REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** [redacted] Chief Executive, St Georges Hospital, Blackshaw Road, Tooting, London. SW17 0QT [redacted] Chief Executive, NHSEI Skipton House, 80, London Road, London. SE1 6LH
1	**CORONER** I am Dr Fiona J Wilcox, HM Senior Coroner, for the Coroner Area of Inner West London
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners' (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On the 31st March 2022, evidence was heard touching the death of **Raymond Griffiths.** This gentleman was admitted to St Georges hospital on 21st May 2013 for coronary artery bypass grafting. The surgery took place the following day. Post-operatively he was taken to ITU where he became acidotic. He died three days later from acute liver failure. He was 71 years old at the time of his death. The case had been referred to Inner West London Coroner's Court at the time of his death and signed up on a 100A. The case was subsequently reviewed as part of the [redacted] Review, organised and implemented by NHSI, and re-referred to the service, on the basis that "Problems in care probably (more than 50:50) contributed to the death." An inquest was thus opened and heard. **Medical Cause of Death** I (a) Acute Liver Failure (b) Chronic Liver Cirrhosis and Coronary Artery Bypass Grafting (22/5/2013) II Type II Diabetes Mellitus, Obesity, Hypertension, Ischaemic Heart Disease.

How, when, where the deceased came by his death:

Mr Griffiths underwent coronary by-pass grafting for severe coronary artery disease on 22/5/2013 at St George's Hospital. The surgery was successful, however post-operatively he developed acute on chronic liver failure and despite all treatment died on ITU at 13:50 on 25/5/2013.

Conclusion of the Coroner as to the death:

Natural Causes, contributed to by recognised complications of essential surgical treatment

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Extensive evidence was taken by the court and following the inquest further written evidence was submitted to the court in relation to background and Regulation 28 matters by two of the surgeons involved in the care of Mr Griffiths.

Background.

The following matters were found:

The inquest was opened following the case having been re-referred to the court as part of the [redacted] Review. The [redacted] Review undertook Structured Judgement Reviews (STRs) of all deaths that occurred post cardiac surgery between the spring of 2013 and the end of 2018.

The court understands that around 205 cases of deaths following cardiac surgery at SGH were examined by a panel of 2-4 clinicians including cardiac surgeons, cardiologists, intensivists, and anaesthetists, all independent of SGH. The review was chaired by [redacted] a consultant cardiac surgeon operating in Brighton. The court understands that the Brighton unit where [redacted] works has fewer and often less complex cases than those managed by SGH between 2013 and 2018.

Each SJR looked at pre-operative, intraoperative and post operative care; graded the quality of care received by the patient at each phase; made judgemental comments about the care, identifying good practice and making determinations as to whether failures in care had contributed to the death. A final score purporting to represent the overall quality of care in the individual case was recorded.

Following the Review, around 67 cases were referred to this court where the SJR found that failures in care had probably or definitely contributed to the death

NHSI, as it was then known, now NHSEI, commissioned the [redacted] review and set its terms of reference.

The [redacted] review was established after a series of reviews concentrating on communications and relationships within cardiac surgery and between cardiac surgery and its allied specialities such as cardiology, anaesthetics and ITU. None of the previous reviews had found any connection between such matters and the quality of care delivered to patients. The High Court became involved in a highly publicised case following the suspension of two of the SGH cardiac surgeons. The court understands that the High Court also found that there was no impact on quality of surgical care delivered, and the two surgeons were re-instated.

In two successive overlapping three-year time periods: 2013-2014 and 2014-2017, NICOR, an independent organisation which monitors deaths post cardiac surgery, had noted that deaths at SGH were higher than expected, and raised an alert. There were around 11 more deaths than expected and most of these occurred in 2014. As 2014 forms part of each cohort, the excess of deaths in this year was responsible for each alert.

