



Controls Assurance Support Unit  
Innovation Centre  
Keele University  
Staffordshire  
ST5 5NB

Tel: 01782 583503  
Fax: 01782 583504  
e-mail: [casu@keele.ac.uk](mailto:casu@keele.ac.uk)

## **DEVELOPING LOCALLY DEFINED INTERNAL CONTROL INDICATORS**

## **CASU MISSION**

The mission of the Controls Assurance Support Unit is to assist the NHS improve risk management and quality in its services through the provision of standards and through acting as a facilitator for identifying and sharing good practice in risk management and control activities

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## INTRODUCTION

### 1.1 Internal Control

NHS Trust Chief Executives are all required to sign an assurance statement on the effectiveness of their Trust's system of internal control. This not only requires the organisation to undertake an annual assessment for the purpose of making its public statement but also requires the board to continually monitor its system to ensure that decisions are made effectively on the risks it faces. This requirement has evolved from developments in the private sector including the "Cadbury Report<sup>1</sup>" and the London Stock Exchange's Combined Code arising from the "Turnbull Report<sup>2</sup>". These are not the only documents which set out the principles of corporate governance and internal control, other international examples include, but are not limited to:

- Cobit
- COSO
- CoCo
- Hampel
- Basle Committee

A common feature of these reports is a definition of internal control. Similar to the Combined Code which focuses on financial, operational and compliance controls, COSO suggests that it is:

*“ a process, effected by an entity's board of directors / trustees, management and other personnel, designed to provide reasonable assurance regarding the achievement of objectives in the following categories:*

- *Effectiveness and efficiency of operations*
- *Reliability of financial reporting*
- *Compliance with laws and regulations<sup>3</sup>*

The Basle committee took the three types of objective and provided the following definitions:

- Operational objectives: efficiency and effectiveness of operations
- Information objectives: reliability and completeness of financial and management information
- Compliance objectives: compliance with applicable laws and regulations<sup>4</sup>.

Each report provides a view of how boards should manage their internal control system. Turnbull requires the board to set appropriate policies on internal control and undertake effective monitoring on a continual basis, with the board regularly receiving and reviewing reports on internal control<sup>5</sup>. Turnbull also requires the board to review all controls whilst, in contrast, the Basle committee limits the

extent of review of the control system to those risks and controls the board wants to review<sup>6</sup>. Clearly, effective monitoring is a key component of ensuring an effective, appropriately functioning system of internal control. As suggested by Spurgeon and Barwell (2000), “*in the private sector, the old adage ‘if you cannot measure an activity you cannot manage it’ has been widely accepted for many years*”<sup>7</sup>. Whilst measurement in the private sector may appear more straightforward, there is equally sufficient reason in a complex NHS environment for boards to receive sufficient information.

## 1.2 Controls Assurance and Internal Control

Controls assurance is a “*process designed to provide evidence that NHS organisations are doing their ‘reasonable best’ to manage themselves so as to meet their objectives and protect patients, staff and the public and other stakeholders against risks of all kinds*”<sup>8</sup>. Fundamental to this issue is the use of self-assessment techniques to ensure that there are adequate internal control mechanisms in place to ensure that risks are properly controlled. The NHS Executive have assisted this process by providing a control framework, which consists of the following:

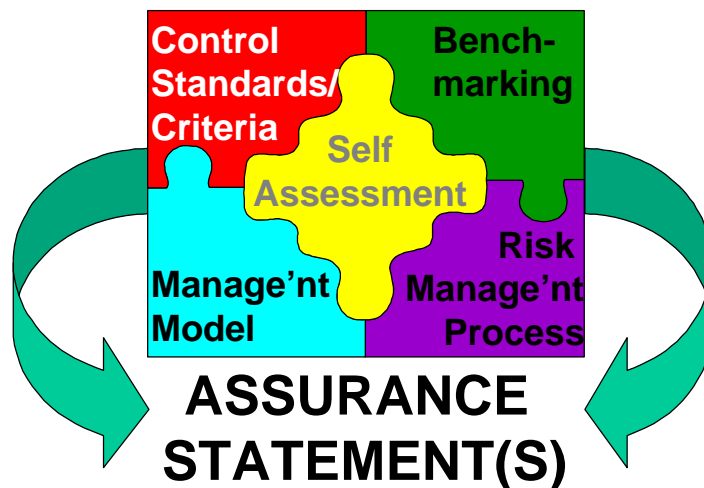


Figure 1 – Control framework for controls assurance<sup>9</sup>

Self-assessment is pivotal to the philosophy of controls assurance, as it represents the belief that cultural change and continuous improvement are more likely to be achieved if they are driven by professionals assessing their own work, rather than by third party auditors judging compliance. A range of management tools exists, which provide a systematic approach to self-assessment. Figure 2 describes the management model developed for Controls Assurance.

