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NHS Foundation Trust

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Dear Madam

Regulation 28 – Report to Prevent Future Deaths, 9 May 2022

I write to provide a response on behalf of St George's University Hospitals NHS Foundation Trust ("the Trust") to the Regulation 28 Report to Prevent Future Deaths (PFD) issued to the Trust and NHS England on 9 May 2022.

This letter responds to each of the matters of concern set out in Section 5 of the PFD Report and provides assurance in relation to actions taken by the Trust to ensure the safety of patients requiring cardiac surgery and mitigate potential risks. In preparing this response, the Trust has liaised closely with NHS England (NHSE) which is best placed to respond to certain matters of concern in the PFD Report that go beyond the remit of the Trust. Our response should be read in conjunction with the response from NHS England, given the overlap in a number of areas.

I hope that the assurances set out in this letter regarding the safety of future patients requiring cardiac surgery demonstrate the seriousness with which the Trust and its partners have approached these matters and the comprehensive actions and risk mitigations that, collectively, have been put in place to enhance both current and future patient safety and strengthen the service going forwards.

1. Context

Before dealing with the specific matters of concern set out in the PFD Report, I hope it is helpful to set in context the challenges faced by the Trust's cardiac surgery service in recent years and the steps taken by the Trust to maintain and improve patient safety, strengthen clinical governance and develop a positive culture, effective leadership and collaborative working relationships within the service. The challenges encountered by the service have been well documented and I will not recount these in detail. However, I hope it is helpful to summarise briefly the elements of these challenges that are material to the matters of concern set out in your PFD Report. Throughout this period, the Trust has been focused on the safety of patients and the quality of care and treatment they receive. The improvements that have been made are evident across a range of measures and the service today is very different from the one the Trust took urgent steps to improve from 2017.

In May 2017, the National Institute for Cardiovascular Outcomes Research (NICOR) issued an alert to the Trust highlighting that the mortality rate for patients who had undergone cardiac surgery at St George's Hospital between April 2013 and March 2016 was higher than expected. Of 2,505 cardiac surgery cases in the period between 1 April 2013 and 31 March 2016, the *risk-adjusted* survival rate for cardiac surgery patients at the Trust was 96.8% compared with a predicted survival rate of 98.3%. A NICOR alert is triggered when a unit's

mortality exceeds the national mean by two standard deviations or more. A second NICOR alert was issued to the Trust in April 2018 covering the period 1 April 2014 to 31 March 2017.

In April 2017, the month prior to the NICOR alert, the national Getting It Right First Time (GIRFT) programme published a review of cardiothoracic surgery across the UK, which was endorsed by the Society for Cardio-thoracic Surgeons of Great Britain and Northern Ireland as "*allow[ing] units to benchmark performance against the national average and…provide a powerful stimulus for improvements in services to patients*". The GIRFT methodology as a whole is supported by the medical Royal Colleges. The report on the cardiac surgery unit at the Trust indicated that the service was a outlier in a number of clinical outcomes, including: a high post-operative mortality for all heart surgery cases; a high readmission rate after surgery; a high rate of new renal placement therapy after surgery; a high rate of further intervention (percutaneous coronary intervention (PCI)) after coronary artery surgery high mortality after elective aortovascular surgery; and a low rate of mitral valve repair versus replacement for degenerative valve disease. Dr [redacted] analysis from April 2014 to July 2017 also suggested that the Trust's cardiac surgery service benchmarked less well against other comparable trusts with a higher relative risk of death following Coronary Artery Bypass Graft (CABG) (first time) and CABG (other) surgical procedures. It also suggested peaks in the mortality risk in June 2014, January 2016 and May 2017. Trust data also demonstrates that, during 2015-16, the service also encountered challenges in relation to surgical site infections (SSIs) and deep sternal infections.

In addition to the NICOR mortality signals and data relating to patient outcomes, the Trust received a number of whistleblowing concerns raised by clinicians between 2016 and 2018 regarding patient safety concerns within the service. These concerns related to, among other matters: mortality; increasing rates of surgical complications; the conduct and effectiveness of care group meetings; and performance concerns regarding named individuals with alleged high mortality rates. Concerns were also raised externally to the Care Quality Commission (CQC) which focused on outcomes and mortality rates, culture, governance and leadership.

In August and September 2018, the Care Quality Commission (CQC) undertook an unannounced inspection of the Trust's cardiac surgery service. The CQC report, which was published in December 2018, identified issues around local governance and leadership, culture, morale, working relationships, learning from incidents, and the quality of mortality and morbidity meetings, and the importance and role of national audit. Concerns around team-working and culture within the service highlighted by the CQC followed similar concerns set out in the independent report by Professor [redacted] (2018) and the earlier independent report by Professor [redacted] (2010).

The challenges faced by the service in the years leading to, and following, the first NICOR alert were clear. The NICOR alert was triangulated with a wide range of internal and external information regarding the service which gave cause for concern and necessitated actions to understand the issues and make improvements. In response, the Trust established a cardiac surgery task force chaired by the Medical Director and Chief Nurse, the purpose of which was to address the concerns that had arisen, monitor and improve the safety of the service, and provide assurance to the Trust's Quality and Safety Committee and Board of Directors. In order to provide assurance that the steps being taken by the Trust were delivering the necessary improvements to the safety of the service with the necessary pace, in May 2018 the Trust commissioned an external independent review, led by Professor [redacted], to confirm that progress was being made in addressing the concerns of excess mortality and advise on further actions that may be necessary. In July 2018, the Trust accepted the recommendations of this review and put in place a clear set of actions to deliver them.

In the context of the challenges faced by the Trust's cardiac surgery service set out above, a set of restrictions on the service were introduced on 3 September 2018 following a Quality Summit convened by NHS England and attended by the Trust and representatives of NHS Improvement (NHSI) , the Care Quality Commission (CQC), Health Education England (HEE), the General Medical Council (GMC), Guy's and St Thomas' NHS Foundation Trust (GSTT) and King's College Hospital NHS Foundation Trust (KCH). The restrictions introduced

in September 2018 limited the procedures that could be undertaken by the service to those with a risk of death of 2% or below, using the EuroSCORE II methodology (later increased to 5% in December 2018). These restrictions continued to be in place until 7 April 2021. There were also restrictions in relation to surgery for acute aortic dissection, and these are discussed in our response to Matter of Concern 2, below.

It is important to recognise that the restrictions were introduced in 2018 in order to decrease the risk to patients, by providing the space necessary for the cardiac surgery service at the Trust to make improvements to safety, clinical governance and culture, leadership and behaviours. There was a consensus among all the stakeholders in the Single Item Quality Surveillance Group responsible for overseeing cardiac surgery at the Trust (i.e. NHS England, NHS Improvement, the CQC, HEE, the GMC, GSTT, KCH and the Trust itself) that these restrictions were in the interests of patient safety. The Single Item Quality Surveillance Group, and St George's Trust Board, maintained close and regular scrutiny of patient safety and outcomes in the service throughout the period that the restrictions were in place, and this oversight continues now that the restrictions have ended.

