

Clinical Outcomes Publication: Technical manual



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1. Background

1.1 About HQIP

The Healthcare Quality Improvement Partnership (HQIP) is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP holds the contract to manage and develop the National Clinical Audit Programme, comprising more than 30 clinical audits and outcome review programmes that cover care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, in the case of some individual audits, by the Health Department of the Scottish Government, DHSSPS Northern Ireland and the Channel Islands.

1.2 About Clinical Outcomes Publication (COP)

Clinical Outcomes Publication (COP) is an NHS England initiative, managed by HQIP, to publish quality measures at the level of individual consultant doctor, team, and unit as well as other levels using National Clinical Audit and administrative data.

COP began with 10 National Clinical Audits (NCAs) in 2013 and expanded to 12 in 2014. Those that published in the inaugural year have continued to build on and develop the number of procedures and quality measures covered including expanding the inclusion of team-based or hospital measures.

Please see *section 1.6 'History and context'* for more details.

1.3 Who this manual is for

This guidance, though generic, aims to be useful for audit providers, Trusts and professional societies. For those audits participating in COP, any variation from this guidance should be justified and published alongside any audit outputs.

1.4 How this manual is designed to help

The aim of this technical manual is to support the work and future development of NCAs with a particular focus on those publishing consultant-level outcomes. It will be of interest to those already participating in the COP programme, but can also provide guidance to audit teams that are considering how to further develop their audits.

The COP Technical Manual was drafted following a data validation guidance development workshop attended by audit providers and professional association representatives and a period of external consultation with our audit providers. HQIP would like to thank those involved for their contributions.

Some commonly-used terms

For the purposes of this document we will use the following definitions:

- Case ascertainment: the number of cases collected in the NCA compared to the expected number of cases (determined from another data source). It is important that all relevant cases are included in the audit to minimise the risk of selective reporting
- Missing data: many of the audits have large datasets and it is common to find items within the datasets that are not recorded, so called missing data. For data to be useful the incidence of missing data must be low; ideally, patient records should miss less than 5% of data across the various data items in the record, and specific data items should miss less than 10% of information across all patients
- Data validation: even if case ascertainment is complete and the incidence of missing data is low, there needs to be further checks to ensure the data submitted to the national audit is a true representation of the data, as it applies to the incidence of risk factors, the procedural type, or the measured outcomes

1.5 Implementing this guidance

In developing this document, we recognise that some recommendations will not be achievable for all audits, and we would like to emphasise that the recommendations for approaches are not requirements. For example, there is an expectation that governance and alerting guidelines in relation to outlier management will be followed rigorously but different approaches will be chosen by audits to deal with particular statistical challenges, and these will be acceptable provided a reasonable argument for variation is provided.

HQIP is not in a position to advise on minimum standards, particularly in relation to data quality issues. The audits participating in the COP programme, and NCA more generally, use a wide range of approaches in different clinical settings looking at very different types of clinical outcomes. Any attempt at 'universalising' what the minimum expectations are would, firstly, fail to recognise that a number of audits are at different stages of development and, secondly, contravene our advice that clinical leadership within each audit should consider and establish its own minimum standards. The leadership of each audit will need to recognise the inevitable tension between seeking to deliver audit results that are statistically robust and working within a defined budget within the organisationally complex and diverse NHS.

1.6 COP: History and context

In December 2012, NHS England announced in its planning guidance 'Everyone Counts' that results of activity and mortality rates for individual consultants would be published for patients and the public to view . This was consistent with the recommendations from the Bristol Public Inquiry in 2001 and pre-empted similar recommendations from the Mid Staffordshire Public Inquiry in 2013. The Secretary of State has subsequently referred to 'Intelligent Transparency' as a key aspect of improving healthcare quality and governance in the NHS and an important stimulus for changing the culture of healthcare providers towards more patient-centric care.

The drive for 'Intelligent Transparency' in healthcare arrives at a time of unprecedented change in digital media with more connected consumers and a desire for healthcare information of many different types. This is further supported by social networking and Freedom of Information legislation. Results of mortality rates for cardiac surgery by hospitals have been available in the UK since 2001 and were published by surgeon from 2005. Consultant Outcomes Publication launched in 2013, publishing consultant-level results for more than 10 other specialties and the programme now covers in excess of 5,000 doctors, with the results published on both NHS Choices, MyNHS and professional society websites.

HQIP recognises the potential benefits of helping a wider range of clinical audits to publish their results on NHS Choices and MyNHS. Use of this platform can improve access to their data by stakeholders and widen the data available to the public where consultant-level outcomes are not presently available.

The 2015/16 round of publications included a number of new team-level audit publications as well as some publications of team-level results alongside consultant-level figures. As such, as of 2016/17, the programme was renamed to Clinical Outcomes Publication (COP) in April 2016.

HQIP is tasked by NHS England to commission and deliver NCA in England, which includes the COP. Increasing transparency across the whole programme will be required to support the wider intelligent transparency agenda.

1.7 COP: Aims and objectives

The central aims of COP are to help:

- Improve the quality of clinical care
- Improve arrangements for monitoring and managing the clinical practise of clinical teams and individuals
- **Reassure** patients that the quality of clinical care is being actively monitored and improved
- **Support** the development of NCA, including driving participation, data completeness and accuracy
- **Support** shared decision-making and empowerment of patients, including treatment options and choice of provider, General Practitioners, and consultants
- **Help** the NHS, NCAs and medical specialty associations to become increasingly transparent and patient-focused
- Support team and individual quality improvement. For individuals, provide information for appraisal and revalidation
- **Celebrate** excellence by learning and spreading best practice from high performing units and individuals



1.8 The scope of COP

While COP began by focusing on individual doctors' results, this has now developed and every team and individual consultant performing a medical procedure within the English NHS could potentially be included in COP. COP may also include private practice, and is not limited to consultants who are members of the representative specialist association. Going forward the programme will be expanded to support more accessible publication of a wider range of process and outcome measures at different levels of granularity.

1.9 The role of HQIP and NHS England

HQIP's role in COP

Overarching: To facilitate the publication of clinical outcome measures on MyNHS/Choices in accordance with HQIP's broader aim of using Intelligent Transparency as a driver for improving the quality of care for patients and the public.

HQIP's approach is to:

- Work in collaboration with the professional leaders of national audit to enhance their existing projects in order to support the COP programme
- Work with the Choices/MyNHS teams to facilitate the accurate, timely and appropriate representation of the COP programme data on those websites
- Work with NHS England, and relevant national bodies, to communicate the aims and activities of the programme and identify opportunities for collaborative working

Operational approaches to this include:

- Communicating programme expectations and aims
- Co-producing methodological guidance across the national audit community
- Sharing best practice across the national audit community
- Facilitating audits to maximise the use of existing system levers to enhance their audits (e.g. quality accounts)
- Working with all partners to achieve balanced media coverage
- Managing programme challenges and, where appropriate, escalating and seeking solutions with NHS England
- Establishing and managing a framework for allocating and providing NHS England with resources to support the participation of audits in the programme

NHS England's role in COP

Overarching: To agree the scope and ambition of the COP programme in collaboration with the Department of Health and HQIP and support positive collaboration within NHS England and other stakeholders.

Operational approaches to this include:

- Identify opportunities to engage with stakeholders and maximise the use of existing system levers to support the success of the COP audits
- Provide financial resource to enable audits to proceed with the collection, analysis and publication of COP data
- Respond appropriately to any specific or overarching programme challenges raised by HQIP or other key stakeholders
- Provide leadership at a national level to communicate the commitment to and support for COP

2. Quality measures and audit period

2.1 Introduction

In 'Everyone Counts: Planning for Patients 2013/14', NHS England mandated the wider publication of activity and mortality figures for clinical teams and individual consultants, a commitment reiterated in the '5-Year Forward View' published in 2014. COP began with volume and mortality rates as its main indicators. But while these are of interest to patients, they are not necessarily the most important measures for improving quality, giving assurance about clinical standards or supporting patient choice. All participating audits are expected to develop quality measures in addition to activity and mortality for their particular specialties, particularly those that are relevant for patients. These are to be included in the transparency outputs from national audit.

