be assessed in relation to IPC, as part of pre-registration nursing education.
- 13.20. Before the pandemic, the amount and quality of IPC education and training varied throughout the UK healthcare systems. In most instances it does not appear to have been very sophisticated or comprehensive. Post-pandemic arrangements differ according to country. The same training is still used for all professional groups and for qualified and unqualified staff across all four nations, and it remains hard to establish precisely what is offered, assessed or how it is quality-assured.
- 13.21. Although IPC is an established nursing specialism in the UK, preparation is ad hoc and there is no clear career pathway. This contrasts with other nursing specialisms, notably critical care nursing.
- 13.22. Many organisations operate IPC link nurse schemes. IPC link nurses are members of the usual nursing workforce who have assumed additional responsibility for infection prevention and control in their own ward or department. They receive additional education to undertake this role and liaise between the ward/unit and the IPC team (Royal College of Nursing 2021). There is scope for extending their responsibilities. Link nurse roles require support from employers matched with on-going education and mentorship. The link nurse role requires dedicated time but are valuable because they have the advantage of supporting career progression in IPC if managed appropriately.

Recommendation E:

- (i) Education and training for all staff working in healthcare should be delivered and updated in line with the official IPC guidelines proposed in Recommendation D. It should be tailored to meet the needs of different occupational groups and health professionals employed in different settings.
- (ii) Regardless of professional group or whether they are registered or unregistered, all staff working in healthcare need to know how to use PPE and RPE. This should be included at induction on entering employment in an organisation and in all updates. They should know where to seek help for practical issues such as fit-testing. Where IPC link nurse schemes are in operation, link nurses could assume these responsibilities.

- (iii) **Post-qualification** IPC education and training should be improved to enable health professionals to protect patients, other staff, all those visiting healthcare premises, and themselves from the risks of infection.
- (iv) Education and training for qualified health professionals needs to build on what has been taught during professional preparation. The pre-registration nursing curriculum laid down by the Nursing and Midwifery Council needs to be updated. Greater emphasis should be placed on the principles of IPC and how to apply them during pre-registration nursing education. Competence in IPC should be a requirement for entry to the nursing register.
- (v) UK healthcare systems should provide a clear career pathway into IPC nursing and a mandatory postgraduate qualification should be established for this specialism. These changes could be modelled on the educational programme offered to critical care nurses. IPC programmes could be run collaboratively between NHS organisations and partner universities. They could be competency based with participants assessed on practical and theoretical aspects of the curriculum. Funding and protected time would be necessary to take the course.

F - Improving NHS IPC capacity

- 13.23. The pandemic has highlighted the critical importance of IPC in the NHS in responding to existential threats like Covid-19. It is not sufficient to have an IPC team which struggles to cope with normal non-pandemic IPC risks and incidents. A robust IPC team of adequate size, proportionate to the size of the NHS hospital, will deliver benefits for patient safety, not least during the inevitable winter pressures from RSV, flu and Covid-19. It will also equip NHS Hospitals to face future pandemics and epidemics.
- 13.24. This capacity is not limited to numbers of IPC staff, but also relates to the training, skills and experience of IPC staff. This is essential for IPC teams to provide effective training, local policies, and monitoring and evaluation of IPC measures on the ground

Recommendation F:

- i. We recommend commissioning a **review of IPC team resources** in NHS hospitals, comparing hospitals of similar size with each other in order to identify which are relatively under-resourced in these important areas.
- ii. This review should include the **size** of the IPC teams, but must also consider the **skill-mix** of these teams, including IPCN leadership, support from infection control doctor(s), antimicrobial pharmacists, microbiologists, virologists etc.
- iii. Any **unwarranted variation** should be identified and resources made available to NHS hospitals with relatively under-resourced IPC teams. This will require investment.

G – Supporting high quality research

- 13.25. The evidence base for many IPC interventions for respiratory pathogens, in all aspects of healthcare, is lacking. While studies have demonstrated the impact of a number of interventions in combination, high quality data quantifying and comparing their relative contributions are largely absent. Increasingly sophisticated *in silico* models of the hospital environment have been used to estimate the impact of surges on capacity, hospital acquired infections, and infection control interventions.
- 13.26. There are many examples of high-quality cohort studies, epidemiological and genomic investigations, and large-scale surveillance projects that have underpinned our understanding of hospital acquired Covid-19 in the UK. These were made possible because of far reaching collaborations between academia, healthcare providers, and public health bodies. However, there is a predominant focus on secondary care.

Recommendation G:

- (i) The UK research funding bodies should work with academic and clinical collaborators to provide additional financial and logistical support to develop studies and underpinning research methodologies to investigate healthcare associated infection, and evaluate interventions to impede transmission. These could be developed for endemic or epidemic respiratory pathogens circulating in the UK, with a view that comparable studies could be rapidly deployed in future pandemics.
- (ii) Methods and studies of *in silico* **modelling** of NHS hospitals, and the broader healthcare system, should continue to be developed as an affordable method of rapidly establishing the burden of nosocomial transmission and evaluating the impact of IPC interventions.
- (iii) The UK should retain capacity for national genomic surveillance of pathogens, which could be increased, at scale, in future pandemics. This would require mechanisms to: develop ongoing collaborations between clinical laboratories and sequencing centres across the country; maintain capacity for storage and sequencing of viral samples; maintain a mechanism for the development and rapid sharing of bioinformatics methods and code for the analysis of genomic data; the maintenance of web-based platforms to synthesise and present key genomic data for a wider range of stakeholders and the general public.
- (iv) Where possible, research should be conducted in areas in which there is currently a limited or inconsistent evidence base. Gaps could be identified through evidence reviews in guideline development processes, as listed above, or stakeholder engagement. This report has identified a gap in our understanding of healthcareassociated infections in community settings.