The court received evidence in relation to how this analysis was conducted between 2013 and 2017. Between these years, the clinical complexity of patients treated, (risk stratification), a fundamental predictor of surgical outcomes, had been downgraded in the NICOR data. This did not reflect the then patient population of the cardiac surgery department, many of whom where clinically complex. Also during 2014, the least unwell patients were being transferred out to a local private hospital as part of a waiting list initiative. When these factors are considered the cardiac surgery department at SGH should never have been in NICOR alert. Similarly, when the operative mortality statistics of each of the surgeons is examined across the range of theatres where they work, no surgeon had then or has now an operative mortality rate higher than expected. One surgeon has a lower-than-expected mortality rate, despite several surgeons at SGH caring for the most clinically complex cardiac surgery patients.

Usually when a cardiac surgery department goes into NICOR alert, and there are several each year, the response is for a team of experts to visit the unit, speak with staff, consider systems, and make recommendations. This normal process was not undertaken by SGH.

Instead, NHSI commissioned an SJR process, based upon clinical record examination by an appointed panel. This approach had never been previously undertaken in cardiac surgery and is not approved by the Royal College of Surgeons. The SJR process has been used in some limited circumstances to identify potential areas of learning, but the system specified here by NHSI did not follow that model either. Instead it adopted a critical approach of grading and fault finding, ending with a contribution to death score.

Clinicians involved in the care of patients were not invited to present evidence to the ████ Review, nor to respond to any criticisms made of their practice by the Review save for some limited feedback from the cardiac surgeons only as outlined below.

Mr Griffiths.

The SJR for Mr Griffiths made a number of criticisms of the care received by him at St George's Hospital following his admission for coronary artery by-pass grafting, (CABG), on 21st May 2013. In summary the SJR concluded that the failures in care identified probably contributed to the death.

As such there was reason to suspect that the death was unnatural, and an inquest was opened on 9th June 2021to establish the sequence of events that led to and caused the death.

An extensive investigation was undertaken by the court, including examination of relevant medical records, and requesting multiple statements and reports.

The evidence was all considered at the inquest on the 31st March 2022.

As the evidence unfolded in court, it became increasingly apparent that all the criticisms of care made within the SJR were unfounded and that the conclusion

of the SJR, that failures in care had probably contributed to the death, was simply incorrect.

On the contrary, the inquest concluded that all the care received by Mr Griffiths was beyond reproach and Mr Griffiths had died of liver failure that could not have been reasonably predicted nor prevented, despite all appropriate pre-surgery assessments, intra-surgical and post-surgical care involving multiple experts and team working.

As part of the inquest the evidential basis and credibility of the SJR's findings were explored.

Of note, this examination was undertaken within the context of this inquest being one of series of around 30 such inquests that the court has so far heard. Of these, in only one case has failures in care identified by the SJR process been substantiated by evidence taken in court. That case was one that this court had already opened as an inquest prior to the ████ SJR evidence being made available to the court, following referral by the treating clinicians.

Note further that each case, including that of Mr Griffiths, in line with proper procedure, has been considered on its own evidence and that this court regularly identifies failures in care in inquests when there is a proper evidential and legal basis to do so.

Recurring themes.

Whilst each case has been considered on its own merits, several recurring themes have emerged in inquests so far heard in relation to the SJRs:

- Each review was undertaken solely on an examination of medical records of SGH given to the panel by SGH.
- These records were often incomplete and rarely included evidence from hospitals referring patients in to SGH, so called feeder hospitals, including the results of pre-operative investigations and multidisciplinary team meetings (MDTs), that had occurred within the feeder hospitals.
- No statements, no discussions nor any other input was allowed or considered as part of the SJR process from any clinician, technician or nurse who was involved in the patient's care. Even where missing notes were later identified these appear not to have been considered.
- Only the cardiac surgeons were allowed to give any feedback. This was limited to written response for each case in which they had been the main operating surgeon. This feedback had to be completed within a strict 2 week time frame, and was mostly ignored.
- No other feedback was allowed, even where there were criticisms of nonsurgical care such as cardiology or intensive care, nor even where the panellists stepped outside their own areas of expertise to criticise areas such as intraoperative perfusion.
- The SJRs took between 10-20 mins of panel consideration of notes for the simpler cases, with the most complex requiring 2-3 hours. This time spent is negligible compared to the time spent investigating and hearing these cases by the coroner's court.
- The SJR's repeatedly make adverse inferences in the absence of evidence, leading to erroneous findings of failures. For example that MDTs did not place, or appropriate investigations were not carried out.
- Some SJRS contain logical inconsistencies, for example finding that a matter *may* have contributed to the death in one section of care looked at, but the final conclusion then stating that failures in care *definitely* contributed to the death.
- Some SJRs contain pejorative subjective comments for which there has been no foundation in evidence, appearing to echo comments of

