Maintaining Good Clinical Practice – Handling of Potential Consultant Outliers

A Joint Report

from UK Cardiac Professional Societies

Commissioned and Chaired by the British Cardiovascular Society
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Executive Summary

This report deals with the steps we believe should be taken when analysis of national clinical audits suggest that an individual consultant might have suboptimal patient outcomes for their procedures. Individual consultant outcomes for an increasing number of specialties are published on the NHS Choices website. For interventional cardiology and cardiac surgery data are derived from the national cardiac audits undertaken in conjunction with their national professional societies. Statistical analysis will result in consultants being identified as an “alert” if their survival figures, on a three year rolling average, fall two standard deviations below the mean and as an “alarm” at three standard deviations below the mean. Hospitals are responsible for ensuring the accuracy and completeness of the data that is submitted for these analyses.

An alert indicates that there might be a problem, but may occur by chance, and hence should be seen principally as an opportunity to review a doctor’s practice. Hospitals must be proactive in ensuring that such reviews are facilitated and supported and that any remedial measures are implemented appropriately.

Effective reflective practice, robust appraisal and a culture of openness should prevent individuals ever reaching alarm status but identification as an alarm indicates a clinical performance problem is highly likely and should trigger prompt external review of practice and notification of the GMC Employment Liaison Adviser. After further rigorous data validation the names of doctors identified as alarms will be made publicly available on the NHS Choices website and are likely to attract media attention. Patient safety is paramount and temporary or permanent restriction of practice may be required. If a problem with individual practice is identified and successfully resolved then the problem and the steps taken to resolve it must be made clear to colleagues, patients and regulators. Hospitals have a responsibility to support consultants in returning to practice when this is judged feasible.

Lay Summary

All doctors performing heart surgery in adults and all doctors performing coronary angioplasty have their results analysed nationally to ensure that they are performing to a good standard. These results are published on the NHS Choices Website. Performance is measured as the percentage of patients treated by each individual doctor who survive their operation. Doctors whose results appear not to be as good as expected are identified as “alerts”. An alert means only that there might be a problem as in at least half of cases further more detailed checks will find that the doctor’s results are actually good. However, where a problem is identified doctors and the hospitals that employ them must take steps to make sure that their results improve. Well run hospitals should have a culture where all doctors routinely reflect on their practice so that any potential problems are identified at an early stage and they can be supported to get their results back up to expected levels.

An alarm means that there is a high chance that fewer patients treated by that doctor are surviving their operation than should be expected. If checks on the figures confirm this then the doctor will be publically identified as an outlier. Sometimes action will already have been taken to bring the doctors’ performance back up to expected levels. If this is the case then this must be made clear on the hospital website. In some situations this might mean that the doctor stops undertaking particular types of operation. All steps will be taken to help the doctor reach a good standard of practice but if this is not possible then they will need to stop operating altogether.

Professor Simon Ray
Chair, Working Group on the Handling of Consultant Outliers
Glossary

BCIS  British Cardiovascular Intervention Society
BCS  British Cardiovascular Society
DH  Department of Health
ELA  Employment Liaison Adviser
GMC  General Medical Council
HQIP  Healthcare Quality Improvement Partnership
NCAS  National Clinical Advisory Service
NICOR  National Institute for Cardiovascular Outcomes Research
RCP  Royal College of Physicians
RCS  Royal College of Surgeons
SCTS  Society for Cardiothoracic Surgery
TDA  Trust Development Authority
1. Introduction: What Good Looks Like

The GMC, in its code of practice for UK doctors, says that it is the duty of any doctor holding a license to practise in the UK “to provide a good standard of practice and care”. The British Cardiovascular Society (BCS) and the Society of Cardiothoracic Surgeons (SCTS), which set specialty-specific standards for cardiologists and cardiac surgeons in the UK, are in complete agreement. Good practice needs to be to a high standard. The public expects that contemporary standards will be upheld consistently by every doctor, demonstrable through their regular re-licensure using the process of revalidation. These standards should never be lower than those currently required for certification as a specialist cardiologist or cardiac surgeon and so are expected of all consultants from appointment to their post.

The primary responsibility for the quality of doctors’ practice lies with the doctor themselves. Most doctors recognise excellence in colleagues and have a view about those they would prefer to look after a close relative and those who they might be less keen to see involved; they know what good looks like in their area of practice. The same is not generally true of patients who, at least until recently, have lacked the means to assess whether the doctor they have seen or been referred to is sufficiently knowledgeable and has the necessary skills and appropriate professional attitudes to provide them with high quality care. Professional Societies are best placed to define what good looks like for doctors in their specialty area and to identify metrics that allow that information to be available for their members, colleagues, the public, employers and regulators. They are also best placed to define processes that should take place within hospitals and clinical departments in order to deliver high standards of practice at both individual and team level.

Within cardiovascular medicine individual consultant outcome data are currently published for adult cardiac surgery and interventional cardiology but it is likely that this will be extended in the near future, for instance those for cardiac rhythm management, as other datasets become more mature. The metrics used to define good outcomes will vary with speciality: so for instance whilst mortality is an appropriate metric for cardiac surgery it would not be relevant for cardiac device implantation. It is important to emphasise that outcome data are only part of the assessment of a consultant’s overall performance and should be seen in the wider context of our collective responsibilities for quality assurance and quality improvement. Other metrics such as patient related experience measures (PREMS) are also important and sophisticated tools such as the Picker Consultation Score have been developed to assess the quality of doctor-patient interaction (Appendix A). An essential element of the wider context is the creation of a working environment that promotes a culture of reflective practice and peer support such that any possible issues of poor performance are identified at an early stage and appropriate and proportionate remedial action taken.

