Appendix 10: HQIP outlier guidance

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Appendix 10a: Identification and management of outliers (English data)

10.1 Introduction

Appendix 10a pertains to guidance for English data and this updates the English 2017 guidance and 2018 implementation guide (which were based on the original 2011 Department of Health guidance). Guidance for Welsh data can be found in ***Appendix 10b***.

Outlier analyses have traditionally been considered primarily a quality assurance activity. The effective operation of an outlier policy also provides opportunities for national clinical audits to support quality improvement. Whilst other less restrictive approaches to differentiating healthcare providers (e.g. quartile ranges) provide a wider scope for supporting quality improvement, outlier based approaches still make an important contribution. Healthcare providers need to demonstrate that they have taken steps to investigate and respond appropriately and proportionately to outliers.

10.2 Outlier identification and management

These recommendations are based on original advice provided by an expert group of statisticians (Appendix 10c). Statistical analyses to identify outliers should be carried out by staff with appropriate statistical expertise and experience.

10.2.1 Choice of performance indicator

Performance indicators must provide a *valid* measure of a healthcare provider's quality of care in that there is a clear relationship between the indicator and quality of care, they must relate to frequently occurring events to provide sufficient statistical power, and should relate to an important quality marker in the domain under review. Traditionally great attention has been placed on mortality as the key indicator and this advice works best when applied to mortality. However, there are many additional metrics and all the national audit reports and the National Clinical Audit Benchmarking (NCAB) initiative, pioneered by HQIP, abound with additional metrics. Further, in both the annual reports and in NCAB slides, statistical techniques have been applied. We are keen that the outlier methodology is applied to these additional metrics and we suggest, to clinicians and audit providers, that they start to consider what additional metrics it would be appropriate to apply this methodology to. As we take this forward, it is our intention to work with clinicians and audit providers to apply these outlier techniques much more widely.

10.2.2 Choice of target (expected performance)

The choice of target (expected performance) may be based either on external sources (research evidence, clinical judgment, audit data from elsewhere) or on internal sources (such as average performance of all healthcare providers).

10.2.3 Data quality

Three aspects of data quality must be considered and reported:

- **Case ascertainment**: number of patients included compared to number eligible, derived from external data sources; impacts on the generalisability (representativeness) of the results
- **Data completeness**: in particular, performance indicator data and data on patient characteristics required for case-mix adjustment
- **Data accuracy**: tested using consistency and range checks, and if possible external sources

It is important that NCAPOP audits describe how they will approach data quality challenges. This might include the use of thresholds to determine statistical significance or the use of imputation to compensate for missing data.

It is recognised that challenges around data quality frequently present barriers in terms of utilising wider metrics for outlier analysis. If these barriers are absolute (e.g. they prevent any meaningful outlier analysis from being undertaken) there would be an expectation that data quality itself should be considered for outlier analysis to facilitate improvement.

The CQC consider how healthcare providers manage data quality and data submission including participation in national clinical audits. As well as responding to formal data quality outliers, CQC will also consider additional activities in partnership with audits seeking to improve data quality.

10.2.4 Case-mix (risk) adjustment

Comparison of healthcare providers must take account of the differences in the mix of patients between healthcare providers by adjusting for known, measurable factors that are associated with the performance indicator. These are likely to include age, sex, disease severity, co-morbidity, socio-economic status and ethnicity.

Adjustment should be carried out using an up-to-date statistical model. The model should have been rigorously tested with regard to its power of discrimination (such as the area under the receiver operating characteristic) and its calibration (such as goodness-of-fit); both attributes should be publicly reported alongside details of the model. Judgment as to the adequacy of a model will depend on the performance indicator selected and the clinical context, so universal, absolute values cannot be provided.

10.2.5 Identification of a potential outlier: alarms and alerts

Statistically derived limits around the target (expected) performance should be used to define if a healthcare provider is a potential outlier: more than two standard deviations (but less than 3 standard deviations) from the target is defined as an ‘alert’; more than three standard deviations is defined as an ‘alarm’.