It is important to set out this context at the outset of the Trust's response to the PFD report as it relates both directly and indirectly to a number of the matters of concern set out in the PFD Report.

2. Overview of assurance regarding current and future patient safety

The years covered in this reply to the PFD Report, and indeed the years leading up to them, have involved some significant challenges for the cardiac surgery department and the Trust as well as for bereaved families. We hope that this reply to your PFD Report sets out clearly the way in which potential risks were mitigated during this period, and the way in which a high level of scrutiny was (and still is) maintained with regards to patient outcomes and survival, to clinical incidents and to local capacity and demand, both at Trust level and at South London system level.

The quality and safety data that was collected throughout the period of the restrictions (and which still is collected) provides robust assurance that patient safety and mortality was not negatively impacted by the restrictions but, on the contrary, was maintained in line with national expectations. Further assurance that quality and safety was maintained throughout the period of the restrictions may be taken from the fact that the unit came out of NICOR alert in October 2019 (for the period covering 1 April 2015 to 31 March 2018) and has remained out of alert since then. Further assurance is provided by the positive reports of the CQC inspections as well as the most recent visit from Health Education England (details are provided later on in this letter).

We would also like to highlight the enhanced oversight of safety governance that has been in place in the unit throughout the period under consideration. Every death after cardiac surgery was, and is, carefully scrutinised at the Trust's Serious Incident Declaration Meeting, whether or not the death was declared as a Serious Incident, and all deaths in the service are reviewed at the departmental Mortality & Morbidity Meetings, and useful safety learning is disseminated. The decisions taken at the Trust's Serious Incident Declaration Meeting are all subject to a further layer of scrutiny which is external and is provided by a senior cardiac surgeon in another Trust. Regular assurance reports on the quality and safety of the service have been provided to Trust Board, either directly or, since July 2020, quarterly through the Trust's Quality sub-Committee of the Board, which is responsible for providing assurance to the Board on quality and safety across the Trust.

The Trust's response to the PFD Report deals, in turn, with each of the 10 matters of concern set out in Section 5 of the Report. In its response, the Trust provides factual information and data which demonstrates the actions it has taken to date to protect patient safety at all times and how these actions provide assurance regarding the safety of patients in future. Taken together, the information set out below provides robust, evidence-based assurance of the steps that have been, and continue to be, taken by the Trust in partnership with the South

London Cardiac Surgery Network, NHS England and other stakeholders to ensure safe, high quality care for patients requiring heart surgery.

While Section 3 of this letter provides detailed responses to each of the matters of concern set out in the PFD Report below, I hope it is also helpful to provide the following summary of the key sources of assurance on patient safety:

- The restrictions on the service which were introduced on 3 September 2018 were lifted on 7 April 2021. The transitional arrangements put in place from April 2021 to support the service to resume full functioning have been implemented and the resumption of the full functioning of the service is expected to be endorsed by NHS England imminently.

- Cardiac surgery units in south London were not overstretched during the time that restrictions were in place at the Trust, and this continues to be the case looking forward. The importance of maintaining capacity to meet demand through the period the restrictions were in place was actively recognised, overseen and managed through the South London Cardiac Surgery Network and by NHS England. As a consequence of the mitigations put in place, overall cardiac surgery activity was maintained across south London. Waiting times were not only maintained during this period but were actually reduced. Patients were not at increased risk of death through any overstretching of any cardiac surgery units during the period the restrictions were in place, and the capacity within the Network provides assurance as to the safety of patients in future.

- There have not been unnecessary deaths of emergency patients in the past because of the restrictions that were in place previously, and arrangements are in place to ensure that care pathways for emergency patients in South London remain safe, and that these pathways will be further improved through the pan-London work currently underway.

- We acknowledge that the challenges the cardiac surgery service has encountered in recent years may have impacted on public confidence in the unit, however this pre-dated the Independent Mortality review. Moreover, this did not make patients less likely to present to some part of the healthcare system and did not make it less likely that they would receive surgery. This did not increase patients' risk of death in the past, and this does not now, or in the future, increase patients' risk of death.

- The recommendations of the Independent Mortality Review identified a range of factors from which lessons were learnt. The Trust has taken action to implement all of the recommendations from the Review which have significantly strengthened the safety and governance of the service. The positive clinical outcomes that have been recorded by the service, including in relation to mortality, demonstrate the value of the recommendations of the Review in improving safety and preventing future deaths.

- We have provided and continue to provide pastoral support to members of the cardiac surgery service and other clinicians to support them throughout the challenging time the service has gone through in recent years. We closely monitor the safety and quality of the service and will continue to do so, and there is no evidence that there has been, or will in future be, a greater risk of death or lower quality care as a result of this.

- We recognise the importance of the reputation of the organisation and have taken, and will continue to take, actions to ensure patients and the public can have confidence in our services. We closely monitor the safety and quality of the service, and there is no evidence of greater risk of death or lower quality care as a result of the impact on the reputation of the service in the context of the recent challenges it has faced. We have been consistently clear publicly that cardiac surgery at the Trust is safe and will

continue to do so. We have worked with partners across the system to provide assurance on quality and safety and to encourage referrals to the service.

- Health Education England has confirmed that cardiac surgery training at the Trust is resuming from August 2022, and that the learning environment for trainees has been significantly improved. The imminent return of trainees, and the fact that the unit has completed a period of six months of transition arrangements following the lifting of restrictions, means that the unit will return very shortly to circumstances that should be as favourable to the conducting of research as they were in the past. Staff turnover is not high and the workforce overall is stable. In the one area with recruitment challenges (cardiac anaesthesia), appropriate mitigations are in place.

- We have recognised the fact that the period of restrictions may have made surgeons understandably more risk averse, and that we have taken care to mitigate this though the six-month transition period after the restrictions were lifted, in particular by supporting arrangements for dual operating, and by measuring and demonstrating positive outcomes during this time. Patients considered complex by virtue of their predicted risk of post-operative death have not been, and are not, denied care. Patients considered complex by virtue of their anticipated post-operative requirement for specialised support – Extra Corporeal Membrane Oxygenation (EMCO) and Ventricular Assist Devices (VADs) – have not been, and are not, denied care.

Further assurance relating to each of the matters of concern in the PFD Report is set out below.

3. Matters of Concern

In this section, we provide assurance in relation to each of the Matters of Concern set out in Section 5 of your PFD Report. We also note the findings of fact set out in section 4 of the PFD report. While we do not recognise some of these findings, we hope that the detail provided below provides clarity on the relevant matters.

Matter of Concern 1: "*That restrictions in cardiac surgical capacity at SGH is causing patients to be diverted to other overstretched units, increasing their risk of death.*"

The restrictions on the Trust's cardiac surgery unit were put in place on 3 September 2018 and were lifted by the Single Item Quality Surveillance Group, which oversaw improvement in cardiac surgery at the Trust, on 7 April 2021. The restrictions is described in the context section above.

