Witness Name: Dr Safia Qureshi
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UK COVID-19 INQUIRY
MODULE 3

WITNESS STATEMENT OF DR. SAFIA QURESHI, DIRECTOR OF EVIDENCE AND DIGITAL ON BEHALF OF THE SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK (SIGN)

I, Dr. Safia Qureshi, will say as follows: -

I am the Director of Evidence and Digital within Healthcare Improvement Scotland (HIS). The evidence and digital directorate is the national authority for the development of evidence-based advice, guidance and standards for health and care professionals across NHS Scotland. I am a member of the Executive Team of HIS. I started my current role in 2019. The Scottish Intercollegiate Guidelines Network (SIGN) team sits within my directorate.

ROLE, FUNCTIONS, ACCOUNTABILITY, LEGAL STATUS & RESPONSIBILITY OF SIGN

1. SIGN was established to sponsor and support the development of evidence-based national clinical practice guidelines and to facilitate their implementation into local practice for the benefit of patients.

2. In 1993, (pre-devolution) the Clinical Resource and Audit Group ("**CRAG**"), the lead body for clinical effectiveness policies of the then Department of Health for Scotland, recommended that Scotland should develop national clinical practice guidelines and that these should be developed by the Royal Colleges and their Faculties in Scotland. SIGN was established to sponsor and support the development of national clinical practice guidelines for Scotland on a multi-professional basis. The first meeting of the Scottish Intercollegiate Group on Clinical Guidelines (renamed SIGN Council in 1994) was held in February 1993. SIGN Council was made up of, and still includes, representatives of all Royal Colleges in Scotland, and reported annually to their co-ordinating body, the

Conference (later 'Academy') of Medical Royal Colleges and their Faculties in Scotland.

3. The Colleges wished to retain professional leadership of SIGN but were concerned about their liabilities for staff and legal responsibilities in guideline development. In 2004, it was agreed that staff should transfer to NHS Quality Improvement Scotland ("**QIS**"). NHS QIS was established on 1 January 2003 as a special health board with a remit to improve the quality of healthcare in Scotland. Healthcare Improvement Scotland ("**HIS**") was established by the Public Services Reform (Scotland) Act 2010, taking over the work of QIS and the regulatory functions in regard to independent healthcare provision. The transfer has preserved SIGN's key features of professional leadership and public funding. Ownership of the SIGN methodology and name was enshrined in the 2005 Transfer Agreement **SIGN/01 – INQ000365686**, which states in section 12.8 that 'NHS QIS (NHS Quality Improvement Scotland) will issue the SIGN guidelines in the name of SIGN and NHS QIS with all logos'.

4. The terms of reference set out the role and responsibilities of SIGN Council and SIGN Executive. Terms of reference were reviewed and updates agreed by Council on 11 March 2020 and are attached **SIGN/02 – INQ000365687.** This was routine SIGN Council governance and the changes were not made in response to the Covid-19 pandemic.

5. Members of SIGN Council were, and still are, nominated by Royal Colleges or other professional organisations or committees. They also represent their specialty or discipline in a wider sense and consult with other specialist societies in their field. Members are selected by the SIGN Senior Management Team (SIGN Chair, Vice-Chair(s) and SIGN Programme Lead) to ensure that diversity and inclusion are addressed across SIGN Council. Interested members of the public are identified from an open call and are recruited as public partners, following a robust selection process, to provide the lay perspective.

6. SIGN Council follows the general principles of the code of conduct for developed public bodies: duty; selflessness; integrity; objectivity; accountability and stewardship; openness; honesty; leadership; respect.

7. The specific responsibilities of SIGN Council as agreed in March 2020 were to:

- ensure that guidelines issued under the SIGN name are based on the methodology set out in SIGN 50
- consider proposals for new guideline topics and to advise if these should be referred to Healthcare Improvement Scotland for further consideration
- approve proposed priorities from the Guideline Programme Advisory Group for keeping published guidelines up to date
- ensure that all relevant specialties are represented on guideline development groups or consulted as appropriate
- monitor progress with the SIGN guideline development and review programme
- receive and approve reports from the SIGN Strategy Group
- consider and approve proposals for changes to SIGN methodology, processes or activities
- provide a forum for sharing information about guideline development, dissemination, implementation and related activities
- ensure that all SIGN guidelines and related products are developed with active patient involvement.

8. Between March 2020 and April 2022, changes in the process for topic referral, the frequency of meetings and changes to the groups sitting under Council were made. The changes were not made in response to the Covid-19 pandemic. The terms were revised to reflect the changes and were agreed by Council on 6 April 2022 **SIGN/03 – INQ000365688**.

9. The membership of SIGN Council includes all the medical specialties, nursing, pharmacy, dentistry, professions allied to medicine, patients, public partners, health service managers, social services, and researchers. The membership of

SIGN Council is set out in the following documents as at June 2020 **SIGN/04 – INQ000365689** and June 2022 **SIGN/05 – INQ000365690**

10. The work of SIGN is undertaken by a team known as the "SIGN Executive", who are all Healthcare Improvement Scotland staff. The SIGN Executive is made up of a Programme Team working closely with the HIS Research and Information Services team. Together they are responsible for delivering the guideline programme to time and on budget.

11. Each guideline on the SIGN programme is developed with a multidisciplinary group of health and care professionals, and people with lived experience. Members of guideline development groups are recruited through nominations by the member organisations of SIGN Council, self-nomination or by guideline development group Chairs.

12. SIGN receives its core funding for the guideline programme from Scottish Government. SIGN is editorially independent from Healthcare Improvement Scotland and the Scottish Government.

13. Members of SIGN guideline development groups do not receive payment for their participation, although independent practitioners and patient representatives may claim expenses.

14. As set out in the SIGN strategy **SIGN/06 – INQ000365691** our objective is to improve the quality of healthcare for patients in Scotland by reducing variation in practice and outcome, through the development and dissemination of national clinical guidelines containing recommendations for effective practice based on current evidence.

15. There were no specific roles nor responsibilities set out for SIGN in the event of a pandemic.

16. Clinical governance and assurance to the HIS board for SIGN's activities is taken through the HIS Quality and Performance Committee. Significant risks or issues are escalated to the Executive Team or HIS Board by the Director of Evidence & Digital.

17. Legal Indemnity - The Scottish Government Health Directorate accepts under the Clinical Negligence and Others Indemnity Scheme (CNORIS), the responsibility for prospective and retrospective liability from the date on which SIGN became legally incorporated into NHSScotland. These points are set out explicitly in the current Terms of Reference, which were reformatted and revised for consistency across committees in the Evidence & Digital Directorate and agreed by the Quality and Performance Committee and SIGN Council on 21 June 2023 **SIGN/07 – INQ000365692** and **SIGN/08 – INQ000365693**.