Note that these definitions of statistically significant differences from expected performance may not indicate clinically significant differences if based on large numbers of patients.

10.2.6 Management of a potential outlier

Outliers at the alarm level (greater than 3 standard deviations from expected performance)

NCAPOP providers should inform the CQC and HQIP of all outliers at the alarm level. Table 10.4.1 indicates the stages of managing a potential outlier at the alarm level. It aims to be both feasible for those involved, fair to healthcare providers identified as outliers and sufficiently rapid so as not to unduly delay the disclosure of comparative information to the public. NCAPOP providers will need to ensure that in their regular local level NHS Trust performance reports, it is clear if a Trust is an outlier at the alarm level.

Outliers at the alert level (greater than 2 standard deviations from expected performance)

NCAPOP providers are to also inform the CQC and HQIP of outliers at the alert level. However, unlike for alarm level outliers, the CQC and HQIP are not mandating a formal NHS Trust notification or response process for alert level. However, CQC plan to include such alert information as part of their ”soft” intelligence and it might come up in a Trust inspection so it should also be clear in the local level NHS Trust performance reports if a Trust is an outlier at the alert level.

The expectation is that NHS Trusts should use ‘alert’ information (available within local NHS Trust reports) as part of their internal quality monitoring process. They should investigate alerts in a proactive and timely manner, acting accordingly before they potentially escalate to alarm level status.

Where NCAPOP providers have specific concerns about the statistical validity of an individual metric, they should discuss this and any important contextual information with the CQC.

10.2.7 Involvement of the regulator

As the health and social care regulator for England, the CQC are included in this guidance to provide them with assurance that organisations are engaging appropriately in the process. The CQC are required to consider outlier information and decide the appropriate response. The CQC will expect to see evidence that the information has been used to drive improvements in quality including appropriate action plans. Outlier analysis and outcomes of the subsequent follow up will feed into CQC’s routine monitoring of healthcare providers. An important part of the assessment of whether the response is appropriate will be to consider the specific clinical and governance risks at a healthcare provider. The CQC have access to a team providing clinical advice to inform regulatory activities. Poorly engaged healthcare providers should also be escalated to CQC in consultation with HQIP.

NCAPOP audits should notify CQC and HQIP of both confirmed alarm and alert level outliers via clinicalaudits@cqc.org.uk as well as the HQIP project manager and associate director. HQIP contact details can be found at: www.hqip.org.uk/about-us/our-team/. CQC will then send a routine six-monthly high level summary to NHSEI of alarm level outliers only.

10.3 Individual NCAPOP provider outlier policies

NCAPOP audits are required to have a project specific outlier policy that describes how they operationalise this national outlier guidance. The audit policy should be approved at project board level (or equivalent) and

be reviewed for each round of analysis (i.e. annually). NCAPOP audits should make their outlier policy publicly available on their audit website.

The policy should describe for each of the measures how the metrics perform in relation to the criteria contained within ***Appendix 10c*** (i.e. with respect to statistical power, validity, objectivity and fairness). NCAPOP audits should also check their policy aligns with the following checklist.

10.3.1 Outlier policy checklist for National Clinical Audits

1. Does the policy describe which specific patient cohort the policy applies to (e.g. xx audit round, patients diagnosed from 20xx-20xx)
2. Does the policy describe where the results of the outlier analysis will be published (e.g. the annual report)?
3. Does the policy describe the metrics that will be subject to an outlier analysis?
4. Will the terms 'alert' and 'alarm' be adopted?
5. If yes, does the policy use >2SD and >3SD to define alerts and alarms respectively?
6. If no, does the policy explain how limits of expected performance will be defined and the reasoning for an alternative approach?
7. Does the policy describe what will happen when issues with data quality or completeness prevent a healthcare provider from having a conclusion drawn about its outlier status?
8. Does the policy describe the timescales, notification and escalation stages for running the outlier process?
9. Of the additional metrics which you collect, have you considered applying an outlier analysis to them and if not please explain why.