2. Publication of Individual Consultant Outcomes: Alerts and Alarms

Consultants in the NHS do not work in isolation and are part of sometimes large and complex multidisciplinary teams that are responsible for the well-being of the patients in their care. The public and press are aware after the Mid Staffordshire Enquiry that poor outcomes are not always the result solely of individual performance or even team performance but can result also from poor organisational culture, and heightened public interest means that poor results will not remain hidden for long. As leaders of clinical teams consultants carry a high level of individual responsibility for outcomes and as a result publication of individual consultant outcome data is a key part of the strategy of NHS England.

The national audits of PCI and adult cardiac surgery, through NICOR and in partnership with HQIP have developed sophisticated statistical processes to identify negative outliers. Currently these lead to the identification of two levels of concern: alert and alarm. Both are generated on the basis of three year rolling data. An alert means that the observed survival is 2 standard deviations below the
expected mean and an alarm means that observed survival is 3 standard deviations below the expected mean. The policies of BCIS and SCTS for notification of alert and alarm status are attached as appendices (Appendix B and C). HQIP have also produced generic guidance on the identification of outliers (1).

The SCTS has led the world in developing this type of model but it is important to recognise that no statistical model is perfect and there is a possibility that individual consultants may be identified as outliers by chance particularly at alert level. At alarm level this is much less likely. For further information on this see Appendix D. It is therefore extremely important that in the event of either an alert or an alarm being identified the individual and institution check and validate submitted data and identify any errors to NICOR so that if necessary a corrected analysis can be performed.

Outcomes at alert level are not published as outliers but should trigger a review of practice. Publication occurs only at alarm level and only after thorough review of the data. Public identification as a negative outlier will have a profound impact on an individual, their colleagues, institution and patients. The purpose of this document is firstly to highlight the steps that can be taken by cardiologists and cardiac surgeons and their employing organisations to reduce the likelihood of becoming a significant negative outlier and secondly to identify the steps that should be taken if these actions fail and alarm status is identified. It is essential that this document is read in conjunction with the guidance from HQIP, the DH and other bodies as appropriate (1, 3, and 4). Whilst the focus here is on individual performance the same assessment principles can be applied to the performance of teams. This is of particular relevance for congenital cardiac services where reporting of outcomes is currently at unit rather than individual level.

3. Maintaining High Quality Practice – The Role of Reflection

As indicated in the introduction, the primary responsibility for maintaining a high quality of practice lies with the individual doctor themselves. Doctors are expected to ensure that they are up to date with appropriate knowledge and skills and competent to perform the roles required of them as defined in the GMC document Good Medical Practice (2). This requires that all doctors engage in audit and other quality improvement activities, have regular appraisal and engage with revalidation.

All doctors are affected when a patient under their care dies or suffers significant ill effects as a result of a treatment that is performed in the expectation of improving quality of life or survival. It is an essential requirement of Good Medical Practice that all doctors reflect on the outcomes of their work and evidence of reflection is required for appraisal. To be effective reflection should be an integral part of the way doctors approach their work and should be an active rather than a passive process. Attendance at relevant MDTs and mortality and morbidity meetings is an essential element of this process but is not in itself sufficient. Reflection is an attitude that continuously questions personal performance and is a key element of modern medical professionalism. For interventional cardiology and adult cardiac surgery individual operators can download their risk adjusted mortality data from the national audits. For other sub-specialties doctors should use local audit and quality assurance to continuously review their practice. Doctors must be proactive in seeking appropriate advice and assistance if they have any concerns about their outcomes or their functioning as part of a clinical team. This may be against a natural instinct to try to resolve any problem themselves but is an essential part of contemporary medical professionalism.

An example of the practical application of reflective practice is given in Appendix E.
4. The Role of the Employer

Effective reflection requires that doctors are provided with the means to monitor their practice but also that there is a culture within the wider organisation that supports and expects transparency of outcomes. There is an onus on all hospitals to provide doctors with ready access to their results so that they can assess their performance continuously. Hospital Medical Directors who are usually also the Responsible Officers for recommendations on revalidation are responsible for ensuring data submission to national audits is complete and timely. Methods for assessing performance will vary from specialty to specialty. In effect this means that local data submitted to the national audit programmes or other quality assurance mechanisms must be made available to doctors in a timely fashion for their appraisal. The Medical Director should also ensure that such data are acted upon where appropriate and that review of data is a continuous process rather than an annual summative review of activity.

Reflective practice is an essential component of robust annual appraisal. Relevant outcome data must be brought to appraisal and there is an onus on appraisers to ensure that any concerns about a doctor’s practice are sought out and identified. There is no place for misplaced collegiality that leaves potentially difficult issues unaddressed. In the past when individuals have been identified as outliers it has been frequently found to be on the background of a long history of other concerns and missed opportunities for those concerns to be addressed and resolved. There must be no placing of these issues into a ‘too difficult box’. The Royal College of Surgeons publication on learning from the experience of invited reviews provides a useful insight into these issues (5).

Traditional methods of local audit, morbidity and mortality meetings and patient feedback may not be adequate to identify potential problems and a more proactive approach can be useful in assuring high quality practice. Examples of such an approach are the anonymised review of PCI cases developed by the Sussex Cardiothoracic Unit (6) and the consultation score developed by Picker which provides a detailed analysis of doctor: patient interactions against the relevant generic standards in Good Medical Practice (Appendix A).