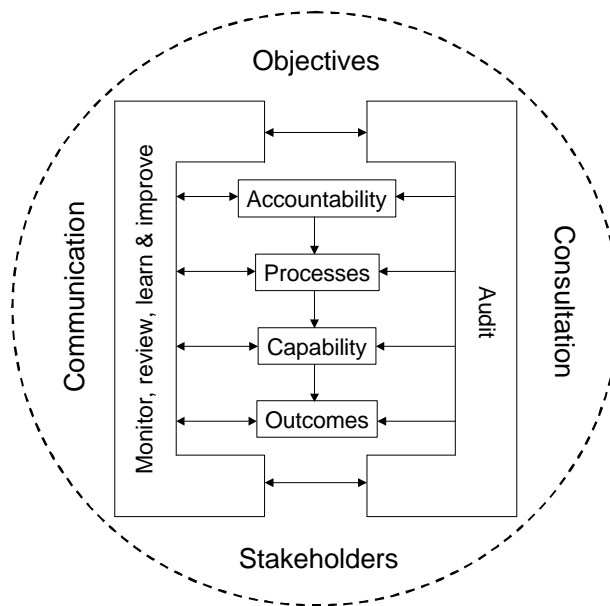


Figure 2 – Controls assurance management model<sup>10</sup>

Whilst each standard represents a significant area of organisational risk for the NHS, the point at which compliance becomes about risk is when the percentage of non-compliance with a standard is analysed. Each standard includes a generic ‘outcome’ category, which has been incorporated into the design to cover the following question:

*What flags or triggers are in place, which let the appropriate group / individual (including the board) know that: defined processes are being followed; control mechanisms are being adhered to and expected outcomes are being achieved?*

Without this information being continually reviewed throughout the organisation, the board will not be able to assure itself that its risks are properly controlled.

At the same time as ensuring that there are appropriate flags for particular risk areas, for example medical devices or health and safety, the controls assurance risk management standard covers a much wider remit encompassing the whole system of internal control. It is, therefore, necessary that there are flags or trigger mechanisms in place relating to the adequacy of financial, operational and compliance controls throughout the organisation. There are many internal and external sources of information that can help the board decide where to focus its monitoring arrangements (financial, operational and compliance). These include but are not limited to: internal risk assessments; self assessment against controls assurance standards; control self assessment; incident, complaint and claim information; internal and external audit results (including clinical audit results); CHI visit; HSE inspection; CNST assessment; and events elsewhere in the NHS. All of these sources can help the board identify both its strengths and weaknesses within its control system. Once a weakness or potential issue has

been identified the board needs to decide whether to monitor the risk, how often it should be monitored and who should monitor it. Obviously, these operational issues will depend on the significance of the risk hindering the achievement of a particular financial, operational or control objective. Indicators are one way of fulfilling this requirement as they provide an objective, quantitative measure, which can flag variances in process or outcomes for early attention.

Baseline self-assessments for year one of the Controls Assurance process suggest that indicators which focus on locally identified risks are not widely utilised<sup>11</sup>, with those few present predominantly focusing on clinical outcomes. This paper is in response to NHS organisations requesting background information, in order to develop their own internal control indicators.

## 2 DEFINITIONS AND TYPES OF INDICATOR

### 2.1 What is an Internal Control Indicator?

Considerable variation exists with regard to what is meant, internationally, by the term indicator. For example, the Canadian Council for Health Services Accreditation (CCHSA) describes indicators as screens or flags which are used as guides to '*monitor, evaluate and improve the quality of clinical care, clinical support services and organisational functions that affect patient / client outcomes*'<sup>12</sup>. Whereas the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) focuses more on the practice of professionals within the environment and in Australia (Australian Council on Healthcare Standards), the focus is on the practice of clinicians<sup>13</sup>. For the purpose of this document, the Canadian definition is considered the closest fit, as it reflects the work of human factors specialists, who suggest that it is the environment that makes those working at the sharp end more prone to failure. As a 'starter for ten' the following definition has been provided for an internal control indicator:

*Screens or flags which are used, throughout the organisation, to monitor risks and evaluate their associated control mechanisms in relation to the achievement of particular financial, operational or compliance objectives.*

### 2.2 Types of Indicator

There are three main types of indicator utilised internationally, which are generally based on Donabedian's three dimensions of quality<sup>14</sup>. These include:

- structure (the rules of the organisation and how well they are being followed, i.e. compliance with statutory health and safety requirements),
- process measures
- outcomes

Whilst compliance objectives can be monitored using structure indicators, NHS organisations will need to decide whether to use process or outcome indicators or a combination of both for financial and operational areas. Considerable debate exists regarding whether processes or outcomes should be utilised as the focus of measurement. Ibrahim et al (1999) wonders whether we should, for example, '*evaluate the technical performance of medical care for cancer by comparing the total number of patients treated with:*