The proportion of patients whose planned care fell under the restrictions that were in place between 3 September 2018 and 7 April 2021 was not high – it was only 8% of the total number of planned operations at the time of the lifting of restrictions in April 2021, and around 20% of planned operations during the six months of transition requirements between November 2021 and May 2022 (see below for further details of these transitional arrangements). Furthermore, the appointment of an external lead for cardiac surgery, who started in December 2018, meant that the team included a highly experienced cardiac surgeon who was not subject to these restrictions. This lead cardiac surgeon was able to operate on the majority of those planned cases at the Trust that fell under the restrictions without them having to be treated elsewhere. Most transfers of care to other hospitals because of the restrictions only happened when the clinical lead was away. The number of planned cases that were transferred from the Trust to other hospitals was therefore low throughout the period of the restrictions.

The largest number of transfers occurred when the restrictions were first put in place, when the external lead had not yet been appointed. At this time, those patients on the waiting list for planned surgery at the Trust

whose planned operations fell within the scope of these restrictions had to be operated on elsewhere. In practice this meant transferring patients who had not yet been admitted to hospital from St George's waiting list to the waiting lists of other providers. The number of patients who were transferred in this way at this time was thirty-five. Unfortunately, because of software changes in the departmental data storage system since 2018, we cannot readily extract the identity of these patients in order to check with the receiving providers as to whether there were any subsequent concerns about the patient pathway or care in any individual cases. What we can say is that in every case the transfer occurred only after a Multidisciplinary Team Meeting (MDT) between the Trust, KCH and GSTT, and these meetings were attended by a consultant cardiac surgeon from the Trust and by the St George's Cardiac Surgery Programme Director. We can also give assurance that no concerns about any of these patients in relation to the transfer of their care were raised with us at the time or subsequently.

Throughout the time that the restrictions have been in place, just one Serious Incident has occurred in which the investigating panel felt that the restrictions may have been a factor in causing delay in the care of a patient who subsequently died. This case is described in more detail in our response to Matter of Concern 2, below.

It is worth highlighting that, during the period the restrictions were in place, between 17 March 2020 and 2 June 2020 and later between 15 December 2021 and 4 February 2021, cardiac surgery at the Trust and most other centres across London was suspended due to the Covid-19 pandemic. During this time, cardiac surgery across the capital was performed at two centres only, St Bartholomew's Hospital and the Royal Brompton Hospital.

At a meeting of the Single Item Quality Surveillance Group, convened by NHSI/E London Region on 7 April 2021, it was confirmed that the restrictions on planned surgery could be lifted. This represented a collective agreement by the key stakeholders who have been involved in overseeing the quality of the Trust's Cardiac Surgery service (as stated above). A set of transitional arrangements were agreed with the Single Item Quality Surveillance Group to support the unit, and the consultants within it, as it resumed full functioning, which included dual consultant operating on cases that would have been subject to restrictions in place previously. Initially, some of the surgeons were reluctant to accept the transitional arrangements given the possibility, which remained at that stage, that they may be investigated by the General Medical Council. The transitional arrangements to support the service to resume full functioning came into effect from November 2021.

The clinical lead for the service has now reviewed the outcomes of all the cases that were undertaken during the six month period between 26 November 2021 and 30 May 2022 during which transitional arrangements to support the service to full functioning were in place. Overall, a total of 255 cases were operated on during this period (this includes cases that would have previously fallen under the restrictions and cases that would not have been restricted) with a mortality rate of 3.92% (10 patients). A total of 54 cases from the higher risk group that would have previously fallen under the restrictions were operated on during this period with 8 deaths (14.8%). The average predicted risk of death by EuroSCORE II for this group overall was 9.76; the average EuroSCORE II for the patients who died was 20.33 and the average EuroSCORE II for the patients who survived was 8.32. As would be expected, among the patients who did not survive there were some extremely high-risk cases, such a patient with a post-infarction ventriculo-septal defect (VSD), patients with endocarditis and a patient with an infected false aneurysm.

On 4 July 2022, the implementation of these transitional requirements was reviewed locally by the Trust following which the Trust is recommending to NHS England that the service is ready to assume full operational activity.

This most up-to-date outcome data, which builds on a number of years of comprehensive safety and quality data, provides a high level of assurance that future patients, whether or not they fall into higher risk groups, are not at increased risk of death, and that the Trust's cardiac surgery unit consistently achieves outcomes that are within those expected nationally.

We hope that this provides you with assurance that:

- There are now no restrictions, and will shortly not be any form of transitional requirement, in place in relation to the cardiac surgery service at the Trust.

With regard to the concern that other cardiac surgery units may have been overstretched when the restrictions at the Trust were in place, data that is relevant in addressing this concern (by providing an overall indication of demand and capacity over time) is available through the South London Cardiac Surgery Network. Data is available regarding activity levels by provider, waiting lists and interhospital transfers.

Unsurprisingly, the issue that had by far the biggest impact during the relevant period was the Covid pandemic – activity fell, interhospital transfers fell and waiting lists rose. The data indicates, however, that by these metrics cardiac surgery in the south London system has now largely recovered from the impact of Covid. The data on activity by provider shows that activity at the Trust did indeed fall from 2018, but that the total activity in the south London system did not fall – the fall in activity at the Trust was accompanied by a corresponding rise in activity at GSTT. From the financial year 2017/18 to the financial year 2019/20 (after which the Covid pandemic made a significant impact) the total number of procedures performed in south London remained almost exactly the same. At the beginning of this period, the Trust accounted for 31% of the activity and GSTT accounted for 16%. By the end of this period, the Trust accounted for 20% and GSTT for 26%. The contribution from KCH remained steady at 37%, and Brompton and Harefield and Barts and Imperial continued to provide steady levels of activity also.

It was recognised in 2018 that changes at the Trust made it important that capacity should continue to meet demand without there being a rise in waiting lists, and so waiting list initiatives were introduced at KCH and GSTT. As a result of this, not only was an increase in waiting lists avoided – the number of patients waiting for surgery actually fell in all three main provider units. In July 2019 (the earliest date for which this data is readily available) there were just over 350 patients on the South London cardiac surgery waiting list, and this steadily fell to just under 250 in April 2020, which was the last month before the Covid pandemic began to have an impact. The waiting list for South London now is back to pre-Covid levels.

The number of interhospital transfers (from hospitals in south London, Kent, Surrey and Sussex) into the cardiac surgery units of south London has also remained fairly steady, at around 500 transfers per quarter, between Q1 of 2018 (i.e. before the introduction of restrictions at the Trust) to the present, except for a significant fall in 2020, at the height of the Covid pandemic.

With regard to the governance and oversight of capacity and demand in south London, it may be helpful to highlight the fact that there has been robust monitoring of this data since January 2020 at a South London Cardiac Surgery Network level to ensure that units are not overstretched, and the Network has at several points throughout the years provided the Trust's cardiac surgery unit with bespoke data to inform on patient flows as part of the network's assurance processes.

During periods of Covid surge and recovery, capacity and demand in south London was reviewed at weekly steering group meetings, and the Network has now returned to reviewing this on a monthly basis. The clinical leads at KCH and GSTT have also been able to, at any point, raise concerns with the Network about capacity if they had them. Additionally, the Network appointed a senior south London cardiac surgeon (from KCH) as Network Clinical Lead, and this role provides further clinical leadership and oversight of any quality or operational issues the might impact on patient safety.