10.4 Outlier management process for alarms (>3SD)

Table 10.4.1: Outlier notification stages for alarms (England only)

Stage	Alarm level (>3SD) actions	Owner	Within working days
1	Healthcare providers with a performance indicator at alarm level require careful scrutiny of the data handling and analyses performed to determine whether there is: *'No case to answer'* • 'alarm' status not confirmed • data and results revised in NCA records • details formally recorded and process closed *'Case to answer'* • potential 'alarm' status • *proceed to stage 2*	NCAPOP provider team	10
2	Healthcare provider Lead clinician informed about potential 'alarm' status and asked to identify any data errors or justifiable explanation(s). All relevant data and analyses should be made available to the Lead clinician. A copy of the request must be sent to the healthcare provider CEO and Medical director.	NCAPOP provider Clinical lead	5
3	Healthcare provider Lead clinician to provide written response to NCAPOP provider team.	Healthcare provider Lead clinician	25
4	Review of Healthcare provider Lead clinician's response to determine: *'No case to answer'* • It is confirmed that the data originally supplied by the healthcare provider contained inaccuracies. Re-analysis of accurate data no longer indicates 'alarm' status • Data and results should be revised in NCAPOP provider records incl. details of the healthcare provider's response • Healthcare provider Lead clinician notified in writing copying in healthcare provider CEO and Medical director and process closed *'Case to answer'* • Although it is confirmed that the originally supplied data were inaccurate, analysis still indicates 'alarm' status or • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of 'alarm' status	NCAPOP provider Clinical lead	20

Stage	Alarm level (>3SD) actions	Owner	Within working days
	• *proceed to stage 5*		
5	Contact healthcare provider Lead clinician by telephone, prior to sending written notification of confirmed 'alarm' status to healthcare provider CEO and copied to healthcare provider Lead clinician and Medical director. All relevant data and statistical analyses, including previous response from the healthcare provider Lead clinician, made available to healthcare provider Medical director and CEO. Notify CQC[1]and HQIP[2] of confirmed 'alarm' status. ~~Healthcare provider CEO advised to inform commissioners, NHS Improvement[3] and relevant royal colleges.~~ Healthcare provider CEO informed that the NCAPOP provider team will publish information of comparative performance which will identify healthcare providers.	NCAPOP provider Clinical Lead/ team	5
6	Acknowledge receipt of the written notification confirming that a local investigation will be undertaken with independent assurance of the investigation's validity for 'alarm' level outliers, copying in the CQC[1].	Healthcare provider CEO	10
7	If no acknowledgement received, a reminder letter should be sent to the healthcare provider CEO, copied to CQC[1] and HQIP[2]. If not received within 15 working days, CQC[1] ~~and NHS Improvement[3]~~ notified of non-compliance in consultation with HQIP[2].	NCAPOP provider team	15
8	Public disclosure of comparative information that identifies healthcare providers (e.g. NCAPOP provider annual report, data publication online).	NCAPOP provider team	*NCAPOP provider report publication date*

[1] Via clinicalaudits@cqc.org.uk.

[2] Via HQIP PM and AD, see the HQIP website for contact details: www.hqip.org.uk/about-us/our-team/

Appendix 10b: Identification and management of outliers (amendments for Welsh data)

This document replaces the Welsh October 2020 guidance in the PTM and the 2018 guidance and implementation guide. It applies to any data from patient cohorts with a collection starting from November 2018. There was no previous guidance for Wales for data from patient cohorts with collection starting before November 2018.