5. Support Where Potential Issues are Identified – Alerts

As indicated previously an alert is precisely that: an indication that there might be a problem, not definitive evidence of poor performance and it should be regarded as a neutral event with no stigma attached. When a potential concern is raised either by a doctor themselves, by colleagues, during appraisal or by identification as an alert from NICOR then this should be proactively dealt with and investigated without undue delay. Individual and institutional confidence is key to achieving good results from interventional and surgical procedures and this can be diminished during the uncertainty that is inevitably associated with investigations and will be amplified by unnecessary delay. Given the relatively high false discovery rate with alerts it follows that in many instances there will be no issues identified after review and it is important to emphasise that this is a positive finding. Indeed it can be argued that alerts provide an opportunity for a more thorough and constructive review of practice than is generally achievable in the context of appraisal.

Locally raised concerns or an alert from NICOR should trigger a review of the whole of a consultant’s practice including relationships with colleagues and other aspects of team functioning. This should cover all sites at which the doctor practises, including any private practice. The precise scope of the review will be determined by individual circumstances but the steps required should be agreed by the consultant and their clinical director and formally recorded. Any investigation should be reasonable in scope, in line with local Trust policies and commensurate with the processes recommended by NCAS (3). External review is not mandatory but might be required depending on particular circumstances.
A number of steps may be required:

a. Further analysis of local data: hospitals must provide the facility for further analysis of locally held data to support investigation of any concern about outcomes. This may require case note review, cross-checking of catheter laboratory or theatre records or review of MDT records.

b. Case review and mentorship: in all instances where there are possible concerns about performance doctors should be offered support which may include formal or informal mentoring by an appropriate internal or external colleague or group of colleagues. This may require that there is a temporary modification in practice and/or change in case-mix to allow support from senior colleagues, adjustment of other competing commitments or a period of supervised practice. There is an onus on the individual doctor to engage with such support and non-engagement should be a matter of serious concern and prompt referral to the Medical Director. Similarly there is an onus on clinical and medical directors to support colleagues who request assistance with a perceived problem. It is unacceptable for such concerns not to be addressed. An example of the approach undertaken in the cardiac surgical unit at Papworth Hospital is attached as Appendix F.

c. Team dynamics: an apparent problem with an individual consultant may be as a result of a dysfunctional team and so any investigation of an individual must include an assessment of their role within the wider clinical team. This may require external review.

d. Involvement of external bodies: Professional Societies acting in conjunction with medical Royal Colleges are best placed to provide advice on areas of specialist practice. In the past external bodies have only become involved at a relatively late stage, often when opportunities for early resolution have been missed and their involvement is seen as a major issue. If appraisal or analysis of outcomes following an alert raises concerns that cannot be dealt with internally then advice should be sought from the relevant professional society at an early stage. For cardiac surgery this is the Society of Cardiothoracic Surgeons, for cardiology the British Cardiovascular Society. Subspecialty societies, such as the British Cardiovascular Intervention Society and the British Congenital Cardiac Association can then be involved as required. The cardiac professional societies collaborate closely with the Royal Colleges. The Royal College of Surgeons is developing a scaled down version of the independent institutional review process that is tailored to a review of individual consultant outcomes. The British Cardiovascular Society participates in the Independent Service Review process of the Royal College of Physicians. The same applies to the GMC where early involvement may be helpful. The GMC’s Employer Liaison Adviser (ELA) can offer support to the doctor’s Responsible Officer who should routinely be discussing with their ELA any confirmed alert level concerns and what steps are being taken to address them.

The outcome of the review process and any appropriate remedial actions should be agreed and signed off by the clinical director and documentation added to the individual consultants appraisal folder. This documentation should also be presented as part of their evidence for revalidation. The Responsible Officer must be fully informed of any concerns, reviews and remedial action.

The aim of this process is to ensure that individual consultants continue to practise to a high standard within well-functioning teams. Ideally robust appraisal, prompt attention to alerts and appropriate reflective practice will prevent consultants progressing from alert status to alarm status. Routine appraisal processes within hospitals should be sufficiently robust to ensure that consultants who have undergone a review of their practice as the result of an alert continue to practise to a high standard without additional levels of scrutiny being required.
6. Handling of Confirmed Outliers at Alarm Level

Identification as an outlier at alarm level occurs only at the end of a process of rigorous data review and validation and should never come as a surprise to the individual or their employer. In most cases doctors identified at alarm level will previously have been flagged up as alerts but it is possible for a doctor to progress directly to alarm level without prior identification as an alert. However, in well run organisations, and where individual doctors use reflective practice, any problems should have been identified and addressed well before they get to the stage where an individual is publically identified as an outlier. NICOR will inform the Chief Executive and the Medical Director/Responsible Officer and they will be responsible for informing the Trust board and relevant lead commissioners. The RO should inform the GMC Employer Liaison Adviser without delay. Alarm status should also trigger prompt external review of the consultant’s practice through the appropriate Royal College or Professional Society if this has not already occurred.

a. Where a problem has been identified and appropriately addressed prior to publication

It is possible that an individual doctor might reach the threshold for identification as an alarm when the problem with their performance had been identified and addressed prior to publication so that their practice is currently at a good standard. It is also possible that a doctor might be identified as a statistical outlier but where further analysis establishes that this is due to their having an exceptionally high risk caseload. We suggest that in either event the hospital should be proactive in publishing this information for patients and colleagues and supporting the individual doctor through what is likely to be a difficult period. An example of how a Trust has managed this process successfully is available on the SCTS website (7). There is also a risk that a doctor who has successfully undergone remedial training to bring their practice up to a demonstrably good standard following an alarm may continue to be perceived as underperforming or as a less than good practitioner if information is not made publicly available.

