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NHS National Services Scotland

Date 26/09/2018

Lewis Macdonald, MSP
Health & Sport Committee
Scottish Parliament

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Dear Mr Macdonald,

CONCERNS REGARDING THE REPORTING OF MORTALITY ISSUES

Further to my letter of 6th September 2018, I have now concluded my investigation into the data analysis and reporting from the Scottish Intensive Care Society Audit Group (SICSAG) and Information Services Division (ISD), following an anonymous letter outlining a number of concerns.

I have undertaken my review with members of the SICSAG team (including statisticians and clinicians within ISD, and clinicians within SICSAG) and ISD's Statistical Governance team, which oversees our compliance with the standards set out in the UK Code of Practice for Statistics.

The SICSAG report is not an official statistics publication but is produced, as with all ISD publications, in line with the principles set out in the Code of Practice. ISD takes its compliance with the Code of Practice seriously and therefore it is important that we investigate the claims made in the letter. I have also copied this response to the Office for Statistics Regulation, the regulatory arm of the UK Statistics Authority, so that they can undertaken an independent review.

It is disappointing that the letter sent to me is anonymous as my preference would be to discuss the issues raised with the complainants directly. Previous experience with other issues has shown that open dialogue between all parties can help build trust and understand the crux of the issues raised and prevent misunderstandings which can happen through written correspondence alone. As noted in the letter to me, the complainants sent a similar anonymous letter to ISD and SICSAG last year. ISD and SICSAG undertook a review at that time but due to the anonymous nature of the letter, it was not possible to respond directly last year.

Responding to this year's letter via the Health & Sport Committee allows us the opportunity to address the points raised by the complainant. That said, my preference would still be for a face to face meeting with all parties to further explore any ongoing issues.

The investigation included a review of all data analysed and reported in the letter, particularly relating to Aberdeen Royal Infirmary (which the complainant has highlighted as an area of concern), a review of the analysis methodology used by SICSAG, a review of current SICSAG governance guidelines and a review of past annual reports commentary. The results of the investigation are given in the appendix attached to this letter. I have grouped the response around key themes raised by the complainant but please let me know if there are any areas which you feel have not been addressed or require additional clarity. The response in relation to the statistical analysis undertaken is technical in nature and this will allow the separate review by the Office for Statistics Regulation to understand ISD's approach and our reasons for adopting this methodology and our subsequent reporting of the results.

I would like to take this opportunity to thank the complainants for their letter. They are clearly passionate about this topic and it is important that their concerns are addressed and acknowledged. ISD always welcome feedback as this provides us with valuable insight into our services and assists us with improving our outputs, and in the case of our audits, inform service improvement and therefore improvements to services for patients.

Please let me know if you have any further questions or comments. I would very much welcome the opportunity for all parties involved to discuss this with you and, if they were willing, the complainants.

Yours sincerely,

Scott Heald,
Head of Profession for Statistics,
NHS National Services Scotland.

Copy:
Ed Humpherson, Director General, Office for Statistics Regulation
Dr Elizabeth Wilson, Chair, Scottish Intensive Care Society
Dr Nick Fluck, Medical Director, NHS Grampian

Appendix

This appendix focuses on the main areas of concern highlighted by the complainant:

1. Use of statistics to determine variation
2. Governance process for handling outliers
3. SICSAG "early warning" mechanism
4. Comparisons between units
5. "Gaming" of data
6. Authorship and Content of the SICSAG report
7. Release of SICSAG data into the public domain
8. Patient Information & Involvement

1. Use of statistics to determine variation

The complainant makes considerable references to the choice of statistics used in the SICSAG publication. This appendix outlines the reasoning behind our choice of statistics used. Importantly, ISD statisticians have worked with members of SICSAG to determine the most appropriate statistics to use. For the publication, it is important that we present the statistics in as accessible a format as possible as the report is intended for a public, as well as a wider clinical, audience. Therefore, we have sought to keep statistical terminology and jargon to a minimum (hence the decisions not to use p-values throughout the main part of the publication). I support the SICSAG statisticians in their approach to the presentation of these data but also welcome the independent review which will be undertaken by the Office for Statistics Regulation as this will give an impartial assessment on the statistics presented by ISD/SICSAG and we will consider any recommendations made by the OSR in future publications.