18. Key decision makers in relation to SIGN's pandemic response functions were:

- Safia Qureshi, Director of Evidence & Digital, Healthcare Improvement Scotland is responsible for the strategy and directorate work programme;
- Roberta James, SIGN Programme Lead is responsible for the SIGN guideline work programme and the team developing the programme of guidelines; and
- Angela Timoney, Chair of SIGN Council is responsible for the activities of SIGN Council.

GOVERNMENT DEPARTMENTS & AGENCIES, PUBLIC BODIES, NHS ORGANISATIONS OR EXPERTS WITH WHOM SIGN CO-OPERATED

19. SIGN worked with the following closely in response to the pandemic:

- Institute of Health and Wellbeing, University of Glasgow to develop rapid evidence review **SIGN/09 – INQ000365696** and
- The COVID-19 Clinical Guidance Cell to support production of and disseminate position statements, advice and guidance.

20. SIGN collaborated with NICE on guideline development, initially agreeing to help out with their rapid guideline process **SIGN/10 – INQ000365695** but the topic SIGN was to take on was cancelled **SIGN/11 – INQ000365697**. The topic was "pregnancy complications". It was agreed not to proceed with this topic because it was comprehensively covered by guidelines published by the Royal College of

Obstetrics and Gynaecology, "Coronavirus (COVID-19) Infection in Pregnancy" and "Guidance for rationalising early pregnancy services in the evolving coronavirus (COVID-19) pandemic", published 03/04/2020.

GUIDANCE PRODUCED IN RESPONSE TO COVID-19 PANDEMIC

21. During the pandemic the responsibilities of SIGN were largely unchanged although, on direction of HIS Executive Team SIGN's programme of work was paused and to focus on COVID-specific projects. **SIGN/12 – INQ000315564** (ref CEO letter to Malcolm Wright).

22. In order to support health and social care services to maintain essential work, on the 16 March 2020 SIGN paused all direct engagement with health and social care staff, including SIGN guideline development group meetings, open consultation and peer review for guidelines and patient booklets, and other events **SIGN/13 – INQ000365698**. Letters were sent to members of guideline development groups in progress **SIGN/14 – INQ000365699**, those about to start up **SIGN/15 – INQ000365700** and SIGN Council **SIGN/16 – INQ000365701** explaining the situation.

23. With the need to prioritise and support the capacity of health and social care services, Healthcare Improvement Scotland took the decision to adapt their normal ways of working to be more flexible and reactive. This action was supported by Scottish Government.

THE COVID-19 CLINICAL GUIDANCE CELL

24. The COVID-19 Clinical Guidance Cell (hereafter "**Clinical Cell**") was created in February/March 2020 to rapidly produce guidance to support clinical decision making, throughout the pandemic, about the management of COVID-19.

25. It stemmed from a group of Infectious Diseases physicians who met on 4 February 2020 to formulate and discuss how to deal with cases of COVID-19. The group was chaired by Professor Tom Evans of Glasgow University and constituted as a Clinical Cell under the auspices of Health Protection Scotland.

26. On 12 March 2020 the Deputy Chief Medical Officer asked Tom Evans to continue to chair the Cell, which would transition to governance under Scottish Government. The Clinical Cell was supported by a professional secretariat from the Chief Medical Officer Directorate of Scottish Government, which managed administrative and planning responsibilities of this group. Creation of the Clinical Cell **SIGN/17 – INQ000365702** summarises the COVID-19 Clinical Guidance Cell from its creation in March 2020 through to Healthcare Improvement Scotland involvement. The document covers membership, meeting arrangements and outputs. An overview of the process for developing guidance is also included. The letter of May 2020 from the Scottish CMO, Dr. Gregor Smith (now Professor Sir) **SIGN/18 – INQ000343755** acknowledges the process and support provided by HIS to the Clinical Cell.

27. The initial work of the Clinical Cell focused mainly on providing rapid advice at a national level, based on informal clinical consensus in the absence of existing evidence. For example, "Pragmatic guide for diabetes services during the coronavirus pandemic" (published 8 April 2020, **SIGN/38 – INQ000365725**), which provided diabetes services with guidance to help support service reconfiguration during early stages of the pandemic and "Definitions of respiratory patients at high risk of COVID-19 infection, for shielding" (published 30 April 2020, **SIGN/39 – INQ000365726**). The Clinical Cell had met with representatives from the respiratory community on 15 April 2020 to agree on guidance for who is at particularly high risk, and therefore should 'shield'.

28. On 8 April 2020, preparing for the point at which more evidence would start to emerge, the Clinical Cell actioned Prof Tom Evans and Dr. John Harden, Deputy National Clinical Director, NHS Scotland to explore the case for HIS to assist in synthesis and publication of evidence-based guidance.

29. In April 2020 immediate areas for support were discussed **SIGN/19 – INQ000365704** and **SIGN/80 - INQ000398904**, setting out the support we could offer in the first instance. This was: hosting Clinical Cell guidance on the SIGN website (diabetes); formatting the continuous positive airway pressure (CPAP) guidance and developing a guidance template from it; working up a process to manage proposed topics, initial topics suggested were CPAP, shielding people

in hospital and older people. SIGN developed a rapid guidance development methodology tailored to Clinical Cell requirements, facilitated a new topic prioritisation process and a dedicated member of the SIGN Executive acted as liaison between evidence review support in Healthcare Improvement Scotland and the Clinical Cell.

30. This approach was endorsed by the Chief Medical Officer (CMO) in a letter to NHS Boards and Scottish Government Health and Social Care senior staff on 18 May 2020 **SIGN/18 - INQ000343755** (see paragraph 26). This letter instructed staff in NHS Scotland that from that point forward, all requests for development of new clinical guidance, or endorsement of existing clinical guidance on COVID-19, should be directed to Scottish Government's Clinical Cell Secretariat and that with support from HIS and SIGN, the Clinical Cell would assess incoming requests for new COVID-19 guidance as well as requests to endorse existing guidance. SIGN would manage the rapid evidence review process and provide the Clinical Cell with the assistance it needed to develop high-quality guidance.

METHODOLOGIES USED

31. The methodology typically used by SIGN when formulating clinical guidelines is published in SIGN 50: A guideline developer's handbook (Revised edition published 2019). **SIGN/20 – INQ000365707** In summary, we collaborate with a network of clinicians, other health and social care professionals, patient organisations and individuals to develop evidence-based guidelines. Our guidelines are based on a systematic review of the scientific literature and aid the translation of new knowledge into action. Literature is critically appraised using a defined process and recommendations are explicitly linked to the supporting evidence.

