SICSAG (2020 version)

Data Management

Contents

Introduction

SICSAG is an ongoing national audit that exists to monitor and improve the quality of care given to patients admitted to Intensive Care Units (ICU) and High Dependency Units (HDU) in Scotland. We have reported on ICU activity, interventions and outcomes since 1995, and HDU interventions and activity since 2005.

Data are entered real-time by clinical staff into the bespoke database, WardWatcher. Local audit coordinators (LAC) complete the collection of data on hospital outcomes for patients admitted to ICU. Data are extracted monthly by LACs or trained clinical staff, and sent electronically via a secure connection (SWIFT) to a central database maintained by the SICSAG team in Information Services Division (ISD). Patient identifiers are sent in a separate electronic file and held separately and no information is published which identifies individual patients.

The General Medical Council (GMC)[1] and the Nursing and Midwifery Council (NMC)[2] have their own guidance around information governance that sits closely to the GDPR.

Section 1: Information Governance

Our information governance framework enables the safe and secure use of sensitive and other information to support the health and well being of the people admitted to critical care units in Scotland. It ensures that we meet our legal and ethical duties in relation to handling and managing information to a high standard.

Information governance covers the following:

- **Caldicott and Confidentiality**
- **Data Protection and GDPR**
- **Information Security**
- **Information Requests**

1.1 Caldicott Guardians

The role was introduced in NHS Scotland by the then Scottish Executive. This followed recommendations in the 1997 report from the Caldicott Committee which had reviewed the sharing of patient-identifiable information within and beyond the NHS in England for purposes other than direct care[3].

The Caldicott Guardian is the professional person in a Health Board responsible for safeguarding patient confidentiality while enabling appropriate sharing of patient information to the highest standards. You should contact your local Health Board Caldicott Guardian if you have any questions.

Confidentiality

Protecting patient confidentiality, a part of Information Governance, is the business of **everyone** working in the organisation. Caldicott Guardians are one of a number of Information Governance specialists who have the role of establishing systems and guidelines that ensure that information is handled in a confidential and secure manner to the highest ethical and quality standards

Below are the six Caldicott principles which should underpin all decisions regarding uses of patient information?

1. Justify the purpose(s) for using confidential information
2. Only use when absolutely necessary
3. Use the minimum that is required
4. Access should only be on a strict need to know basis
5. Everyone must understand his or her responsibilities
6. Understand and comply with the law.

These principles should be considered along with local NHS Health Board Confidentiality Guidelines when in doubt about confidentiality issues. If you require additional help with a question please contact your line manager in the first instance.

1.2 Data Protection Act 2018

The Data Protection Act 2018[4] is the UK's third generation of data protection law that commenced on 25 May 2018. The new Act aims to modernise data protection laws to ensure they are effective in the years to come. The Act makes provision for the regulation of the processing of information (personal data) relating to individuals where most processing of personal data is subject to the GDPR.

1.3 The European General Data Protection Regulation (GDPR)

The European General Data Protection Regulation (GDPR)[5] came into force on 25th May 2018.

There are seven key principles that lie at the heart of the GDPR. They are set out right at the start of the legislation, and inform everything that follows. Compliance is therefore a fundamental building block for good data protection practice. These principles should lie at the heart of your approach to processing personal data.

The GDPR seven key principles are:

- Lawfulness, fairness and transparency
- Purpose limitation
- Data minimisation
- Accuracy
- Storage limitation

- Integrity and confidentiality (security)
- Accountability

Failure to comply with the principles may leave you open to substantial fines. Article 83(5)(a) states that infringements of the basic principles for processing personal data are subject to the highest tier of administrative fines. This could mean a fine of up to €20 million, or 4% of your total worldwide annual turnover, whichever is higher.

