

Witness Name: Andrew Garrett

Statement No.:

Exhibits:

Dated:

UK COVID-19 INQUIRY

WITNESS STATEMENT OF ANDREW GARRETT, PRESIDENT OF THE ROYAL STATISTICAL SOCIETY

I, Andrew Garrett, will say as follows: -

1. Introduction

- 1.1.1 The Royal Statistical Society (RSS) was founded in 1834 – and is now a professional body for statisticians and data scientists with over 10,000 members. As a charity, the RSS works UK-wide to advocate for the key role of statistics and data in society and works to ensure that policy formulation and decision making are informed by evidence for the public good. The RSS represents professionals with a wide range of backgrounds working in all types of organisations.
- 1.1.2 During the Covid-19 pandemic, statistics and data played an important role in helping us to understand the pandemic. Statisticians played vital roles in analysing data to understand the effectiveness of treatments, infection control measures and vaccines – informing policymakers, healthcare providers and the public.
- 1.1.3 Our focus here is on the preparedness of the UK’s statistical and data ecosystem, in respect of which the RSS makes twelve recommendations:

- i. Review the UK's new health and social care data landscape covering: (a) the systems and organisational structures for gathering and publishing health and demographic data; (b) levels of investment; (c) joining up data across nations and organisations; and (d) aligning the infrastructure with the data analysis.
- ii. Social care data is an essential counterpart to healthcare data. It is important that the production and publication of official statistics regarding care homes continues to be developed and that a focus on integrated social care data is developed.
- iii. Develop a plan for a small-scale continuous health surveillance programme based on random sampling that could be scaled up very rapidly when needed, and that integrates information from multiple data streams. For example, by linking prevalence survey data with calibrated information from a range of traditional and non-traditional data streams such as primary care records, NHS111 calls, non-prescription medication sales, wastewater sampling.
- iv. Review and re-design the First Few Hundred (FF100) study approach, as an add-on to the proposed continuing surveillance programme.
- v. Use personal identification numbers more widely across the UK to improve research record linkage.
- vi. Further develop Trusted Research Environments (TREs) as an effective and agile process for securely sharing government and NHS data with researchers.
- vii. Legislate to ensure that registration of the fact-of-death is not delayed when a death is referred to the coroner in England, Wales and Northern Ireland – as is the case in Scotland.
- viii. Prepare mechanisms for engaging relevant expert statisticians with skills in both data analysis and study design and increase investment in

statistical training for civil servants, ministers, and other policymakers across government to support an effective evidence-based response.

- ix. Develop an optimal strategy for evaluating the effectiveness of treatments and vaccine programmes; build a framework for agile evaluations of non-pharmaceutical interventions (NPIs) whenever appropriate to ensure that decisions are based on the best possible evidence.
- x. Well-designed studies that evaluate diagnostic tests in the real-world settings where they are used must become standard practice. Evaluation must consider the intended and unintended consequences. Some consequences will not be evaluable before test implementation, so post-marketing surveillance for a new intended use requires ongoing assessment.
- xi. Ensure that, as at other times, communication of data and analysis during a pandemic is independent and non-political – in line with the Code of Practice for Statistics.
- xii. Include plans to enable rapid replication of the UK's world-leading data dashboards as part of preparedness protocols – clear visualisations and access to underlying data are prototypes of how data should be presented in a pandemic.

1.1.4 Notwithstanding the above recommendations, it is important to stress that there were several ways in which the response of the UK's statistical system and the wider community of statisticians and data scientists was very impressive. At the start of the pandemic there were a number of systemic issues (which are detailed in this statement) that were overcome through the hard work of statisticians and data scientists working throughout the governments of the nations of the UK and their agencies, in academic institutions and in the private sector. Some of their achievements – notably the Covid-19 Infection Survey (CIS), REACT and the dashboards for each nation – were genuinely world-leading. The RECOVERY (Randomised Evaluation of Covid-19 Therapy) trial was highly effective in evaluating re-purposed treatments to treat Covid-19 with impact beyond the UK.

These statistical successes should be built on and entrenched as a key part of preparedness planning for future pandemics.

2 Data infrastructure

2.1 Overview

2.1.1 Data plays an essential role in a pandemic: from providing understanding on the circulating pathogen to informing decisions about what interventions should be put in place to limit transmission. Data also enables effective communication with the public. It is vital for pandemic preparedness to ensure that the UK's data infrastructure is fit for this purpose. This means making sure that relevant datasets are collected, linked securely, analysed, documented and shared as appropriate with trusted parties.

2.1.2 Prior to the Covid-19 pandemic the RSS had highlighted a number of concerns around the UK's data infrastructure. Data should be regarded as a critical part of the UK's infrastructure in precisely the same way that physical infrastructure such as roads and rail are. The RSS has argued (RSS/12 - INQ000114784) that data has primarily been seen as a tool for transparency, rather than as an asset that, when acquired unbiasedly, can improve decision-making as well as driving growth. This important principle is also evoked in the RSS's data manifestos (RSS/09 - INQ000114794 and RSS/22 - INQ000114767).