The guidelines are intended to:

- help health and social care professionals and patients understand medical evidence and use it to make decisions about healthcare
- reduce unwarranted variations in practice and make sure patients get the best care available, no matter where they live

- improve healthcare across Scotland by focusing on patient-important outcomes.

32. NHS Boards and Integration Authorities are required to consider SIGN recommendations for planning and delivering services. **SIGN/21 – INQ000365708**

33. SIGN's approach to developing rapid COVID-19 guidance is laid out in the CMO letter of 18 May 2020. This approach differed from SIGN's standard methodology by providing quicker routes to the development of recommendations using either evidence identified through literature searching or (where insufficient evidence was available) by informal consensus of experts. It allowed for the development of both new topics and the consideration of existing guidance. A key principle of this approach was flexibility and avoidance of methodological barriers to produce timeous guidance. While evidence was almost always unavailable or inadequate, the need for best practice guidance was a priority and therefore the intention was to develop recommendations or good practice points based on the best available information at that point in time. Guidance developed using this approach was published as COVID-19 Position Statements.

34. The SIGN Executive initiated an update of this approach in April 2021 which led to the development of a new rapid guideline methodology **SIGN/22 – INQ000365709**. This was partly driven by SIGN's aim to place quality improvement at the centre of all its activities, and also by a review of the working procedures of the Clinical Cell. A key objective of the review was to ensure the Cell's working practices harnessed the expertise of Healthcare Improvement Scotland in evaluating evidence **SIGN/23 – INQ000365710**.

35. The update added several elements which are core features of SIGN's standard methodology used for developing evidence-based guidelines on non-COVID-19 topics, including:

- Recruitment of a multidisciplinary guideline development group (GDG) which includes patient or carer representatives

- Definition of key questions using the People; Intervention; Comparison; Outcome (PICO) format

- Conducting a systematic literature search for each key question, across relevant sources, but the date range may be shorter, the range of sources smaller and the inclusion/exclusion criteria more focused than for a full SIGN guideline.

- Depending on the volume and/or the nature of evidence identified, studies are either critically appraised or a general observation is made about the robustness of the overall evidence base (e.g. if it includes preprints then a caveat is given that the quality of the evidence is undetermined).

- The guideline development group develops recommendations (where possible) based on a synthesis of the evidence provided by SIGN and their clinical and personal experience of providing care/lived experience.

- Targeted peer reviewers (including patient and carer reviewers) are invited to provide feedback on the interpretation of the evidence and feasibility and appropriateness of the recommendations. All feedback is addressed by the GDG and actions recorded in the consultation report.

- An editorial group ensures that consultation feedback has been adequately addressed.

- Development of a version of the guideline for patients is considered.

- A flexible approach to updating is used to ensure rapidly emerging evidence can be incorporated.

36. While many of these steps had already been used with individual position statement guidance earlier in the pandemic, updating the methodology to require all of them was only possible at a later stage when the urgency for immediate guidance had slowed, and a larger body of relevant evidence had become available. These steps increased the quality and validity of guidance while reducing the additional time and resources required, compared with traditional SIGN guideline methods. It was possible to follow the requirements set out in the

rapid methodology from its publication in April 2021. Guidance developed using this approach was published as a SIGN rapid guideline (and associated patient version) **SIGN/24 – INQ000365711** and **SIGN/25 – INQ000365712**.

37. The interdisciplinary structure of SIGN ensures cross-sectoral involvement of a wide range of stakeholders in every SIGN project.

38. Requests for the development of advice are received and processed through a rigorous selection process in the Evidence & Digital Directorate in HIS **SIGN/26 – INQ000365713**. As one of several teams, SIGN can be allocated clinical topics for guideline development which may involve the input of other HIS teams. For example, to align expertise at a national level, SIGN guideline 160, Management of suspected bacterial lower urinary tract infection in adult women was developed with the involvement of the Scottish Antimicrobial Prescribing Group (SAPG) which also sits within the Evidence & Digital Directorate at HIS **SIGN/27 – INQ000365714**. All SIGN guidelines refer to and align with appropriate advice from the Scottish Medicines Consortium which also sits within the Evidence & Digital Directorate at HIS.

COLLABORATION

39. SIGN has worked with NICE on many occasions and a collaboration agreement was revised in 2021 and finalised in February 2022 **SIGN/28 – INQ000365715**. The Collaboration Agreement set out the nature of the partnership between NICE and SIGN, part of Healthcare Improvement Scotland (HIS) over the next 2 years (February 2022 to February 2024). Specific areas for potential collaboration as set out in our agreement are:

- Topic prioritisation criteria
- Methods and processes that enable more rapid guideline development and updating
- Technologies that enable digital presentation and easier access to guideline recommendations
- Opportunities to develop UK-wide guidelines.

The Scottish NHS is a distinct and separate entity from that of the rest of the UK. While SIGN and NICE have a collaborative agreement, we do not collaborate on all the work we do. Each receives requests for work from different sources and collaboration is not always appropriate or relevant. SIGN did not collaborate with NICE on most of their Covid-related guidelines as when we began discussions, the waves of guidelines requested by the Department of Health were almost complete. We did not ask NICE to collaborate on the Clinical Cell guidelines. SIGN has a long-standing collaboration with the British Thoracic Society (BTS) since 1999 to develop the British Guideline on the Management of Asthma. More recently, this was extended to a collaboration with NICE and BTS to develop a new UK-wide national guideline on asthma diagnosis and monitoring and chronic asthma management.

40. SIGN has an ongoing collaboration with the Joanna Briggs Institute Centre of Excellence at Robert Gordon University, Aberdeen, where researchers have provided expertise on qualitative research for SIGN guidelines on epilepsy in children, eating disorders and dementia.

41. In addition, SIGN guideline 163 on Prevention and management of venous thromboembolism in patients with COVID-19 included a lay representative recruited via Thrombosis UK, which also helped us develop a plain language summary of the guideline.

42. SIGN 161 on managing the long-term effects of COVID-19 was developed jointly by SIGN, NICE and the Royal College of General Practitioners (RCGP) **SIGN/29 – INQ000365716**. Representatives for the GDG and peer reviewers were identified from Long COVID Scotland who also helped support the development of the patient version of this guideline.

43. The rapid review on Assessment of COVID-19 in primary care was developed in collaboration with the Institute of Health and Wellbeing, University of Glasgow (see paragraph 72).