1.4 Information Security

Information security is the protection of information systems against unauthorised access to or modification of information, whether in storage, processing or transit; it also includes those measures necessary to detect, document, and counter such threats. Information Security covers not just information but all infrastructures that facilitate its use (e.g. processes, systems, services, technology, etc). The greatest risks to data security is people, not the technology, so it is important that healthcare staff follow their local guidelines to reduce the risk

The three elements of information security, generally referred to as the *three pillars* of information security or the *CIA triad,* are:

- **Confidentiality** – ensuring that information is accessible only to those authorised to have access
- **Integrity** – safeguarding the accuracy and completeness of information and processing methods and
- **Availability** – that the information and data is available when the user requests it.

Good Practice in Information Security specifically relating to electronic data is to:

- Always logout of the computer system or application when work is finished
- Never leave a terminal unattended if logged in
- Never share log ins with other members of staff
- Never reveal passwords to others
- Change your passwords regularly to prevent others using them
- Avoid using short passwords, or passwords that others may guess e.g. favourite team, pets name etc
- Always clear the screen of a previous patient's information before accessing another patient's details
- Use a password protected screen saver to prevent 'casual' viewing of patient information by others.

If you have any questions regarding information security please contact your local Health Board information security team.

1.5 Information Requests

SICSAG welcomes opportunities to collaborate with colleagues to further understanding of Intensive Care.

To request data please complete an Information Request Form available on the SICSAG website www.sicsag.scot.nhs.uk and email to PHS.sicsag@nhs.net. You are advised to speak to the Clinical Co-ordinator or Senior Information Analyst before requesting audit data.

The Clinical Co-ordinator must be provided with a copy of any written report or submission (prior to publication) where audit data has been used – this is to ensure appropriate interpretation of the data.

If a unit is identifiable, then the Lead Audit Consultant should also be shown the report prior to publication.

The source of data must be acknowledged in any presentation or publication.

Rules regarding the release of data

Lead Audit Consultants and Local Co-ordinators have unrestricted access to their own centre's data.

Requests for regional or national *named-hospital* data must be sanctioned by each Lead Audit Consultant and the following people will be notified and copied into the information provided:

- Chairman
- The departmental Clinical Lead in each named hospital
- The hospital's Chief Operating Officer
- The Chairperson of the local Clinical Effectiveness Committee or Head of Clinical Governance
- Any other relevant clinical leads

It is the responsibility of the Lead Audit Consultant to ensure the relevant parties in his/her hospital are kept informed.

National anonymised data will be released at the discretion of the Chairman of the audit.

Requests received for hospital data from applicants employed by the hospital or requests from hospital management or clinical effectiveness groups will be discussed with the Lead Audit Consultant and departmental Clinical Lead at the hospital in question and each will receive copies of any information provided.

Requests from Health Boards will be discussed with the Lead Audit Consultant for the audit.

Requests from the Scottish Government (including Parliamentary Questions) will be discussed with the Chairman or Vice Chairman (in the absence of the Chairman).

Requests from the media must be referred to the Chairman immediately – under no circumstances should any audit employee converse with media representatives.

Requests for patient identifiable data will be referred to the Chairman of the audit and the Caldicott Guardian at ISD.

National Reporting

All National Reporting must follow the ISD Publication Protocol, a requirement by ISD and the Scottish Government to standardise the manner in which ISD publishes and publicises all its releases. This ensures that any National report is previewed by relevant people and that all reports are published on relevant websites at the same time (second Tuesday of every month at 9.30am). A press release is sent at the same time with a brief summary of all reports that have been published that month.

Disclosure Control

PHS Disclosure control policies will be applied before the release of data.

Application for release of data form.

Recipients will complete and sign an ‘Application for Release of data form’ before expecting receipt of data, to indicate their legal responsibility to comply with the General Data Protection Regulation (GDPR), the Data Protection Act 2018 and Public Benefit and Privacy Panel for Health & Social Care (PBPP) Guidelines.

Section 2: Data Analysis

2.1 Methodology

Data collection

Data were collected prospectively from all general adult ICUs, Combined Units and the majority of HDUs using the WardWatcher system developed for this purpose. In February 2020, an initial extract of 2019 data was sent to ISD servers. Validation queries relating to discharges, outcomes, ages and missing treatment information were then issued and fed back to individual units for checking by local and regional audit coordinators. A final validated extract was submitted to ISD in March 2020, which has been used for the annual report.