2.2 Health data structure and gaps

Introduction

2.2.1 The UK's health and social care data structure is complicated. Health and social care data in the UK is devolved and a variety of organisations produce data – each of the four nations of the UK has data collection split between its government, NHS, civil registration agency and public health bodies. When coherent UK-wide data is required, this calls for a level of collaboration and communication which is difficult at the best of times, and harder still in the pressure of a pandemic. Further, because data is sometimes collected in

response to a particular policy, if the policies of the four nations are sufficiently different then there will be occasions where data collection cannot be harmonised.

2.2.2 Prior to the pandemic the statistical infrastructure for health data had developed differently across the four nations. In England there were particular challenges due to successive reorganisations of the NHS and its health statistics, which led to fragmentation and made the task facing statisticians especially challenging. The other nations were better prepared in some ways: Scotland's Information Services Division (ISD) – which was merged into Public Health Scotland (PHS) at the start of the pandemic – was well-established and effective, in Wales, health statistics were collected centrally in government and in Northern Ireland health and social care statistics were being collected by its Department of Health and its Public Health Agency which is part of Health and Social Care Northern Ireland. Registration of births and deaths was the responsibility of the three registration services covering England and Wales combined, Scotland and Northern Ireland.

2.2.3 During the pandemic improvements were made in in England: the Department for Health and Social Care (DHSC) improved its data capabilities – bringing together some of the previously fragmented organisations – and the UK Health Security Agency (UKHSA, formerly the Joint Biosecurity Centre – itself set up during the pandemic) was established.

Recommendation 1

2.2.4 Review the UK's new health and social care data landscape covering: (a) the systems and organisational structures for gathering and publishing health and demographic data; (b) levels of investment; (c) joining up data across nations and organisations; and (d) aligning the infrastructure with the data analysis.

Rationale

2.2.5 Within England, NHS England and its data collection function had been fragmented into multiple agencies. This began in 2007 with the dispersal of statistical staff from the Department of Health and the formation of the NHS

Information Centre. This was intended to unify statistical functions across the Department of Health and NHS, but had the effect of fragmenting statistical functions under the leadership of people without a statistical background. In particular, the 2012 Health and Social Care Act led to the establishment of the Health and Social Care Information Centre, known as NHS Digital, to bring together data on NHS-funded care with information about IT infrastructure. NHS Digital's requirement for complex data sharing agreements – even within government – caused delays in sharing health data within England. The Office for Statistics Regulation (OSR) published a valuable systemic review of health and social care data in 2015, concluding that “there was no single individual or organisation with clear leadership responsibility and this had led to problems with the coherence and accessibility of these statistics”. The English Health Statistics Steering Group (EHSSG) was formed in 2016 to improve the coherence and accessibility of health and care statistics in England. The RSS expressed the view in RSS/32 - INQ000114797 that, while this had led to some improvement, there were still systemic problems at the time that the pandemic started.

- 2.2.6 Because of the fragmentation in England, statisticians and data analysts were spread throughout the health system and there was a shortage of statisticians centrally in the DHSC, where data from a disparate array of sources had to be brought together. This changed during the pandemic and some of the fragmentation in England was reversed, in large part because DHSC absorbed the non-communicable diseases public health responsibilities of Public Health England when the UKHSA was created. This shift in DHSC back towards a stronger focus on the production of statistics is supported by the RSS and should be maintained.
- 2.2.7 The situation was better in the other three nations. In Scotland, the vast majority of health statistics relating to Covid-19 are produced by PHS. Though planned before the pandemic, PHS was formed during the pandemic (on 1 April 2020) and tackled the challenge of Covid-19 ambitiously and with energy.
- 2.2.8 The RSS's concern is primarily that data is accessible and comparable across the range of UK health and social care services. Fragmented structures make

this more difficult – progress was made during the pandemic in communication on statistical issues between the four nations. It is important to review the structures and working practices that emerged during the pandemic, learn from what has worked and make whatever changes are necessary to ensure that, in the event of another pandemic, the appropriate data structures are in place at the start.

2.2.9 It is also important for metadata – the data about the data – to be coherent: consistency of data-definition is important. Defining what counted as a Covid-19 death was unclear at the start of the pandemic (multiple options were available) and it took time for the range of statistics to bed down as part of a clear framework, including: death within 28 days after a positive test and a weekly registration measure based on death registrations from the Office for National Statistics (ONS), National Records of Scotland and the Northern Ireland Statistics and Research Agency. Similarly, the methodology for computing the derived measure of excess death, which allows international comparisons, should be clearly articulated. It would be helpful, as part of preparedness planning, to have a process for developing a reliable and transparent framework from the outset.

Recommendation 2

2.2.10 Social care data is an essential counterpart to healthcare data. It is important that the production and publication of official statistics regarding care homes continues to be developed and that a focus on integrated social care data is developed.