Standardised Mortality Ratio (SMR) – use of the recalibrated Apache II approach

SICSAG takes a holistic view of care quality using multiple metrics and adopted the use of the Standardised Mortality Ratio (SMR) as just one, albeit important, measure of quality of care in Scottish Intensive Care Units (ICU).

The standard APACHE II risk prediction model was used to calculate SMRs until 2014. This model is a scoring system which was developed in ICUs in the United States of America over 30 years ago and published in 1985. It has subsequently been widely adopted and used for international benchmarking. Further details on the standard APACHE II model are available in the paper by Knaus etc:

- *Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. Crit Care Med. 1985 Oct;13(10):818-29).*

However, since its development, ICU populations have changed, and newer diagnostic techniques and ICU treatments have been developed. For this reason, there is evidence that risk prediction models should be recalibrated to ensure that benchmarking of care in ICUs is accurate and fair *(See:*

- *Moreno RP. Outcome prediction in intensive care: why we need to reinvent the wheel. Curr Opin Crit Care. 2008 Oct;14(5):483-4; and*
- *Paul E, Bailey M, Van Lint A, Pilcher V. Performance of APACHE III over time in Australia and New Zealand: a retrospective cohort study. Anaesth Intensive Care. 2012 Nov;40(6):980-94).*

Therefore, SICSAG undertook a programme of work to recalibrate the standard APACHE II model for the Scottish ICU population. It is recognised that **risk prediction models are imperfect and inevitably do not reflect the complexities and nuances of treating the critically ill patient will multi organ failure.** However, the SICSAG steering group agreed that the recalibrated model would be the primary model to calculate SMRs used to benchmark Scottish ICU performance, which was

implemented in the 2014 (on 2013 data) annual report, and the standard APACHE II model retained only for international benchmarking and country-level trends over time.

This process of recalibration has been undertaken in other similar ICU audits internationally. For example:

- *Intensive Care National Audit and Research Centre (ICNARC) (see Ferrando-Vivas P, Jones A, Rowan KM, Harrison DA. Development and validation of the new ICNARC model for prediction of acute hospital mortality in adult critical care. J Crit Care. 2017 Apr;38:335-339) covering the remainder of the UK;*
- *Australia New Zealand Intensive Care Society Centre for Outcome and Resource Evaluation (ANZICS CORE) (see Paul E, Bailey M, Pilcher D. Risk prediction of hospital mortality for adult patients admitted to Australian and New Zealand intensive care units: development and validation of the Australian and New Zealand Risk of Death model. J CritCare. 2013 Dec;28(6):935-41) covering Australia and New Zealand.*

To avoid confusion for readers of the SICSAG report, we have consciously chosen not to publish the funnel plot using the standard APACHE model, and instead present information using the recalibrated APACHE II model which allows fairer and more accurate benchmarking of Scottish ICUs.

Use and interpretation of the SMR

This recalibrated APACHE II model is used to predict 'expected' deaths for Scottish ICUs. The SMR is calculated by dividing the number of Actual (observed) deaths by the number of Expected deaths (using the recalibrated APACHE II calculation). **However, higher SMRs do not represent avoidable excess deaths.** There will be cases where deaths can be fully explained by other factors, such as inadequate case-mix adjustment, or variation in admission practices. '**Expected' deaths as calculated in a statistical model, therefore are not the same as 'avoidable' or 'preventable' deaths due to poor care**.

For this reason, it is important that ICUs that fall outside the 'control limits' should not be assumed to be providing poor quality care. The purpose of identifying an outlier is to inform the relevant health board and provide them with the opportunity to commission a more in-depth review of the affected unit, for example, the outlier status of NHS Grampian and NHS Greater Glasgow & Clyde based on 2015 data (published in 2016) was highlighted to these Boards by SICSAG.

In adopting this methodology it is correct that two-tailed tests are an appropriate method for these data. In addition, even if a perfectly accurate risk prediction model where used, it is correct to report that there is a 1 in 20 chance that a unit will be an outlier due to chance beyond 2 Standard Deviation (SD) of the Scottish mean SMR (i.e. a 1 in 20 'false positive rate'), or 1 in 333 for those lying beyond 3SD.