It is possible that hospitals will be challenged by families of patients with adverse outcomes treated by a doctor identified at alarm level particularly if he or she is continuing to practise. It is essential that robust data can be produced both to detail the process undertaken to justify continuing practice but also to confirm that current outcomes are good. It is essential that external review and validation are performed as part of this process.

b. Where problems have not been adequately addressed

In this situation the presumption must be that there are on-going concerns for patient safety if the doctor continues with unrestricted practice and it is the responsibility of the Medical Director to take appropriate action. Patient safety must be the primary concern but the doctor and their colleagues require on-going support. It is impossible to cover every scenario but some general principles apply:

Doctors should be given every opportunity to address any problems identified with their practice. This may require a period of additional training or supervised practice. In some instances where particular areas of clinical activity are identified as problematic it may be possible to restrict practice so as to avoid these areas but this must be explicitly agreed by the consultant, clinical director and Responsible Officer and be robustly monitored. Failure of the individual doctor to engage with retraining or restriction of practice is unacceptable and should be notified immediately to the GMC ELA.

Trusts also need to consider how information should be disseminated within their organisation, and particularly among the immediate colleagues of the named consultant. It is essential that any restrictions on practice whether temporary or permanent are fully understood by the whole clinical team and any colleagues who may be referring patients.
In some situations it may be concluded that continuing safe practice is not achievable despite all feasible remedial action but this point should not be reached without formal external review.

7. Informing Patients and the Public

Patients and their relatives rightly expect that the doctor treating them is demonstrably competent to provide that treatment. Publication of an individual consultant as an outlier will raise understandable concerns amongst their past and present patients to which hospitals will have to respond. Hospitals should consider carefully how to handle their response to publication but, as a minimum, information should be provided on the hospital website. It should be clear what problem was identified and how this being addressed. If remedial action has been put in place and has been successful, allowing continuation of practice, then how and why this has been achieved must be made clear. Any statement should be supported by externally validated data. Similarly if practice has been restricted in any way this must also be made clear. Opportunities should be provided for patients or relatives to discuss their concerns if required. The Trust must also consider carefully how to respond to media enquiries and whether advice from HQIP or the appropriate professional organisation is required.

8. The Future

Methods for the identification of outliers are evolving rapidly but will never be perfect. The procedures pioneered by the SCTS, NICOR and HQIP are at the forefront of a very complex discipline and will improve further in the future. Consultants are a precious resource to the NHS and whilst poor outcomes cannot be left unchallenged it is in nobody's interest to restrict the practice of a doctor on the play of chance alone. A culture of patient focussed reflective practice and organisational support for individuals with remediable problems with their performance needs to be embedded throughout the service. This should in time prevent many of the past issues that have led to alerts being overlooked and issues continuing to the point where actual patient harm occurs.

9. Summary Points

- Individual doctors have a responsibility to reflect continuously on their practice and to raise any concerns they may have.
- Trusts, through their medical directors have a responsibility to create an environment that reinforces and supports reflective practice.
- Alerts are raised by NICOR if outcomes are outside the 95% confidence limit.
- Alarms are triggered if outcomes are outside the 99.8% confidence limit.
- Confirmed outliers at alarm level are made public. Alerts trigger a review of practise.
- Trusts must ensure that resources are made readily available for review of data to confirm or refute outlier status.
- Trusts must ensure that doctors at alert or alarm level are provided with all necessary support both internal and external to bring their results back to acceptable levels.
- Failure of an affected doctor to engage with remediation is unacceptable and should trigger a referral to the GMC.
- Any restriction of practice as a result of confirmed alert or alarm status must be proportionate and based on risk to patients.
- Where restrictions are placed on practice to ensure patient safety this information should be made publically available.
10. Useful contacts

- British Cardiovascular Intervention Society: bcis@bcs.com.
- British Cardiovascular Society: Vice President for Clinical Standards BCS: 020 7383 3887.
- Royal College of Physicians Invited Service Reviews: http://www.rcplondon.ac.uk/resources/clinical-resources/invited-service-reviews
- Royal College of Surgeons Invited Reviews: https://www.rcseng.ac.uk/healthcare-bodies/support-services/irm
- President of the Society of Cardiothoracic Surgeons: sctsadmin@scts.org

11. References

3. Handling Concerns about a Professionals Behaviour and Conduct. NCAS June 2012
4. Tackling Concerns Locally. DH 2009
Working Group on the Handling of Consultant Outliers: Members

Professor Simon Ray (Chair)
Sir Donald Irvine (Past President GMC)
Ms. Sarah Boseley (Health Editor, The Guardian)
Mr. Alan Keys (Patient Representative)
Mr. Trevor Fernandez (Patient Representative)
Professor Huon Gray (National Clinical Director (Cardiac), NHS England)
Mr. Simon Kendall (Secretary SCTS)
Mr. David Jenkins (SCTS Audit Lead)
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The working group would like to acknowledge the invaluable input of Professor Ben Bridgewater, Dr. Peter Ludman, and Mr. Douglas Bertram in the preparation of this document.
Appendix A: Picker Consultation Score – summary charts

Chart 1: Your Picker Consultation Score

Confidence intervals
The confidence interval shows the range within which your overall score would fall in 95 out of 100 equivalent samples of patients. This shows how reliably your level of communication skill has been estimated.