Along with the measures taken to ensure data validity, the comprehensiveness of the data, incorporating data on all patients receiving care in participating units during 2019, ensures that the findings included in this report have a high degree of reliability at the national, health board and individual unit level.

Data management

SICSAG data has undergone an extensive review. All SICSAG data from 1995 onwards is now stored within a rationalised set of databases, and variables and values have been made consistent. SICSAG are constantly striving to improve data quality through ongoing validation and therefore the SICSAG database should be regarded as dynamic and the data may be subject to change.

All SICSAG data from 1998 to 2019 have been through a linkage process that aims to match SICSAG Critical Care episodes to Information Services Division (ISD) SMR01 data scheme which collects data on all general/ acute inpatient and day case admissions. All patients recorded in the SICSAG database should have SMR01 records relating to the same hospital stay. 96% of all SICSAG episodes have been matched to an SMR01 stay. This provides an alternative source of information on hospital, ultimate hospital, discharge dates and outcomes. Where the value of these fields is not documented in SICSAG, it has been overwritten with the value derived from linkage to SMR01.

Presentation of the data

The analysis of the data and the presentation of the findings are based on that adopted in previous annual reports.

Additional Tables, along with more detailed data on subject areas that are not included in the annual report, are available on the SICSAG website www.sicsag.scot.nhs.uk. Further information on the interpretation of funnel plots is also published on this website.

WardWatcher had a major upgrade during 2008/2009 with 2010 being the first complete year of data based on the upgraded version of WardWatcher. In 2014 and 2018 there was another minor upgrade to the HAI variables. Changes that will affect trend data have been referred to in the text. 2020 will see a further upgrade with a new look and additional fields added to capture height, weight, clinical frailty and ethnicity.

Funnel plots

A number of the clinical indicators within this report are presented in graphs called control charts. A control chart is a simple way of presenting data that can help guide quality improvement activities, by flagging up areas where there appears to be marked variation and where further local investigation might be beneficial. Control charts have been used widely in the manufacturing industry, and have more recently been applied in healthcare settings. While the presentation of clinical indicators as league Tables is advised against, the use of control charts has become increasingly popular.

Within this report funnel plots (a type of control chart) have been used to allow comparisons to be made between different services providers, in this case Critical Care Units.

A performance indicator is shown on the y-axis, while generally the number of admissions is shown on the x-axis. There is a data point for every unit in the funnel plot. There are five key lines in the funnel plots used in this report. The first is the average for the type of Critical Care Unit (either 'ICU or Combined Units' or 'HDU'). Plotted on either side of the average are two sets of warning limits. Warning limits are plotted at 2 and 3 standard deviations from the mean. Each of the five key lines is depicted in red on the charts.

Data points within the control limits (the red lines) are said to exhibit common cause variation or to be 'in control'. Data points out with the control limits are said to exhibit something called 'special cause variation' (sometimes referred to as 'outliers').

SICSAG will always highlight units outside 2 standard deviations from the mean as "might be different" and outside 3 standard deviations as "are different". It should be recognised that in a comparison of 25 units there is a considerable chance of an outlier at the 2 SD (5% or 1 in 20) level. Differences may arise from many sources: differences in data accuracy, case-mix, service provision or practice. Sometimes a difference will be just a random difference caused by chance alone. SICSAG would encourage readers to use the data to examine practice in the context of the factors listed.

For some performance indicators, more than a few units are outside the outer control limits. This typically arises when the units are heterogeneous, for instance ICU versus Combined Units, or Surgical versus Medical HDUs. Then small institutional factors contribute to more variability than would be expected by chance alone. These differences may not be particularly important nor point to real differences in the performance indicators. Although the positions of the units differ in the statistical sense, they might not be of any clinical significance.

To account for excess variability the control limits can be adjusted in several ways. In this report they are calculated with a procedure derived from Spiegelhalter[6].