Rationale

2.2.11 A consequence of having a fragmented health and social care data landscape is that it is not always immediately apparent where there are problematic gaps in the data. The most striking data gap was around care home data. Most information on social care came from local authorities and did not give a clear picture of the number of people in care homes or of their demographic characteristics. This problem was known prior to the pandemic – the OSR

released a report detailing data gaps and issues in January 2020 – but the significance of the problem was not widely appreciated. This data gap meant that in the first phase of the pandemic there was a poor understanding of the impact of Covid-19 on care homes. As the pandemic progressed the situation regarding social care data improved – DHSC started providing monthly official statistics with information about vaccinations, infections, testing and the availability of PPE in care homes.

2.2.12 Since the pandemic, work on data about social care – which was due to start before the pandemic but had to be postponed – has resumed and there has been considerable progress. Despite this, there are areas where information is still needed. For example, there are no definitive publicly available statistics on care home capacity or occupancy by type; the size of the care home labour market is unknown – making it impossible to assess the impact of the pandemic on the workforce; and data about social care in the community is also needed since the most vulnerable in a pandemic may not always be older people. So, while progress has been made, there is still some way to go before social care data is in a suitable state to properly inform a pandemic response.

2.3 Surveillance

Introduction

2.3.1 Surveillance of population data and patterns is an essential part of the UK’s pandemic response – it is one of the means of obtaining accurate, timely and reliable data to inform decision-making.

2.3.2 In the aftermath of the 2009 H1N1 influenza pandemic a Statistical Legacy Group – including RSS representation – established by the Chief Medical Officer (CMO) recommended that “Preparedness plans should include the actual mechanisms/processes for data collection, harmonisation of data streams and definitions, and how surveillance responses will be calibrated to the apparent severity of a future pandemic” (RSS/03 - INQ000114786, p.31). The RSS understands that efforts were made to establish surveillance systems that could be swiftly adapted – but that response was hampered both by successive years

of cuts to Public Health England's budget as well as key staff departures in January 2020. Consequently, at the start of the current Covid-19 pandemic the government could not swiftly roll-out or establish a well-functioning surveillance system. This delayed the availability of data to build statistical models that would provide estimates for the spread of the virus. Surveillance systems need to be established as an ongoing operation that is regularly reviewed so that they can be readily and robustly scaled up during a pandemic.

Recommendation 3

2.3.3 Develop a plan for a small-scale continuous health surveillance programme based on random sampling that could be scaled up very rapidly when needed, and that integrates information from multiple data streams. For example, by linking prevalence survey data with information from a range of traditional and non-traditional data streams such as primary care records, NHS111 calls, non-prescription medication sales, wastewater sampling.

Rationale

2.3.4 Historically, England's system of communicable disease surveillance relied on cooperation between local authorities and health services. The local system had been eroded and run down prior to the pandemic. This meant that England started the pandemic without adequate surveillance mechanisms – it was welcome that two powerful population surveys were developed as a means of surveillance during the pandemic: the UK-wide ONS CIS and, for England only, Imperial College London's REACT. Both programmes were designed remarkably quickly in the circumstances, with data collection beginning around two months after the WHO's declaration of a pandemic through the extraordinary efforts of the staff concerned. In March 2022, the RSS's then-president (for 2021-2022), Professor Sylvia Richardson, praised the studies as "unique in the world" and argued that surveillance studies still had an important role to play in the future (RSS/50 - INQ000114775). But both have now been stopped.

2.3.5 The best way to ensure that a surveillance tool is ready to go at the time of a pandemic is to maintain a continuous surveillance system – even during periods

with no pandemic pathogens in circulation. This could be on a relatively small scale, ready to be scaled up when the need arises. Any such system needs to cover multiple pathogens (eg, respiratory, gastro-intestinal, fever, etc) and be designed to achieve the right balance between precision and affordability. This will require sophisticated statistical methodology for the robust calibration, and hence integration, of information from multiple data streams. A range of non-traditional, non-randomised data streams (eg, primary care records, NHS111 calls, non-prescription medication sales, wastewater sampling, etc) could be calibrated against a relatively small-scale prevalence survey that employed random sampling of the kind exemplified by CIS and REACT, that would be targeted to detect a newly identified health threat.

- 2.3.6 It is not the best use of limited resources to be running multiple surveillance programmes during a pandemic. The proposed approach would avoid the need for this. It is important to learn from CIS and REACT – there should be a critical appraisal of these two approaches to establish how surveillance can work most effectively in the future and provide the best possible value for money.

Recommendation 4

- 2.3.7 Review and re-design the First Few Hundred (FF100) study approach, as an add-on to the proposed continuing surveillance programme.

Rationale

- 2.3.8 Part of the UK's planned pandemic response is a FF100 study . The aim of this approach is to gain an early understanding of some of the key clinical, epidemiological and virological characteristics of the first cases of a new virus. The studies are intended to provide estimates of: the clinical presentation and course of the disease; secondary infection rate among close contacts; the period of time from the onset of symptoms in an index case to the onset of symptoms in a contact case; the proportion of cases that are symptomatic; the reproduction number (R); the incubation period distribution; the effectiveness of antiviral treatments; and, information around case-hospitalisation and case-fatality ratios.