It may also be helpful to highlight the fact that the Cardiothoracic Surgery Getting It Right First Time (GIRFT) visit to St George's took place on 29 November 2021 and in feedback afterwards the GIRFT lead praised the south London cardiac surgery units for the way that non-elective demand and capacity is managed flexibly

across the three sites through the south London integrated interhospital transfer system wait list and weekly operational meetings.

In addition, it is worth noting that the rise of interventional cardiology procedures, such as Transcatheter Aortic Valve Implantation (TAVI) and Percutaneous Coronary Intervention (PCI), means that patients who would have previously been offered cardiac surgery are undergoing alternate procedures and, as a result, there has been a corresponding fall in activity for cardiac surgery more generally.

We hope that this provides you with assurance that:

- Cardiac surgery units in south London were not overstretched during the time that restrictions were in place at the Trust;
- The importance of maintaining capacity to meet demand through this period was actively recognised, overseen and managed through the South London Cardiac Surgery Network and by NHS England;
- As a consequence of the mitigations put in place, overall cardiac surgery activity was maintained across south London while waiting times were not only maintained but actually reduced; and so
- Patients were not at increased risk of death through any overstretching of any cardiac surgery units.

Matter of Concern 2: "*That emergency patients being diverted away from SGH has resulted in unnecessary deaths*."

We are not aware of any incident in which the diversion of an emergency patient away from the Trust because of the restrictions on cardiac surgery resulted in the death of a patient.

The condition that accounts for the majority of cases that require emergency cardiac surgery is Type A Acute Aortic Dissection (i.e. dissection of the ascending aorta). In most parts of the country, cardiac surgery units work together to provide a regional aortic dissection rota, and patients requiring emergency surgery will be transferred from whichever hospital they happen to have presented at to the cardiac surgery unit that is on the rota to provide aortic dissection surgery on that particular day. Such an arrangement has been in place in south London for some years.

Emergency presentations with acute aortic dissection are important but infrequent – as an example, eighteen such cases have presented at the Trust's emergency department in the last four years. In London as a whole, since 2018 the number of operations performed for Type A Acute Aortic Dissection has been in the range of 120 to 160 per year. Acute Aortic Dissection is recognised to carry a high mortality – approximately 15-20% of patients die following emergency surgery for this condition. Given the number of cases involved, and the link between quality and volume of cases, there has been a longstanding ambition across the system, which pre-dates the restrictions being introduced at the Trust in September 2018, to consolidate Type A Acute Aortic Dissections.

In August 2018, shortly before the restrictions were first introduced on cardiac surgery, the Trust informed all the hospitals in the catchment area that the unit would not, for the time being, be receiving emergency transfers for aortic dissection surgery, and that the Trust would be transferring its aortic dissection patients for surgery at the neighbouring cardiac surgery units in south London, unless they were not stable enough to be transferred safely, in which case they would still receive their emergency surgery at the Trust. Details of the rota, and the mechanism of making referrals to these units, were provided to every emergency department in south London, Kent, Surrey and Sussex to ensure the change was widely communicated. Letters setting this out were also sent to the chief executives and medical directors of Trusts in these areas. There was, importantly, no interruption to the ongoing rota of provision of emergency aortic dissection surgery in south London, and there

was careful oversight through the South London Cardiac Surgery Network to ensure that the system retained adequate capacity to meet the demand.

During the period that the Trust has not been part of the aortic dissection rota, patients presenting with Type A Acute Aortic Dissection at other hospitals will have been referred to the cardiac surgery unit on the rota to take such cases on the day. It is not possible, therefore, to identify individual patients who would have been transferred to St George's had the restrictions not been in place. The assurance that no unnecessary deaths occurred in this group of patients as a result of the restrictions comes rather from the evidence provided through the South London Cardiac Surgery Network that that capacity has always been adequate to meet demand. Indeed, in the two years following the introduction of the St George's restrictions, the number of operations performed in south London for Type A Acute Aortic Dissection actually rose slightly, indicating that the restrictions did not have any negative impact on the capacity of the system.

From the start of the period of restrictions in September 2018 to the present time, seven patients with acute aortic dissection have been transferred from the Trust's emergency department to another hospital's cardiac surgery unit for emergency surgery. Three of these patients died post-operatively and four survived. Concerns around one of these cases in which the patient died are described below. In the other two cases, we have received assurance through the medical directors of the receiving Trusts that there were no concerns raised at the receiving Trusts at the time about any of the care provided, and in all three cases we have received assurance that there was no concern raised about any deterioration during hospital-to-hospital transfer.

In the same time period, eleven patients with Type A Acute Aortic Dissection have been operated on at the Trust rather than being transferred, either because they were too unstable to be safely transferred, or because other clinical circumstances made this appropriate. Ten of these patients survived and one died.

Of those patients who died, in one instance only, concerns about a delay in transfer were explored through a Serious Incident Investigation ([redacted]). The patient presented in May 2021 to the Trust's emergency department with an acute aortic dissection. The patient was too sick for safe transfer until they had been stabilised, but when the patient was ready to be transferred the other centres on the aortic dissection rota were all coincidentally busy at the same time, and it took three hours before a transfer took place. The patient was operated on at the unit to which they were transferred, but subsequently died. The local coroner opted not to open an inquest into the death. The Serious Incident investigating panel concluded that the transfer could have been managed more smoothly. The investigating panel agreed that regardless of any restrictions, it was still most likely that the decision would have been to transfer the patient to the on call dissection centre, but that in this case there was confusion about the restrictions which contributed to the delay. The investigating panel concluded that even if this had not been the case, the outcome for the patient might not have been any different, and that the factor that contributed most to the delay was the unavailability of emergency operating capacity at multiple centres on the dissection rota at that particular time on the same night. To address the risk of similar delay occurring again, a new Standard Operating Procedure was introduced at the Trust that clarified the way in which such transfers were to be arranged, and the details of the south London dissection rota were made more readily available. We enclose a copy of the Serious Incident investigation report, the Action Plan and the Standard Operating Procedure for your information. The Trust can confirm that all of the actions set out in the Action Plan have been completed in full. We hope this provides you with assurance that the risk of a similar delay in care recurring in the future has been appropriately addressed.

With regard to the future, pan-London work is now underway to implement the recommendations of the national NHS England Cardiac Pathways Improvement Programme, which sets out key principles on which to base care for emergency acute aortic dissection patients. This will include the creation of a quality assurance strategy for London, based on robust and standardised data collection. Pathways will be agreed for London, with local implementation in north and south London. Following the lifting of restrictions, the cardiac unit at the Trust is fully ready to help and participate in any necessary changes or improvements identified through this process.

We hope this information provides you with assurance that:

- There have not been unnecessary deaths of emergency patients in the past because of the restrictions, and
- Arrangements are in place to ensure that care pathways for emergency patients in south London remain safe, and that these pathways will be further improved through the pan-London work currently underway.