Funnel plots for Standardised Mortality Ratios

Over the time that the audit has been in existence, various units have been outliers at 2 SD level. We have sought reasons as to why they might be different and informed and supported individual units in seeking an explanation. Being an outlier at this level may be explained by data quality, questions over standards of care, different referral patterns, admission policies or resources but it also may be due to random variation. Therefore, we are using a very stringent definition of variance. For comparison, Hospital SMRs produced for the SPSP by ISD and also the Intensive Care National Audit & Research Centre (ICNARC) will use 3 SD to identify outliers.

2.2 APACHE II

The outcome measure used by SICSAG is the patients' survival status (alive or dead) when they finally leave an acute hospital (even if this is not the original hospital). Patients admitted to ICU are at significant, but varied, risk of death. Simply comparing the proportion of patients who die in each unit can give a misleading impression because the severity of their illnesses is different. To overcome this, we use the APACHE II system to adjust for case-mix[7]. This is a validated scoring system, which takes account of both the patients' acute condition and their chronic health[8].

Certain groups of patients are excluded:

- Less than 16 years of age
- Unit stay less than 8 hours
- Readmitted to unit during the same hospital admission
- Primary diagnosis for which the system was not developed: burns, coronary artery bypass graft,ECMO and liver transplant.

WardWatcher provides similar codes as reasons for excluding unit admissions from APACHE II scoring. Taking into account non-response, these were re-coded to reflect the hierarchy of decision-making within units. Automatic exclusions such as 'diagnosis', 'patient under 16' and 'patient stayed for less than eight hours' were excluded first and existing codes changed to reflect this prioritisation. Readmissions were excluded next, followed by 'other' cases where no rationale for automatic exclusion was provided. The remaining exclusions were optional, where it was possible to generate a score but this was not done (e.g. HDU patients).
If unit admissions are scored, case-mix adjusted mortality estimates may only be calculated in cases where an appropriate diagnosis is available. All exclusions and cases with missing or excluded diagnoses (e.g. liver transplant) are shown schematically in the decision tree.

APACHE II produces an expected mortality rate for a unit, which can be compared to the actual observed mortality rate to give a standardised mortality ratio (SMR). An SMR significantly greater than 1 suggests that mortality is higher than expected, and a value of less than 1 that it is lower than expected. It is important to interpret SMRs with caution. It should be appreciated that whilst the APACHE II scoring system adjusts for case-mix, it does not do so perfectly. This scoring system is now nearly 30 years old. Many units admit a relatively small number of patients each year and the confidence intervals around the

SMR are therefore wide. Exact confidence intervals for SMR are calculated by the method described by Ulm[9].

The standard APACHE II model has been recalibrated based on data from Scottish ICU and Combined Units between 2009 and 2011. The standard APACHE II model has been consistently over predicting mortality for patients admitted to Scottish ICU and Combined Units. This has meant that the old model was not as useful for calculating SMR for the Scottish population. The standard APACHE II model will continue to be available, and could be used to produce trend information and for international comparison. WardWatcher will continue to calculate predicted mortality based on the standard APACHE II model at this time.

2.3 CUSUM

CUSUM stands for the **CU**mulative **SUM** of outcomes.

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[10].

An **increase indicator** and a **decrease indicator** are calculated for each patient. These values are based on the patient's APACHE II mortality prediction and whether the patient was alive or dead on discharge from hospital.

Cumulative totals of these indicators are kept. The increase indicator is added to the cumulative increase indicator, and the decrease indicator is subtracted from the cumulative decrease indicator. The cumulative increase indicator is restricted to be above zero, and the cumulative decrease indicator is restricted to be below zero.

The **cumulative increase indicator** measures whether a sequence of hospital outcomes is **worse** than might be expected from these patients' APACHE II mortality predictions. The **cumulative decrease indicator** measures whether a sequence of hospital outcomes is **better** than might be expected from these patients' APACHE II mortality predictions.

