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Maintaining good clinical practice: publication of outcomes and handling of outliers

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There is a growing expectation that information about the performance of clinical services and individual doctors is made publicly available. Patients have a legitimate interest in knowing the care they receive is of high quality, but there are some potential risks in public reporting of these data, not least that of risk-averse behaviour by clinicians concerned about loss of reputation and livelihood that potentially denies patients appropriate treatment. The development of reliable metrics to assess clinical performance is complex, evolving and often controversial. In the USA, the Society of Thoracic Surgeons and the American College of Cardiology (ACC) have published principles for public reporting of outcomes central to which is the use of high-quality, robust and validated clinical data.[1] National registries such as the National Cardiovascular Data Registries (NCDR) in the USA and the National Institute for Cardiovascular Outcomes Research audits in the UK are fundamental to the quality of clinical data used for performance reporting as is the involvement and oversight of the respective professional societies who are best placed to define what good looks like. Approaches to publication differ. In the UK, National Health Service England has published individual consultant outcomes for 11 specialties including interventional cardiology and cardiac surgery.[2] In the USA, the ACC and NCDR have launched a voluntary programme of public reporting of performance data by institution.[3] Although in its infancy, it is gaining considerable professional and public support.

For interventional cardiology and adult cardiac surgery in the UK, there are two levels of negative outlier on the basis of 3-year rolling analysis of national audit data: alert and alarm. An alert means that observed survival is 2 SD below the expected mean and an alarm that survival is 3 SD below the expected mean. Data review and validation is rigorous, but no statistical model is perfect and there is a possibility that at some point during their career individual consultants may be flagged up as outliers at alert level purely by chance. This is much less likely at alarm level and individual consultants are only publicly identified as outliers if they are confirmed at alarm level after thorough review.

CLINICAL CULTURE

It is understandably difficult for clinicians to accept that their practice might be called into question at alert level by statistical chance alone. For this to become acceptable, it has to be accompanied by some important shifts in the way that hospitals monitor and support their staff. Doctors do not work in isolation and institutional culture has a major role to play in the maintenance of high-quality reflective practice. This requires that an institution provides staff with the means to accurately monitor and review their practice, and a culture within the wider organisation that supports and expects transparency of outcomes. Clinicians should expect that the output of their work and its impact on their patients is continuously monitored but must also have confidence both in the mechanisms for monitoring and in the support they will need to review their practice in more detail should an alert be raised. They must also be confident that any investigation of their practice will be objective and proportionate and that they will be supported in correcting any remediable problems that are identified.

INSTITUTIONAL RESPONSIBILITIES

The responsibility for fostering a supportive and transparent culture lies with the senior medical management of an institution and is a hallmark of a high-quality service (figure 1). Excellent clinical services have structures in place that seek continuous feedback from service users and which can identify and deal with potential performance problems at an early stage and so avoid getting to the point where patient safety is at risk. Central to this is a requirement that clinicians are properly trained and certified for their roles and supported in complying with the requirements for continuing education and recertification or relicensing. In the UK, all practising clinicians must undergo annual appraisal and must revalidate (relicense) in their specialty every five years, but anecdotally the rigour of this process varies widely between institutions and its true value has been questioned.[4] In the USA, the American Board of Internal Medicine (ABIM) provides a Maintenance of Certification (MOC) programme to evaluate physician competencies of medical knowledge, practice-based learning, system-based practice, patient care and professionalism. However, this programme has been challenged by some clinicians who believe that the current requirements are not fit for purpose. As a result, the ABIM has temporarily withdrawn requirements for the assessment of patient safety and satisfaction and for ongoing practice improvement leaving only a requirement for an annual open book assessment of medical knowledge and a proctored knowledge examination every 10 years. A recent informal survey by the American Board of Medical Specialities (ABMS) found that while 68% of hospitals include current ABMS, American Osteopathic Association or equivalent certification among requirements for medical staff privileges only 49% require participation in MOC.

HANDLING OF INDIVIDUAL OUTLIERS

In response to concerns about the publication of individual outcome data, the British Cardiovascular Society convened a Working Group to provide guidance on what should happen when the outcomes of an individual doctor's practice are called into question.[5] The concept of alerts and alarms provides a useful framework as an alert is precisely that: an indication that there *might* be a problem, not definitive evidence of poor performance and hence should be regarded as a neutral event with no stigma attached. It is essential that any alert is dealt with proactively and quickly. Individual and institutional confidence is key to achieving good results and can be diminished by the inevitable uncertainty associated with investigations and further amplified by unnecessary delay.