2.3.9 For FF100 studies to be effective, it is important that they can be completed quickly. Prior to the 2009 H1N1 influenza the FF100 surveillance design had not been subject to peer-review (RSS/02 - INQ000114791) and the database was poor quality, inconsistent and incomplete. There were also issues with the FF100 study for Covid-19, particularly in early March 2020, when the majority of known cases were in travellers who had acquired infection abroad and may have passed the peak of their infectiousness by the time they returned to the UK, complicating the assessment of transmission to contacts.

2.3.10 As it happened, the outbreak aboard the Diamond Princess enabled a close study of some early cases, which lessened the negative impact of the lack of success of the FF100 approach. As part of preparedness for future pandemics, it is important to think about whether and, if so, how FF100 studies can be made to work reliably. FF100 has been tested in the UK after the H1N1 pandemic (eg, during the Middle East respiratory syndrome (MERS) outbreak), but its implementation during a fast moving and intense pandemic needs further assessment. This should be a pan-European process.

2.4 Data sharing and record linkage

Introduction

2.4.1 The RSS has consistently called for improved data sharing – both within government and in terms of improved access to data. Relatedly, when dealing with data from multiple sources, record-linkage is important. This is the process of joining up data relating to an individual without disclosure about the individual being possible. Effective record-linkage prevents double-counting, helps identify under-reporting and is a vital part of a functioning surveillance system. Identifying people by a number – such as the NHS number in England and Wales, the Health and Care Number in Northern Ireland, or Community Health Index (CHI) number in Scotland – is an effective way to do this.

Recommendation 5

- 2.4.2 Use personal identification numbers more widely across the UK to improve research record linkage.

Rationale

- 2.4.3 The pandemic showed the importance of tracking an individual's interactions with health services (while protecting their personal and identifying information). Bringing together data from a variety of sources about, eg, testing data, vaccination data, acute care admissions data and hospitalisation outcomes can improve our understanding of how the virus is spreading and how it should be tackled. Before the pandemic, some key record linkage permissions had not been established in England, which slowed the establishment of a suitable surveillance system.
- 2.4.4 This contrasts with the situation in Scotland, where PHS were able to get permissions quickly and routinely linked data from the early stages of the pandemic. Patients in NHS Scotland are identified by a well-designed 10-digit CHI number. CHI numbers contain information about a person's age and sex – meaning that if that information is not included in a dataset for any reason, it can be inferred and that it can be deduced when being entered, improving coverage – and they also contain a check digit – preventing data entry errors. The Scottish model was underpinned by public consultation on, and support for, Scotland's CHI by which national health-related databases on mortality and morbidity, including prescriptions, can be linked on a no-names basis for analysis in trusted research environments. NHS numbers were used in England and Wales for record linkage but, because there are multiple bodies in England using health statistics, data is not always in one place and linkable. In Wales, the SAIL (Secure Anonymised Information Linkage) Databank at the Swansea University works with many Welsh organisations to link together their data. In Scotland, PHS had the data in one place, the CHI made it readily linkable and there was also a process for linking health and non-health information, enabling improved analysis.
- 2.4.5 The RSS had sought to raise the importance of record linkage both before (RSS/17 - INQ000114803 and RSS/18 - INQ000114812) and during the

pandemic (RSS/27 - INQ000114793, RSS/30 - INQ000114798, RSS/32 - INQ000114797 and RSS/44 - INQ000114795). In July 2020 (RSS/27 - INQ000114793) the RSS suggested that Test and Trace (T&T) could use two key statistical methods – record-linkage and random sampling – to learn about transmission of the virus. Record-linkage would have allowed T&T to see how many of the quarantined persons in each high-risk group tested positive for the virus during (or soon after) their quarantine period. This – coupled with random sampling of households – would have allowed the government to evidence the required duration of isolation and assess T&T's effectiveness in stopping chains of transmission. The quality of T&T data was a major barrier with much data collection outsourced to private sectors companies who lacked experience and expertise. It took until September 2020 to achieve the record-linkage step, but dissemination took much longer. It was not until late 2021 that Public Health England formally studied asymptomatic testing of contacts: that initiative culminated in the STOP COVID randomised controlled trial in mid-2022 which recruited rapidly.

- 2.4.6 The approach of assigning citizens a personal identity number – either by expanding the use of NHS and CHI numbers or assigning new numbers designed in-line with CHI numbers – across a range of services is worth exploring: implemented properly, it has the potential to support record linkage while protecting privacy.

Recommendation 6

- 2.4.7 Further develop Trusted Research Environments (TREs) as an effective and agile process for securely sharing government and NHS data with researchers.