Chart 2: Your communication skills in detail

* Lower sample size (question only applied to some patients)
## Chart 3: How you compare to others

<table>
<thead>
<tr>
<th>Question</th>
<th>Your score</th>
<th>Average score</th>
<th>Significant difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explaining the reasons for advice*</td>
<td>10</td>
<td>9.5</td>
<td>None</td>
</tr>
<tr>
<td>Involving your companion in the consultation in the way you wanted*</td>
<td>10</td>
<td>9.4</td>
<td>Above average</td>
</tr>
<tr>
<td>Treating you with respect and dignity</td>
<td>10</td>
<td>9.6</td>
<td>Above average</td>
</tr>
<tr>
<td>Speaking clearly</td>
<td>10</td>
<td>9.6</td>
<td>None</td>
</tr>
<tr>
<td>Examining you sensitively*</td>
<td>9.9</td>
<td>9.6</td>
<td>None</td>
</tr>
<tr>
<td>Explaining what would happen next</td>
<td>9.9</td>
<td>9.4</td>
<td>Above average</td>
</tr>
<tr>
<td>Explaining any risks and/or benefits of treatment options*</td>
<td>9.9</td>
<td>9.5</td>
<td>None</td>
</tr>
<tr>
<td>Making you feel at ease</td>
<td>9.9</td>
<td>9.4</td>
<td>Above average</td>
</tr>
<tr>
<td>Listening carefully</td>
<td>9.9</td>
<td>9.4</td>
<td>Above average</td>
</tr>
<tr>
<td>Explaining things</td>
<td>9.9</td>
<td>9.5</td>
<td>Above average</td>
</tr>
<tr>
<td>Treating you as an individual</td>
<td>9.8</td>
<td>9.3</td>
<td>Above average</td>
</tr>
<tr>
<td>Letting you talk</td>
<td>9.8</td>
<td>9.3</td>
<td>Above average</td>
</tr>
<tr>
<td>Involving you as much as you wanted in decisions about your care and treatment</td>
<td>9.7</td>
<td>9.1</td>
<td>Above average</td>
</tr>
<tr>
<td>Being prepared</td>
<td>9.7</td>
<td>9.3</td>
<td>None</td>
</tr>
<tr>
<td>Fully understanding your worries or concerns</td>
<td>9.6</td>
<td>9.2</td>
<td>Above average</td>
</tr>
<tr>
<td>Giving you emotional support</td>
<td>9.6</td>
<td>9</td>
<td>Above average</td>
</tr>
</tbody>
</table>

* Lower sample size (questions only apply to some patients)
Appendix B: Advice on Outliers from SCTS

Advice for surgeons

The introduction of mandatory publication of consultant outcomes for surgical specialties by NHS England has focused more attention on surgical results. SCTS has traditionally defined 3 levels of ‘negative’ outlier; yellow (95% CL), amber (99% CL) and red (95% CL with adjustment for multiple comparisons).

In keeping with the other specialties publishing consultant level outcome data, and on the advice of the external statistical review of the audit last year, for 2015, we are moving to 2 levels; alert which represents the old yellow and amber levels and alarm which represents the old red. In 2015 we have used two tailed exact binomial confidence intervals at 95% and 99.8%.

There is a reasonable possibility that alert level alarms may occur due to chance alone. It is unlikely that alarm level outliers will occur solely due to chance. The methods for analysis are complex and have been subjected to external statistical review and are given in detail in Appendix D.

Alarm level outliers (99.8%) will have their survival results published as ‘?’ lower than rather than worse than expected on the NHS Choices website. We believe that with improved internal governance procedures, it should be possible to avoid any alarm outliers in future years.

SCTS has two responsibilities in this process:

- To provide advice on understanding and explaining any lower than expected survival
- To provide support for members and units

Any surgeon or unit that triggers an alert or alarm has a duty to explain the divergence of their results. Divergence is a cause for looking at the data in more detail and is not a sufficient reason in itself for restricting a surgeon’s practice unless there are clear concerns about the safety of patients. It is important that all investigations are reasonable and proportionate.

By the time any data is published it should have gone through a robust analysis to ensure that it accurate (with respect to the activity, mortality and risk factor data). We would then recommend:

- Analysis of the caseload to ensure that the risk stratification mechanism accurately reflects expected outcomes (e.g. is there any subspecialist practice which is not adjusted for by the risk prediction model).
- Analysis of institutional factors that may contribute to the divergence in clinical outcomes such as referral practices, the provision of intensive care, or other post-operative services.
- More detailed analysis of the surgeon’s performance
- It is important to look for trends in mortality over time to ascertain at what stage survival rates started to decline, and whether it is possible to identify any precipitants.
- The SCTS believes that all intra-operative or post-operative cardiac surgical mortalities should be reviewed in detail, and that both the hospital and the individual have a responsibility here.
- The hospital should be reviewing cases of mortality as part of their routine clinical governance meetings, to learn and feed-back to improve practice.
- The surgeon should be reviewing all mortality through the process of reflective practice, and documenting this for their appraisal portfolio.
- In addition to reviewing overall mortality rates and each death in detail, we would recommend a wider benchmarking of additional process and outcomes data.
• All benchmarking of outcomes should be conducted in the full knowledge of the case mix and risk profiles. It may in this context be appropriate to benchmark complete practice and/or outcomes for specific operative groups.
• It important that there is organisational engagement with these investigations to support the process. SCTS would suggest that this is supported by clear action plans with defined timescales and personal responsibilities.