H - Strengthening NHS Occupational Health Capacity and Capability

13.28 Although none of us are occupational health (OH) professionals, we have worked closely with OH colleagues during the pandemic and before. It is our understanding that in general, NHS OH is under-resourced, with no surge capacity in the face of an emergency. The pandemic has highlighted strategic priorities relevant to OH, for example, staff surveillance testing at scale, conducting individual risk assessments, managing staff sickness due to the new pathogen, supporting staff with mental health difficulties, and overseeing and/or delivering the staff vaccination programme. We are concerned that unless NHS OH services are not improved before the next pandemic or major epidemic, OH services will once again be unable to cope.

Recommendation H:

- (i) We recommend that OH services are reviewed across the UK, perhaps by an independent body, and investments made to improve NHS OH services to ensure that they can adequately cope with the demands of the current NHS workforce, particularly during surges of infectious disease in winter crises. Even without a new pandemic, good OH services are needed to support an NHS workforce traumatised by this pandemic. The NHS workforce, on which we depend in an emergency like the pandemic, deserves a robust, well-resourced OH service.
- (ii) We support increased investment in NHS OH services to address issues of understaffing, poor morale and high staff turnover in many NHS OH departments.
- (iii) If, despite the above, it proves impossible to expand NHS OH services in a sustainable fashion, planning assumptions for the next pandemic should assume that existing NHS OH services will be quickly overwhelmed, so contingency plans should be made to scale up emergency OH services.

I – The precautionary principle

- 13.27. Our views on the precautionary principle in relation to PPE are noted earlier in this report. There are two sides to this coin and we are aware of both. In an emergency, difficult decisions must be made based on a range of complex factors.
- 13.28. Absence of evidence should not be interpreted as evidence of absence where there is insufficient evidence on an intervention during the earlier stages of an outbreak, it should not be assumed that interventions will definitely have no effect. Equally, assumptions about the benefit-risk ratio should be carefully scrutinised, and updated where necessary. Consideration of a broader range of different types of evidence, mechanistic as well as epidemiological, is always needed but is especially important during this phase.

Recommendation I:

- (i) In a future pandemic, it is likely that the causative pathogen will initially be classified as a HCID, with commensurate levels of PPE that will very likely include respirators. If/when the pathogen is declassified as a HCID and/or consideration is given to relaxing IPC measures, this should occur when there is robust scientific evidence to do so. Policy makers have a responsibility to be transparent about decision-making, including whether logistical challenges or resource constraints have influenced their decisions.
- (ii) We support local risk assessment by individual NHS hospitals based upon their own circumstances, such that when IPC policies are changed, especially when they are relaxed, the local IPC team, working with subject matter experts and OH, decide how to implement the new IPC guidance. For example, if the ventilation in certain hospitals does not meet current HTM standards, higher levels of RPE may be prudent in that location. NHS hospitals should be supported in making these local risk assessments in a future emergency.

J – A coordinated approach

13.29. At times during this pandemic, there was clearly tension between many different IPC stakeholders. This included the national agencies responsible for IPC, local IPC teams and ward staff, and different professional organisations. Hearts and minds were lost. Regardless of the specific IPC policy choices made, in itself, this tension made protecting everyone in healthcare settings from the threat of Covid-19 an even greater challenge.

Recommendation J:

- (i) There should be greater collaboration between national bodies responsible for setting IPC policy and specialist organisations and societies. This could help to ensure that there is a) appropriate cross-disciplinary expertise in the formation of guidance as mentioned in recommendation D (ix); and b) consistency in guidance produced from different groups. This is especially true of clinical settings with different risks of transmission through clinical activities, such as critical care or cardiac arrest.
- (ii) We recommend that there should be a single UK-wide organisation or process with oversight of healthcare-associated infection – including surveillance, compiling evidence on transmission and measures to tackle transmission, and synthesising best practice guidance, with representation from research and public health bodies to model the pandemic and the impact of interventions. Each of these processes should be considered now, in advance of any future pandemic and mechanisms put in place to roll out any measures as soon as possible in the event of that pandemic. This is likely to require additional funding and resources to develop such systems.

Abbreviations

Aerosol Generating Procedure	AGP			
Filtering Face Piece type 3	FFP3			
Fluid Repellent Surgical Mask	FRSM			
Health Building Notice	HBN			
Healthcare Worker	HCW			
Health and Safety Executive	HSE			
Health Technical Memoranda	HTM			
High Consequence Infectious Disease	HCID			
Infection Prevention and Control	IPC			
Intensive Care Unit	ICU			
Occupational Health	ОН			
Powered Air Purifying Respirator	PAPR			
Personal Protective Equipment	PPE			
Polymerase Chain Reaction	PCR			
Public Health England	PHE			
Respiratory Protective Equipment	RPE			
Respiratory Syncytial Virus	RSV			
Turn Around Time	TAT			
Tuberculosis	ТВ			
United Kingdom Health Security Agency	UKHSA			
World Health Organisation				

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