If the patient is **alive** on discharge from hospital:

- the increase indicator is negative, and so the cumulative increase indicator goes down, towards the middle of the chart
- The decrease indicator is positive, and so the cumulative decrease indicator goes down, towards the bottom of the chart.

If the patient is **dead** on discharge from hospital:

- the increase indicator is positive, and so the cumulative increase indicator goes up, towards the top of the chart
- The decrease indicator is negative, and so the cumulative decrease indicator goes up, towards the middle of the chart.

The size of the increase and decrease indicators depends on the mortality prediction.

- If the patient has a **low** mortality prediction and is **alive** on discharge from hospital then
  - the increase indicator will be small and negative
  - the decrease indicator will be small and positive.
- If the patient has a **low** mortality prediction and is **dead** on discharge from hospital then
  - the increase indicator will be large and positive
  - the decrease indicator will be large and negative.
- If the patient has a **high** mortality prediction and is **alive** on discharge from hospital then
  - the increase indicator will be large and negative
  - the decrease indicator will be large and positive.
- If the patient has a **high** mortality prediction and is **dead** on discharge from hospital then
  - the increase indicator will be small and positive
  - the decrease indicator will be small and negative.

So, if the expected happens, that is, a patient expected to live lives, it has a small effect on both cumulative indicators pulling them slightly downwards. If a patient expected to die dies, this has a small effect on both indicators, pulling them slightly upwards.

However, if a patient expected to die lives, this has a much larger effect on both cumulative indicators, pulling them both downwards. A sequence of outcomes where more patients with high predicted mortality survive will cause the decrease indicator to signal– the sequence of outcomes is better than expected. In this situation, the cumulative increase indicator will usually reach zero, and because it is restricted to be above zero, it will remain there.

Similarly, if a patient expected to live dies, this has a big effect on both cumulative indicators, pulling them both upwards. A sequence of outcomes where more patients with low predicted mortality die will cause the increase indicator to signal– the sequence of outcomes is worse than expected. In this situation, the cumulative decrease indicator will usually reach zero, and because it is restricted to be below zero, it will remain there.

If either the cumulative increase or decrease indicators signal, they are reset to zero.

The cumulative increase indicator has been designed to signal when the odds of mortality are **double** that expected given the APACHE II mortality predictions.

The cumulative decrease indicator has been designed to signal when the odds of mortality are **half** that expected given the APACHE II mortality predictions.

CUSUM versus Standardised Mortality Ratio (SMR)

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 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 make 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.

Also, 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.

Calculation

ApMortProp = Mean of the APACHE II mortality predictions for the selected 300 patients

Increase indicator

If hospital outcome = dead:
Increase indicator = ln(2/ (1+ApMortProp)).

If hospital outcome = alive:
Increase indicator = ln(1/ (1+ApMortProp)).

Decrease indicator

If hospital outcome = dead:
Decrease indicator= ln(.5/ (1-.5*ApMortProp)).

If hospital outcome = dead:
Decrease indicator= ln(1/ (1-.5*ApMortProp)).

The increase control limit is set at 4.5 and the decrease control limit is set at -4.5. The increase indicator of the CUSUM chart tests the hypothesis that the odds of mortality have doubled against the null hypothesis that the odds of mortality have remained at the expected rate. The increase control limit is the point at which the cumulative evidence suggests that the null hypothesis should be rejected: the odds of mortality have changed.

Limits in CUSUM charts need to balance the risk of a series of outcomes signalling on the increase indicator through chance alone (a false alarm), and the risk that an unsatisfactory series of outcomes does not signal.