44. During the COVID-19 pandemic, all guidance approved through the approaches highlighted above was developed collaboratively through joint working by HIS, clinicians across NHS Scotland and Scottish Government. SIGN's role was to

lead on the technical, organisational, editorial and administrative elements of guidance creation and to facilitate and support the guideline development process, including formatting and publication via the SIGN website.

SUPPORTING AND UPDATING SCOTTISH GOVERNMENT CLINICAL ADVICE

45. In March 2020, Scottish Government published a Clinical Advice document for health and social care services which provided a range of clinical, ethical and organisational advice during the COVID-19 pandemic **SIGN/30 – INQ000365717**. To facilitate more co-ordinated access, from December 2020 the clinical advice from this document was moved to the SIGN website where it was available alongside the rapid position statements on COVID-19 developed by SIGN, HIS and the Scottish Government Clinical Guidance Cell. Individual chapters of this comprehensive Clinical Advice document were updated and republished as standalone guidance on the SIGN website but using Scottish Government branding to emphasise that these had not been subject to the methods used by SIGN/Clinical Cell for development of rapid position statements. The original Clinical Advice document was retained on the Scottish Government website and amended to include the remaining high-level considerations which were not updated by SIGN. Topics republished on the SIGN website as Scottish Government Clinical Advice were:

- Critical Care (Original publication March 2020, multiple updates by SG, last updated July 2021) **SIGN/31 – INQ000365718**
- Hospital Admission and Management (republished as "Emergency department management of suspected COVID-19 in adults" (Original publication April 2020, multiple updates by SG, last updated April 2021) **SIGN/32 – INQ000365719**
- Community Assessment and Referral to Secondary Care (Original publication March 2020, multiple updates by SG, last updated Nov 2020) **SIGN/33 – INQ000365720**
- Maternity Care (Original publication March 2020, multiple updates by SG, last updated Feb 2021) **SIGN/34 – INQ000365721**

46. SIGN also supported the development and updating of an additional Scottish Government document which was not originally part of the Scottish Government Clinical Advice document, but was presented on the SIGN website alongside those materials:

- Supporting people with COVID-19 related illness in the community setting (Original publication May 2020 – **SIGN/35 – INQ000365722**, updated Nov 2020 – **SIGN/36 – INQ000365723**)

47. SIGN supported the availability of these advice documents by carrying out literature searches and sourcing evidence as required, facilitating discussion and review of draft versions and reformatting material originally developed by Scottish Government.

48. In order to provide a single repository for national clinical guidance on COVID-19 the following documents were published on the SIGN website based on materials provided by Scottish Government. Neither SIGN nor any other part of HIS were involved in developing content for these:

- Clinical advice and ethical framework (Original publication April 2020) **SIGN/37 – INQ000233594**
- Pragmatic guide for diabetes services during the coronavirus pandemic (Original publication April 2020) **SIGN/38 – INQ000365725**
- Definitions of respiratory patients at high risk of COVID-19 infection, for shielding (Original publication April 2020) **SIGN/39 – INQ000365726**

CLINICAL CELL GUIDANCE DEVELOPED WITH SIGN SUPPORT

49. The following guidance was developed jointly by the Clinical Cell and SIGN using methods described in the CMO letter of 18 May 2020:

- Continuous positive airway pressure (CPAP) for COVID-19-related respiratory failure (Original publication 18/05/2020 **SIGN/40 – INQ000365727**, updated 09/09/2020 **SIGN/41 – INQ000365728**

- Maternal critical care provision (Original publication 19/05/2020 **SIGN/42 – INQ000365729**, updated 25/11/2020 **SIGN/43 – INQ000365730**)

- Prevention of circuit thrombosis in adult inpatients who are COVID-19 positive and undergoing renal replacement therapy (RRT) on critical care wards **SIGN/44 – INQ000365731**

- Presentations and management of COVID-19 in older people in acute care (Original publication 29/05/2020 **SIGN/45 – INQ000343837** updated 01/03/2021 **SIGN/46 – INQ000365733**)

- The prevention and management of thromboembolism in hospitalised patients with COVID-19-related disease (Original publication 20/07/2020 **SIGN/47 – INQ000365734**, updated 15/12/2021 as SIGN 163 – Prevention and management of venous thromboembolism in patients with COVID-19)

- Management of patients attending an endoscopy unit for any endoscopic procedure not requiring general anesthesia (Original publication 25/01/2021 **SIGN/48 – INQ000365735**, updated 29/01/2021 **SIGN/49 – INQ000365736**

50. On 21 August 2020 SIGN and the Clinical Cell published a position statement – Reducing the risk of postoperative mortality due to COVID-19 in patients undergoing elective surgery – to provide NHSScotland with advice on assessment and isolation of adult and paediatric patients prior to all elective surgery **SIGN/50 – INQ000365737**. This was updated in February 2021 **SIGN/51 – INQ000365738**.

51. On 29 November 2021 this document was superseded by the Elective Surgery Infection Prevention and Control Principles developed by Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland (part of NHS Assure within National Services Scotland). These principles were available in an appendix to the National Infection Prevention and Control Manual (NIPCM) Winter (21/22) Respiratory Infections in Health and Care Settings Infection Prevention and Control Addendum. The National Infection Prevention and Control Manual is an evidence-based manual for use across Scotland aiming to

reduce the risk of healthcare-associated infection and ensure the safety of those in the care environment, including those being cared for, staff and visitors. The purpose of the principles was to reduce the risk of transmission of COVID-19 among staff and patients in elective surgery pathways.

52. SIGN worked closely with ARHAI to facilitate a number of significant changes to the infection prevention and control protocols. Further details on the content and version control of the NIPCM can be requested from ARHAI Scotland, which is responsible for ensuring that the manual remains evidence-based and reflects best practice.

53. SIGN and the Clinical Cell jointly developed a guide for clinicians on the interpretation of tests for COVID-19. This was published as pages on the SIGN website on 22/12/2020 **SIGN/52 –** **INQ000365740**

54. SIGN was not involved in any international collaboration in synthesising evidence and/or producing guidelines for the treatment and diagnosis of COVID-19.