previous reviews looking at professional relationships, for example "silo working".

- Some SJRs criticise areas of expertise outside the expertise of the panel, for example perfusion.
- Some SJR findings have been contrary to the European Guidelines in force at the time.
- Some SJRs apply 2018 standards and systems of care to cases for example in 2013 when other standards applied.
- Some SJRs have misinterpreted investigation findings.

Current Cardiac Surgical Practice.

The court understands that there are current restrictions on cardiac surgery being undertaken at SGH, reducing its surgical capacity. Only one surgeon, relatively recently appointed, is allowed to operate on the more complex cases. This means that patients with emergency presentations such as leaking aneurysms must often be diverted to other hospitals. Operating rights of the other surgeons are restricted, and thus the pressure on other cardiac surgical departments has been increased for both emergency and elective work.

The overall clinical capacity within cardiac surgery is down by 60%.

The operations in the restricted list include:

- Euroscore II above 5%
- Double valves
- Redo surgery
- Aorto-vascular operations (arch and beyond, despite BMJ Clinical Leadership Award in 2018 for work in this area).
- Multiple co-morbidities
- Patients with left ventricular ejection fraction <30%
- Endocarditis.

For emergency procedures, the operating surgeon needs to obtain special permission to proceed and/or balance the risk of performing the operation or transferring the patient out.

Staff are becoming deskilled and reputations damaged, referrals are declining.

Training has been severely constricted, staff have left, research has collapsed, public confidence has been shaken, huge amounts of money have been spent and there has been negative impact on individual surgeons and allied teams within the hospital. The whole reputation of the cardiac surgery department and the hospital has been damaged with no evidence that this court has so far seen of deficiencies in care.