Appendix 10a *identification and management of outliers (English data)* applies to Welsh data with the following amendments:

10.2.6 Management of a potential outlier

Outliers at the alarm level (greater than 3 standard deviations from expected performance)

NCAPOP providers should inform the **Welsh Government** and HQIP of all outliers at the alarm level. Table A10.4.1 indicates the stages of managing a potential outlier at the alarm level. It aims to be both feasible for those involved, fair to healthcare providers identified as outliers and sufficiently rapid so as not to unduly delay the disclosure of comparative information to the public. NCAPOP providers will need to ensure that in their regular local level **Health Board** performance reports, it is clear if a **Health Board** is an outlier at the alarm level.

Outliers at the alert level (greater than 2 standard deviations from expected performance)

NCAPOP providers are to also inform the **Welsh Government** and HQIP of outliers at the alert level. However, unlike for alarm level outliers, the **Welsh Government** and HQIP are not mandating a formal **Health Board** notification or response process for alert level.

The expectation is that **Health Boards** should use 'alert' information (available within local **Health Board** reports) as part of their internal quality monitoring process. They should investigate alerts in a proactive and timely manner, acting accordingly before they potentially escalate to alarm level status.
Where NCAPOP providers have specific concerns about the statistical validity of an individual metric, they should discuss this and any important contextual information with the **Welsh Government.**

10.2.7 Involvement of the inspectorate

The **Welsh Government** monitors the actions of organisations responding to outliers and takes further action as and when required. Health Inspectorate Wales (HIW) does not act as regulator and cannot take regulatory action in relation to NHS providers. However, HIW can request information on the actions undertaken by organisations to ensure safe services are being delivered. The **Welsh Government** can share information with HIW where appropriate and advise on the robustness of plans in place to improve audit results and outcomes.

10.4 Outlier management process for alarms (>3SD)

Table A10.4.1: Outlier notification stages for alarms (Wales only)

Stage	Alarm level (>3SD) actions	Owner	Within working days
5	Contact healthcare provider Lead clinician by telephone, prior to sending written notification of confirmed 'alarm' status to healthcare provider CEO and copied to healthcare provider Lead clinician and Medical director. All relevant data and statistical analyses, including previous response from the healthcare provider Lead clinician, made available to healthcare provider Medical director and CEO. Notify **Welsh Government**[1] and HQIP[2] of confirmed 'alarm' status. Healthcare provider CEO informed that the NCAPOP provider team will publish information of comparative performance which will identify healthcare providers.	NCAPOP provider Clinical lead/ team	5
6	Acknowledge receipt of the written notification confirming that a local investigation will be undertaken with independent assurance of the investigation's validity for 'alarm' level outliers, copying in the **Welsh Government**[1].	Healthcare provider CEO	10
7	If no acknowledgement received, a reminder letter should be sent to the healthcare provider CEO, copied to **Welsh Government**[1] and HQIP[2]. If not received within 15 working days, **Welsh Government**[1] notified of non-compliance in consultation with HQIP[2].	NCAPOP provider team	15
8	Public disclosure of comparative information that identifies healthcare providers (e.g. NCAPOP provider annual report, data publication online).	NCAPOP provider team	*NCAPOP provider report publication date*

[1] Via wgclinicalaudit@gov.wales

[2] Via HQIP PM and AD, see the HQIP website for contact details: www.hqip.org.uk/about-us/our-team/

Appendix 10c: Statistical principles for identifying poor performance in National Clinical Audits

Advice of an expert group prepared for the National Clinical Audit Advisory Group, 27 June 2010

I.Introduction

1. The Department of Health has requested the National Clinical Audit Advisory Group (NCAAG) to produce statistical guidance on how potentially outlying performance of healthcare providers can be identified. A growing number of National Clinical Audits publish quantitative data that allow comparisons of processes and outcomes. These audits will flag up providers that have results which do not seem to be in line with what can be expected compared to other providers or to existing benchmarks.

2. An expert group has produced guidance on the statistical principles that build on a range of statistical approaches that have been used for this purpose over the years.