PREVENTION AND MANAGEMENT OF THROMBOEMBOLISM IN HOSPITALISED PATIENTS WITH COVID-19-RELATED DISEASE

55. On 22 April 2020 the Clinical Cell discussed the British Thoracic Society (BTS) guidance on Venous Thromboembolic Disease in Patients with COVID-19 and its implications for Scotland **SIGN/53 –** **INQ000365741** According to World Health Organization the two most common manifestations of venous thromboembolism (VTE) are deep vein thrombosis and pulmonary embolism. Deep vein thrombosis (DVT) is a condition in which a blood clot, or thrombus, develops in a deep vein - usually in the lower leg. Symptoms of DVT are principally pain, tenderness and swelling of the affected part. DVT can be detected through medical testing and can be treated. It can be life-threatening when associated with thromboembolism. Thromboembolism occurs when a blood clot (from a deep vein thrombosis) in a leg vein breaks off and travels through the body to the lungs where it becomes lodged and blocks blood flow. This is known as pulmonary embolism, and symptoms include chest pain and breathing difficulties. VTE can be treated, but if it is not, it can lead to death. Members reported some inconsistency of practice around administration of anticoagulants and in particular, uncertainty regarding

optimal dosages of antithrombotic medication **SIGN/54 – INQ000359181** We do not hold any further information about this meeting, which was supported by a Scottish Government administration team. To the best of our understanding, the inconsistencies were likely to be uncertainty about who should get anticoagulation and at what dose, using which drugs and what evaluations should be carried out. These topics provided part of the remit of the SIGN/Clinical Cell position statement on the prevention and management of thromboembolism in hospitalised patients with COVID-19-related disease **SIGN/47 - – INQ000365734** Due to the dynamic situation and range of circumstances in patients presenting to hospital with COVID-19 disease, it was agreed that national guidance on this point would be valuable, however, such guidance would need to allow for individualised risk-benefit decisions. The Cell agreed that the BTS guideline could be built upon by utilising guidance developed in NHS Greater Glasgow and Clyde by Dr. Catherine Bagot.

56. Further discussion highlighted uncertainty in the context of COVID-19 around the value of D-dimer tests in different population groups, the balance of benefits and harms associated with thromboprophylaxis in people who were being discharged and in other settings **SIGN/54 - INQ000359181** . We cannot provide a summary of the competing views underpinning this uncertainty as we do not hold any further information about this meeting (see paragraph 55).

57. The Clinical Cell agreed that a brief summary encompassing both the BTS guideline and NHS Greater Glasgow and Clyde advice would be valuable **SIGN/54 - INQ000359181** The Cell's new document could also address the relevant points not covered in the BTS guideline, such as extended thromboprophylaxis and treatment of the pregnant woman. The Cell actioned Dr. Catherine Bagot (Consultant Haematologist, NHS Greater Glasgow & Clyde) and Dr. Martin Johnson (Director, Scottish Pulmonary Vascular Unit, Golden Jubilee National Hospital, Glasgow and Consultant Respiratory Physician, Queen Elizabeth University Hospital and Gartnavel General Hospitals, Glasgow) to work with Dr. Safia Qureshi and Dr. Roberta James (Healthcare Improvement Scotland) to draft a one-page guideline on anticoagulation and submit to the Clinical Cell Chair for consideration and dissemination by the Scottish Government Professional Advisory Group. According to Merriam-Webster

medical dictionary anticoagulation is the process of hindering the clotting of blood, especially through the use of an anticoagulant medicine to prevent the formation of blood clots.

58. A development group of clinicians with expertise in thromboembolism was established and, following discussion, agreed that the remit of the guidance should be the prevention and management of thromboembolism in hospitalised patients with COVID-19-related disease. It was acknowledged that separate advice on prevention of circuit thrombosis in adult inpatients who are COVID-19 positive and undergoing renal replacement therapy on critical care wards was required. During development, it became clear that a longer document than the single page originally envisaged was required to communicate key information. The need for guidelines was first recognised on 22 April 2020.

59. The SIGN/Clinical Cell position statement on the prevention and management of thromboembolism in hospitalised patients with COVID-19-related disease was first published on 20 July 2020 **SIGN/47 - INQ000365734** The position statement included recommendations that all patients with COVID-19-related disease who are admitted to hospital should receive anticoagulants to prevent blood clotting unless there is a significant risk of bleeding and/or another contraindication. The choice and standard dose of anticoagulant drugs would be made based on local prescribing protocols determined at health board level, but recommendations were provided for considering intermediate doses (which are higher than standard preventative doses, but lower than doses used for treatment of established venous clotting) in patients in critical care settings who have, or are suspected of having, COVID-19-related disease and who have no contraindications to anticoagulants. A recommendation was provided for the dose of anticoagulant to be adjusted in patients with high body weight. Recommendations were provided for investigations in patients with COVID-19-related disease who are suspected of having venous clotting. Gaining an objective diagnosis of those who do not have confirmed venous blood clotting prevents exposing such patients to unnecessary higher doses (therapeutic) of anticoagulation which are associated with increased bleeding risks. There was a discussion on whether patients should continue to take preventative doses of anticoagulation after leaving hospital. No evidence was identified to allow

recommendations to be made on this topic, however, the clinical rationale for it to be considered in patients at high risk of venous blood clotting and low risk of gastrointestinal bleeding was made. Additional tools for assessing the risk of venous blood clotting were identified and it was noted that the choice of drug and duration of treatment should be discussed and agreed upon between clinician and patient once the risks and benefits had been discussed. Finally, recommendations were provided for choice and duration of anticoagulant treatment of blood clotting in a vein. Guidance/information that was in place between April 2020, when the need for the guidelines was identified due to inconsistencies in practice, and July 2020 when the guidance was published included:

Moores LK, Tritschler T, Brosnahan S, Carrier M, Collen JF, Doerschug K, Holley AB, Jimenez D, LeGal G, Rali P, Wells P, Prevention, diagnosis and treatment of venous thromboembolism in patients with COVID-19: CHEST Guideline and Expert Panel Report, CHEST (2020) https://doi.org/10.1016/j.chest.2020.05.559. (Published as preprint 26 May 2020)

British Thoracic Society. BTS Guidance on Venous Thromboembolic Disease in patients with COVID-19. [Available from url: https://www.brit-thoracic.org.uk/document-library/quality-improvement/covid-19/bts-guidance-on-venousthromboembolic-disease-in-patients-with-covid-19/] (First published March 2020)

Also from:

Global COVID-19 Thrombosis Collaborative Group

International Society on Thrombosis and Haemostasis

60. Monitoring use of SIGN guidelines is not the responsibility of HIS or the SIGN Executive. The use of this guideline was not specifically monitored by SIGN, however, a survey of NHS Board Chief Executives, Chairs, Medical Directors, Directors of Public Health and GP practices in May 2021 reported that over half of those who responded were aware of the Clinical Cell and its guidance (40/76)

and over one third had used the guidance (30/76) and interim survey results **SIGN/57 – INQ000365744**.

61. Over ninety percent of respondents who had used the guidance (28/30) said they found it very useful (it influenced their practice) or slightly useful (it reinforced their practice).

