



Created: November 2015

Reviewed and updated: July 2019

Next review date: July 2021

Maintaining Good Clinical Practice – Handling of Potential Consultant Outliers

A Joint Report from UK Cardiac Professional Societies

BCCA, BCIS, BHRS, NICOR, SCTS

Commissioned and Chaired by the British Cardiovascular Society

Contents

Section Title	Page Number
Executive Summary	p. 3
Lay Summary	p. 3
Glossary	p. 5
1. Introduction: What Good Looks Like	p. 6
2. Publication of Individual Consultant Outcomes: Alerts and Alarms	p. 6
3. Maintaining High Quality Practice – The Role of Reflection	p. 7
4. The Role of the Employer	p. 8
5. Support Where Potential Issues are Identified – Alerts	p. 9
6. Handling of a Confirmed Outlier at Alarm Level	p. 10
7. Informing Patients and the Public	p. 11
8. The Future	p. 12
9. Summary Points	p. 12
10. Useful contacts	p. 13
11. References	p. 13
12. Working Group Membership List	p. 13

Executive Summary

This report deals with the steps we believe should be taken when analysis of national clinical audits (National Cardiac Audit Programme, NCAP) suggest that an individual consultant might have suboptimal patient outcomes for their procedures (outlier status). Individual consultant outcomes for an increasing number of specialties are published on the NHS website. For cardiac specialties data is derived from audits within NCAP which are undertaken in conjunction with the relevant national professional societies.

The definition of an outlier is based on setting a target for an indicator, and then defining what level of variation from that target is acceptable, based on theories of statistical probability and /or clinical judgement. Outlier status can either be at an alert or alarm level.

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 are 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 website and professional society websites 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 website and professional society websites. 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 many 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. 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

President, British Cardiovascular Society

November 2015

Review and Updated January 2019

Dr Andrew Wragg

Vice President Clinical Standards, British Cardiovascular Society

On behalf of the BCS Clinical Standards group in consultation with BCIS/ SCTS/ BHRS/ BCCA

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

NCAP National Cardiac Audit Programme,

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 for 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 a doctor’s 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 speciality 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. It is also important that clinician’s do not adopt risk adverse behaviour which might deprive some patients of the access to potentially beneficial treatment. 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. This is whilst supporting clinicians to offer the most effective treatments to all patients.

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. However, responsibility for a consultant's outcomes also sits within the department that they work and also with senior leaders and ultimately with their hospital's executive team.

The national audits of percutaneous coronary intervention and adult cardiac surgery, through NCAP and NICOR, and in partnership with the relevant professional societies and 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. NICOR has developed a standard operating procedure for managing outlier status for NCAP (1). HQIP have also produced generic guidance on the identification of outliers (2).

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. 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 NICOR, HQIP, the DH and other bodies as appropriate (1, 2, 4, and 5). 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.

As the definition of outlier status (alert and alarm) is based on a statistical analysis of data there is the possibility that outlier status may have arisen by chance. Although NICOR, in collaboration with the professional societies, have developed sophisticated statistical models, there is also the possibility of an outlier status occurring due to the model not adequately correcting for the case mix of patients. Therefore it is important that there is always a comprehensive review of the data when a possible outlier status is raised.

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 (3). 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.

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. Medical Directors should ensure that there are sufficient resources to support the NCAP audits and the audit data are regularly reviewed and analysed. 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 the 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 (6).

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.

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.

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. A flow sheet laying out the steps a hospital needs to follow after being notified of a potential alert or alarm has been included in Appendix 1. 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 hospital policies and commensurate with the processes recommended by NCAS (4). External review is not mandatory but it is encouraged and 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. The relevant professional societies will be able to provide assistance with regard to mentoring if required. 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.
- 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. Both societies are able to offer Invited Service Reviews in collaboration with relevant Royal Colleges. Subspecialty societies, such as the British Cardiovascular Intervention Society and the British Congenital Cardiac Association can then be involved as required. Early involvement with the GMC may also be helpful. The GMC's Employer Liaison Adviser (ELA) can offer support to the doctor's Responsible Officer.

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

For more detailed guidance for Medical Directors, Chief Executives, and local NCAP audit leads on how to respond to a NCAP individual operator 'alert' or 'alarm' please refer to Appendix 1

Identification as an outlier at alarm level occurs only at the end of a process of rigorous data review and validation and should not 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 hospital board and relevant lead commissioners and the relevant Royal Colleges. The Medical Director/Responsible Officer 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 and 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. 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 and distributed.

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.

Hospitals 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. It should be clear what problem was identified and how this is 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 hospital 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.
- Hospitals, through their medical directors have a responsibility to create an environment that reinforces and supports reflective practice.
- Confirmed outliers at alarm level are made public. Alerts trigger a review of practice.
- Hospitals must ensure that resources are made readily available for review of data to confirm or refute outlier status.
- Hospitals 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

- President of the British Cardiovascular Society: enquiries@bcs.com
- President of the Society for Cardiothoracic Surgery: sctsadmin@scts.org
- British Cardiovascular Intervention Society: bcis@bcs.com
- 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>

11. References

1. NICOR Standard Operating Procedure (SOP), NCAP Outlier Policy, 2019
2. Consultant Outcome Publications. Manual for National Clinical Audits. NICOR 2015
3. https://www.gmc-uk.org/-/media/documents/Good_medical_practice_English_1215.pdf 51527435.pdf
4. Handling Concerns about a Professionals Behaviour and Conduct. NCAS June 2012
5. Tackling Concerns Locally. DH 2009
6. <https://www.rcseng.ac.uk/publications/docs/improving-surgical-practice>
7. Appendix 1, Guidance for Medical Directors, Chief Executives, and local NCAP audit leads on how to respond to a negative NCAP individual operator 'alert' or 'alarm'

12. 2015 Working Group on the Handling of Consultant Outliers: Original 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)
- Dr. Francis Murgatroyd (BHRS Audit Lead)
- Dr. Jim Hall (Deputy Medical Director South Tees NHSFT)
- Dr. Adam de Belder (BCIS)
- Dr. Rob Martin (President BCCA)

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.

Review and Update Group January 2019

In January 2019 the document was reviewed and updated by the BCS clinical Standards group with involvement of the following:

BCCA

BCIS

BHRS

NICOR

SCTS

Mr Alan Keys patient representative