Matter of Concern 3: "*That public confidence has been so dented that patients requiring care have been discouraged from presenting to SGH thus increasing their risk of death*."

We acknowledge that recent years have been a challenging period for the cardiac surgery service at the Trust and that the negative publicity surrounding the unit, which pre-dates the commissioning of the Independent Mortality Review, may have impacted on public perceptions of the unit. The response to the PFD from NHS England sets out that if patients requiring cardiac surgery do not wish to present to St George's there are other local centres within the South London Cardiac Surgery Network to which patients can present or be referred.

Patients who eventually proceed to planned cardiac surgery will in general present initially to primary care, and through primary care to their local cardiology service, and from the local cardiology service they will then by referred to a cardiac surgery unit. Some patients who eventually proceed to planned cardiac surgery will present initially to their local hospital's emergency department, and if they are not discharged to have outpatient cardiology follow up as above, they may then be transferred to a local cardiac surgery unit through interhospital transfer.

We have provided information in our response to Matter of Concern 1 above that we hope provides assurance that (leaving aside the impact of Covid, which clearly did discourage many patients from presenting anywhere) overall cardiac surgery in south London has not fallen in the period under consideration, and any decrease in the planned surgery carried out at the Trust was fully compensated for by increased activity elsewhere. This was consciously and carefully overseen and managed through the South London Cardiac Surgery Network which provided regular reporting to the NHS England London Region Cardiac Surgery Quality Summit in relation to data on demand and capacity and involved the oversight of the London Regional Medical Director and clinical and operational representatives from each of the south London cardiac surgery centres.

We have also provided information that interhospital transfers for cardiac surgery in south London (leaving aside the period of the Covid pandemic) did not fall.

We hope this provides further assurance that even if public confidence in the Trust's cardiac surgery unit was dented (which of course we acknowledge is likely to have been the case), nevertheless:

- This did not make patients less likely to present to some part of the healthcare system and did not make it less likely that they would receive surgery, and
- This did not increase patients' risk of death in the past, and
- This does not now or in the future increase patients' risk of death.

Matter of Concern 4: "*That the evidentially inadequate and critical SJR process has failed to identify factors from which lessons could have been learnt and thus patient safety improved, and future deaths prevented*."

With regard to your concerns about the Structured Judgement Review process, as the Review was commissioned independently of the Trust this Matter of Concern is for NHS England to respond to, and we note that response to the PFD from NHS England addresses these concerns.

We would, however, make a number of observations regarding the overall findings and recommendations of the Independent Mortality Review, which the Trust accepted. These were consistent with the other evidence about the longstanding problems in the service and we found the recommendations, which also reflected modern best practice, helpful as part of the ongoing process of making improvements to the service in order to protect and strengthen patient safety and secure the long-term future of the service. The 12 recommendations set out in the Review are, evidentially, reasonable and have contributed to significant improvements in the service and positive outcomes, which are reflected in the process of ultimately returning the service to full functioning.

Examples of significant improvements made as suggested by the Review:

- Recommendation 6 of the Review, for example, stated that "*all referrals for cardiac surgery should be discussed at the relevant sub-specialist MDT, which should ensure the availability of all necessary data before review of the clinical care*". It further recommended that the MDT should have a pre-defined minimal quorum, with full representation from sub-specialist cardiac surgery, interventional and non-interventional cardiology, and radiology, and be appropriately recorded. We have implemented this recommendation and have established effective MDTs which reflect the good practice described in the recommendation from the Review. All significant complications are discussed at the monthly Mortality and Morbidity Meeting.

- Recommendation 7 of the Review stated that risk-scoring, using up-to-date risk scoring algorithms, should be embedded in practice and that all risk factors should be considered, and accurate risk prediction made, and the risk prediction be recorded on the consent form. We have implemented this recommendation and all patients are risk assessed, normally using the EuroSCORE II risk assessment algorithm. This has been embedded in practice and the risk according to EuroSCORE II is recorded on the patient's consent form. If the risk of surgery is considered to be significantly different from that calculated by EuroSCORE II, the reason for the variance is recorded on the electronic patient record.

- Recommendation 9 of the Review stated that a range of new guidelines / standard operating procedure (SOPs) for patient care be developed and implemented, including an SOP for the management of urgent inter-hospital transfers, a guideline for the management of myocardial protection, guideline for the management of operative and post-operative haemorrhage, a multi-disciplinary guide for post-operative ECG interpretation, a multi-disciplinary guideline for selection and management of patients requiring mechanical support, and a guideline for outreach services for patients who are not in intensive care environments. We have implemented this recommendation and have developed a range of SOPs, guidelines and processes to address the areas for strengthening our approach as recommended by the Review.

- Recommendation 10 stated that "*the Trust should develop a robust, independent, multi-disciplinary review of mortality with appropriate governance oversight to ensure that lessons are learnt*". We have implemented this recommendation, and all cardiac surgery deaths are reviewed at the monthly multi-disciplinary Integrated Cardiac Surgery Governance Meeting and the treatment provided is graded according to the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) Assessment of Care Scale. All cases are also discussed at the Serious Incident Declaration Meeting.

The positive outcomes the service has recorded demonstrates that the actions that we have taken in response to the recommendations of the Independent Mortality Review have greatly assisted the Trust in strengthening

the safety and operation of the service. The mortality rate for cardiac surgery at the Trust demonstrates that the service is performing within nationally expected limits and complications arising from surgery are within expected norms.

We hope this provides you with assurance that:

- The recommendations of the Independent Mortality Review identified a range of factors from which lessons were learnt.
- The Trust has taken action to implement all of the recommendations from the Review which have significantly strengthened the safety and governance of the service.
- The positive clinical outcomes that have been recorded by the service, including in relation to mortality, demonstrate the value of the recommendations of the Review in improving patient safety and preventing future deaths.

Matter of Concern 5: "*That this SJR process has undermined the department unnecessarily, impacting on morale and the mental health and confidence of the cardiac surgeons and other clinicians and non-clinicians within SGH which may translate into a lower quality of care for patients*."

Recent years have been very challenging for all those working within and alongside the cardiac surgery service and the Trust has consistently offered a range of pastoral support to staff. It is important to recognise that the challenges regarding the cohesion and functioning of the team are longstanding and pre-date the commissioning of the Independent Mortality Review. These challenges, and the issue of low morale in the service, were described in some detail in the Care Quality Commission's report of its inspection of the service in August and September 2018. Similar issues were identified in the reviews undertaken by Professor [redacted] (2018) and Professor [redacted] (2010).

In relation to the morale, mental health and confidence of clinicians, it is important to clarify that the decision by the Quality Summit, convened by NHS England, to introduce restrictions on the service in September 2018 were explicitly designed to ease the pressure on the unit and its staff and provide the unit with the space needed to make improvements to safety, governance, leadership and culture. Likewise, following the lifting of restrictions in April 2021, the transitional arrangements introduced to support the service resuming full functioning – including measures such as dual consultant operating – were introduced in order to provide practical support to members of the team recognising the duration the restrictions had been in place. The Trust has, in addition, provided a range of pastoral support to the team, which has included appointing an external expert to work with the service to develop a strong and effective culture and team working, supporting staff in raising concerns, promoting psychological safety, providing feedback and managing team conflicts. In addition, the Trust has provided support in the form of in-theatre similariton training to support consultants to lead scenario-based team development to further foster psychological safety.