Rationale

- 2.4.8 It is not straightforward to access NHS data for statistical purposes in England – this is more difficult in England than in either Scotland or Wales who are world-leaders in data linkage. Partly this is because this is easier in smaller nations. The Scottish model for data sharing is effective and, in Wales, the SAIL Databank is a very effective collaboration between Swansea University and the

Welsh government. In England the ONS's secure research service provides a well-established desktop TRE, which incorporated some public health datasets during Covid-19. However NHS data as a whole remains challenging to access at scale – in part this is due to public concern about privacy, so it is important that this is handled in a way that is transparent and builds trust. The RSS has pursued this consistently, calling for a change of culture in government (see RSS/13 - INQ000114804, RSS/17 - INQ000114803 and the RSS's data manifestos, RSS/09 - INQ000114794 and RSS/22 - INQ000114767). The RSS welcomes the ONS's integrated data service (launched in October 2021) as a positive step towards giving researchers greater access to data from a wider range of sources.

2.4.9 During the pandemic data sharing improved, though this required force of law, and technical issues remained as detailed in RSS/48 - INQ000114799. Others – eg, Bacon and Goldacre (RSS/23 - INQ000114768) – have also detailed frustrations with accessing health data in the UK. They point to datasets that change location or structure without warning, are impossible to locate or require a user to respond to a CAPTCHA (Completely Automated Public Turing test to tell Computers and Humans Apart) test. At the start of the pandemic, Control of Patient Information (COPI) notices were introduced, which made it easier to access data. This process enabled some groups – eg, OpenSafely – to effectively analyse data and draw lessons around how variables such as age, ethnicity and deprivation impacted outcomes, but the process around COPI notices was inefficient and they were not accessible for a wide range of researchers.

2.4.10 It is important to establish TREs – secure analytical platforms that use open analysis code while preserving patient privacy – that can become the normal means for academics, NHS analysts and others to access and analyse health data wherever there is privacy risk to patients. The RSS supports the recommendations of the Goldacre Review (RSS/53 - INQ000114779) on the development of TREs. Had good TREs been in place, the need for COPI notices may have been removed – this should be an important part of the UK's preparedness planning. Relying on COPI notices being issued by ministers – and

giving them a level of control over who can analyse data – should not be how the process runs in the next pandemic.

2.4.11 Research access to data is of great importance and has the potential to identify issues that might not otherwise be picked up. For instance, the Intensive Care National Audit and Research Centre were the first in the UK to report observational data suggesting a disproportionate effect on ethnic minority groups (*ICNARC report on COVID-19 in critical care*, 4 April 2020) and the Institute for Fiscal Studies was the first to study the UK population at large and show that fatalities from Covid-19 were affecting some ethnic groups more than others (*Are some ethnic groups more vulnerable to Covid-19 than others?* 1 May 2020). In an emergency, sharing data with the research community is even more important – as there is a community of experts who will bring a wide range of analytical perspectives and contribute to tackling a pandemic in ways that the government alone – or even with the help of its science advisory bodies – might not have seen, given that the fast pace of demands on government statisticians during a pandemic understandably tends to limit the breadth of analyses carried out.

2.4.12 Better public engagement alongside the proposed protections around data usage is required to earn and sustain public trust.

3 Death registration

Introduction

3.1.1 The RSS has for over ten years been pointing to deficiencies in how deaths referred to coroners are registered in England, Wales and Northern Ireland compared to the situation in Scotland, where deaths must be registered within a fixed period, without delay when cases are referred to the coroner. The central problem, as detailed in RSS/29 - INQ000114771 is that when deaths are referred to the coroner for investigation, the fact-of-death is not registered with the relevant registration service until cause of death has been determined. This means that some deaths are registered months later than they have occurred. This is not a problem in Scotland, where fact-of-death must be registered within eight days even if it has been referred to the coroner.

Recommendation 7

3.1.2 Legislate to ensure that registration of the fact-of-death is not delayed when a death is referred to the coroner in England, Wales and Northern Ireland – as is the case in Scotland.

Rationale

3.1.3 The RSS has two main concerns. First, given current technology, fact-of-death should be reported promptly. Second, official death counts, based on registration-week – but without adjustment for registration-delay – are not as useful to policymakers, public health authorities, the press and the public as they could be. In a pandemic, official statistics are needed that are both timely and accurate. Based on registration-week, the true rate of increase in Covid-mention deaths¹ in England was under-estimated in March and April 2020; the peak-week was misplaced; and the rate of decrease in Covid-mention deaths also under-estimated when deaths were counted by registration-week rather than by occurrence-week (RSS/28 - INQ000114764). See the RSS's September 2020 evidence to the Justice Select Committee (RSS/29 - INQ000114771) for the most recent public statement.

3.1.4 In England, Wales and Northern Ireland the law is that deaths should be registered within five days unless they are referred to the coroner – in which case the death is registered when the cause of death is known. In Scotland it is already the case that coroner referral does not delay registration of fact-of-death – though in Scotland eight days are allowed for registering a death. Ideally there would be consistency in the process across the four nations – including on the number of days within which fact-of-death should be registered.

3.1.5 Following the 2009 H1N1 influenza pandemic, this point was picked up in a report by the Statistical Legacy Group for the CMO as part of the pandemic

¹ Deaths with Covid-19 mentioned anywhere on the death certificate – as opposed to deaths due to Covid-19, where the virus is identified as the underlying cause of death.

influenza preparedness programme (RSS/03 - INQ000114786, p.21) and in the RSS's view should now be addressed urgently through legislation as options short of legislation have been found wanting (RSS/21 - INQ000114763).