In regard to queries regarding Aberdeen Royal Infirmary (ARI) ICU in the 2017 report of 2016 data, the SMR under the recalibrated model for Aberdeen ICU was 1.07. This figure is based on episodes that were eligible for inclusion in the APACHE calculation and were scored in the unit. This figure does not take into account all the admissions to ARI ICU. As outline above, there are recognised reasons as to why some admissions are not suitable for inclusion in the model, e.g. admission diagnosis of burns, ICU length of stay less than 8 hours, age under 16 years). The 1.07 is based on a calculation of 161 observed deaths divided by 150 expected deaths out of 617 included admissions. This means 26% of admissions to ARI ICU that were eligible for inclusion in the APACHE model died before ultimate hospital discharge. This cannot be interpreted as indicating that these 'excess' deaths were avoidable deaths, only that there were more deaths than expected using the Scottish APACHE II model, nor does it provide a causal link with poor care for these patients.

For the purposes of this response, we have produced the chart below which shows the SMRs for ARI

ICU and the Scottish mean with a 95% Confidence Interval (CI).

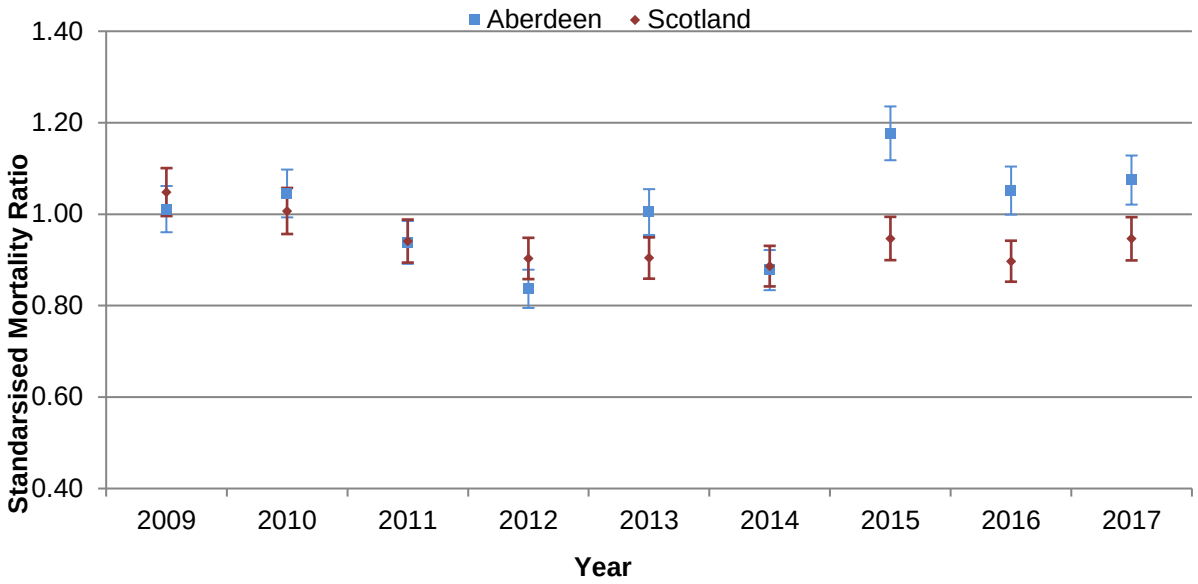

Chart of Table with ARI and Scotland with 95% CIs

2. Governance process for handling "outliers"

SICSAG is a voluntary collaborative audit that relies on the actions, enthusiasms and goodwill of the critical care community throughout Scotland to input detailed data on over 10,000 ICU patients and over 35,000 HDU patients each year. SICSAG constantly strives to improve patient care and seek to deliver improved patient outcomes for the critically ill population in Scotland.

SICSAG has a multi-faceted approach to governance including SMR outlier status, data errors and Minimum Standards and Quality Indicator variances. Whilst there is a focus on SMR outlier status there is the aim to have all units participating in robust and reliable 'Morbidity and Mortality Meetings' and that these are embedded into core practice with inter-disciplinary teams. In these meetings all deaths would be discussed in the ICU and learning points disseminated. This should happen irrespective of whether a unit is an SMR outlier or not. All deaths should be reviewed and discussed with relevant staff so that all key lessons are shared locally and healthcare improved. This quality improvement methodology will in time, lead to higher standards and a culture of continuous improvement if properly resourced.

With SMR outlier status SICSAG takes this very seriously and the correct process is an independent review by experts to comprehensively investigate the unit.