62. 16.67% of the clinicians surveyed had used the position statement on the prevention and management of thromboembolism in hospitalised patients with COVID-19-related disease in their clinical practice.

63. On 3 February 2021, the Clinical Cell identified and prioritised topics for potential development into guidance **SIGN/23 - INQ000365710**

64. Topics identified included primary care triage of COVID-19 and thromboprophylaxis in COVID-19, both of which were added to SIGN's work programme.

65. Using a new rapid guideline methodology, development of SIGN 163 - Prevention and management of venous thromboembolism in COVID-19 began in April 2021. The guideline provides recommendations based on current evidence for best practice in the pharmacological prophylaxis and management of thrombotic complications of COVID-19. It includes advice for non-pregnant adults in hospital in intensive care units (ICU) and non-ICU settings, as well as (non-pregnant) patients in the community. It covers all degrees of severity of COVID-19. The earlier position statement 'The prevention and management of thromboembolism in hospitalised patients with COVID-19-related disease' would be withdrawn when this updated and extended guideline was published.

66. This guideline does not address risk assessment, diagnosis or investigation of possible thrombotic events, for which existing guidance for patients without COVID-19 (for example SIGN guideline 122 on prevention and management of venous thromboembolism) should be used **SIGN/59 – INQ000365746**. It excludes specific advice for the prophylaxis or management of thrombotic complications of COVID-19 in pregnancy or in patients under the age of 16. At the time of publication, advice on COVID-19 in pregnancy, including prevention

of venous thromboembolism (VTE), was available from the guideline 'Coronavirus (COVID-19) Infection in Pregnancy' developed collaboratively by Royal Colleges and public health agencies, from the position statement 'Maternal Critical Care Provision' developed by SIGN and the Clinical Cell and the 'COVID-19 Clinical Advice Maternity Care' developed by The Scottish Government. This guideline excludes advice on the management of thrombotic complications following vaccination against COVID-19.

67. At the time of publication, advice on this topic was available from the British Society for Haematology guidance 'COVID-19 Vaccine-induced Immune Thrombocytopenia and Thrombosis' and the National Institute for Health and Care Excellence (NICE) COVID-19 rapid guideline 'Vaccine-Induced Immune Thrombocytopenia and Thrombosis'.

68. This new guideline contained a chapter on prevention of thromboembolism in patients with COVID-19 in community settings. No evidence was identified on risk factors for venous thromboembolism (VTE) or pharmacological prevention of VTE in community settings in the context of COVID-19 and therefore no recommendations were developed. The guideline contains a number of good practice points on these topics.

69. The previous recommendations on prevention and management of thromboembolism in patients with COVID-19 in hospitals were updated and further information provided on extended thromboprophylaxis in patients discharged from hospital after recovery from acute COVID-19. The guideline development group included a representative of the patient perspective and a summary for patients was developed. This included:

- risk factors for VTE in people living in the community
- medicines to prevent and treat VTE for those in hospital.

70. SIGN guideline 163 and the accompanying patient guide were published in December 2021.

ASSESSMENT OF COVID-19 IN PRIMARY CARE

71. On 30 March 2020 an academic General Practitioner (GP) (researcher) at the Institute of Health and Wellbeing, University of Glasgow emailed GP colleagues with some starter questions on areas of uncertainty and received feedback over the next two days. The revised questions were then sent out to them again, as well as other GPs working in the COVID-19 assessment hubs on 8 April 2020. Responses received between 8 and 11 April 2020 highlighted that there was a gap in knowledge around predictors of severe disease. The GPs reported that patients were presenting with mild symptoms which could be self-managed at home, but some then progressed to severe illness several days later. They needed to know what signs and symptoms were predictive of the likelihood of progression to severe disease so they could identify which patients required further monitoring. This work was carried out by the University of Glasgow, so we hold no record of it. After preliminary discussions with HIS colleagues **SIGN/60 – INQ000365747**, on 14 April 2020 Professor Olivia Wu, Professor of Health Technology Assessment, University of Glasgow, approached SIGN to work collaboratively to produce a review of the evidence on signs and symptoms associated with progression to severe disease **SIGN/61 – INQ000365748**, attaching a suggested remit for the work **SIGN/62 – INQ000365749**

72. The evidence at the time was preliminary, mostly from outside the United Kingdom, and had not been peer reviewed. It was, therefore, not sufficiently robust to support recommendations. The report produced was not a guideline. It was an overview of the evidence with a summary of key findings. The date on which it was recognised that these guidelines were required was 31 March 2020. These guidelines were first published on 7 May 2020. Between 31 March 2020, when the need for the guidelines was identified, and 7 May 2020 when the guidance was published, the Scottish Government's COVID-19 Scottish Primary Care Hub Triage Guide (**SIGN/63 – INQ000365752**) provided advice on initial consultations with a patient presenting with potential COVID-19. Clinicians could refer to other UK or international sources of evidence, such as the Centre for Evidence-Based Medicine at the University of Oxford COVID-19 symptoms tracker: COVID-19 Symptoms Tracker - The Centre for Evidence-Based Medicine (cebm.net).

73. Monitoring use of SIGN guidelines is not the responsibility of the SIGN Executive. Usage was not formally monitored, however, anecdotal feedback was sought from clinicians when determining whether or not to update the evidence review.

74. The guidance was produced in both an app format and PDF. The aim was to make it widely accessible, whether it was viewed on a desktop computer, tablet or mobile phone, or printed out.

75. Information on signs and symptoms had been identified as the priority for GPs. This was not a guideline, so no recommendations were made.

76. The Scottish Government had produced the COVID-19 Scottish Primary Care Hub Triage Guide which covered self-management, monitoring and referral to acute care **SIGN/63 – INQ000365752**.

77. The reason for including within the guidance a section on vaccination effectiveness was that the evidence review reported on comorbidities that were associated with high risk of severe disease. It was important to review evidence to determine whether vaccination reduced the risk, as this may have changed the advice on which signs and symptoms were red flags for severe disease in people who had been vaccinated.

78. The evidence review was updated at the following times:

21 July 20 SIGN/64 – INQ000365753 (SIGN/69)

- Amendments to key findings:
    - addition of 'silent' hypoxia,
    - changed 'Asian ethnicity' to 'minority ethnic background',
    - addition of smoking and solid organ transplantation to list of comorbidities/risk factors associated with severe disease,
    - separation of immunosuppressive conditions and immunosuppressive medications,

- promotion of socioeconomic status and frailty as potentially associated with poor outcomes.