4 Statistical skills

4.1 Overview

4.1.1 Especially in a pandemic, civil servants, ministers, and policymakers across government need to be able to make sound evidence-based decisions, and to publish and communicate the data underlying decisions in an effective manner. Statistical knowledge is also needed by press officers, speech writers, and other communication professionals in government who communicate statistics.

4.2 Integration of statistical expertise and policymaking

Introduction

4.2.1 The RSS believes that a culture of statistical thinking within government is a crucial building block to enable the government to respond adequately in an emergency where fast-paced evidence-based decisions must be made. This means that statisticians need to be engaged with policymakers as they are making decisions – feeding in evidence to help inform their choices as well as communicating uncertainties. It also means that policymakers need to be comfortable in understanding key statistical concepts.

Recommendation 8

4.2.2 Prepare mechanisms for engaging relevant expert statisticians with skills in both data analysis and study design and increase investment in statistical training for civil servants, ministers, and other policymakers across government to support an effective evidence-based response.

Rationale

- 4.2.3 The pandemic has shown that there are areas where a better integration of statistical expertise into decision-making processes could have led to better policy outcomes. The OSR's report *Statistical Leadership: Making analytical insight count* (February 2021) makes a similar point about the importance of integrating statistical and policymaking functions. In RSS/32 - INQ000114797 the RSS highlights T&T and the initial plans for mass asymptotic screening as key examples where greater input from statisticians was needed. In these cases, when work was outsourced to private sector organisations, the contracting process needed to provide assurance, with corresponding transparency, that the tendering process was fit for purpose in relation to assessing the relevant expertise and experience of those private sector organisations. Getting statistical input into policy decisions at the earliest stage has the potential to improve policy outcomes – RECOVERY's early discovery of the effectiveness of dexamethasone is a world-leading example of a randomised controlled platform trial. The RSS organised a series of events discussing statistical aspects of the pandemic and the need to integrate statistical expertise in policymaking was a recurring theme of the discussion around evidence and policymaking (RSS/55 - INQ000114777).
- 4.2.4 There were areas where statistical expertise seemed to be missed – for example in the diagnostic test research area. Some of the government reports and discussions seemed to make simple statistical errors in measures such as sensitivity and specificity as well as positive and negative predictive values – in RSS/45 - INQ000114774 (p.49) there is an example of government communication to schools which mistakenly took specificity to mean how well cases are identified. The RSS understands that statisticians with expertise in test research and study design were not engaged until relatively late in the pandemic. Preparedness would be improved by having a mechanism to engage statistical experts in place.
- 4.2.5 The decision that was taken to extend the interval between first and second doses of the vaccine to twelve weeks is an example where limited evidence involving various uncertainties can be fed into policymaking. Two studies published in February 2023 have suggested that this decision had a big positive

impact – potentially preventing 32,000-72,000 hospitalisations and 4,000-9,000 deaths over the ten months of the campaign. It is not entirely clear what evidence was used in making the decision on extending the approved gap between doses – though the vaccine clinical trials did report efficacy and immunology data on the first dose. Limited vaccine supplies and logistics clearly played a role.

4.2.6 The pandemic underlined the importance of improving statistical literacy among politicians. Following a survey that the RSS conducted in 2022 (RSS/49 - INQ000114780), the Society recommended that the situation would be improved by providing statistical training to current politicians, and that people with statistical skills should be given more support to move to leadership positions within the civil service – particularly to positions outside the Government Statistical Service (RSS/32 - INQ000114797, RSS/38 - INQ000114816 and RSS/44 - INQ000114795). The establishment of the Data Science Masterclass and the subsequent development by the ONS Data Science Campus is welcome as a first step, but more can be done. We have also called for more investment in improving data and statistical skills specifically within the NHS (RSS/18 - INQ000114812). The recommendation to improve statistical literacy among policymakers is one that the RSS made repeatedly before the pandemic (RSS/08 - INQ000114809, RSS/10 - INQ000114807, RSS/11 - INQ000114808, RSS/14 - INQ000114806 and RSS/19 - INQ000114789).

4.3 Evaluation

Introduction

4.3.1 During a pandemic, the government needs to make policy decisions based on imperfect and changing information. It is important that when decisions relating to treatments, testing, vaccinations and NPIs are made, robust empirical evaluations are conducted in order to inform later decisions and ensure that they can be made on a firmer evidence base. While details are difficult to prescribe in advance of a pandemic, it is important that an evaluative framework is considered as part of preparedness planning.

Recommendation 9

4.3.2 Develop an optimal strategy for evaluating the effectiveness of treatments and vaccine programmes; build a framework for agile evaluations of non-pharmaceutical interventions (NPIs) whenever appropriate to ensure that decisions are based on the best possible evidence.