3. This document complements one on the procedures that should be followed once a provider with potential outlying performance has been identified (i.e. what action should be taken, who should take it, and when). Although the identification of outlying performance and the subsequent handling of it are separate activities, there is a mutual interaction. For example, the threshold levels distinguishing acceptable from outlying performance that are being used in the statistical analysis depend on what is going to happen when a provider has been identified as a potential outlier (see paragraph 17). Furthermore, data quality as well as differences in case mix that are not fully adjusted need to be taken into account when potential outlying performance is being investigated. This requires an understanding of the underlying statistical analyses.

4. The document is targeted at stakeholders of national clinical audits (clinicians, providers, commissioners, policy makers, patients and the public) who have a basic understanding of statistical principles. Rather than addressing detailed statistical issues, it sets out fundamental principles that need to be followed and provides advice on how that could be implemented. Methodological information related to more advanced topics is made available through references of key papers.
5. This document is not comprehensive and sets out only one of many possible options. However, it was our intention to be relevant to as many as possible of the scenarios that are encountered within National Clinical Audits.

6. The identification of outlying performance touches on many fundamental statistical principles. There is an increasing body of research that aims to further develop the available methodology in this area. It is therefore crucial in our view that the analyses are carried out by individuals with appropriate statistical expertise and experience.

II. Choice of the performance indicator

7. In this document, we consider *performance indicators* that are quantitative measures of either processes or outcomes of care. This indicator should be carefully chosen. First, the s*tatistical power* should be considered (i.e. the probability that a provider with truly outlying performance will be detected) which depends on the number of patients (or any other “unit of interest”) per provider as

well as on the frequency of events if the performance indicator is derived from a discrete outcome or on a measure of variability if it is derived from a continuous outcome. Second, the *validity* of the outcome should be assessed. Important considerations are the extent to which the outcome is *attributable to care provided by the unit* and the *clarity about the relationship between indicator and good and poor quality of care*. A further issue is the *objectivity* of the indicator or the extent to which there is the potential that the indicator can be manipulated by the provider (e.g. "gaming"). Third, the anticipated adequacy of adjustment for potential differences in important risk factors needs to be considered as this will determine the *fairness* of the comparison.

8. Performance indicators can be derived from *different types of data*. Roughly speaking, one can distinguish indicators based on discrete outcomes expressed as proportions or counts or based on summary measures of continuous measures expressed as means or medians as well as on various derived measures. The statistical approach to determine the limits of the acceptable range will need to take the type of data into account, especially when numbers of cases or events are low. In that case, appropriate methods for small samples should be used.

III. Design

9. Two different types of design can be distinguished. The first is a comparison of providers based on data collected over a *given period of time* or including a *given number of patients*. The second is based on *sequential monitoring techniques* (e.g. CUSUM methods) that allow an update of the assessment of performance of a provider after each case accrued. In this document, we only consider the analysis of data collected over a given period of time or a given number of patients as those are most commonly used in ongoing National Clinical Audits.

10. There is an obvious trade off between the statistical power of the analysis and the timeliness of detecting outlying performance. If the reporting time period is short, the number of included patients may be small and truly outlying providers may not be detected because of a lack of statistical power. On the other hand, if the reporting time period is relatively long outlying providers may remain undetected for a considerable amount of time.

IV. Definition of an outlier

11. A provider will be identified as an outlier if the value of the performance indicator is outside the range of *acceptable performance*. This range will be determined by a *target* and a *range of values* around that target that are defined on the basis of statistical principles.

IVa Choosing the target

12. The *target* can be set on the basis of external criteria (e.g. historical data, data collected elsewhere, a clinical practice guideline, or clinical judgement) or on the basis of internal criteria derived from the audit data under consideration. An example of the latter is the use of the average over all cases among all providers included in an audit.