Quality measures may be related to the outcomes of procedures, or to process measures that have been shown to be associated with clinical outcomes, improved safety or better patient experience. Ideal measures should be of interest to patients, should support overall improvement and discriminate between the quality of healthcare provided by organisations or individuals.

Determining whether variation between clinical teams or consultants indicates potential differences in the quality of care (rather than simply reflecting random influences) requires data to be collected on a sufficient volume of cases.

2.2 Quality measures

Quality measures may include:

Outcome measures – these are items that measure the outcomes of healthcare interventions. Ideally, they should be outcomes that are important to patients (rather than solely reflect the healthcare provider's perspective) and there should be evidence that the outcome measure is associated with the quality of care.

Process measures – these are items that measure the quality of the process of care, such as the prescription of appropriate

antibiotic prophylaxis for surgery within a required timeframe. The process measure should be associated with better outcomes of care, and ideally, should be important from a patient's perspective

Volume of cases – volume is often associated with better outcomes of care. Higher volumes also make it easier from a statistical perspective to demonstrate that the quality of care is either as expected or is deviating from expected in a meaningful way. Volume of care seems to be of interest to patients, and creating transparency on volume is, on its own, an important aspect of the COP programme.

From a statistical perspective, successful measures would be considered in relation to:

- The clinical validity of the indicator (it should measure accurately what is intended)
- The objectivity of the indicator (it should not vary greatly when measured by different individuals at different times if a patient's condition remains unchanged)
- The adequacy of adjustment of the indicator to ensure that comparisons are fair

For consultant-level outcomes, the minimum expectation for COP is:

- The number of procedures carried out by a consultant
- Risk adjusted or crude mortality rate/numbers by consultant
- Additional quality measure as appropriate to each specialty/audit. These may include average length of stay, complication rate, re-operation, data completeness etc

We recognise that mortality does not fulfil all the above criteria for many specialties (particularly those with low annual volumes and low mortality rates). Specialties included in the COP programme have been asked by NHS England to develop and report additional measures that are appropriate as performance indicators.

All clinical audits are expected to publish these additional outcome measures once they have addressed the issues of



data quality, case ascertainment and risk adjustment. Where an audit does not have more meaningful measures for publication, ongoing participation in the programme will be dependent on clear timescales for their development (usually no more than two years).

As this process develops, we encourage clinical audits, medical colleges and specialist associations, to work with patients, to develop more relevant measures, including those, where appropriate, that recognise the role of training.

In summary, to be meaningful for patients and the public as well as for organisations and professionals, it must be clear the measures are valid. The ideal measure or group of measures:

- Should demonstrate the quality of care provided
- Discriminate between providers with variable quality of care
- Support quality improvement as well as quality assurance, and not be associated with perverse incentives, whereby providers change their behaviours to achieve good results on the selected measure, in a way which is not in the patients' and public's best interests

2.3 Audit period

The audit period that is covered by the published figures must be contemporaneous, ideally incorporating the previous financial year. Audit periods must cover at least 12 months but may extend over longer timeframes if appropriate. Cases may be selected for inclusion in the audit period based upon dates of diagnosis, admission, procedure or discharge, as appropriate.

The appropriate audit period is for the audit team to determine but the focus for NCAs is on contemporaneous data and we would not expect extensive legacy data to be included, especially when this creates data completeness/analysis challenges. A number of clinical audits run on three-year data cycles with the latest year of data replacing the oldest.

3. Data quality

3.1 Introduction

The quality of data collected in NCA is obviously important. Collecting large volumes of data across multiple sites in a real world, rather than a clinical trial setting, inevitably raises many challenges. The ultimate responsibility for data quality resides with the organisations where the data is collected and the professionals and clinical audit staff who work there.

3.2 Data quality and responsibilities: Overview

National audit providers have a responsibility to support this process by giving clear guidance on data definitions and data quality standards, and then putting various strategies in place, such as data import checks and comparative analyses, to help detect potential data errors. Ensuring that all relevant cases are included in the audit is important, and while this is a local responsibility, various checks can be made by audit providers such as comparing data submitted to the national audit with data from other sources. Those audit providers who are well established and have regional networks could utilize such networks to encourage regional validation exercises to promote complete data acquisition.

It is recognised that securing positive engagement from providers is challenging, particularly when moving national audit from enthusiastic early adopters to the wider clinical community. There will inevitably be some missing data returned by healthcare providers and national audits must develop strategies for managing this. We recommend approaches that demonstrate benefits for provider participation e.g. data can be used by Trusts in their commissioning process, by departments in quality assuring their services and individuals in appraisal and revalidation. It would be unrealistic to expect that a new audit could start at 100% data completion/ascertainment but it should be able to quickly establish case ascertainment of around 70%. This could then be expected to rise in increments to near 100%. When deciding to publish at lower initial ascertainment/completion rates this should be done alongside emphasised caveats that explain the results are from a select group of hospitals and/or clinicians and that such analyses are preliminary and in anticipation of wider participation.

At a mature stage, national audit providers should regularly feedback on data completeness/ascertainment to submitting hospitals and should openly name providers who do not submit any data or who do not reach standards that are set by the audit. It may be useful to develop either a composite data quality score or a dashboard of data quality to stimulate improvement and provide assurance. Audits should consider self-assessment processes for units to enable them to compare their processes against set standards. Audit process/quality visits should be considered based on the type of audit and the required resource.

Trust clinical leads need to be involved in these processes so that they act as a catalyst in each unit by promoting compliance with these data requirements. Audits should consider producing examples of good practice so that departments not conversant with national audit are given tools and case studies of how to promote best practice in data collection. These audit leads should be encouraged to inform medical directors, Trust chief executives and Board members of the development of such new audits in their establishments so that Trust structures, such as risk registers, accommodate their presence.

Prior to publication, healthcare providers are expected to provide assurance to the NCAs that they have had an opportunity to validate their data and that they are not aware of any issues with data quality that should prevent that data from being published.

3.3 Data quality and responsibilities: National clinical audit providers

 a) NCA providers should have a robust governance structure that ensures the process of running and managing the audit is clear and transparent. There should be a properly



constituted management group with patient involvement and a designated clinical lead. Communication with the clinicians involved in the activity/procedure is paramount and the lead clinician should take charge of this communication process

- b) National audit providers must ensure that the data validation process is documented clearly, along with the rationale behind the methodology and timeframes allowed
- c) NCA providers should produce notes to accompany the results of any outcomes data and analysis that are distributed to Trusts for validation purposes. As well as supporting healthcare and audit staff to submit accurate data, it will reduce the amount of queries that have to be dealt with by the audit team. HQIP can assist with this if required
- d) NCA providers are responsible for assuring the quality of data. Data irregularities should be communicated before any analysis or findings are published and prior to being used for outlier processes. This assurance should be provided by NCAs implementing clear minimum data standards and communicating unexpected variation in data used to risk adjust analysis or calculate measures of quality
- e) Trusts/hospitals and consultants should be given the opportunity to check and add/amend data where necessary prior to publication
- f) HQIP legal advice confirms it is lawful to publish consultantlevel outcome information without consent as long as reasonable steps have been taken to ensure the data used in the analysis is robust. This requires appropriate data validation processes
- g) Validation timelines must be submitted to HQIP as soon as they are finalised. This is so that they can be included in a high level communication to Trusts, in addition to assisting HQIP in monitoring progress and assisting projects
- h) National audit providers must have a documented process for managing missed deadlines – this may include exclusion of the data from analysis, notification of regulators/ NHS England and publication of non-compliance with the national audit programme

i) Audits are required to carry legal liability for their activities and we would recommend they ensure that this cover includes the activities of committee members and others involved in the work of the audit to ensure that there is no questions regarding legal liability status