Rationale

4.3.3 The evaluation of treatments during the pandemic was very effective, largely due to the success of the international RECOVERY Trial, which quickly identified whether treatments (initially repurposed treatments) were effective, informing decisions on wider use. Although this work was very successful, there were still challenges around how different trials engaged with each other to avoid duplication, eg, with the WHO Solidarity trial. The government should look to build on the success of master protocols to ensure that this can be replicated in future pandemics, while helping to minimise duplication.

4.3.4 Evaluation of the vaccination programme and of NPIs could, with better preparedness, have been improved. Logistic and supply challenges meant that not all first priority groups could be vaccinated at once. There was an opportunity therefore to use cluster randomisation and stepped-wedge designs to roll-out vaccines to care homes, say, in a way that would have provided stronger evidence in relation to vaccine effectiveness and safety. Similarly, for teachers and schools.

4.3.5 The public debate around NPIs may also have benefited from better information and clearer protocols around evaluation. Facemasks, for example, became contentious and political in an unhelpful manner. Better information on how aerosols were implicated in transmission would have been helpful to increase their acceptance by the wider public as a precautionary measure. The most common NPIs in the Covid-19 pandemic involved combinations of testing and isolation policies. Such policies can be evaluated by appropriate choice of designs, like cluster randomised trials. These were used, for example, to compare effectiveness of different isolation protocols in schools, but their utility is hampered in a fast-moving context. To ensure the timely provision of evidence on NPIs in a pandemic, we recommend building a framework which places

constraints of agility at the core of evaluation – this was discussed by Professor Sylvia Richardson in her 2022 Presidential address (RSS/57 - INQ000114819).

4.4 Evaluation and regulatory matters in in-vitro diagnostic tests

Introduction

4.4.1 When there is a novel virus, an effective regulatory programme becomes very important – there will be new diagnostic tests, vaccines and treatments that should be assessed before they are made available to the public. The RSS has a long history of emphasising the importance of statistical methods in drug regulation – in 1991 we successfully called for posts for senior statisticians within the Medicines Control Agency – the predecessor body of the Medicines and Healthcare products Regulatory Agency (MHRA) (RSS/01 - INQ000114815). During the pandemic the RSS became aware of the lack of appreciation of key statistical issues in test evaluation and established a working group on diagnostic testing, which produced a report highlighting some of the evaluation and regulatory issues (RSS/45 - INQ000114774).

Recommendation 10

4.4.2 Well-designed studies that evaluate diagnostic tests in the real-world settings where they are used must become standard practice. Evaluation must consider the intended and unintended consequences. Some consequences will not be evaluable before test implementation, so post-marketing surveillance for a new intended use requires ongoing assessment.

Rationale

4.4.3 During the pandemic the RSS focused on the issue of the evaluation and regulation of in-vitro diagnostic (IVD) devices – tests that are used on biological samples to determine health – such as antibody, antigen, and molecular tests. There are important differences between analytical studies and clinical or field studies. Studies of the analytical performance of a new test are performed in controlled laboratory settings to establish the measurement properties of the assay under ideal conditions. Analytical performance assesses whether the

assay can deliver basic quality specifications that are required for the test to have the potential to be a usable detection mechanism for the infection (present or past). Analytical studies provide necessary but insufficient evidence to implement IVDs . Field or clinical studies are needed to evaluate the performance of an IVD for each intended use, and in the setting and population in which it will be used. Definition of each intended use requires specification of: (a) the people, place and purpose of testing; (b) the target condition that testing aims to detect; (c) the test's specimen-type and how the specimen is taken, stored and transported and by whom; and (d) details of the individuals, training and facilities where testing is done.

4.4.4 Undertaking well-designed, adequately powered and correctly analysed studies of the clinical performance of an IVD is important for each intended use of the test. Study completion may be easier and faster in pandemics because of the rapid accrual of cases, although there seems to have been a lack of coordination and collaboration with experienced trial units across the country by government departments. Several tests were implemented during the pandemic without evidence of their accuracy for their intended use, or without strong studies. The implementation of the Innova lateral flow tests (LFT) in school children is a clear example, where only 17 students had both LFT and PCR tests (of which 14 had false-positive results) before their implementation in all schools.

4.4.5 Accurate, comprehensive information about the evaluation and performance of diagnostic tests is essential: to allow the public and clinicians to make informed decisions on being tested and on interpreting test results; to enable policymakers to decide on testing strategies and the procurement and deployment of tests; for researchers to be fully informed about existing research and to plan appropriately the next studies. The importance of well-organised, transparent reporting of all stages of research has been established for randomised trials of interventions, encompassing: prospective registration of studies, prospective publication of study protocols and statistical analysis, timely publication of full study methods and study findings. The same principles equally apply in IVD research as for interventions. However, the same emphasis has not yet been applied to test

evaluation studies, particularly with concerns to the lack of protocols driving selective publication and data driven analyses.