13. If an internal target is used, one could consider using a *cross-validation approach* and compare each provider against a target derived from all other providers. An advantage of using cross-validation is that it removes the influence of a provider on the target against which it is being compared. If the

number of providers is relatively large, cross-validation has only a marginal impact on the target that is used for each provider. Conversely, if cross-validation is used when only a small number of providers are being compared, the influence on the target could be substantial.

14. Alternatively, one may want to avoid the influence of outlying providers on an internal target by *resetting the top and bottom values of a performance indicator to a specified percentile* (e.g. 5%), a process sometimes referred to as "winsorising". A further option for defining an internal target is to take the *average observed in providers that were recognised centres of excellence* on the basis of pre-defined criteria.

IVb Limits of acceptable performance

15. The definition of the *limits of acceptable performance* should be based on statistical criteria. Statistical process control processes developed in an industrial context typically define a range of values that are within three standard deviations from the target value as "in control" (i.e. acceptable). This would correspond to statistically testing whether a performance indicator is different from the target at a two-sided significance level of 0.002. In practice, this would imply that 99.8% of all providers are expected to be within the acceptable range, if all providers are in control (i.e. performing according to the target). *Alternative significance levels* can be used. For example, a two-sided significance level of 0.05 would define all values within two standard deviations from the target as acceptable. If all providers are in control, 95% would be within these limits.

16. We recommend that as a starting point the two-sided significance levels of 0.05 and 0.002 should be used to define limits of acceptable performance. These limits could be considered as the thresholds for an "*alert*" or an "*alarm*", respectively. As a consequence, the use of other significance levels will require an explicit justification (see paragraph 17).

17. The final choice of the actual significance levels needs to take into account the *relative weight of the two potential errors*: erroneously identifying a provider as an outlier (a false-positive result or Type I error); and erroneously considering a provider's performance as acceptable (a false- negative result or Type II error). Further relevant determinants of the limits are data quality, the adequacy of the risk adjustment, and the issue of multiple testing (see paragraph 31).

18. It is important to note that the limits of acceptable performance defined in this way depend on the number of cases per provider. Especially when the number of cases is large, differences that are *statistically significant* may not always be *clinically significant*. For this reason, it has been suggested to use separate thresholds: one to demonstrate evidence for safety and one to demonstrate evidence for danger.[1]

[1] Demonstrating safety through in-hospital mortality analysis following elective abdominal aortic aneurysm repair in England. Br J Surg 2008; 95:64-71.

V. Assessment of data quality

19. A report comparing performance indicators among providers should explicitly describe data quality. A number of measures of data quality should be made available. First, *case ascertainment* should be given as a proportion of included cases out of all eligible cases. The number of eligible cases should be derived from external sources. Second, *completeness* of critical data fields should be presented as a proportion of non-missing values of fields containing information on process or outcome measure under consideration as well as on case mix factors that are likely to be included in the risk adjustment models. Third, *accuracy* of critical data fields should be investigated. This can be done "internally" through consistency and plausible range checks within the available data sets and – if feasible – "externally" through comparison with another data source.

20. The *generalisability* (i.e. representativeness) should be assessed by comparing characteristics of the included cases against those that are not included or against all eligible cases. The potential of using existing data – if possible linked at patient level – should be explored for this purpose.

VI. Risk adjustment

21. The process of identifying outliers should always include adjustments for potential variations in risk due to case mix. The development of the risk adjustment approach depends on what *outcome* (or process) is being considered, the *time frame*, and the *population*. As a result, the risk adjustment approach should always be "tailor-made" and match the specific requirements of the comparison that is being carried out.

22. Most risk adjustment methods rely on *stratification* or *statistical modelling*. Stratification implies that the comparison is being carried out within strata that are homogeneous according to pre-specified risk factors. A risk adjusted result is then produced by pooling the estimate from the two or more strata into a single pooled estimate. The advantage of stratification is that it is relatively straightforward to implement and comprehend, but it has two important drawbacks. First, there is a potential of information loss as continuous variables have to be categorised. Second, there is the problem of low numbers within strata especially when multiple risk factors are being considered. For these two reasons, we recommend statistical modelling.