In terms of the impact of the wellbeing of clinicians within the service on patient safety and quality, there is no evidence that outcomes have been impacted negatively by the work of the Trust to improve the service in response to the Independent Mortality Review. Detailed assurance regarding the safety and quality of care provided in cardiac surgery has been provided regularly to the Trust Board via the Quality Sub-Committee of the Trust Board throughout this period. These reports set out the clinical outcomes achieved by the service. As referenced elsewhere in this document, the service is no longer and outlier for mortality and is no longer in NICOR alert. Mortality rates are within nationally expected limits. We carefully track complication rates, which (although there is no systematic national benchmarking as there is for mortality) are also within national norms. In its most recent inspection of the service, the Care Quality Commission found service to be safe, concluded that there had been "*significant improvements*" to the leadership of the service, and that there had been improvements in the way the service learned from incidents and in the overall governance of the service,

particularly in mortality and morbidity meetings. In taking its decision to lift the restrictions on the service in April 2021, the Single Item Quality Surveillance Group was able to take assurance regarding safety and quality in the service. In turn, Health Education England has recognised that the evidence provided by the Trust has enabled it to take the decision to remove the suspension from placing trainees in the service from 30 June 2022, and initiate a phased return of training to the service at all levels from August 2022.

Through all of our internal quality and safety governance and monitoring processes, and the data reviewed by external bodies, there has been – and continues to be – no evidence of an increased risk of death within the Trust's cardiac service, or any evidence that patients undergoing cardiac surgery are receiving a lower quality of care.

We hope this provides you with assurance that, both retrospectively and looking forward:

- We have provided and continue to provide pastoral support to members of the cardiac surgery service and other clinicians to support them throughout this challenging period.
- We closely monitor the safety and quality of the service and will continue to do so, and there is no evidence of greater risk of death or lower quality care.

Matter of Concern 6: "*That the apparently unnecessary restrictions on operating rights of the cardiac surgeons is reducing the overall capacity for cardiac surgery and thus may increase the risk of death for patients awaiting such surgery, as they die on waiting lists*."

We have provided information on the context in which restrictions were introduced, and why they were thought by the Trust and by other key stakeholders to be necessary, in the section entitled "context" above. We have provided assurance that there are no longer any restrictions in place in our response to Matter of Concern 1 above. We have also provided assurance that the overall capacity for cardiac surgery in London was not reduced, and that waiting lists did not rise, in our response to Matter of Concern 1 above.

It may be helpful here to add some further information about cardiac surgery waiting times. As part of the elective surgery recovery programme for the NHS nationally, patients waiting for planned surgery are categorised by clinical priority. Priority 1 patients are those needing emergency and urgent surgery, and are categorised as Priority 1, and should be operated on within 24-72 hours – our provision of emergency surgery is discussed in our response to Matter of Concern 2 above. Patients waiting for planned (elective) surgery are categorised as Priority 2 (patients who should be operated on within 4 weeks) and Priority 3 (patients who should be operated on within 12 weeks). The most recent data (June 2022) from the South London Cardiac Surgery Network indicates that based on recent activity levels, the time required to operate on all the Priority 2 patients currently on the Trust's waiting list is 4 weeks, which meets the national target, and the time required to operate on all the Priority 3 patients is 5 weeks.

We hope that this waiting list and activity data provides you with further assurance that:

- The Trust's cardiac surgery patients are not waiting too long for surgery, and national expectations regarding waiting times for these patients are being met.

With regard to the question of how many patients have died while on the waiting list for cardiac surgery at the Trust, we are aware of three such deaths since October 2020. [redacted]

One of these deaths on the waiting list [redacted]) was investigated as a Serious Incident. The patient was on the waiting list for planned surgery and received an early date for this, but their surgery had

to be cancelled at short notice because of the number of urgent inpatient cases requiring surgery, which were judged to be of higher clinical priority. A new date was arranged for surgery, less than two weeks later, but unfortunately the patient died on the day of this planned surgery. The Serious Incident investigating panel noted the impact of the Covid pandemic in reducing cardiac surgery capacity at that time (May 2021), and felt that the cancellation had been appropriate at the time, given the absence of any warning signs that the case had become more urgent, and the large number of urgent inpatient cases that needed to be done. The panel recommended that all cancellations should always be fully discussed with the team and the rationale for any cancellation should be documented (which was done in this case). A copy of the Serious Incident Report and Action Plan can be supplied if this would be helpful.

Another of these deaths on the waiting list [redacted] was that of a patient who was on the waiting list but who needed a considerable number of pre-operative investigations of other health issues before surgery could take place. The patient elected to have these booked at their local hospital rather than having them done at the Trust. It was a considerable amount of time before they could all be completed, and during that time (October 2021) the patient unexpectedly died. This was not investigated through a Serious Incident investigation, but the relevant learning was shared with the referring hospital so that a local review at that hospital could be carried out if thought to be indicated.

The third of these deaths, in June 2022 [redacted], was also that of a patient who was on the waiting list surgery. The Trust is waiting to learn the cause of death as established by the inquest, after which the Trust will identify the nature and extent of investigation that is necessary to learn any lessons that could improve safety for other patients in the future.

It is recognised that, regrettably, any cardiac surgery unit will inevitably have some deaths of patients on waiting lists, and that such deaths to not necessarily imply a mismatch between capacity and demand. The South London Cardiac Surgery Network has nevertheless identified this as an area in which data collection needs to be more robust and consistent so that the network can be assured that all such deaths are scrutinised in a consistent manner and that a consistent approach is taken to the timely identification of any learning, and the embedding of any necessary changes to systems or pathways.

We hope this provides you with further assurance that:

- The restrictions on cardiac surgery did not create a reduction in capacity that increased the risk of death of patients on waiting lists, and
- Those deaths that did occur on the waiting list were, or are being, appropriately identified and investigated, and any relevant learning is being acted upon, and
- The current waiting list data indicated that the capacity and activity at the Trust is being maintained such that patients waiting for cardiac surgery can be treated within the expected national targets and are not at increased risk of death.

Matter of Concern 7: "*That apparently unfounded damage to the reputation of the cardiac surgery department will take years to repair, increasing the risks of future deaths by damaging public confidence in SGH and the NHS*"

We recognise the recent years have been a challenging time for all those working in and in support of cardiac surgery at the Trust, and we acknowledge that the reputation of the department has been impacted by the challenges the service has faced. The impact of these challenges on the reputation of the department was evident prior to the establishment of the Independent Mortality Review.

We have been clear throughout, both in our public statements and in our publicly available Board papers, that cardiac surgery at the Trust is safe, and the evidential basis for this has been provided. Reporting to the Board in the public domain has consistently set out how patients and the public can have confidence in the safety of our cardiac surgery services. This has included stating publicly that the Trust is no longer an outlier for mortality and no longer subject NICOR alert, and being open and transparent about current mortality levels within the service, which are in line with national expectations, and current morbidity and complications which, as we have set out elsewhere in this document, are in line with established norms.