An alert should trigger a review of the whole of the doctor's practice across all institutions where they work, including relationships with colleagues and other aspects of team functioning. The precise

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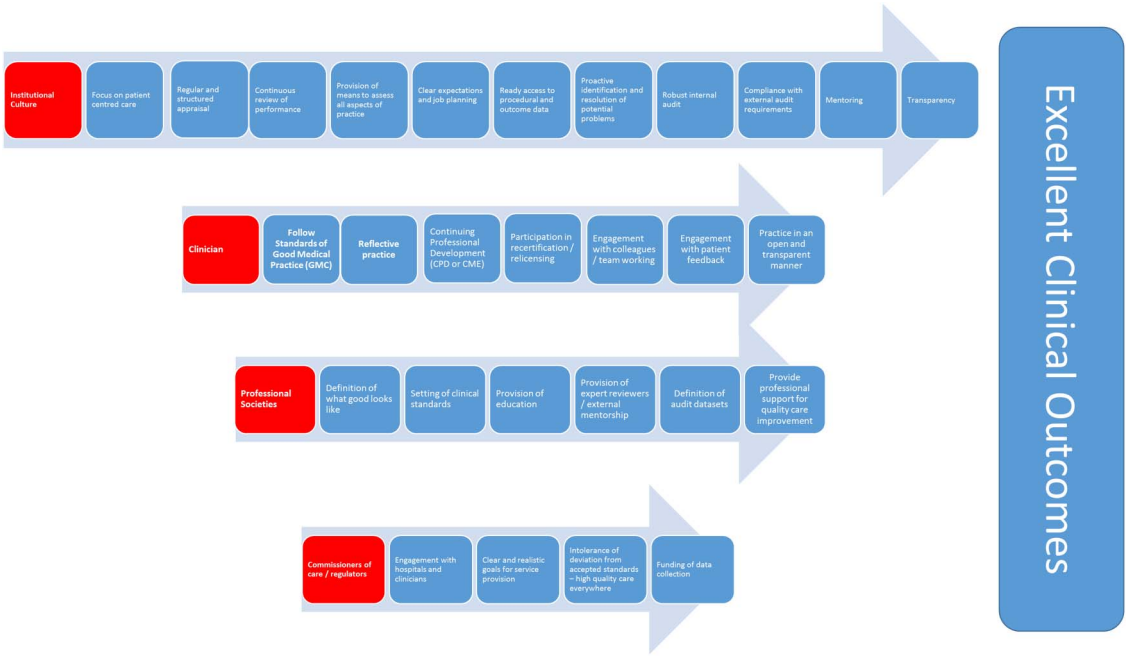

Figure 1 Working towards clinical excellence.

scope of the review should be determined by individual circumstances and should be agreed and recorded by the doctor concerned with their clinical manager. Any investigation must be proportionate, reasonable in scope and in line with hospital and regulatory policies. External review may be required in some circumstances. The outcome of the review process and any remedial actions should be agreed and signed off by both the doctor and their clinical manager. The aim of this process is to ensure that individual doctors continue to practice to a high standard within well-functioning teams. Given the relatively high false discovery rates with alerts, it follows that in many instances there will be no issues to answer after review and this must be regarded as a reassuringly positive finding. Processes of ongoing appraisal of a doctor's performance should be sufficiently robust to ensure that doctors who have undergone such a review continue to practice to a high standard without the need for additional levels of scrutiny.

Identification at alarm level implies concerns for patient safety and in well-run organisations any problems should have been dealt with well before they get to this stage, but if they persist it is the responsibility for the senior medical management of the hospital to take appropriate action. Doctors should be given every opportunity to address any problems with their practice and 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 but this must be specifically agreed and robustly monitored. Failure to engage with retraining or restriction of practice is unacceptable. In some instances, it may be concluded that despite all efforts at remediation safe continuation of practice is not feasible but this point should not be reached without external review. Hospitals need to consider carefully their response to identification of one of their staff as an outlier at alarm level. If a problem has been successfully addressed allowing continuation of practice, then data to support that decision should be made publicly available and it should be made clear what the problem was, how this has been addressed and if practice has been restricted. It is not acceptable for a doctor to resign or be dismissed and then to move to unrestricted practice in another institution if there are ongoing concerns for patient safety.

PUBLIC AND PROFESSIONAL CONFIDENCE

Patients need to have confidence that they will receive high-quality care and the medical profession needs to have confidence that it is able to provide it. Public reporting of outcome data is an important contributor to these aims, but it needs to use robust risk-adjusted registry data supported by public education as to its strengths and limitations. It provides an important opportunity for the early detection of falling performance and prevention of progression to poor quality care. It follows that institutions and individual operators must have the confidence that published data will be used appropriately as a tool for both quality assurance and quality improvement, not as a competitive league table or as a means to castigate clinicians who are actually performing at a high level.

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REFERENCES

1 Drozda JP Jr, Hagan EP, Mirro MJ, *et al*. ACCF 2008 Health Policy Statement on Principles for Public Reporting of Physician Performance Data: a report of the American College of Cardiology Foundation Writing Committee to Develop Principles for Public Reporting of Physician Performance Data. *J Am Coll Cardiol* 2008;51:1993–2001.
2 My NHS consultant outcome data. https://www.nhs.uk/service-search/performance/Consultants (accessed 11 May 2016).
3 Dehmer GJ, Jennings J, Madden RA, *et al*. The National Cardiovascular Data Registry Voluntary Public Reporting Program: an interim report from the NCDR

Public Reporting Advisory Group. *J Am Coll Cardiol* 2016;67:205–15.
4 Umbrella: shaping the future of medical revalidation. http://www.gmc-uk.org/UMbRELLA_interim_report_FINAL.pdf_65723741.pdf (accessed 20 May 2015).
5 Maintaining Good Clinical Practice—Handling of Potential Consultant Outliers. http://www.bcs.com/documents/7F8_Handling_of_Outliers_v_final_approved.pdf (accessed 11 May 2016).

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