23. A statistical risk adjustment model should aim to include all patient and disease characteristics that are available *before the start of the care process* and that are accepted as potential risk factors for the outcome under consideration. Important factors that should be considered for inclusion are age, sex, disease severity, and co-morbidity. Depending on the specific clinical context other candidate risk factors are socio-economic deprivation and ethnicity, but it is important to realise that adjustment for these risk factors may mask established inequalities.

24. The risk adjustment model can be either based on *existing statistical models* that are generally accepted as appropriate for the purpose of risk adjustment or *newly developed* within the data under consideration. Irrespective of whether an existing or newly developed risk adjustment model is being used, its performance should be examined. Parameters of the model's *goodness-of-fit* and *discrimination* or *explanatory power should* be presented and its appropriateness should be

discussed. It is not possible to set minimum criteria for the risk model's performance as these will depend on the type of indicator that is being used as well as the specific clinical context.

25. We recommend that as a first step the risk adjusted performance estimates are based on "*indirect standardisation*". This implies in its simplest form that for discrete outcomes the observed number of events for a provider is divided by the number expected on the basis of the statistical model. A ratio of one would indicate that the outcomes are as expected. A risk adjusted performance estimate on the same scale as the original indicator can be calculated by multiplying this ratio by the average over all providers. For continuous outcomes the differences between the observed result and that expected (i.e. "residual") is calculated for a provider. In this case, a difference of zero would indicate that the outcomes are as expected. A risk adjusted estimate that can be directly compared with the unadjusted results is calculated by adding this difference to the average over all included providers.

26. An important argument to use indirect standardisation is that it allows an explicit comparison of the unadjusted and the adjusted results provided that the risk adjustment model is well *calibrated* (i.e. the observed and expected results are equal when averaged over all cases). A direct comparison of unadjusted and adjusted results is helpful as it provides an opportunity to evaluate the direction and size of the impact of risk adjustment. In addition, the unadjusted and adjusted results, if derived from a well calibrated model, can be compared against the same limits of acceptable performance (see paragraph 16).

27. Risk adjustment will always be *incomplete* as it will never be possible to fully measure all relevant case mix factors or represent them adequately in a risk adjustment model. It is therefore important to accept that there will always be "*residual confounding"*. In other words, it should always be highlighted that even risk adjustment differences in case mix can never be excluded as possible explanations for outlying performance.

VII. Presentation of provider comparisons

28. A *"funnel plot"*, a form of control chart, provides an attractive graphical format for the presentation of the performance indicators. In a funnel plot, the result for each provider is presented as a function of its precision. The target as well as the limits of acceptable performance can be pre-specified as they do not depend on the actual results. The precision parameter corresponds to the number of cases (or an equivalent measure of volume) for each provider.[2]

29. Potential outlying providers can be detected as those with results outside the funnel limits (see paragraph 11). An important advantage of funnel plots is that they clearly demonstrate how the limits of acceptable performance depend on the number of cases. It is therefore easy to appreciate the difference between a provider's performance and the target and its position with respect to the acceptable range.

[2] Funnel plots for comparing institutional performance. Stat Med 2005; 24:1185-202.

30. We recommend that for each provider measures of case ascertainment, data completeness (separate for performance indicator and for case mix variables), and data accuracy are also available to inform the interpretation of these plots.

VIII. Further issues

Multiple comparisons

31. It has been argued that the limits of acceptable performance should be adjusted to take into account that many providers are being compared simultaneously. If we use *limits of acceptable performance* based two- sided significance levels of 0.05 and 0.002 as explained earlier (see paragraph 16), we may identify providers with results outside these limits simply by chance alone (i.e. a "false-positive result").