We have set out elsewhere in this document the assurance that can be taken from the work that has been undertaken to establish the South London Cardiac Surgery Network and the ongoing actions to develop the Network, as well as the London-wide capacity that exists to treat of patients requiring cardiac surgery in and around the capital.

Public confidence in the Trust is a matter we, our commissioners and regulators take extremely seriously. That is why we have continued to work with NHS England, referring hospitals and partners across South West London and Surrey to provide assurance around the safety of the service and to support and encourage referrals to the cardiac surgery service. It is vital that our patients and the populations we serve can rely upon the safety and quality of the services we provide. The current safety and quality data relating to cardiac surgery provides this assurance in relation to this service. More broadly, the public can have confidence from the fact that a number of our services are rated "good" by the Care Quality Commission, by the fact that our children's services are rated "outstanding" by the CQC, and by the pioneering clinical treatments we offer across the Trust, some of which have been documented recently in the national media.

We have in place robust clinical governance arrangements at the Trust to monitor and seek assurance on patient safety and quality across all of the services we provide, and have recently taken steps to further strengthen these. We have described elsewhere in this document the safety and quality data relating to cardiac surgery which provides assurance on cardiac surgery outcomes. There is no evidence that the particular challenges encountered by the cardiac surgery service in recent years have damaged public confidence in the Trust as a whole or increased the risk of deaths, either in the cardiac surgery service or any other service at the Trust.

We hope this provides assurance that, both retrospectively and looking forward:

- We recognise the importance of the reputation of the organisation and have taken, and will continue to take, actions to ensure patients and the public can have confidence in our services.
- We closely monitor the safety and quality of the service, and there is no evidence of greater risk of death or lower quality care as a result of the impact on the reputation of the service in the context of the recent challenges it has faced.
- We have been consistently clear publicly that cardiac surgery at the Trust is safe.
- We have worked with partners across the system to provide assurance on quality and safety and to encourage referrals to the service.

Matter of Concern 8: "***That restrictions on training, collapse of research and staff leaving, further damages not only the cardiac surgery at SGH but also the wider cardiac surgery field, increasing the risk of death to patients by reducing their access to high quality care***."

We have provided information in our response to Matter of Concern 1 above that we hope provides assurance that (leaving aside the impact of Covid, which clearly did discourage many patients from presenting anywhere) overall levels of cardiac surgery in south London have not fallen in the period under consideration, and any decrease in the planned surgery carried out at the Trust was fully compensated for by increased activity

elsewhere. As set out above, this was consciously and carefully overseen and managed through the South London Cardiac Surgery Network which provided regular reporting to the NHS England London Region Cardiac Surgery Quality Summit in relation to data on demand and capacity and involved the oversight of the London Regional Medical Director and clinical and operational representatives from each of the South London cardiac surgery centres. We have also provided information above that interhospital transfers for cardiac surgery in South London (leaving aside the period of the Covid pandemic) did not fall. This provides assurance that patients have not been, and are not now or in the future, at increased risk of death as a result of any reduction in access to services.

The response below deals with the specific issues raised in the PFD Report with regards to training, research and staff retention.

Training

With regards to the concern about training, cardiac surgery trainees were removed from the cardiac surgery unit at the Trust by Health Education England (HEE) in September 2018, due to concerns around "*a lack of appropriate caseloads and case mix*", and concerns that "*the training environment was not conducive to the teaching and oversight of the trainees*".

Health Education England's Postgraduate Dean for South London has confirmed that the restrictions on training at the Trust did not have any impact on the total number of doctors training in cardiac surgery, nor on the quality or timing of their training, as they were trained elsewhere instead. The Postgraduate Dean for HEE Wessex, who is the Lead Dean for Cardiothoracic surgery, has furthermore confirmed that the current level of supply of trained cardiac surgeons nationally is higher than the current demand, and that there has consequently been a corresponding reduction in the number of doctors being recruited to training posts.

The potential for the removal of trainees to have a negative impact on the delivery of the cardiac surgery service at the Trust was mitigated by the appointment of locally employed specialty doctors and these appointments ensured that the provision of clinical services to patients was not interrupted or reduced.

This provides a high level of assurance that the removal of trainees from the Trust's cardiac surgery unit did not increase the risk of death to patients, either at the Trust or elsewhere.

Health Education England carried out a Quality Review visit to the cardiac surgery unit on 16 June 2022, and the HEE Postgraduate Dean for South London wrote to the Trust on 29 June 2022 to confirm that HEE will remove the suspension of training from 30 June 2022. The letter explained that, subject to satisfactory curriculum and timetable planning, there will be a phased reinstatement of training from August to October 2022, and HEE's aim is to fully reinstate specialty training in cardiac surgery at the Trust from the 2023/2024 training year. The letter added that "*HEE would like to acknowledge the significant improvements made to the learning environment and culture in the Cardiac Surgery department*". On 29 July 2022, the Postgraduate Dean for South London wrote again to the Trust and confirmed that, having considered the Trust's proposed curriculum plans, HEE is satisfied that it is appropriate to reintroduce training in cardiac surgery at the Trust in the 2022/23 training year, and that this would proceed in the phased way described in their 29 June correspondence.

We hope this provides you with assurance that:

- Cardiac surgery training at the Trust is resuming, and that the learning environment for trainees has been significantly improved.

Research

With regard to the concern about research, it is the case that the removal of trainees, along with the restrictions in the planned surgery that could be undertaken in the unit, did reduce the ability for cardiac surgeons in some areas to conduct local research. This is difficult to quantify in terms of local research output. Grant applications and Fellowship applications are determined in part by the surgical centre as well as the applicant. It may be the case that some grant applications could have been viewed less favourably because there were restrictions in place. We would make the point, however, that research obviously continued unabated in other centres nationally and internationally, and that any diminution of research for a time locally at the Trust could not have caused, or increased the risk of, the death of patients. As we have stated above, overall levels of cardiac surgery in south London have not fallen in the period under consideration, and any decrease in the planned surgery carried out at the Trust was fully compensated for by increased activity elsewhere.

We hope this provides you with assurance that:

- The imminent return of trainees, and the fact that the unit has completed a period of six months of transition arrangements following the lifting of restrictions, means that the unit will return very shortly to circumstances that should be as favourable to the conducting of research as they were in the past.

Staffing

With regard to the concern about staff leaving, in general the staffing of the cardiac surgery unit has been quite stable, both in terms of total numbers of staff and in terms of staff turnover. Reviewing numbers from 2017 up to the present we would like to provide the following summary:

- The total number of substantive consultants in cardiac surgery has risen from six in 2017 to seven now: the six consultants who were in post in 2017 are still in post now, and the seventh, the lead for the service, joined in December 2018.

- The number of locum consultants in cardiac surgery has varied as might be expected – there were none in 2017, there is one now.

- The number of non-consultant doctors in cardiac surgery since the removal of trainees in 2018 has remained within the range of six to nine – there are currently eight. No substantively employed non-consultant grade doctor in cardiac surgery has left in the last year.