3.4 Data quality and responsibilities: Trusts and professionals

- a) While data quality is ultimately the responsibility of the NHS Trust, clinicians and all other relevant employees (for example, data entry clerks) are responsible for submitting accurate and complete data to NCAs
- b) NHS Trusts are responsible for ensuring that there is adequate resource in terms of software, hardware and human resource to support the audits and data validation processes
- c) All audits should consider having a named individual in each organisation responsible for the audit data to give ownership to the process and to act as a point of communication between the national audit provider and the Trust/professionals. GMC requirements for Good Medical Practice (GMP) support involvement in audit as part of continuous professional development. Participation in national roles at national audits should be recognised by Trusts as part of these activities. In light of this we would encourage Trusts to support clinicians undertaking this activity, particularly when considering professional leave requests and job planning
- d) Trusts should ensure that NCA data are embedded in their local governance and quality assurance processes, to help improve the quality of data and, ultimately, the quality of patient care
- e) It is the duty of individual clinicians and Trusts to respond appropriately to requests from NCAs to validate data, on the basis of supporting information provided, within given timeframes. These responsibilities are documented in the GMC GMP

3.5 Data definitions

All data items should have appropriate definitions in line with the NHS Data Dictionary. These must be clinically appropriate, in line with contemporary practice, and sufficiently objective so that they are robust to inter-observer variability. Clinical practice changes over time so all definitions should be reviewed periodically and changes made where necessary.

3.6 Guidance for use of data definitions

Audit providers need to communicate data definitions, and particularly any changes made, with hospitals, software providers and individuals who are collecting the data. The processes of managing dataset changes need careful project management. Alongside any data definitions, there also needs to be guidance on the implementation of the definitions. For example, a NCA should provide advice where a risk factor is subject to repeated measurements, possibly with differing measurement modalities. Any such guidance needs to be regularly reviewed and responsive to new issues that arise within the audit.

3.7 Case ascertainment

National audit providers should issue guidance for local validation of case ascertainment (for example comparison of NCA data with other local IT or clinical data such as PAS, theatre logs or logs of implanted devices).

NCA providers should develop centralised methods for looking at case ascertainment. For example:

- Comparison with historical data looking for significant change on an annual, quarterly or monthly basis
- Comparing with other alternative data sources such as Hospital Episode Statistics (HES) data (but it should be noted that neither NCA nor HES can be regarded as 'gold standard' in this regard). However, by the triangulation of data sources, the robustness is greatly increased

3.8 Missing data

It is common for any dataset to contain patient records that are missing values in various data items. In any audit analysis, these missing data can affect the analysis in various ways and may correspond to missing:

- Outcome data
- Healthcare provider (ID) data
- Data on variables used to stratify patients or risk adjust outcomes
- Administrative data e.g. treatment dates

Audits should set clear acceptable standards for data completeness, and they may include very important data fields (used for risk adjustment and COP outcome information) and less important fields (used for analyses not included in the COP). While audits should aim for and support providers to achieve 100% completion, priority should be given to data pertaining to mortality or characteristics feeding into risk adjustment algorithms. Data collection should be rationalised wherever possible to minimise the collection of data considered to be of low importance. All these factors should be considered by the steering committee when setting its data quality thresholds with consideration given to how providers may be supported to meet them.

It should be emphasised that the most important approach to missing data is to work with healthcare providers to make it as complete as possible. In some circumstances, it is possible to add missing data values by data linkage with other definitive sources (for example 'backfilling' missing mortality data using ONS life status data). There are also techniques available to 'impute' missing data, where statistical modeling is used to 'fill in' data gaps rather than discarding those entries or assuming 'expected' values. Further, the dataset can have default settings so that if the data is not complete, the characteristics are assumed not to be present e.g. comorbidities of patients. Any such imputation methods that are used should be described in publications. Any imputation technique is not a substitute for ensuring complete data submission for any important fields (see also statistical guidance). But the choice of process and justification for this should be reported openly alongside the methods for data cleaning. It should be emphasised



again, however, that all audits should be aiming for their data completeness levels to be sufficiently high that the need for any form of imputation is minimised or unnecessary.

Engagement with providers that submit high levels of missing data can range from direct approaches to individuals or unit clinical directors. Where high levels of missing data are having a significant impact on the ability of an audit to calculate key fields and where direct approaches to units and individuals do not improve participation, direct approaches to Trust medical directors and external organisations (e.g. commissioners and regulators) should also be considered. HQIP also supports the publication of individuals or units that are not participating or have high volumes of missing data.

3.9 Data validity

Complete case ascertainment with full data still requires the data to be valid. Both the outcome data fields and those used for risk adjustment must be valid (i.e., free from systematic errors) otherwise analyses may produce confounding information.

Avoiding errors relating to the production of outcomes information is crucial as small errors in fields such as numerators or denominators can have profound implications. National audit providers should issue guidance to hospitals that includes:

- Advice on validating all outcomes in the national audit against the clinical record
- Central validation of submitted outcomes against an independent source i.e. correlating submitted mortality data against ONS mortality
- Feeding back adverse outcomes to the responsible consultant locally, in real time, for local validation
- National audit providers feeding back the results of national analysis to hospitals and responsible consultants to allow final validation prior to publication

It is also important that clinical audits review the data fields used for risk adjustment as inaccurate risk factor data can lead to misleading predictions of risk. This can have potential effects on the categorisation of risk adjusted outcomes of providers (e.g. false identification of outlier status). Data accuracy can be improved by ensuring that national audit is integrated into existing patient management processes (for example integrated care records, the WHO checklist or discharge summaries).

3.10 Import logic

Software used to collect data should have built-in logical checks to help ensure that data is valid. For example, this might include preventing the submission of records that include fields with impossible values such as a height of 176 metres. It may also be appropriate for the software to include internal logic checks that flags up records that include possible internal conflicts for further consideration.

3.11 Local validation

National audit providers should issue guidance on appropriate methods for local validation of risk factor data. This could typically include routine validation of a routine sample of case notes (such as 10%) by using an independent observer to resample the data and ensure the original data is robust. Simple local exercises such as a review of the theatre register (or mortuary log) against the records in the local audit database, with open reporting, can drive up compliance. HES data is good at recording events such as length of stay, transfer of care (marker of possible patient deterioration) and readmission, while death is well coded by ONS.

As more NCA data are taken from existing electronic patient record data used for patient management it is likely this will become less of an issue over time.

National audit software should facilitate data validation processes in the local hospitals. Ideally, this would enable clinicians to manage data at a patient level to resolve any issues that arise.

Adequate time for involvement in NCA data should be included in both consultant and other staff's job plans. Issues about compliance with NCA – including data submission, validation, outcomes and subsequent response to the data – should be included in the annual appraisal of consultants. Failure of engagement should feed into revalidation decisions.

3.12 National validation

National audit providers should develop a policy for looking for 'abnormal' data to feed back to units as a way of supporting local data validation processes. This may include looking for submitted incidence of risk factors with an incidence that falls statistically outside the national accepted level or evidence of internal inconsistency within the submitted dataset.

Hospitals should have the opportunity to respond and improve their data in response to analyses conducted nationally.

It is possible that data at a national level will have some degree of imprecision. This may involve the need for exercises such as synonym mapping or resolution of duplicate record submissions. Other examples include the need to map procedures into hospital 'spells' and subsequent allocation of the outcome of interest to the appropriate procedure. All processes for these data manipulations need to be clearly documented and freely available, and the outputs following manipulation must be returned to the submitting hospital for subsequent validation.

3.13 Conflict resolution

No matter how 'tight' the data definitions, clinical medicine is likely to throw up some questions about classification of procedures or recording of risk factors that are open to interpretation. All NCA providers should have a point of contact to help support decision-making in this event and a process for resolving potential conflicts that arise.