32. One can adjust the limits of acceptable performance for multiple comparisons by using lower significance levels. One classic approach would be to divide the proposed significance levels of 0.05 and 0.002 by the number of providers (i.e. the *Bonferroni correction*). This ensures that the probability of one or more false-positive results among all included providers is not greater than 0.05 or 0.002, respectively. However, this criterion is too strict as it will strongly reduce the statistical power to detect true outliers (see paragraph 13). Alternatively, an approach based on the "*false discovery rate*" can be used. The false discovery rate can be considered as the probability that a provider is not an outlier if its p-value is found to be lower than the defined significance level. The false discovery rate will produce more false-positive results than the Bonferroni correction but less than if no adjustment of multiple comparisons is being applied.[3]

33. A fundamental issue in this context is *whether an adjustment for multiple comparisons is justified* in the first place. One could consider that each provider is to be compared to the target on an individual basis and that the consequences of this comparison only relate to this provider itself. If that is accepted, no adjustments for multiple comparisons should be made.

Overdispersion

34. Many comparisons of healthcare providers have demonstrated a greater level of variability among providers than can be explained by chance and the existence of a few outlying units. This phenomenon is often referred to as *overdispersion*. Important explanations for overdispersion are the limitations of the available risk adjustment methods and the variable data quality.[4]

35. A number of options for dealing with overdispersion have been proposed that could be incorporated when the limits for acceptable performance are set: for example by improving the risk adjustment through the analysis within groups of providers that are expected to be more homogeneous, or the use of an interval as a target. It is also possible to estimate the level of overdispersion and to adjust the limits by estimating an *overdispersion factor* and inflating the limits of acceptable performance around the target by this factor (i.e. *multiplicative* adjustment). Alternatively, one can estimate the between-provider variance (the "random effects") and add this to the variance expected if there were no differences between the providers. It should be emphasised that these adjustments for

[3] Use of the false discovery rate when comparing multiple health care providers. J. Clin. Epidemiol. 2008; 61:232-40.

[4] Handling over-dispersion of performance indicators. Qual. Saf. Health Care 2005; 14:347-51.

overdispersion reflect the limitations of the risk adjustment and data quality. Attempts should continue to explain the excess variability, to improve the risk adjustment, and to improve data quality.

Multilevel or random-effects models

36. An important advantage of *multilevel models* is that they explicitly incorporate the overdispersion (i.e. between-provider variance). Furthermore, these models provide a flexible framework for incorporating determinants of outcome at different levels of the hierarchal structure. This implies that provider characteristics as well as characteristics of groups of providers can be simultaneously included in the model and their impact on outcome investigated.[5] A further extension of these models is their use from a Bayesian viewpoint.[6]

37. Multilevel models also allow the estimation of risk adjusted estimates which are "*shrunken*" towards the overall mean. The level of *shrinkage* is stronger for the providers with fewer cases. These shrunken estimates compensate for the *regression-to-the-mean* effect which is especially relevant if the number of cases per provider varies substantially. It has been recognised that multilevel models are more conservative than conventional approaches based on fixed-effects models. As a result the chance of a false positive result is lower but chance of false-negative higher.[7]

Imputation of missing values

38. Data sets from National Clinical Audits will inevitably contain a number of cases for whom not all data are available. Imputation techniques could be used to deal with missing values for the case mix factors that are candidates to be included the risk adjustment model. Multiple imputation of missing data has the potential to increase the statistical power (cases with missing values can be retained in the analysis) and to reduce bias (mechanism of missingness may depend on case mix).[8]

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[5] Statistical and clinical aspects of hospital outcomes profiling. Statist. Science 2007; 2:206-226.
[6] Identifying outliers in Bayesian hierarchical models: a simulation-based approach. Bayesian Analysis 2007; 2:409-44.
[7] The use of fixed- and random-effects models for classifying hospitals as mortality outliers: a Monte Carlo assessment. Med. Decis. Making 2003; 23:526-39.
[8] Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls BMJ 2009; *338*:b2393

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