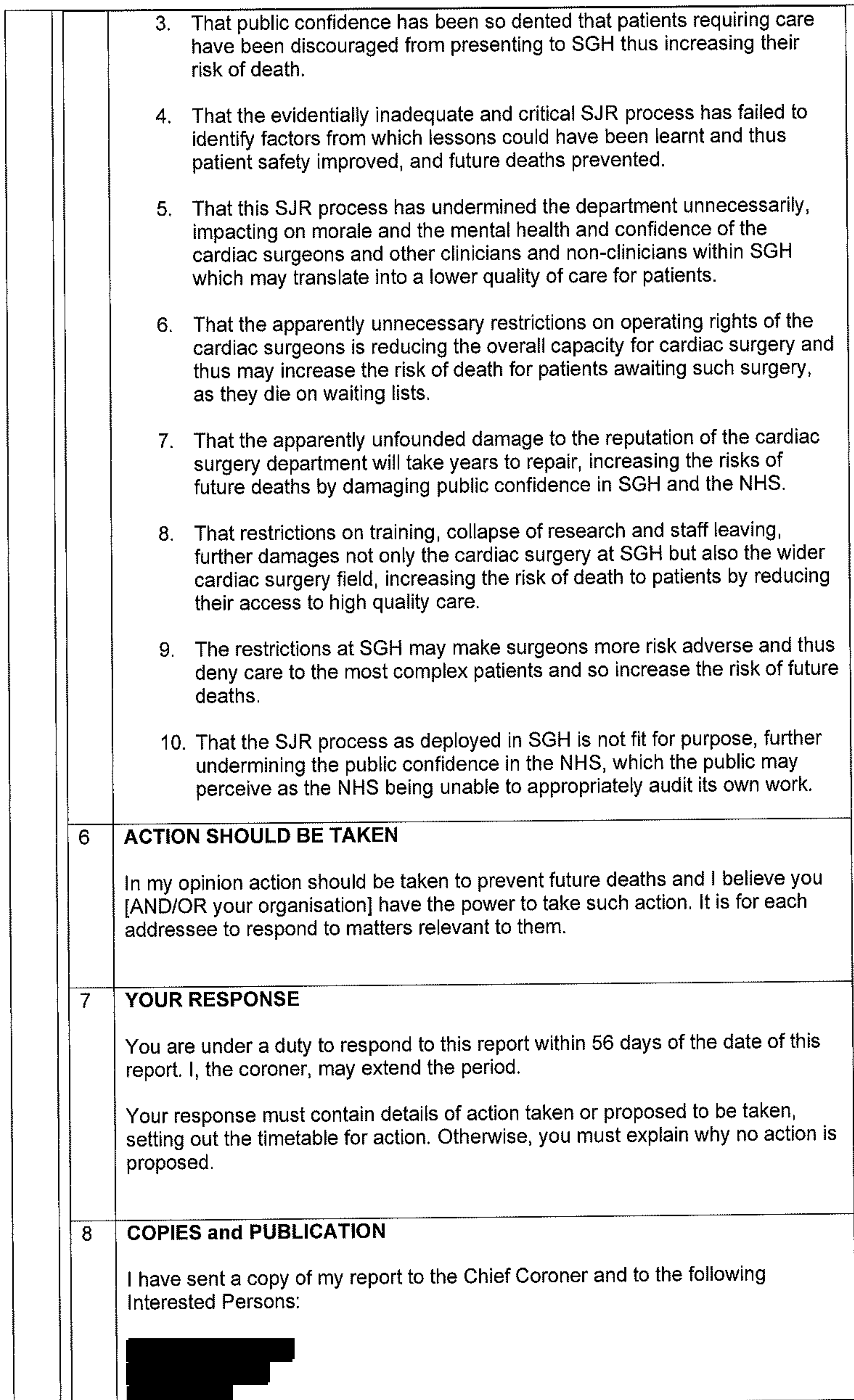
The cardiac surgeons have been referred to the GMC.

The pain and distress caused to relatives of the deceased by the unfounded criticisms of care in the SJRs, requiring inquests to be held to allow independent evaluation of how their loved ones came to die has been immeasurable.

5 **Matters 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.

2. That emergency patients being diverted away from SGH has resulted in unnecessary deaths.



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.

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.

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.

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.

7. That the 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.

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.

9. The restrictions at SGH may make surgeons more risk adverse and thus deny care to the most complex patients and so increase the risk of future deaths.

10. That the SJR process as deployed in 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.

6 ACTION SHOULD BE TAKEN

In my opinion action should be taken to prevent future deaths and I believe you [AND/OR your organisation] have the power to take such action. It is for each addressee to respond to matters relevant to them.

7 YOUR RESPONSE

You are under a duty to respond to this report within 56 days of the date of this report. I, the coroner, may extend the period.

Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise, you must explain why no action is proposed.

8 COPIES and PUBLICATION

I have sent a copy of my report to the Chief Coroner and to the following Interested Persons:

	Head of Legal, St George's Hospital, Blackshaw Road, London. SW17 0QT. , Consultant Cardiac Surgeon, St George's Hospital, Blackshaw Road, London. SW17 0QT , Professor of Cardiac Surgery, St George's Hospital, Blackshaw Road, London. SW17 0QT. Associate Medical Director, St George's Hospital, Blackshaw Road, Tooting, London. SW17 0QT I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**9th May 2022** **Professor Fiona J Wilcox** **HM Senior Coroner Inner West London** **Westminster Coroner's Court** **65, Horseferry Road** **London** **SW1P 2ED** **Inner West London Coroner's Court,** **33, Tachbrook Street,** **London.** **SW1V 2JR** **.**