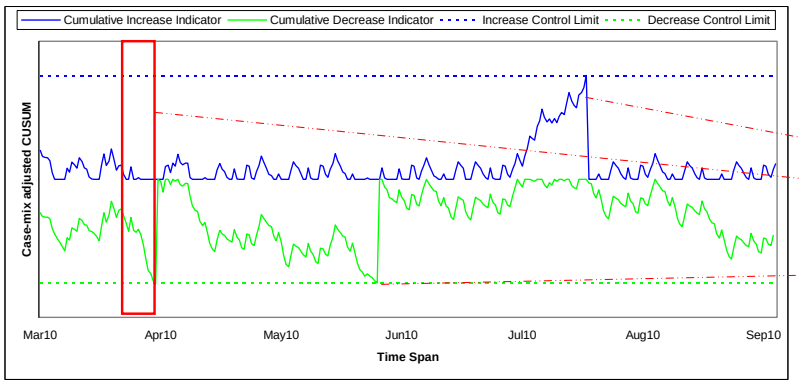
The ICU CUSUM charts have resulted in around 1 signal on the increase indicator each year.

Example report using dummy data

Example report containing dummy data

Any Hospital Intensive Care Unit	September 2010

1. Track Chart for Case-mix Adjusted Hospital Mortality



Summary table

	First date	Last date	Predicted mortality	Increase control limit	Decrease control limit
ANY ICU	01/03/2010	26/09/2010	34.73%	51.56%	21.01%

Table showing data for patients discharged during selected time period

Patient Number	Discharge Date	APACHE II mortality prediction	Hospital Outcome	Increase Indicator	Decrease Indicator	Cumulative Increase Indicator	Cumulative Decrease Indicator
1	23-Mar-10	49.80	Lived	-0.40	0.29	0.22	-1.58
2	26-Apr-10	56.4	Lived	-0.45	0.33	0.00	-1.91
3	27-Apr-10	60.2	Lived	-0.47	0.36	0.00	-2.27
4	29-Apr-10	-	Lived	-	-	-	-
5	29-Apr-10	15.5	Died	0.55	-0.61	0.55	-1.65
6	29-Apr-10	85.4	Lived	-0.62	0.56	0.00	-2.21
7	29-Apr-10	16.4	Lived	-0.15	0.09	0.00	-2.30
8	30-Apr-10	86.6	Died	0.07	-0.13	0.07	-2.17
9	01-May-10	40.5	Lived	-0.34	0.23	0.00	-2.40
10	01-May-10	73.6	Lived	-0.55	0.46	0.00	-2.86
11	01-May-10	88.8	Lived	-0.64	0.59	0.00	-3.44
12	02-May-10	30.1	-	-	-	-	-
13	03-May-10	81.2	Lived	-0.59	0.52	0.00	-3.96
14	04-May-10	26.00	Lived	-0.23	0.14	0.00	-4.10
15	05-May-10	53.20	Lived	-0.43	0.31	0.00	-4.41
16	05-May-10	27.60	Lived	-0.24	0.15	0.00	-4.56
17	07-May-10	25.60	Lived	-0.23	0.14	0.00	0.00

The cumulative increase indicator cannot go below 0

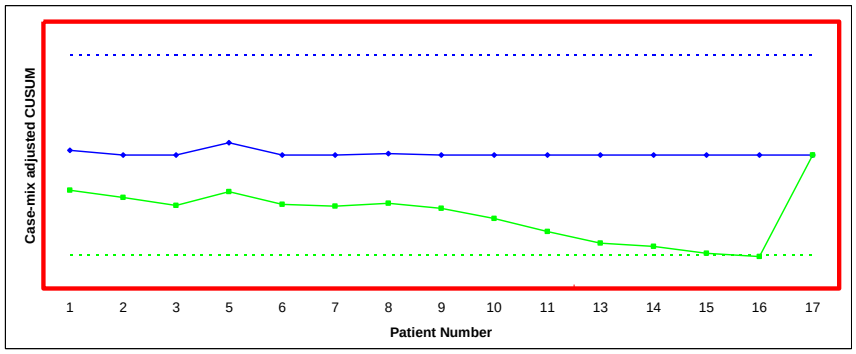
Excluded from CUSUM as Apache mortality prediction is not documented or not appropriate for this patient

Excluded from CUSUM as hospital outcome is not currently available for this patient

The decrease indicator signals here, indicating that the mortality rate is lower than expected given the Apache mortality predictions.

The cumulative decrease indicator has been reset to 0.

Detail of track chart for patients discharged during selected time period



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