- Addition of new evidence and published revisions to preprint evidence in Table 2: Comorbidities and risk factors associated with COVID-19 in adults:

  - Socioeconomic status – changed from no reported evidence to significantly associated with severe disease

  - Smoking – changed from 'evidence of association is unclear' to 'significantly associated with severe disease'

  - Chronic liver disease – changed from 'has not been associated with severe disease' to 'evidence of association is unclear'

  - Chronic respiratory disease – changed 'evidence of association is unclear' to 'significantly associated with severe disease'

  - Frailty – addition of 'significantly associated with sever disease'

  - Immunosuppressive conditions – new category created

  - Solid organ transplants – new category created

- Published revisions to preprint evidence amended in Table 3: Clinical measures considered for identifying symptoms of COVID-19

03 February 21 SIGN/65 – INQ000365754 (SIGN/70)

- Amendments to key findings:

  - Occupation as health or social care worker added as a characteristic significantly associated with severe disease. This was added because by this point studies using UK data had been published, which included analysis of characteristics such as socioeconomic and occupational status. The studies showed that health and social care workers had a greater risk of severe COVID-19 compared to non-essential workers. This association remained when adjusted for age,

gender, country of birth, ethnicity socioeconomic factors of deprivation, education, shift work, health conditions and lifestyle factors.

- Chronic liver disease – changed from 'evidence of association is unclear' to 'associated with severe disease'.

- Severe mental illness, learning difficulties, Down's Syndrome, neurological conditions and dementia added to comorbidities and risk factors associated with severe disease.

- Advice on pregnancy added. The evidence found that most pregnant women would have asymptomatic or mild disease that would not impact their pregnancy. The risk of hospital admission with COVID-19 increased in pregnant women with a minority ethnic background. There was emerging evidence that pregnant women may be at greater risk of severe disease requiring admission to intensive care and/or need for invasive ventilation than non-pregnant women, particularly in the third trimester. COVID-19 may increase the risk of pre-term birth and admission to a neonatal care unit.

- Revisions to Section 2: Method of patient consultation, merged with the section on prognostic tools (section 2).

- Table 2: Revised to incorporate Scottish and UK data. New categories included for pregnancy, occupation, mental illness and learning difficulties

- Table 3: Revised to incorporate UK-based studies.

- New sections added on signs, symptoms and comorbidities associated with severe COVID-19 in children and young people.

28 March 22 SIGN/66 – INQ000365755 (SIGN/71)

- Full revision of each section to reflect UK-based studies.

- Update of routine data in the section on children and young people.

- Delirium as a symptom was added to the key findings.
- A link to advice on eligibility for treatment with antivirals or neutralising monoclonal antibodies was added.
- Data on associations with pharmacological therapies was withdrawn as it was agreed amongst the review team that the analysis was too complex for this overview.

LONG TERM EFFECTS OF COVID-19

79. In July 2020 the Scottish Government COVID-19 Professional Advisory Group discussed reports of individuals with diverse long-term, persisting symptoms after recovery from acute COVID-19 and supported a proposal for the Clinical Cell to develop national guidance on this topic. It noted that several teams in Scottish Government were working on different approaches to support people with ongoing symptoms. These included:

80. **The Mental Health Services COVID Response Team** which was developing a national care pathway with package of multidisciplinary support for Intensive Care Unit (ICU) patients hospitalised due to Covid-19

81. **The Chief Allied Healthcare Professionals Office** which was developing a Transition and Rehabilitation Framework, and

82. **The Neurological Conditions, Chronic Pain and Long-term Conditions Team** which had, before the pandemic, commissioned the Scottish Health Technologies Group (which sits alongside SIGN in the Evidence & Digital Directorate of HIS) to review the evidence on the effectiveness of graded exercise therapy (GET) and cognitive behavioural therapy (CBT) in treating Chronic Fatigue Syndrome.

83. On 17 July 2020, HIS corresponded with colleagues at NICE to share its plans for development of guidance on post-COVID effects and investigate the opportunity to collaborate. NICE stated that at this point it was not planning to develop guidance for England/Wales on longer-term effects of COVID-19 **SIGN/67 – INQ000365756**. In discussion with the Clinical Cell, it was suggested

that a clinical guideline on this topic would serve to pull together recommendations on measures to support recovery from COVID-19 infection and could link with existing developments in Scotland.

84. In August-September 2020 SIGN developed a scoping document which set out the need for a guideline on post-COVID-19 syndrome, the remit of the guideline, areas of clinical management to be covered and the potential target audience **SIGN68 – INQ000365757**. SIGN also created draft clinical questions that would underpin this guideline.

85. As an intercollegiate network, SIGN had provided information to its medical Royal College and professional society members about plans and progress with the development of relevant guidance being carried out in partnership with the Clinical Cell. It was noted that the burden of demand for supporting people affected by COVID-19 was being felt in primary care, as affected individuals were increasingly presenting to GPs with a wide range of unexplained symptoms despite no longer testing positive for SARS-CoV-2. On 24 September 2020, the Royal College of General Practitioners (RCGP) had offered support for a Scottish guideline on long-term effects of COVID-19 to better support the needs of its members, and a further email was received on 25 September 2020 from Dr. Carey Lunan, President of RCGP Scotland, suggesting that the scope of the SIGN guideline in development could be widened to UK level and could involve collaboration with NICE to avoid "competition or confusion". **SIGN/69 – INQ000365758**

86. At around the same time, there was consideration for establishing a four-nations working group at UK senior clinician level on 'long COVID' which strengthened the collaborative focus and highlighted the initiative taken by Clinical Cell / SIGN to this point **SIGN/70 – INQ000365759** and **SIGN/71 – INQ000365760**.

87. Correspondence from NICE on 28 September confirmed they were about to receive a commission to do a guideline on long COVID **SIGN/72 – INQ000365761**. On 30 September we received support from the CE of HIS to embark on the collaboration **SIGN/73 – INQ000365762**. This led to a series of

joint planning meetings between SIGN, NICE and RCGP which resulted in an agreement to develop a single, jointly badged guideline using NICE methods.

88. It was first recognised in July 2020 that the guidelines with NICE and The Royal College of General Practitioners were required.

89. The guideline was first published by SIGN (SIGN 161 - Managing the long-term effects of COVID-19) and NICE (NG188 - COVID-19 rapid guideline: managing the long-term effects of COVID-19) as separate documents with a vast majority of identical recommendations on 18 December 2020. The different formats aligned with house styles for each organisation to avoid alienating the clinical audience and support more immediate implementation.