- Cardiac anaesthesia is the area in which some consultants have left, either because of retirement or to take up posts elsewhere. Substantive recruitment to these specialised anaesthesia posts can be challenging, but a number of initiatives and mitigations are in place to maintain and grow the capacity of this team, and these include the recent conversion of a locum consultant appointment to a substantive one, and the appointment of a further substantive consultant.

- The service manager and the deputy general manager have been in post for some years, providing stability in local service management.

We hope this provides you with assurance that:

- Staff turnover is not high;
- the workforce overall is stable; and
- in the one area with recruitment challenges (cardiac anaesthesia), appropriate mitigations are in place.

Matter of Concern 9: "*The restrictions at SGH may make surgeons more risk averse and thus deny care to the most complex patients and so increase the risk of future deaths.*"

It is recognised that clinicians may, understandably, feel more risk averse, or less confident, if the scope of their clinical work has been restricted for a time. This was one of the main reasons that the Single Item Quality Surveillance Group meeting in April 2021 agreed that measures, including dual consultant operating, be put in place for a limited period as the unit made the transition from the lifting of the restrictions to the resuming of a full scope of cases, including those carrying higher risk. We suggest that the outcomes achieved by the unit in the time leading up to the lifting of restrictions, and the outcomes over the last six months of operating on higher-risk cases, are sufficiently assuring to give our clinicians an appropriate level of confidence that does not leave them feeling unduly risk averse.

We are not aware of any evidence that complex patients have been denied care. While there is no formal definition of complexity, it may be helpful to consider the term as including two groups of patients – firstly, those whose predicted post-operative mortality (for instance, as estimated by EuroSCORE II) is high (for instance, greater than 5%), and secondly, those patients whose anticipated post-operative care needs include particularly specialised interventions not routinely provided in all cardiac surgery units, and not provided at the Trust. These interventions are ECMO and VADs. In our response to Matters of Concern 1 and 2 above, we believe we have provided assurance that patients with a predicted risk of death of more than 5% were not denied care during the period of the now-lifted restrictions. Patients who are complex by virtue of an anticipated need for post-operative ECMO or VADs are transferred preoperatively to a cardiac surgery unit that does have these facilities. Such transfers represent normal and good practice for any cardiac surgery unit that does not have these postoperative facilities, and are clinically appropriate irrespective of any restrictions, and continue to be made when necessary. The need to do this arises very infrequently – the number of such transfers made by the Trust since 2018 is less than ten.

We hope this information provides you with assurance that:

- We have recognised the fact that the period of restrictions may have made surgeons understandably more risk averse, and that we have taken care to mitigate this though the six-month transition period after the restrictions were lifted, in particular by supporting arrangements for dual operating, and by measuring and demonstrating positive outcomes during this time;
- Patients considered complex by virtue of their predicted risk of postoperative death have not been, and are not, denied care; and
- Patients considered complex by virtue of their anticipated post-operative requirement for specialised support (ECMO and VADs) have not been, and are not, denied care.

Matter of Concern 10: "***That the SJR process as deployed at SGH is not fit for purpose, further undermining the public confidence in the NHS, which the public may perceive as the NHS being unable to appropriately audit its own work***."

We note the concerns you have expressed in relation to the Structured Judgement Review process used by the Independent Mortality Review. As the Review was commissioned independently of the Trust, we defer to the response to the PFD provided by NHS England.

4. Concluding observations

This letter has focused on the specific Matters of Concern raised in the PFD Report, but we hope it is helpful if we provide the following summary and overview.

The years covered in this reply to the PFD Report, and indeed the years leading up to them, have certainly involved some significant challenges for the cardiac surgery department and the Trust as well as for bereaved families. The unit has had to adapt to the restrictions that were put in place with the intention of maintaining patient safety. The unit has also then had to adapt to the requirements of the transition period following the lifting of restrictions, designed to support the unit in ensuring that the return to full practice is managed safely. The removal of trainees and the reduced opportunity to conduct research have also been challenging, and there have been periods of intense media reporting that have been difficult. Public confidence in the cardiac surgery unit can only have been dented at the most difficult times, and this has been reflected in an initial dropping off of referrals. This was evident prior to the commissioning of the Independent Mortality review. There is no doubt that this has been a very difficult and stressful time for the cardiac surgeons, and for others who work in and with the service.

We hope that this reply to your PFD Report sets out clearly the way in which potential risks were mitigated during this period, and the way in which a high level of scrutiny was (and still is) maintained with regards to patient outcomes and survival, to clinical incidents and to local capacity and demand, both at Trust level and at South London system level.

We hope also that this reply, in setting out the context in which the now-lifted restrictions on cardiac surgery were originally imposed, has provided you with assurance that the restrictions were a measured, proportionate and necessary step to ensure patient safety at a time when the cumulative concerns about the unit had reached the point that it was essential to ease the pressure on the unit and its staff and provide the unit with the space needed to make improvements to safety, governance, leadership and culture.

With regard to the Matters of Concern, we believe that we have provided robust assurance that patient safety has been – and continues to be – maintained, and that the positive outcomes of the unit demonstrate that this risk of patients dying has not been increased over this time and, on the contrary, has been reduced through very significant service improvements that are reflected in the patient outcome data and the reports and decisions of external stakeholder organisations including the CQC and Health Education England, as well as NHSE/I London.

With regard to the Matters of Concern relating to the risk of future deaths, we believe that we have provided robust assurance that patient safe is being maintained, and that the Trust's cardiac surgery unit is meeting the current demand with sufficient capacity to treat patients on the waiting list within the expected time frames. We also believe we have provided assurance that the South London Cardiac Surgery Network is able to match demand with capacity both now and in the future, that any fall in referrals to the Trust has been matched and accommodated by a corresponding rise in referrals elsewhere in this system, and that the providers within the system are working collaboratively at the highest level to make sure that the needs of the people of South London are met by our collective cardiac surgery services.

Finally, while we believe that we have provided assurance that in the past the restrictions in cardiac surgery, the removal of trainees and the fall in patient referrals did not create an increased risk of death to patients, we have also provided assurance, by describing current arrangements and by providing recent data, that patients in the future are not at an increased risk of dying. We have highlighted the facts that the transition from a time of restrictions to a time of unrestricted working has been managed safely and successfully, and that trainees will shortly be returning to the unit, and this again is assurance that major progress has been made and improvements have been embedded. We would like to acknowledge the central role that our cardiac surgeons and wider staff have played in making this very significant progress possible, and the improvements we have described in this reply would not have been possible without their engagement and commitment, often under very difficult circumstances, for which we thank them. We believe that the cardiac surgery unit at the Trust has

a very positive future, playing its part in the wider South London Cardiac Surgery Network, within which the people of south London can be confident that they will continue to receive safe, high quality and timely care.

We hope you find this reply both helpful and assuring, but please do not hesitate to get in touch with us if there is any more information you require.

Yours sincerely

[redacted]
Group Chief Executive Officer
St George's University Hospitals NHS Foundation Trust