4 Trust data assurance and sign-off processes

4.1 Introduction

As outlined in Section 3 'Data Quality', the ultimate responsibility for the completeness and accuracy of audit data rests with the units within which the data is collected. National audit providers must implement a process by which the participating units provide assurance that they have had an opportunity to validate their data and that they are not aware of any issues that should prevent that data from being published.

4.2 Responsibilities for data assurance and sign off

To support healthcare providers in fulfilling their data assurance responsibilities, NCAs should implement a formal process by which participating units provide assurance to the national audit providers that they have had an opportunity to validate their data and that they are not aware of any issues from their perspective that should prevent that data from being published.

The medical director and local clinical audit lead need to be assured that all clinical teams performing procedures are submitting their data and that all their cases are being included. If any of the COP audits is included in Quality Accounts, there should be complete submission of cases. There will be other drivers such as the medical director, on behalf of the Board, insisting that all clinicians performing the index procedure submit data. The audits can communicate with medical directors when they know that there is a clinician not submitting data. Similarly on both the audit's website and on the NHS Choices/MyNHS site the relevant units and clinician can be flagged as non-participants. If the guidance in this document is followed, all data submitted to the national audit should enable outcome information to be produced for publication. HQIP recommends that each submitting organisation provide written assurance that their submitted data is fit for purpose prior to any publication.

HQIP recommends that this assurance should be given by answering the following statement:

"That the hospital has followed the guidance given by the NCA to ensure data quality and, where appropriate, confirming appropriate action has been taken in relation to key data quality issues that could significantly affect the data quality of the audit."

HQIP believes the responsibility for giving this assurance should sit with the Trust Board, although they will, of course, delegate this to an appropriate individual.

If an organisation cannot give this data quality assurance, this should be published openly alongside the NCA outputs. This information will be fed from the national audit provider, through HQIP.

Decisions regarding the publication, or non publication of results when data quality assurance hasn't been undertaken, will need to be considered on an audit-by-audit basis taking account of all the facts relating to that specific publication.

5 Analysis, reporting and transparency

5.1 Introduction

NCA providers will need to address a number of technical and presentational challenges when analysing their data and producing audit reports. The key challenges are risk adjustment, defining acceptable ranges and identifying statistical outliers. Management of any statistical outliers is covered separately in Section 6 'Management of outliers' including decisions related to publication of outliers. The related sections in this chapter cover the statistical approaches to determining and defining them.

5.2 Statistical outliers

Hospital or surgeon figures for surgical outcomes may be better or worse than expected. When the figures are outside the defined range of acceptable variation, these hospitals or surgeons are referred to, within national audit, as outliers. Outliers may be positive (better than expected) or negative (worse than expected). Any finding of outlier status does not, in the first instance, indicate a problem with the quality of care provided. It implies that the difference between the expected value and result for that unit or individual is unlikely to have arisen from random influences. It should, therefore, automatically trigger further analysis and investigation.

When comparing results for healthcare providers or individuals with the expected value, the choice of the expected standard and the range of variation that is acceptable are both critical. The expected standard may come from the data submitted to the audit or from external sources. The acceptable variation must have both statistical and clinical relevance. Some of the most important factors that determines expected clinical outcomes in many branches of medicine are the exact diagnosis, the nature of any intervention, and presence of any co-morbid diseases. These "case mix" factors can be adjusted for when the data are analysed, which enables the fair comparison of healthcare providers. The method used to adjust for case mix must be robust and should be described in any publication so that the process is transparent.

There may be residual variation in the outcomes of healthcare providers as a result of statistical dispersion alone, as discussed in more detail below. This may result in some healthcare providers falling outside the acceptable range, although the care they deliver is similar. This phenomenon is called over-dispersion, and it is possible to test and adjust for this with a variety of statistical techniques.

Classical statistical techniques set a probability that any deviation from expected has a defined level that the finding may be due to chance alone. When many comparisons are made at the same time this increases the possibility that abnormal findings may be due to chance alone. This should be considered by national audit providers, and appropriate adjustments or contextualizing analyses should be performed to allow appropriate interpretation of any abnormal finding.

When results are published for patients and the public, appropriate techniques should be used to display outcomes against the statistical certainty that those findings may not be real. This may include the use of a false discovery rate analysis. All methods for analysis of national audit should be published openly.

Please also refer to <u>Section 6</u> of this manual.



5.3 Defining 'outliers'

- A founding principle is that any identification of 'outlier' status indicates a statistically significant value and does not necessarily mean outlying performance by a consultant or organisation. Judgements on performance can only be made after a full examination of all the issues involved in the delivery of care, and this may be multi-factorial and complex. It will always be possible for a healthcare provider to be flagged as an outlier due to chance alone, and any abnormal findings may not represent poor care. Audits may choose to use the term statistical outlier to reflect this
- The definition of an outlier is based on setting a target (expected value) 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

Please also refer to <u>Section 6</u> of this manual.

5.4 Choice of target

As described in the Department of Health 2011 guidance, (revised by HQIP in 2016) targets can be external (not developed from the dataset under consideration) or internal (based on the data under consideration). External targets can be derived from published standards, historical data or clinical judgement. These issues are considered in more detail in the guidance.

It is essential that the value of the target for the COP programme is published alongside the results of the organisation. There are various options for this. The target value could be included in the text accompanying a table of results or as a column/row in the table. If results are shown graphically, the target can be given in the accompanying text or shown on the graph in an appropriate way (e.g. as a centre line in a caterpillar or funnel plot). The selected approach should minimise the risk of someone making judgements about performance simply because a provider has an indicator value above or below the target. When an external target is chosen, its appropriateness must be established specifically for the dataset used to derive the indicator values and reported to HQIP prior to its use, as external targets are prone to error for a number of different reasons, such as the incomparability of patient populations, or changes in outcomes over time.

5.5 Defining acceptable/non acceptable variation

The key to measuring outcomes that are meaningful is data that is both complete and accurate. This is true for reporting all indicators but becomes increasingly important for outcomes derived at the individual consultant-level, given the often small volume of cases involved and the potential consequences of incorrectly defining outlying or non-outlying status. This is considered in more detail above.

Greater levels of inaccurate data will increase the risk of an organisation and consultant being wrongly labelled as an outlier (false positive) or failing to be detected as an outlier (false negative). All publications of outcome information must be accompanied by information on data quality and with a commentary on how this may affect the results of the analyses.

All outcome estimates derived from patient data will have a degree of statistical uncertainty. The amount of uncertainty will be linked to the number of patients available for analysis. Estimated values of an outcome indicator for consultants should be presented with an indication of its statistical precision.

We recommend that definition of outliers is based on a twosided statistical approach (two and three standard deviations or equivalent) with threshold p values of 0.05 for alert and 0.002 for alarm. Any deviation from this guidance should be justified and openly published. Particularly in relation to public identification of outliers, the final choice needs to take into account the risk and implications of a false positive/ negative result. Consideration to public identification of alert level outliers is considered in the next chapter on management of outliers.

5.6 Adjustment for risk

Where the outcomes of any analysis are affected by patient case mix (e.g. the co-morbidities of the patients), the indicator values of organisations or consultants should be adjusted to take account of differences in the groups of patients that they have treated. The process of risk adjustment can be complex and all analyses should be designed and conducted by people with the appropriate level of statistical expertise. All methods for case mix adjustment should be published openly and be accessible from the main COP. Models should be chosen on the basis of their discrimination (the ability to correctly classify those across the full spectrum of risk) and calibration (the ability to accurately predict the risk of the specific outcome under scrutiny).

If a clinical audit chooses to use an existing risk adjustment model, it should check whether or not the model requires updating, because of calibration drift, i.e. calibration drift is an effect produced by the improvement in clinical practice over time, leading to older models over-predicting the expected mortality for contemporary practice. If the model is found to require modification, there are a number of different options for updating it, and it is not possible to be prescriptive about the most appropriate method. Nonetheless, all clinical audits should describe their processes with sufficient clarity on publication to enable external scrutiny.