Support for members

• Any member who is identified as either an alert or alarm will be contacted by the President of SCTS or a nominated senior officer deputy.
• This contact will take the form of a preliminary phone call
• This will be followed up by written contact from NICOR/SCTS
• The initial contact will:
  o Explain the nature of the process
  o Offer a choice of senior officers of SCTS to act as a supporter through the process
• The colleague will:
  o Offer personal support throughout the process
  o Provide advice about other sources of support
  o If necessary provide advice on the gathering of other sources of evidence to support good practice, such as colleague and patient 360 appraisal data.

<table>
<thead>
<tr>
<th>Personal Support</th>
<th>Confidential</th>
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<tbody>
<tr>
<td></td>
<td>Listening</td>
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<td></td>
<td>Advice confined to area of expertise</td>
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<table>
<thead>
<tr>
<th>Other sources of support</th>
<th>IRM</th>
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<td></td>
<td>BMA</td>
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<td>Defence organisation</td>
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<td></td>
<td>NCAS</td>
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<td></td>
<td>Occupational Health Department</td>
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<td></td>
<td>General Practitioner</td>
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<table>
<thead>
<tr>
<th>Other sources of evidence</th>
<th>Appraisal</th>
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<tbody>
<tr>
<td></td>
<td>Other evidence to show that standards of Good Medical Practice (GMC)</td>
</tr>
<tr>
<td></td>
<td>Good Surgical Practice (RCSEng) are maintained</td>
</tr>
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</table>

Advice for medical directors

• The introduction of mandatory publication of consultant outcomes for surgical specialties by NHS England has focused more attention on surgical results. In keeping with the other specialties publishing consultant level outcome data cardiac surgery are conducting analysis at 2 levels alert and alarm with worse and better than expected risk adjusted survival respectively.
• The alarm is a 99.8% confidence interval deviation from expected and will be published on NHS choices with results worse than expected. This finding is unlikely to be due to chance alone.
• Alert is a 95% confidence interval deviation from expected and will be published on NHS choices as ‘as expected’. There is a reasonable probability that results may be abnormal at this level due to chance alone, but it is flagged up to surgeons and their hospitals to enable further investigations and understanding to take place as necessary, to help prevent a future alarm.
• In addition to defining survival rates that are worse than expected, we have been asked by NHS England to identify and publish results for units and surgeons that are better than expected – again at 99.8% (which will be published) and 95% (which are for internal
• The SCTS in conjunction with NICOR (the audit provider) will write to the medical director of all hospitals and surgeons that are identified as having results that differ from expected at 99.8% limits and to those below expected at 95%.

• By the time any data is published it should have been validated by the units themselves. All hospitals should ensure that they have the appropriate resource and infrastructure to do so, and SCTS is aware that HQIP and NHS England have written to Trusts about this in the past.

• It is recognised that the data processes and risk adjustment algorithms are complex. Should a Medical Director or his representative need to have detailed discussions about this we would suggest contacting Anthony Bradley a.j.bradley@ucl.ac.uk in the first instance.

• Any results that are significantly better or worse than expected will be published and are likely to attract some media attention. If the Trust should wish to coordinate communication strategies we would suggest they contact HQIP and SCTS – James Thornton, James.Thornton@hqip.org.uk.

• By the time results are published we would expect that the organization would have a good understanding of why survival rates are not as expected. We have given specific advice to surgeons on looking into mortality rates in our document advice for surgeons.

• The experience of SCTS from the IRM is that results which are worse than expected are often related to organisational issues, team-working or behavioural factors rather than surgical skills. We understand that these issues may be challenging to define and resolve. SCTS strongly recommends that any survival alarm, for either hospital or surgeon, should lead to an invited review from the college of surgeons, unless the reasons for the divergence are already clearly understood and have been resolved.

• SCTS recognises that risk adjusted survival rates are only one aspect by which surgeons’ performance may be judged. There are many others including incident reporting, the results of M and M discussions, coroners’ inquest reports and investigations, MSF and patient experience measurement. SCST would encourage all aspects related to surgeon performance to be considered in the round. SCST understands that the modern regulatory landscape involves discussion with regulators (CQC and the GMC) and is aware that HQIP have written to all medical directors involved in consultant outcomes publication about these issues.
### Appendix C: BCIS Outlier Policy

#### BCIS policy for handling potential outliers

<table>
<thead>
<tr>
<th>Stage</th>
<th>Process</th>
<th>Details</th>
<th>Personnel</th>
<th>Time scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Annual analysis by NICOR of calendar year data.</td>
<td>Data assessed: 2012 calendar year, then additional year to a 3-year rolling total. <em>Data Analysis:</em> 1. Total PCI numbers; 2. Risk adjusted MACE using NOC/IP model; 3. Plan to use new mortality only model (tracing E&amp;W only) <em>Definition of Potential Outliers:</em> 1. PCI numbers &lt; 75 ps 2. Outcomes: a) outside 3 SD after 1 year or b) outside 2 SD on 2 successive years (but alert operator at 1 year)</td>
<td>BCIS audit lead NICOR statisticians</td>
<td>6 weeks</td>
</tr>
<tr>
<td>2</td>
<td>Initial validity checks</td>
<td>Initial contact just with potential outlier: 1. Inform them; 2. Suggest they can inform others; 3. Ask them to review data for accuracy; Analysis of the data for accuracy. Look for obvious probable errors and guide operator and data lead at trust to help with internal validation</td>
<td>BCIS audit lead NICOR statisticians Potential outlier Trust’s data collection team Clinical governance lead</td>
<td>6 weeks</td>
</tr>
</tbody>
</table>