In reference to the outlier status of Glasgow Royal Infirmary (GRI) ICU in the 2016 report, this unit went through a similar governance process with independent investigators from SICS. No data errors were found and no cause/effect was found. Their outlier status was believed to be a combination of factors across the whole critical care department in GRI/ NHS Greater Glasgow & Clyde (GGC).

For ARI ICU this was undertaken in 2016 through the Scottish Intensive Care Society (SICS) with a group of consultants external to both NHS Grampian and ARI ICU.

Past reporting of governance investigations for ARI ICU is a matter for NHS Grampian to address. It has been the case that all governance investigations are initiated by the identified outlier's own health board. It has been for that board to decide what action needs to be taken and whether to publish the results of any investigation.

However, as part of an overall Scottish Healthcare Audits review, SICSAG will be addressing its governance policy in its next Steering Group meeting in November 2018. We aim to include as part of participation in the audit that our governance policy will require that at least a redacted form of the governance investigation report should be made available which would be included in the SICSAG annual report and placed on the SICSAG website. Not only will this instil further clinical and public confidence in the audit and participating units, but also allow shared learning across the critical care community.

3. SICSAG "Early Warning" Mechanism

The complainant refers to a 'three monthly early-warning mechanism'. Whilst SICSAG does not have such a 3 monthly mechanism, it does have a mechanism of monthly reports to all ICUs with a **CU**mulative **SUM** of outcomes (CUSUM). Monthly reports are not published as they include levels of data that could, when used with other sources, identify individual patients. Only unit audit leads, clinical/medical directors and other unit selected clinicians and charge nurses get the reports.
The SICSAG monthly ICU reports include a CUSUM track chart for a unit's 300 most recently discharged patients. The CUSUM chart provides an early warning system for changing mortality rates based on APACHE II predictions and documented hospital outcomes. A signal occurs when a sequence of outcomes is better or worse than might be expected from these patients' APACHE II mortality predictions.

The CUSUM charts included in ICU monthly reports and the SMR funnel plots included in the SICSAG annual reports both measure outcomes taking consideration of recalibrated APACHE II mortality prediction, however the two methods are not the same. A unit with a signal on a CUSUM chart will not necessarily be an outlier in the annual SMR funnel chart. Conversely, a unit that is an outlier in the annual SMR funnel chart may never have had a signal in its monthly CUSUM charts.

SMR funnel charts compare a unit's annual results against Scotland's. A short spell of increased mortality can trigger the CUSUM signal but not show in an annual SMR calculation. Higher mortality over a longer period would show in a top heavy CUSUM (where the increase indicator is generally nearer to the increase control limit than the decrease indicator is to the decrease control limit) and could result in a high SMR, even if there is no signal.

In addition, SMRs are based on ultimate hospital outcome whereas CUSUM charts are based on hospital outcome. This is because CUSUM charts need to be timely and ultimate hospital outcomes take longer to be complete. As a result, units which transfer out a higher proportion of patients may be an outlier on SMR funnel plot when the CUSUM chart gave no reason for concern.

4. Comparisons between units

SICSAG uses standard, evidence-based methodology to identify outliers using funnel plots in the report to show SMR (*see Spiegelhalter DJ. Funnel plots for comparing institutional performance. Stat Med. 2005 Apr 30; 24(8):1185-202 for detailed explanation*). Comparable audits, such as ICNARC (Intensive Care National Audit and Research Centre), do not show the line at 2 standard deviations (2SD) and would only commence a governance procedure above 3 standard deviations (3SD). SICSAG on the other hand commences its governance process when a unit is more than 2 SD. SICSAG therefore adopts a very strict policy for instituting governance procedures.

In the funnel plot, SICSAG uses 2SD and 3SD lines to indicate how far units are from the mean. Best practice in interpreting funnel plots is to compare the unit mean with the Scottish mean. Between-unit comparisons of SMR are not possible due to differences in case mix. There is a clear literature explaining this**. It is not appropriate to compare different unit means directly with each other.** For example, in the letter, two very different units are directly compared. Glasgow Royal Infirmary (GRI) ICU is a combined Intensive Care/High Dependency Unit (ICU/HDU) which will have a mix of

patients at various levels of severity, whereas ARI ICU is a standalone ICU with more patients of a higher severity. **Direct comparisons between ARI ICU and GRI ICU therefore are not appropriate here.** Similarly, it is simply not valid to substitute one unit SMR for another and to calculate excess deaths in the way the letter writer has done.