This guideline covers the care of people who have signs and symptoms that:

- develop during or after an infection that is consistent with COVID-19
- continue for more than four weeks and are not explained by an alternative diagnosis

Evidence and recommendations are provided on:

- Identification, assessment and referral
- Planning care and management
- Self management
- Multidisciplinary rehabilitation and additional support
- Follow up monitoring and discharge
- Sharing information, continuity of care
- Service organisation
- Common symptoms

SIGN also published a patient version of the guideline on 18 December 2020 **SIGN/74 – INQ000365763**.

90. Monitoring use of SIGN guidelines is not the responsibility of the SIGN Executive. Use of the guideline by clinicians and healthcare providers was not formally monitored.

91. An interactive decision support toolkit was developed for patients, based on the updated patient version of the joint guideline on managing the long-term effects of COVID-19. The app went live on 10 January 2022. Third-sector organisations involved with the SIGN Patient and Public Involvement Network were given prior notification on 13 December 2021 and contacted on 10 January to let them know it was live. The Patient and Public Involvement Network is a 'virtual' group of patients, carers, members of the public and patient involvement staff from within NHS Scotland. There were approximately 400 members at this time.

Patients were made aware of the app through these third-sector organisations and charities. Long Covid Scotland is not on the network so they were notified in separately along with the two patients who had given feedback on the app. We asked Long Covid Scotland to promote this to their members but we hold no record of this happening. A media release was issued by HIS on 11 May 2022. The app was evaluated in March 2023. Results revealed that between January 2022 and November 2022, approximately 2,000 users were engaged with the toolkit. Feedback suggested that the app is useful for people with long COVID, particularly the symptom diary to allow people to monitor their symptoms and share with their GP. The SIGN Patient Decision Support toolkit for 'Managing the long-term effects of COVID-19' was welcomed and respondents indicated that it would be beneficial to users to update this when there are updates to the guideline **SIGN/75 – INQ000365764**.

92. A review of the guideline was commenced in June 2021 and the updated version was published on 11 November 2021. This version was provided as a single joint guideline and was published by NICE, on behalf of the joint developers, on MAGICapp **SIGN/76 – INQ000238545** The updated patient version was published by SIGN in December 2021 **SIGN/77 – INQ000365766**.

93. For the November 2021 update, new evidence reviews were undertaken for key questions on:

- case definition (quantitative and qualitative reviews)
- referral to services (qualitative)
- children and young people
- impact of vaccines on the long-term effects of COVID-19.
- Additionally, updates were undertaken to evidence reviews on:
- signs, symptoms and prevalence
- risk factors.

94. Expert testimony was heard for the key questions of

- vaccines (Steves 2021)
- rehabilitation (Nicol 2021, Nuffield Health 2021, Locke 2021)
- children and young people (Whittaker 2021, Stark 2021, Stephenson 2021).

95. There were no updates to evidence reviews on investigations, monitoring and referral, interventions, service organisation and views and experiences of patients, their families and carers.

OTHER CONCERNS OR ISSUES

96. HIS is committed to equality and diversity and assesses all its publications for likely impact on the nine equality groups defined by age, disability, gender reassignment, race, religion/belief, sex, sexual orientation, marriage and civil partnership and pregnancy and maternity. Standard SIGN guidelines are produced using a methodology that has been equality impact assessed to ensure that these equality aims are addressed in every guideline. This methodology is set out in the current version of SIGN 50. The equality impact assessment (EQIA)

SIGN/78 – INQ000365767 of the manual is available on the SIGN website alongside it.

97. The rapid methodologies developed in response to the pandemic were not equality impact assessed. Developing a rapid guideline requires balancing time, rigour and resources and may mean shortening, omitting or accelerating the processes and methods used for developing full guidelines. For this reason, and as we were in an emergency response situation, we did not include an equality impact assessment in the rapid methodology.

98. Since 2019 an EQIA has been carried out for standard guidelines in development. The EQIA is discussed by the guideline development group and will inform the remit of the guideline.

99. EQIA was not carried out for the rapid publications developed with the Clinical Cell. Developing a rapid guideline requires balancing time, rigour and resources and may mean shortening, omitting or accelerating the processes and methods used for developing full guidelines. For this reason, and as we were in an emergency response situation, we did not conduct equality impact assessments for the rapid publications developed with the Clinical Cell. No post-implementation assessments were conducted. SIGN did not produce a guideline equivalent to the "Clinical Frailty Score" produced by NICE. We were not asked to develop this by the Clinical Cell or any other group. We do not routinely publish the same guidelines as NICE.

100. Characteristics and individual circumstances were considered to ensure that recommendations in the guideline managing the long-term effects of COVID did not exacerbate inequalities. Potential equality issues identified during the development were documented in an equality impact assessment (EQIA), as well as actions for the guideline panel to consider when making the recommendations. The EQIA for Managing the long-term effects of COVID-19 (**SIGN/81 - INQ000398905**, published 18 December 2020) details the characteristics and circumstances covered, including disability, age, gender reassignment, pregnancy and maternity, race, religion or belief, sex, sexual orientation, socioeconomic factors, other definable characteristics (refugees, asylum

seekers, migrant workers, people who are homeless), and digital accessibility. Recommendations and the corresponding rationales outline the panel's consideration of equality issues. This includes encouraging a holistic and person-centred approach to assessment, providing extra time or additional support during consultations and raising awareness about possible symptoms and how they might impact on daily activities. One recommendation and corresponding rationale encourages following up people in underserved or vulnerable/high risk groups who have self-managed in the community.

101. The evidence review for the guidance Assessment of COVID-19 in primary care identified that the following protected characteristics were associated with higher risk of severe disease in both the vaccinated and unvaccinated population **SIGN/09 - INQ000365696**

- older age
- minority ethnic background
- male sex
- less advantaged socioeconomic status
- comorbidities such as severe mental illness, learning disabilities and Down's Syndrome.

102. These were highlighted as key findings in the guidance Assessment COVID-19 in primary care v1 7 May 20 **SIGN/09 - INQ000365696**

103. Excepting the issues raised here, SIGN is not aware of further inequality-related issues that were identified, which arose or which were exacerbated during the relevant period.

104. The work of SIGN during the pandemic did not impact directly on the matters set out in the Provisional Outline of Scope for Module 3. How health and social care professionals used the evidence and guidance we provided, including that on inequality and people with protected characteristics, would have a direct impact

on these matters. It is not within SIGN's remit to monitor how health and social care professionals used guidelines.

105. Lessons learned were covered in the evaluation work carried out across the whole of HIS. No evaluation was carried out by the SIGN team.

STATEMENT OF TRUTH

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

Signed: Personal Data

Dated: 31/01/2024