#### 3. Result of initial validity checks

<table>
<thead>
<tr>
<th>3a</th>
<th>Outlier status not confirmed</th>
<th>Report from BCIS audit lead sent to: Potential outcome BCIS President DMA, NICOR</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Apparent outlier due to simple data collection, recording and upleading errors. Document process and reason for errors; Correct the processes that led to errors</td>
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**END**

<table>
<thead>
<tr>
<th>3b</th>
<th>Potential outlier,</th>
<th>BCIS audit lead NICOR statisticians Potential outcome Cardiology lead Clinical governance lead Medical director BCIS president Trust to respond within 6 weeks</th>
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<tr>
<td></td>
<td>Potential outlier contacted initially. They cardiology lead and medical director. They are requested to validate the results, identify any data errors and justifiable explanations. Formal written response requested. An NICOR analysis will be made available to the trust. Stress limitations in methodology. Expect the following approaches: 1. Analysis of the data for accuracy, both case ascertainment, data completeness and data accuracy (range checks, internal consistency and validation) 2. Analysis of the caseload to ensure that the risk stratification mechanism accurately reflects expected outcomes 3. Analysis of institutional factors that may contribute to the divergence in clinical outcomes</td>
<td>BCIS audit lead NICOR statisticians Potential outcome Cardiology lead Clinical governance lead Medical director BCIS president</td>
</tr>
<tr>
<td>4a</td>
<td><strong>Outlier status not confirmed</strong></td>
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<td></td>
<td>Confirmed that data do not accurately reflect practice and outcomes</td>
<td>When data and analyses are corrected, operator is no longer classified as an outlier.</td>
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<td></td>
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<td>Report from BCS audit lead sent to:</td>
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<td>Potential outlier</td>
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<td>Cardiology lead</td>
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<td>Medical director</td>
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<td>BCS president</td>
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<td>NCOR</td>
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**END**

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<thead>
<tr>
<th>4b</th>
<th><strong>Potential outlier</strong></th>
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<tbody>
<tr>
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<td>Outlier status unexplained</td>
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Appendix D: NICOR False Positives Statement

NICOR NACSA False Discovery Rate Analysis 17th August 2015

Due to the large number of tests being conducted in the NACSA audit we can expect false positives to occur in the hospital and consultant level analyses, even if all have acceptable performance. The proportion of those units or surgeons found to be outliers that are false positives gives the chance of a positive finding being a false positive, the “False Discovery Rate”, i.e. the chance that a unit determined to be outlying is in fact performing within the ‘control limits’.

Estimate of False Discovery Rate

We used the upper bound estimate for False Discovery Rate

\[
\frac{n \alpha}{k}
\]

suggested by Professor Sir David Spiegelhalter (“How confident can we be that ‘outlying’ units are ‘truly outlying’?”, communication July 2015) for the False Discovery Rate where \(n\) is the number of units eligible for reporting, \(\alpha\) is the level of significance and \(k\) is the number of outliers found.

Numbers of units

There are 39 hospitals eligible for reporting (and 282 eligible consultants).

Alarms

Using the level of significance \(\alpha = 0.001\) (99.8% limits), we found 2 hospitals and 2 consultants to be Alarms.

For hospitals the expected number of chance Alarm findings, assuming all hospitals to have acceptable performance, is 0.039 each year (1 every 26 years). The Alarm False Discovery Rate is estimated to be 0.02, i.e. we can expect at least 98% of the 2 hospitals found to be Alarm to be true outliers.

For consultants the expected number of chance Alarm findings, assuming all hospitals to have acceptable performance, is 0.282 each year (1 every 3.5 years). The Alarm False Discovery Rate is estimated to be 0.14, i.e. we can expect at least 86% of the 2 consultants found to be Alarm to be true outliers.

Alerts

Using the level of significance \(\alpha = 0.025\) (95.0% limits), we found 5 hospitals (2 Alarms) and 14 consultants (2 Alarms) as Alert or Alarm.

For hospitals the expected number of chance Alert or Alarm findings, assuming all hospitals to have acceptable performance, is 0.975 each year. The Alert or Alarm False Discovery Rate is estimated to be 0.20, i.e. we can expect at least 80% of the 5 hospitals found to be Alert or Alarm to be true outliers.
For consultants the expected number of chance Alert or Alarm findings, assuming all hospitals to have acceptable performance, is 7.05 each year. The Alert or Alarm False Discovery Rate is estimated to be 0.50, i.e. we can expect at least 50% of the 14 consultants found to be Alert or Alarm to be true outliers.

**Significantly Higher than Expected**

Using the level of significance $\alpha = 0.001$ (99.8% limits), we found 3 hospitals and 0 consultants as Significantly Higher than Expected.

For hospitals the expected number of chance Significantly Higher than Expected findings, assuming all hospitals to have acceptable performance, is 0.039 each year (1 every 26 years). The Significantly Higher than Expected False Discovery Rate is estimated to be 0.01, i.e. we can expect at least 99% of the 3 hospitals found to be Significantly Higher than Expected to be true outliers.