For the same reason, ranking of units on SMR performance is not appropriate. "Spurious ranking" of institutions was one of the reasons Spiegelhalter recommended using funnel plots to display this type of data.

If we review the funnel plots over the years of the audit, we note that around half of the units are above the mean. However, it is not then correct to interpret this as indicating that all the units above the Scottish mean are poorer performing units.

5. **'Gaming' of Data**

Deliberate 'gaming' or inputting of erroneous data is not tolerated in SICSAG/ISD. Any suggestion of deliberate gaming or inputting of erroneous data would be thoroughly investigated by the SICSAG team. The complainant makes reference to an anonymous consultant speaking about gaming and it is important that such allegations are raised by the complainant with the Medical Director of that NHS Board.

The review of data submitted to SICSAG is essential to ensure that the data held in the audit is valid and robust. This ensures that the modelling for CUmilitve SUM of outcomes (CUSUM) charts and SMR reporting is accurate.

SICSAG has a robust 4-stage validation process in place:

1. At point of data entry – Data is error checked by the data collection platform Wardwatcher
2. Case-note validations – Inter-Rater Reliability validations are carried out randomly across participating units where the SICSAG regional coordinator and quality assurance manager check all available data for a random selection of patients entered against what is in the case notes to find agreement or variance in what data has been entered.
3. Central validations – All data extracted to the central team goes through a data validation process before being analysed.
4. 3 monthly validations - were any data discrepancies noted through the central validation process are sent back to the units for clarification.

At the end of the year a full year's data is then sent to ISD and this then goes through a preliminary central validation process and analysis. As with other national and international audits preliminary data can then be reviewed by units to ensure that the data is accurate. This is in line with Standards for a National Clinical Audit or a Quality Improvement Study by Healthcare Quality Quest (2016):

Preliminary data and peer review	Preliminary data are available on a timely basis to participating sites to enable a peer review and feedback process in participating sites before findings are published. The local peer review includes analysis of findings and any cases not consistent with good practice to identify and feed back to the national organization any clinically acceptable exceptions not previously acknowledged in data collection.
Rationale for criteria	Data collected should be formally reviewed by participating sites through a local peer group process prior to the publication of data. The peer review process at site level should review the analysis of risk-adjusted results and cases not consistent with good practice at local level. Participating sites should be able to correct or modify the data held in the national clinical audit related to their performance prior to publication, if evidence of error or inappropriate judgement in data collection is supplied to the national clinical audit.

Criteria and definitions of key terms	Prior to the publication of national clinical audit data, data collected are formally reviewed by each participating site through a local peer group process. The peer review process at site level reviews the analysis of risk-adjusted results and cases not consistent with good practice at local level. Prior to the publication, participating sites are able to correct or modify the data held in the national clinical audit related to their performance, if evidence of error or inappropriate judgement in data collection is supplied to the national clinical audit.
Definitions	Peer group review for this purpose refers to the clinical group whose patients or service users are included in the audit review together with any cases of patients or service users whose care is not consistent with the quality-of-care measures in the audit for the purpose of identifying if there is any clinical reason for the failure to meet the quality measure/s. An exception is a clinically acceptable reason or justification that explains why the quality-of-care measure/s used in a national clinical audit were not met for one or more patients or service users in the audit.

6. Authorship and Content of the SICSAG annual report

One concern highlighted in the complaint letter was the authorship of the annual report. All clinical authors of the report are members of the SICSAG Steering Group It should also be noted that these authors contribute to the report and are not the sole authors. Staff in ISD (the senior statistician, along with the National and Regional Clinical Coordinators, and the Quality Assurance Manager) and staff from Health Protection Scotland (HPS) all contribute to the publication.

There is no deliberate bias in the writing of the report. Given the lead role ISD has in the production of the report, any concerns around bias or misleading reporting would be escalated to me as Head of Profession for Statistics. All reports, prior to release, are also independently reviewed by an editorial panel in ISD, comprising senior staff who are not directly involved in the production of the reports.

It is also important to stress that participation in the audit by all participating units is entirely voluntary. The audit relies heavily on consultants, trainees, nurses and Allied Health Professionals (AHP) to input data, review data, report data and use the data for quality improvement projects both locally and nationally. Without the contributions of these staff the audit simply would not meet its aim and objectives. Engagement of these individuals is therefore essential to the function of the audit continuing to add to the quality of care for patients admitted to Critical Care in Scotland.