5.7 Multiple comparisons and over-dispersion

Some audits have made corrections for multiple comparisons (because of concern that the simultaneous multiple comparisons of a large number of providers at one time with a set standard are likely to detect a number of outliers due to chance alone). We do not recommend adjustment for multiple comparisons as routine. However, we do recommend the publication of the likely number of outliers who would be defined at the different thresholds based on the number of comparisons which are made, to enable the results of any analysis to be seen in context.

The distribution of indicator values is said to show overdispersion when there is greater variability than would be expected by chance, for example, when a high number of providers fall outside of the thresholds although we would expect to find only a few divergent healthcare providers. There are statistical techniques that can be used to test for, and methods for dealing with, over-dispersion (such as by adjusting the threshold limits). The need for an analysis to adjust for over-dispersion should be considered on a case-by-case basis with explicit justification given for their use.

5.8 Private practice

Where private practice data are collected, it is for individual audits to decide whether and how to include these data in analysis. Projects may wish to make a distinction between private practice carried out in NHS hospitals, and private practice carried out in private units, for example. HQIP is unable to provide additional funding specifically to support the publication of private practice carried out in private hospitals.

5.9 Minimum numbers for inclusion

NCAs should adhere to the <u>Office for National Statistics</u> <u>policy</u> for the publication of small numbers to protect patient confidentiality. In addition, audit teams may decide the most appropriate minimum number of episodes to render a consultant eligible for inclusion in COP in order to produce robust figures. This may be based on specialty guidance for small number operating, and/or statistical expertise.

5.10 New vs. low volume consultants

It is important for patients to be aware of how many procedures their consultant has carried out during the analysis period. This should include the analysis of established consultants who do low volumes of procedures where possible. It is important to enable the public to distinguish between a consultant who carries out a small number of procedures over time, and a consultant who has a small number of procedures due to having only been appointed recently. The methodology used to do so should be decided by the audit provider in collaboration with HQIP.



5.11 Multiple responsible consultants

Where it has been agreed with HQIP that more than one consultant is responsible for the care of a patient (e.g. where multiple procedures by different consultants during one operation), the GMC codes of all consultants should be collected, and the procedure and outcomes should be allocated to all relevant consultants. This methodology must be clearly explained, as it will differ from other NCAs, and result in the number of procedures performed by all consultants adding up to more than the total number for the hospital.

5.12 Presentation of results

It is crucial the results of analyses are presented in a format that is easy for patients and the public to use and understand. Naturally, these must also remain accurate and be fair to healthcare providers, both hospital and individual doctors.

The COP style guide – <u>www.hqip.org.uk/resources/clinical-</u> <u>outcomes-publication-style-guide/</u> should be referred to in creating results for presentation. It includes specific guidance and support on all aspects of publication including language, accessibility and design and has many best practice examples to support you. For reference, a section of the style guide can be found in <u>Appendix B</u> of this guide.

Further guidance and support is available via HQIP's 'Reporting for impact' resource, which also includes elements on communications and media planning as well as design and style advice: <u>http://www.hqip.org.uk/resources/</u> reporting-for-impact/

5.13 Reporting of methodology

HQIP recommends that all audits describe their methods using the framework defined in the STROBE statement for reporting observational studies. Appendix C provides an example checklist of items that should be included.

6 Management of outliers

6.1 Introduction

NCA and the COP programme will inevitably identify organisations and individuals with values for outcomes measures that are higher or lower than expected due to chance alone. The COP has placed increased emphasis on the processes used by NCAs to identify and manage providers with outcomes data that falls outside of the expected range. There are many reasons why a unit or individual might be a positive or negative outlier, including operating on higher or lower risk patients, limited risk adjustment algorithms or individual and team performance issues. It may also be a result of chance alone. There is a need for increased consistency of approach across all NCAs that collect data on the quality of clinical care, irrespective of their level of maturity or technical infrastructure.

The finding of a negative outlier may indicate performance issues that may need to be addressed. A positive outlier may display excellent practice that would be beneficial to describe in detail and disseminate to other healthcare providers. Neither category of outlier is definitive however, but should lead to further investigations, or scrutiny of previous investigations. This is to either ensure that the quality of care is satisfactory or identify issues for improvement or even identify what has led to excellence. As such, NCAs may choose to describe outliers as statistical outliers in order to make clear that this status is not definitive.

There is existing guidance on management of outliers at organisational level, which was produced by HQIP and DH in 2011. An updated version is due for publication in 2016. This manual will be compatible with that guidance but builds on pathways and responsibilities for managing individual outliers.

In Section 5, 'Analysis, reporting and transparency', categorisation of outliers as 'alerts' and 'alarms' is described and reiterated below. 'Alerts' will happen more frequently than 'alarms' and have a greater possibility of occurring due to chance alone. Any such finding should come as no surprise to the provider and there should be mechanisms in place within the organisation, supported by the NCA, to respond to these alerts appropriately. Monitoring outcomes locally, ideally in real time, should support prompt and efficient responses. Indeed, such monitoring should flag up deviation from the norm at an early point, prior to any confidence limit being breached. Any necessary remedial action in the unit or with the individual can then take place promptly so that practice is adjusted. This should bring the results back in line, avoiding risks to patients and avoiding units flagging as negative outliers as they move further outside of confidence intervals.

Any finding of alarm has a small possibility of being due to chance alone and suggests a variation from expected which is quite significant. Providers need to demonstrate that they have taken appropriate steps to investigate and respond appropriately and proportionally.

Consistently applied national guidance on the management of outliers is needed to ensure the quality of patient outcomes, as well as:

- Maintenance of both public and medical professional trust in COP
- Data accuracy
- Clinical understanding of variation (e.g. case mix)
- Reflective practice and professional development
- Ensuring the quality of the appraisal and revalidation processes

There will be instances of differences in opinion between NCAs, and the medical specialties they represent in relation to determining outliers. As such, HQIP aims to identify common principles that are needed, not prescribe identical methodologies.

Individual clinicians, audit departments, clinical leads, medical directors, HR, the Trust Board, national audit providers, clinical societies, HQIP, the GMC and CQC all have roles in the management of outliers.

Please also refer to <u>Sections 5.2</u> and <u>5.3</u>, covering outlier analysis.



6.2 Existing guidance

Several organisations have produced national guidance on the management of high mortality/complication rates, but these do not meet all the needs of COP. We hope that this document will complement such guidance so that a more uniform approach is developed across all of our specialties.

6.3 Publication and timing of investigation

The guidance in this document describes identification of outliers from the perspective of the audit, organisations and individual clinicians. In addition, the identification of outliers for the public should also be considered (for example through the NHS Choices website or through an audit provider's website).

HQIP recognises that for patients and the public, any effort to provide assurance and explanation regarding the aforementioned distinctions between the meaningfulness of alerts and alarms may fall short of adequate. This requires audits to be cautious when proceeding on the basis that they can secure public understanding of the difference of reliability at alert and alarm level. As such, we advise NCAs to give consideration to determining whether alert level outliers will also be publicised as part of the audit findings. Publication of alert level outliers is not routine at present and is not a HQIP expectation.

As detailed in Section 5, 'Analysis, reporting and transparency', alerts are much more likely to be a result of statistical chance. The extent to which this is the case will be different for each round of audit analysis. Where the false positive rate is high, greater consideration should be given to non publication of alerts.

Decisions on the level of statistical variation from expected that is appropriate for publication will need to be decided on a caseby-case basis. It will depend on the number of comparison and the false positive detection rate. HQIP is happy to give further advice on this issue as necessary. Where a decision is taken not to publish at alert level, the rationale for this decision should be published alongside the audit results.

Comparative outcomes should only be published at the end of the audit data validation and analysis process. This can lead to providers being flagged as an outlier, which may or may not reflect clinical performance, be it positive or negative. It is a matter for local investigation and further diagnostics, should there be concern or a desire to celebrate excellence. As such, the identification of outliers should neither act as a barrier to publication pending investigation or as a reason to delay investigation before publication. Best practice would be information about initial investigative steps to be made available alongside publication in keeping with the timescales identified below.