**Higher than Expected**

Using the level of significance $\alpha = 0.025$ (95.0% limits), we found 5 hospitals (3 Significantly Higher than Expected) and 7 consultants (0 Significantly Higher than Expected) as Higher than Expected.

For hospitals the expected number of chance Higher than Expected findings, assuming all hospitals to have acceptable performance, is 7.05 each year. The Higher than Expected False Discovery Rate is estimated to be 0.20, i.e. we can expect at least 80% of the 5 hospitals found to be Higher than Expected to be true outliers.

For consultants the expected number of chance Higher than Expected findings, assuming all hospitals to have acceptable performance, is 7.05 each year. The Higher than Expected False Discovery Rate is estimated to be 1.00, i.e. we cannot expect any of the 7 consultants found to be Higher than Expected to be true outliers.
Appendix E: Individual experience of dealing with variance in outcomes

Dealing with variance

A personal experience

Personal experience?

- Managed the Adult Cardiac Cardiac Surgery Audit since 2007
  - Validation
  - Methodology
  - Responding to alerts
  - Supporting and conducting RCS IRM visits
  - Other governance reviews
- Managed the HQIP COP programme since 2013
- Active cardiac surgeon with run of mortality in 2013/14

Dealing with variance

- Should suspect it at the time
- Diligent, sensitive and supportive observation of the workplace is the most important factor
  - by individual
  - by line management
- Supported by local IT and national benchmarking
- In Adult Cardiac Surgery high risk adjusted mortality is usually associated with high crude mortality
- Local investigation should be triggered by the individual involved
- If not should be initiated by local line management
- Full investigation should have taken place prior to any ‘flag’ from national audit

Wider context of governance

- Audit
- Governance
- M&M meetings
- Incident reporting
- Coroners
- COP
- Appraisal/revalidation
Towards a managed process...

Personal practice experience

- Obsession on performance
- Detailed discussion with professional network
- Personally driven structured review of practice
  - Developed a proposal
  - Formally ‘signed off’ with line management
  - Independent review of plan and findings
  - Planned to feed appraisal/revalidation

- Bad run 2013/14
- Temporally related to
  - retirement of senior colleague
  - appointment and mentorship of junior colleagues
- Bad run set against history of better than average risk adjusted mortality
- Busy national commitments

Personal practice experience

- Benchmarking
  - 1 year mortality data
  - 3 year mortality data
  - Total practice mortality data
  - Non-mortality performance markers
    - IABP use
    - Re-exploration for bleeding
    - Return to ICU
- Detailed review of cases
Review of cases

- Structured review of practice
  - All mortality
  - Several morbidity cases
  - Gibbs reflective cycle
  - Each case individual action plan
  - Total practice review action plan
  - Shared with independent senior colleague for signoff
  - Added to appraisal documentation

Example 1

- Redo mitral replacement
- Damage to right ventricle in sternotomy
- Groin vessels exposed prior to sternotomy
- On to bypass without difficulty
- Patient suffered major stroke intra-operatively

  - Bypass before sternotomy?
  - No clear practice guidelines
  - Consensus of experts
  - Change in practice

Example 2

- 76 year old lady
- Severe symptomatic AVR
- Routine surgery
- Arrest on ward on 2nd post-op day
- ? Hypertrophied ventricle/ hypovolaemic/hypotensive vicious spiral
- HIRS
  - External investigation
  - Relative communication
- Changes in organisational practice for post-op AVR care
Reflection – personal example

- Overall mortality benchmarking
- Time trends
- Non-mortality data
- Individual case reflection
- Case series reflection

Reflection – inter-relationships

So – am I an outlier?

- But if I was …
  - Reflective practice
  - Documented process and actions
  - Wider benchmarking of data
    - Non mortality data
    - Data from historical and most contemporary time epoch
  - Multi source feedback
    - Colleagues
    - Patients
  - External input
  - All included in revalidation submission
    - R.O. signoff
Appendix F: Internal governance example for adult cardiac surgery

At Papworth hospital we have a monthly audit meeting where risk adjusted mortality is tracked and presented for all surgeons on a rolling year basis. We use an internal target threshold of 50% of the calculated logistic EuroSCORE (this predates the availability of the recalibration formula from NICOR). The audit department, clinical governance and audit lead actively follow any surgeon whose in-hospital mortality is rising. Dependent on volume of cases, case mix and trends (rather than a defined single threshold limit), action is taken internally with the aim of preventing the surgeon’s outcomes deteriorating further. The surgeon meets with the audit lead and chairman of the surgeon’s sub-committee, i.e. an internal surgical rather than directorate meeting, to discuss an action plan. The action plan is dependent on the cause of the deteriorating outcomes. In most cases in the past, there has not been a clear reason apart from case-mix or just bad luck. Steps that have been used include, in an escalating fashion:

1. Restriction of cases to elective for an initial period of 3-6 months, as recognised that in-house urgent transfer cases may be less predictable and higher risk.
2. Review of their elective waiting list and removal, with redistribution to other colleagues, of cases that are perceived to be high risk.
3. The invitation to bring any new referrals that are higher risk to the surgical council discussion, for a second opinion, with the possibility that the operation may be performed jointly with another colleague.
4. Active mentoring so that the surgeon discusses operative plans for individual more complex cases with a nominated colleague in advance.

In many cases, the first step alone may be enough. We have recognised that some surgeons require more help than others and are slower to recognise the fact that they actually require help.

Mr. David Jenkins
September 2015, for Working Group on the Handling of Consultant Outliers