The complainant raised further issues relating to text in the 2016 and 2017 annual reports, the removal of Excel files, and the date of the annual publication:

Text in 2016 and 2017 Annual Report

SICSAG/ISD always seeks to be objective, competent and fair in reporting outcomes. The complainant's letter addressed issues around the language used in the report when discussing the SMR outlier status of ARI. On review, I agree that the language used presents a picture that is not accurate to the data presented in the funnel plot. Specifically the word 'above' instead of the word 'at' should have been used when referring to Unit W outlier status in 2015. We thank the writer for highlighting this oversight and will amend the publication to reflect this.

In the 2018 report, we have changed the way we comment on the funnel plots and other figures in the report so that the interpretation is as clear as possible to users.

Excel report removed

We can find no evidence that any information that has been previously published on the SICSAG website has then been subsequently removed as stated in the complaint letter. The graphs screenshot in the letter from the 2016 annual report on 2015 data are still available on the website.

However, in April 2017, it was found that the 2016 excel file available on the website had the title of '2015'. Although the title was wrong, the data contained in the file was correct. This title name was corrected in April 2017.

Annual Report Publication date

SICSAG endeavours to publish the annual report as rapidly as possible. The time-lag between final data entry (for ultimate hospital mortality, not ICU date of admission) and report publication is necessary to ensure data are accurate and validations are undertaken. We hope that planned future developments, including web-based data entry, will allow the timeframe to reduce.

The timetable for publications is set out as:

End February	Previous year's annual data is sent to ISD to ensure all patients for whole previous year (including those admitted to Critical Care on 31/12 of that previous year) are included.
March	The data checked for errors by ISD analyst and returned to units for validation.
End March	Second extract is obtained at the end of March with validations.
April to May	Data linkage is carried out with the national mortality records.
May	Draft analysis sent to units for commentary about their results that can then be included in the report.
May/June	Writing of the report that takes place over May and into June.
July	Publications work on drafting the report in the format ready for publication Report proof read by the business manager, senior nurse, public health consultant and report writing team.
End July	Report sent for early access to the Scottish Government, Health Board executives and unit audit leads.
August	Publication on the second Tuesday of August.

The report has always been published in late July or into August (second Tuesday since 2012). The suggestion that the publication is deliberately published on the same date as SQA Higher Education results and in parliamentary recess is untrue. The table below demonstrates as there are only two conceding publication dates in 10 years.

Year	SICSAG		SQA	
	Date	**Day**	**Date**	**Day**
2010	27 July	Last Tues	05 August	1st Thu
2011	30 August	Last Tues	04 August	1st Wed
2012	14 August	2nd Tues	07 August	1st Tue
2013	13 August	2nd Tues	06 August	1st Tue
2014	12 August	2nd Tues	05 August	1st Tue
2015	11 August	2nd Tues	04 August	1st Tue
2016	09 August	2nd Tues	09 August	2nd Tues
2017	08 August	2nd Tues	08 August	2nd Tues
2018	14 August	2nd Tues	07 August	1st Tue
2019	13 August	2nd Tues	Unknown	Unknown

7. Release of SICSAG data into the public domain

All data collected by SICSAG are governed and controlled in compliance with ISD Information Governance standards, Local Health Board Information Governance standards, the Data Protection Act (2018) and the General Data Protection Regulations (GDPR)(2018).

SICSAG currently reports to a level of transparency and detail which I believe is appropriate for professional and public scrutiny.

The SICSAG data set has many variables that, if taken with other datasets, have the potential to identify individual patients even where this may not seem to be likely. Care is always taken in releasing data for audit, research, and publication. For this reason, wholesale release of data from

SICSAG is not appropriate.

8. Patient Information and Involvement

All units have patient information leaflets available explaining the collection and use of data in SICSAG. There are also posters available for units. All patients have the right not to have their data collected or to have it removed at any time.

We will write to all unit audit leads emphasising the need to have these leaflets available in patient and relative areas.

SISAG has discussed having representation from patients and/or relatives in the past but as yet no decision has been taken to include on the Steering Group. This will be discussed again with the Steering Group in November with changes to the constitution being proposed.