6.4 Right to respond

Any individual or unit identified as a negative outlier should have the opportunity to produce a response (on the professional society or Trust website) to go alongside their published results.

In certain exceptional circumstances, individuals or organisations may raise significant concerns regarding the validity of the data related to their clinical activity. While there is an expectation of publications describing the analytical steps to assure data quality has been taken, where such concerns are raised, the national audit team should discuss with HQIP action that may need to be taken ahead of publication.

Audits should involve professional leadership early on when encountering difficulties in determining the suitability of publication. However this involvement would be part of the input that will be provided by the clinical leadership of the audit.

6.5 Outliers: Roles and responsibilities

Clinical audit and quality improvement within Trusts is a shared responsibility of many colleagues, including data clerks, IT departments, individual clinicians, the medical director and the Board.

Much of the day-to-day activity relating to NCAs is conducted locally in hospital departments and by individual employees, with support provided by the Trust.

It is the responsibility of the Trust Board, through the chief executive and medical director, to assure that this activity is taking place and leading to quality improvement and reassurance.

Trust senior management will not be closely involved in the process of collecting data and working with resulting analysis unless issues arise. Their involvement is likely to occur when problems with data collection and validation issues are identified or when investigations into results of clinical audit are required. Organisational buy-in is essential to resolve these problems when they arise, but some issues can be effectively dealt with at department level – on occasion it may be Trust-level resource and infrastructure that leads to outlying data, not the performance of individual clinicians.

All national audits that supply information into the COP, should aim to run as real time audits in their clinical departments. By doing this any unit or individual whose outcomes data strays close to unacceptable confidence limits will be identified at an early stage. This will enable prompt identification of any underlying adverse outcomes enabling the unit or individual to work within the department and Trust to rectify the situation. In turn this means that the likelihood that patients will experience poor care will be minimised. In addition the individual, department and Trust can be assured that all patients are receiving good care.

When there is an individual outlier we would expect that the audit provider clinical lead communicates with the clinician and the department clinical lead by phone. This is followed up with a letter to the medical director and chief executive, copied to the department clinical lead and the clinician. This letter will set out the concerns and inform the medical director and chief executive of their responsibilities to investigate including informing the GMC Employment Liaison Adviser (ELA) if outlier status at alarm level is confirmed.

A medical director (and/or Responsible Officer {RO}), when faced with information suggesting that one of his/her consultants is an outlier, would need to discuss the situation with the consultant and clinical lead for the department (who should already be aware of the situation). In relation to a negative outlier at an alarm level, prior to initiating exclusion or investigative actions, the medical director should seek help and advice from the Royal College, professional society, audit clinical lead or the HQIP medical director. HR input may be appropriate. There will be occasions when the medical director is concerned that patient safety will be compromised and, under Maintaining High Professional Standards, might wish to exclude or restrict an individual pending an investigation. The medical director/RO should also notify the GMC Employment Liaison Adviser (ELA) of alarm level outliers (see Section 5.5). The clinical audit lead for the relevant audit should be available for discussion with the medical director so that such issues could be rehearsed and unnecessary exclusions avoided.

Issuing guidance that is specific to every scenario is challenging; but any analysis that suggests mortality or complication rates are higher than expected should trigger appropriate discussion and action within the organisation concerned. The Trust Board must be reassured at all times that their services are safe and effective.

We would emphasise that medical practice should not be restricted or suspended, unless indicated as necessary by other factors, while the above processes are being followed.

In all situations when the clinical lead for the audit is not reassured that appropriate action is being taken and the regulators informed, they should inform the relevant regulator as appropriate in consultation with the medical director of HQIP.



6.6 The role of the regulator and HQIP

The Care Quality Commission (CQC) has a responsibility for organisational regulation of the quality of care, the General Medical Council (GMC) has a responsibility for regulating individual clinicians, and HQIP has a responsibility for managing the COP process. It is possible that the COP process will bring to light possible performance concerns that will need to be flagged up to the appropriate regulator.

This is a complex issue. It is important that processes ensure the quality of care but do not inappropriately affect organisations, individuals or the NCA programme. As mentioned there is separate guidance on the role of HQIP and regulators at team level. This guidance is therefore more specific to the involvement of HQIP and regulators in relation to individuals.

As mentioned, RO/medical directors should routinely be discussing 'alarm' level concerns with their Employment Liaison Advisor (ELA) and what local steps are being taken to address them. ELAs routinely meet with the RO/medical directors of healthcare providers throughout the UK to offer advice and support on the management of concerns including encouraging robust local clinical governance and GMC thresholds.

If there is no reassurance from the Trust to the audit provider clinical lead that such communication has taken place or if there is a refusal to communicate this may raise concerns in relation to wider governance issues at the Trust and as such we would expect the clinical lead of the audit to advise the CQC in addition to the GMC ELA in consultation with HQIP medical director.

HQIPs role will primarily be to advise and support the audit in decision making in this area. However, HQIP reserve the right to contact the Trust and CQC and/or the GMC if satisfactory action has not been taken.

6.7 Outlier management checklist

Below we have created a checklist for individual outlier management.

As described above and considered in more detail in Section 5: 'Analysis, reporting and transparency' HQIP recommends that definition of outliers is based on a two-sided statistical approach with threshold p values of 0.05 for 'alert' and 0.002 for 'alarm'. Please note this checklist recommends different actions depending on the categorisation.

Data alert and alarms action summary checklist

Stage	Action Required	Who?	Timing	Completed
1	When an individual flags up with one or more of their performance indicators as a statistical outlier (positive or negative) at an 'alert' or 'alarm' level, these should lead the NCA provider to carefully scrutinise the data (to ensure the validity of the statistical results, taking into account statistical threshold levels, data accuracy and risk adjustment). Where potential statistical outlier status is not confirmed data and results should be revised in NCA records and the details formally recorded. When, after further scrutiny, potential outlier status persists proceed to stage 2.	NCA provider	Within 10 working days	
2	The lead clinician in the Trust for that department and the individual involved should be informed by phone about the potential statistical outlier status and requested to confirm, again, that the data submitted was complete, accurate and validated. They are asked to identify any data errors or justifiable explanations for a negative outlier and reasons why the results might be better than average for a positive outlier. All relevant data and analyses should be made available to the lead clinician and individual. A follow up letter of the request should be sent to the medical director and chief executive of the provider organisation, copied to the department clinical lead, clinician, setting out concerns.	NCA provider lead*	Within five working days	
3	The department lead clinician, in conjunction with the individual clinician, should provide a written response to the NCA provider clinical lead with a copy to the Trust medical director and chief executive.	Provider lead clinician	Within 25 working days	



4	Review of lead clinician's response to determine:	NCA provider	Within 30 working days	
	'Following review, no remaining concerns'		wonking days	
	 It is confirmed that the data originally supplied by the provider contained inaccuracies. Reanalysis of accurate data no longer indicate statistical outlier status 			
	 Data and results should be revised in NCA records. Details of the provider's response and the review result recorded 			
	Lead clinician and medical director notified in writing			
	 Request from the NCA provider lead to Trust lead clinician as to why the original data was inaccurate and what had been put in place to prevent a re-occurrence 			
	'Following review, concerns remain'			
	 It is confirmed that although the data originally supplied by the provider was inaccurate, analysis still indicates statistical outlier status; or 			
	 It is confirmed that the originally supplied data was accurate, thus confirming the initial designation of potential outlier status 			
	Proceed to stage 5			
5	Contact lead clinician and individual by telephone, prior to written confirmation of potential outlier status, addressed to the chief executive and medical director, copied to the Trust lead clinician and individual clinician. In the case of a negative outlier, all relevant data and statistical analysis, including previous response from the lead clinician, made available to the medical director and chief executive. In the case of a positive outlier, discussion as to possible explanations and whether there are any aspects of individual or local practice that might be shared and/or celebrated. Alert: In the case of an 'alert', we would expect that the medical director and departmental clinical lead would initiate a local review and might wish to triangulate this information with other governance information to see if any further action is required.	NCA provider lead	Within five working days	
	Alarm:			
	In addition to the instructions related to the 'alert' the medical director/chief executive should be advised, to inform the GMC Employment Liaison Adviser (ELA).			
	Informed that the NCA supplier will proceed to publishing information of comparative performance that will identify individuals and providers including outliers.			
6	Acknowledgement of receipt of the letter, and, in the case of a requirement to inform the ELA, confirmation that this has taken place.	Provider medical director/chief executive	Within 10 working days	