4.4.6 During outbreaks, particularly when tests are being used outside their intended use, it is prudent to monitor test performance with regard to public safety, by requiring data collection and public reporting on: (a) test results, to assess whether a test is performing as expected in the target population; and (b) disease prevalence, to ensure tests are only used when they will do more good than harm. The importance of this is highlighted by a letter that the RSS sent to the MHRA (RSS/39 - INQ000114783). In March 2021 an asymptomatic lateral flow screening programme was introduced in secondary schools without PCR adjudication of test positives. The RSS argued that at that time the risk of false positives was high as prevalence was low, making it likely that around half of the LFT-screen--positives in secondary pupils in March 2021 would be false-positives, having a negative impact on pupils who may have been excluded from education unnecessarily. Evaluation of the impact of tests should ensure that both intended and unintended consequences are considered. Some consequences will not be evaluable before test implementation, so post-marketing surveillance for a new intended use requires ongoing assessment.

4.5 Government preparedness to communicate statistics, data and modelling

Introduction

4.5.1 Communication during a pandemic is of utmost importance. When referring to data, transparency and clarity in government communication is vital for maintaining public confidence. Being prepared to communicate data effectively should be a core part of preparedness plans. Data and evidence underpinning policymaking must be published when decisions are announced (RSS/10 - INQ000114807) and communication of data must be politically neutral (RSS/11 - INQ000114808).

Recommendation 11

4.5.2 Ensure that, as at other times, communication of data and analysis during a pandemic is independent and non-political – in line with the Code of Practice for Statistics.

Rationale

4.5.3 Government communication in a pandemic should aim to inform – not to persuade. This means: publishing all relevant data whenever a decision is made (ideally via a dashboard, see recommendation 12); clearly signposting this to the public and enabling people to explore it for themselves; presenting the balance of evidence and, crucially, avoiding partial presentation of evidence; being clear on the quality of evidence supporting a decision and open about its associated uncertainty. This was generally done quite well in Scotland but did not seem to come as naturally to the Westminster government.

4.5.4 There were occasions during the pandemic – especially during 2020 – when government communications were driven by a political agenda. The two most notable examples of this were the government claiming to have met a target of carrying out 100,000 Covid-19 tests per day by posting that number of tests (see RSS/26 - INQ000114802) and the misleading presentation of modelling when making the case for the second lockdown at the end of October 2020 (see RSS/32 - INQ000114797). There were also numerous occasions where limited efforts were made to explain the uncertainty inherent in the evidence that was being used to inform decisions (see also RSS/30 - INQ000114798, RSS/31 - INQ000114785 and RSS/44 - INQ000114795).

4.5.5 Communicating statistics to inform rather than persuade is difficult. It requires a detailed understanding of the evidence and well-informed confidence in responding to questioning. It is hard to expect politicians to be able to do this – both because they are unlikely to be sufficiently well-versed in the evidence and because their mode of communication is usually aimed at persuasion. This is why it is set out in Government Statistical Service release procedures that new data and statistical publications should initially be presented by statisticians. New mechanisms could help to ensure independent and non-political communication of data during a crisis – this might include a regular briefing to journalists by, eg,

the national statistician that could be ramped-up during public health emergencies.

Recommendation 12

4.5.6 Include plans to enable rapid replication of the UK's world-leading data dashboards as part of preparedness protocols – clear visualisations and access to underlying data are prototypes of how data should be presented in a pandemic.

Rationale

4.5.7 Government statisticians worked incredibly hard to ensure the regular release of data and, after a slow start, the UK can justifiably be seen as a world leader in the presentation of data. The UK's dashboards in particular were the only example in the world that we know of which both presented data clearly and helpfully while also making the underlying data reliably available. This was especially impressive given that each of the devolved nations had their own – very good – dashboards and pulling together the overall UK dashboard required coordination across the nations. The efforts that went into making government data regularly available were huge (some light is shed on this by Clare Griffiths in RSS/47 - INQ000114792) and the teams involved should be recognised for this.

4.5.8 Our sense is that the level of transparency that was eventually reached did not come naturally to the political leadership of the Westminster government. In the first year of the pandemic, lack of transparency was a consistent problem and there did not seem to be a culture of publishing the data underlying policymaking – as set out in the Code of Practice for Statistics. This cultural issue is starkly demonstrated by the manner in which SAGE (Scientific Advisory Group for Emergencies) membership, minutes and background papers were kept confidential during the first wave. Other examples include the government not publishing the evidence underlying decisions around: home and garden visits, risk levels informing the tier system and decisions around lockdowns (RSS/30 - INQ000114798, RSS/31 - INQ000114785, RSS/33 - INQ000114818, RSS/42 - INQ000114814).

4.5.9 The dashboard team was initially quite small and at the start of the pandemic produced four metrics relating to cases and deaths. By the end of 2021, the team were publishing nearly 200 metrics every day. As part of preparedness planning for the next pandemic, the RSS would like to see a plan for providing a fully-fledged data dashboard at the earliest possible stage of a pandemic. Such a dashboard should draw on all relevant sources and contain, or link to, analytical material to help all users understand the full picture, based on official statistics, other government data, and other sources (such as the Zoe app developed during Covid-19). There should also be testing that the dashboard meets user needs and a communications plan for ensuring that the dashboard is trusted and widely used.

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.

Personal Data

Signed: _____

Dated: 21 April 2023