7	Public disclosure of comparative information that identifies outlier status.	NCA provider lead	Timetable determined by NCAPT but not to be delayed by a failure of a provider organisation to comply with timescales of the outlined process	
8	If non compliance with point 6, reminder letter to be sent to chief executive/medical director.	NCA provider lead	Within five working days of Stage 6 deadline expiry	
9	Failure of the chief executive/medical director to comply with point 6 would lead the NCA provider lead to disclose non compliance to the GMC and CQC in consultation with HQIP medical director.	NCA provider lead in conjunction with HQIP medical director	Within five working days	



7 Assessment criteria

7.1 Introduction

HQIP's five-year plan for COP, <u>'The Clinical Outcomes</u> <u>Publication Project Briefing 2016-20</u>' (2016) describes in more detail the strategic ambition and expected direction of progress for COP going forward.

A key development will be to make the process for widening the scope of the COP programme more transparent and provide opportunities for NCAs to identify development needs that will enable them to reach a threshold for publication.

Going forward, the following assessment criteria will be used as the first step in HQIP and NCAs identifying their suitability for publication as part of the COP programme.

The purpose of COP is to stimulate quality improvement through the publication of unit and consultant-level outcomes. In line with the NHS England document '*MyNHS* – *greater* transparency for better health and care. MyNHS planning 2015-2017'. The five-year plan is to expand COP up to 2020 to include new specialties as well as new patient-useful metrics and new unit and consultant-level data. Currently, there is no guidance as to the criteria for assessing NCAs to be considered for inclusion in the COP programme. The COP assessment criteria (7.2, below) is to be used to inform NCAs of the criteria on which they can be assessed for inclusion into COP during the next five years, including improvement plan development to ensure NCAs are 'COP-ready'. Performance against these criteria will be one of a number of factors considered when making decisions regarding admission including capacity and the overall clinical diversity of the programme.

7.2 COP assessment criteria

For consideration into the COP programme each of the criteria in the table should be met. For those criteria that are partially met, an assessment of the development needs required to meet the inclusion criteria will be required.

No	COP assessment criteria	Justification/rationale for inclusion				
Audit	Audit management criteria					
1	Clinical leadership to include integration or formal involvement of the relevant specialist association(s)	The purpose of COP is to stimulate quality improvement which is the responsibility of the clinical leadership of each audit. Clinical leadership is also required for the defining of other entry criteria, for the appropriate interpretation of results and for the detection and management of outliers (COP manual)				
2	Appropriate infra-structure to ensure delivery of COP (for example, project management/administrative support)	To ensure likelihood of being able to meet workload and complexity requirements generated by other criteria				
3	An intent to operate as a long-term and established project with prospects for development	NHS England's commitment is to expand COP up to 2020. Snapshot audits would not meet the requirements for supporting continuous improvement				
Meth	odological criteria					
4	Collect data on at least one area of care that is considered appropriate for the speciality by relevant stakeholders	Audits should provide data relating to areas of care generally considered of clinical significance in terms of providing or being considered to impact on outcomes				
5	Allocate each patient/procedural record reliably to a team and individual responsible consultant . Consultant identifiers must have the ability to be linked to both name and GMC code	'Reliable' attribution of consultant to record relies upon consultant identifiers being validated at local level. The number of records not attributed to a consultant must be reported alongside any analysis				
6	Report on at least one patient-meaningful outcome measure in year 1 of publication, with additional patient-meaningful measures to be reported on in subsequent years	NHSE five-year plan is also to include more patient-meaningful outcome measures				
7	Have a high level (as defined by the professional society) of participation/compliance, (including case ascertainment)	COP manual: participation/compliance defined as submitting the required number or proportion of relevant records within the data collection timeframes Professional society: Define what is considered appropriate for the speciality, verified by HQIP				
8	Collect data to a specified minimum data quality standard (accuracy and completeness)	Included in COP manual. Level defined by clinical leadership and verified by HQIP				
9	Have a robust data validation methodology, including a) risk and outcome variables, b) Trust-level sign off of data submission to COP	HQIP producing guidance document for 2016				
10	Have a published risk adjustment methodology, where appropriate, based upon a contemporary cohort of patients, no more than two years in retrospect	Included in COP manual. HQIP producing guidance document for 2016				
11	Have a robust methodology for the identification and publication of negative and positive outliers	Detailed guidance available in COP manual with suggested boundaries and analysis				



8. Legal framework and indemnity

8.1 Legal framework

Consent

For the publication of consultant-level data, consent is not required for reporting individual clinician's results provided that all reasonable steps are taken to:

- Communicate to eligible consultants that their data are to be published
- Ensure published data are adequate and accurate
- Ensure that support and improvement mechanisms are in place for statistical outliers
- Demonstrate that COP is necessary to achieve legitimate aims (e.g. to improve the quality of care)

The above statement cannot be taken as legal advice by a third party. For more information, please contact HQIP.

Legal counsel

HQIP received independent legal counsel on 30 January 2014 relating to the lawfulness of reporting of individual medical practitioners' results.

Electronic copies of this legal counsel have been distributed to COP NCA project teams. The counsel cannot be taken as legal advice by a third party.

The conclusion of the legal counsel was:

"...my view is that on balance...publication of this data would be lawful in the circumstances." – Robin Hopkins

Important caveats were that **all reasonable steps should be taken to ensure data are adequate and accurate** by allowing and documenting reasonable time periods for data to be checked and corrected if necessary prior to publication **and support and improvement mechanisms should be in place for statistical outliers.** These should be outlined in audit provider outlier policies, in line with national guidance.

HQIP would advise audits to first identify measures they could take to improve their assurance (e.g. if long history of legacy data with low reliability for older data, reduce the time period of the audit).

8.2 Indemnity

NCAs that are part of the National Clinical Audit Patient Outcomes Programme (NCAPOP) are required by a clause in their headline contract with HQIP to obtain a) professional indemnity and b) public liability insurance cover for a minimum for £5 million each for both a) and b).

Non NCAPOP audits that are managed by specialist associations should also be protected by professional and public liability insurance to cover the inherent risks of managing a NCA.

Should there be a requirement for additional insurance cover, **specifically** relating to the publication of individual consultants' results, this may be considered as part of any application for funding from HQIP. NCAs should discuss the COP process with their insurer to obtain a quote for any additional cover.

Appendix A: Stakeholders

Multiple stakeholder groups are integral to the COP and NCA initiative. These, and their primary reason for involvement, are outlined below.

Patients and the public	The target audience of COP, for; 1. Information/education 2. Reassurance 3. Informed decision-making
Unit and consultants	 Submit and validate all eligible data to COP NCAs Use the results along with their team's for reflective practice and quality improvement
	 Use the audit as a real-time tool so that poor results are noted early and appropriate action taken prior to reaching outlier status, and maintaining patient safety
Trusts	1. Verify and facilitate consultant and hospital-level engagement with NCA; including providing resource for data validation
	2. Respond to audit provider requests to check data accuracy and notifications of outlying data
	3. Provide a positive assurance that the data submitted is valid
	4. Work with clinicians and audit providers to use audit data 'real-time' for quality improvement
	5. Promote the value of clinical audit across all work streams, not just those involved in COP
	 Seek help and advice prior to initiating exclusion or investigative actions when an institutional or individual outlier is identified
Audit providers	1. Provide the informatics and project management infrastructure for the audits
	2. Work in collaboration with key stakeholders to publish meaningful quality measures that will improve care
	a. Feed back data quality issues to individuals and Trusts
	b. Define and flag outlying data to Trusts
	3. Work with trainee organisations to incorporate trainee experience (i.e. number of cases done under specific consultants' supervision) into the COP data
Specialist	1. Provide the clinical leadership for audits
associations	 Working in collaboration with audit providers to develop and publish meaningful quality measures that will improve care and identify outlying data, including discussions with individuals and Trusts
	3. Communicate with the membership to disseminate best practice
	4. Provide inquiry support to membership and Trusts
	5. When required contact Trust medical directors/chief executives informing them if one of their consultants has triggered an "alarm". Inform them that there are support services available and that it is their responsibility to discuss the matter with the GMC Employment Liaison Officer and to confirm this back to the clinical lead of the audit



Royal colleges	1. To contribute to improvement and change in practices based on results of audit reports
	2. Communications and membership support
	 Contribution to Trust inquiries and reviews (in particular using processes such as the Royal College of Surgeons Invited Review Mechanism)
	4. Give leadership and work with other stakeholders to develop the COP programme
	5. Advise NHS England on further audits for inclusion in COP
	6. The investigation of potential outliers, be it at institutional or consultant level, when validated should be investigated appropriately. The societies and colleges may wish to develop groups who could perform robust investigation of such concerns so that appropriate actions could be implemented as quickly as possible
HQIP	1. Manage COP
	2. Ensure consistency of approach across the audits
	3. Act as a central repository for outlying data notifications and reports
	4. Function as a gateway with regulators
	5. Function as the link between the audit providers and choices
	 Provide support to specialty associations, colleges and Trusts in the interpretation and management of this process
NHS England	1. Fund and define the scope of publication
	2. Engage HQIP, escalating issues as necessary
	3. Briefing the Secretary of State for Health
CQC	Appropriate regulatory action taken regarding outlying data
GMC	Seek assurance from responsible officers that there is appropriate interaction between NCA analyses and revalidation recommendations
NHS Choices	Work in partnership with audit suppliers and specialist associations, through HQIP, to make available simple and consistently presented consultant outcomes on its high-volume patient focussed website

Appendix B: Presentation of results

It is important that the results of analyses are presented in a form that is easy for a patient and the public to understand, but is fair to healthcare providers, both hospital and individual doctors. The following is some general advice on format:

- **Keep it simple:** Avoid 'flashy' and busy displays, as this can be confusing and make it hard for people to find the information they need. It also means that internet pages can take a long time to load and are more likely to produce error messages
- Font: Use at least size 12 in an easy-to-read font such as Arial or Calibri. See the Royal National Institute of Blind People (RNIB) guidance on clear print for more information
- Line spacing: Make sure text has enough space between the lines so that it is easy to read. This is referred to as 'leading' or 'line-spacing' depending on the programme you use
- **Paragraphs:** Avoid long paragraphs and break up text with headings where possible, so that people can skip to the sections that interest them
- **Pictures:** Can speak a thousand words. Make sure the images used are high enough quality resolution. For documents that may be printed (e.g. PDF reports) make sure they are in 300dpi at the size you want to print it and in CMYK colour format (unless for use in Word which only accepts RGB). For example, an image that is to be 10cm in print needs to be 300dpi at 10cm or higher, if it was 300dpi at 2cm it would not be good enough quality. For websites, images can be of a lower resolution (72dpi)
- Colours: Make sure your colour palette choices are complementary and give adequate contrast so that different sections and points on graphs can be distinguished (even if printed in black and white). Colours should be in CMYK for PDF reports and RGB for websites
- Feedback: As well as getting input from patient representatives, give the public a way of feeding back about reports/websites so that ongoing improvements are enabled. Something as simple as providing a telephone number, email and postal address works well. If referencing an email on a website, ensure the email is a 'clickable' link where possible

- Website URLs: If referencing another website or web page, make sure that it is hyperlinked to 'open in new window/tab' so that people can go directly to the content without automatically moving away from your site. If making a PDF make sure the full website address is included in bold so that people who have printed it out can tell that it is a web address
- **Take professional advice:** If budget permits, a professionally designed report or website will mean that content is shown in the best possible way

Designing charts

Due to differences between medical specialties, data, and analysis methodologies involved in COP, it may not be appropriate for all of the detailed information hosted on specialist association/audit provider websites to be presented in the same way. To make sure that patients have a place where they can view all results in a uniform way, we are asking all audits to submit their COP information to NHS Choices as well as hosting it on their own websites.

HQIP has collected feedback on the graphical and tabular presentations of data from 2013 from the general public, the HQIP Service User Network (SUN), audit providers and specialist associations. Best practice examples of those chart types that have been approved by the HQIP Service User Network (SUN) are shown on the following pages. If you wish to use a chart type not included in the best practice examples, please discuss this with HQIP and your patient representative(s).

















- Make sure patients can tell what the graph shows, and doesn't show
- Keep it simple!
- Use familiar graph types (that people will have used in school) where possible
- Choose a chart type that doesn't need a lengthy explanation (it's hard to make these patient friendly, and not everyone will read them)
- Use bold, bright colours. Reports and web pages may be printed in black and white, so a black and white 'test print' should be carried out to make sure that different parts of each chart are still clear
- Use colours consistently; if a particular procedure is represented by a green bar in one chart, make sure it is colour coded green in all other charts
- O Use bold, clear lines
- Give your chart a descriptive title, so that your audience can tell if it is of interest to them and have an idea of what it should tell them
- O Clearly label different parts of the chart

- Ensure that all text on graphs (including labels) is in font size 12 or larger when the graph is viewed at 100% (if being viewed electronically)
- Clearly show the date range that you are looking at
- Use high resolution images (300 dpi or higher, at the size it is to be)
- Avoid abbreviations, acronyms and technical terms
- Where you need to use abbreviations, acronyms or technical terms, explain them alongside the graph where possible (possibly using 'pop' ups when a term is hovered over)
- Provide a tabular version of the results along with the chart if possible
- Design professionals may be able to assist data analysts to export data to an acceptable design format
- If possible, make a video presentation/ YouTube clip available to explain how to understand the graphs



Appendix C: STROBE Statement

STROBE Statement-checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	a. Indicate the study's design with a commonly used term in the title or the abstractb. Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any pre-specified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	 a. Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants b. Cohort study—For matched studies, give matching criteria and number of exposed and unexposed Case-control study—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why

Statistical methods	12	a. Describe all statistical methods, including those used to control for confounding
		b. Describe any methods used to examine subgroups and interactions
		c. Explain how missing data were addressed
		d. Cohort study—If applicable, explain how loss to follow-up was addressed
		Case-control study—If applicable, explain how matching of cases and controls was addressed
		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy
		e. Describe any sensitivity analyses
Results		
Participants	13*	 Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		b. Give reasons for non-participation at each stage
		c. Consider use of a flow diagram
Descriptive data	14*	a. Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders
		b. Indicate number of participants with missing data for each variable of interest
		c. Cohort study—Summarise follow-up time (e.g., average and total amount)
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures
		of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	a. Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		b. Report category boundaries when continuous variables were categorized
		c. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses



Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the websites of PLoS Medicine at http://ournals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.oo40296, Annals of Internal Medicine at http://annals.org/article.aspx?articleid=737187&resultClick=3, and Epidemiology at http://journals.lww.com/epidem/fulltext/2007/1000/The_Strengthening_the_Reporting_of_Observational.27.aspx. Information on the STROBE Initiative is available at http://www.strobe-statement.org



HQIP Healthcare Quality Improvement Partnership



Further information is available at: www.hqip.org.uk ISBN NO 978-1-907561-14-6

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