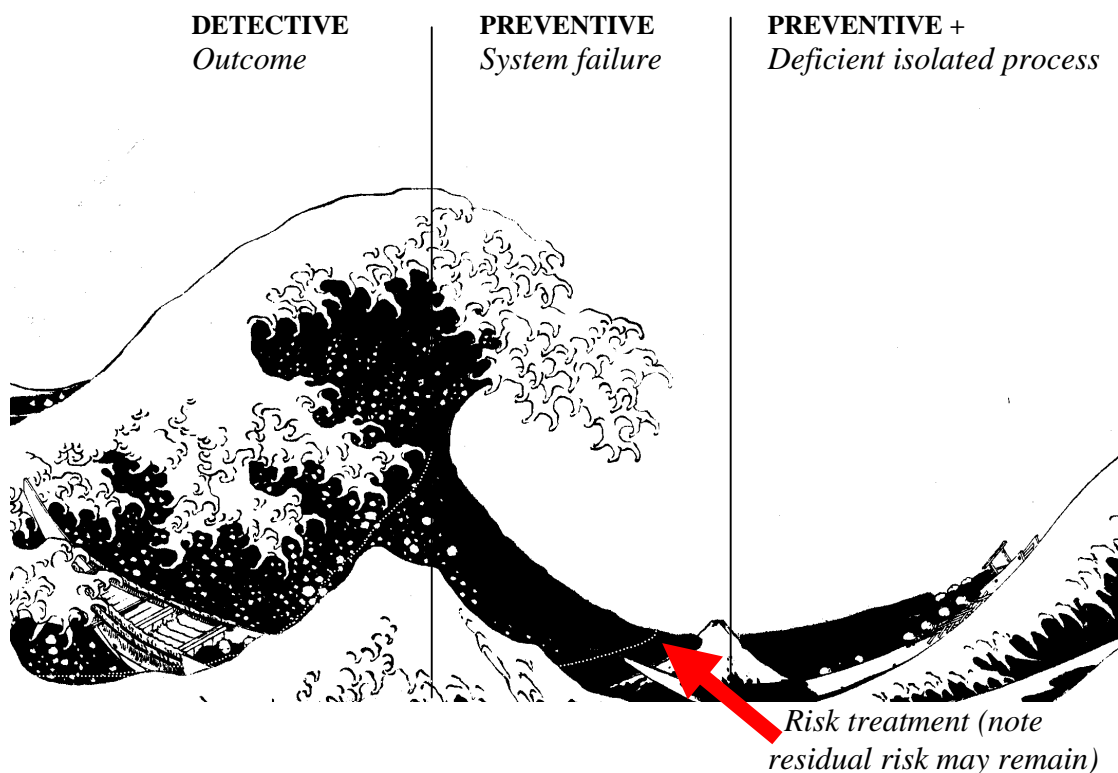
- ◆ *The number of patients who survived 5 years (i.e. outcome) or;*
- ◆ *The number of patients who received the correct dose of chemotherapy? (i.e. process)*'<sup>15</sup>

Ibrahim et al continue to explain that '*until the critical links between the process of care and the outcome of care are established, this debate cannot be resolved.*



*At the centre of the debate is the capacity of the human body to accommodate poor care and still have a good outcome and the fact that excellent medical care cannot guarantee against a poor outcome' (P9). Certainly, if it is accepted that poor outcomes are the result of combined organisation failures, then from an internal control perspective it is important to focus attention on prevention rather than detection. This is not to say, however, that outcomes do not need to be monitored, as it important to ensure the process adopted produces the outcome expected.*

The diagram provided below, which has been influenced by the work of Reason, visually demonstrates the importance of identifying risk and control failings as early as possible.



*Figure 3. The Wave Effect. Adapted from Katsushika Hokusai. The Great Wave off Kanagawa 1831*

The wave begins (at the right of the diagram) with deficient isolated processes or management decisions such as poor design, inadequate maintenance cycle or a poorly structured organisation. These vulnerabilities (latent failures) lead, as suggested by Reason, to error producing conditions. For example, if an organisation does not have a training programme in place for infection control, it could result in practitioners with inadequate knowledge of infection control measures. Whilst it may be difficult to quantify the potential outcome of latent failures at this stage, the wave can be flattened if these issues are identified and treated as early as possible (although a degree of residual risk may remain). An indicator relating to an isolated operational process could be:

the number of consultants who undertake refresher training for infection  
the number of infection control refresher training places available for  
consultants doctors within a given time period.

If the isolated process remains unnoticed or is not treated, then it has the potential to combine with other organisational failings. These multiple faults aggregate to create a chain of events and their accumulation results in an accident<sup>16</sup>. This unanticipated interaction is commonly known as a systems failure. A system can be described as “*a set of interdependent elements interacting to achieve a common aim. The elements may be both human and non-human (equipment, technology etc)*”<sup>17</sup>.

Developing system indicators is more problematic, as any outcome can have multiple combinations of causes. It is possible, however, to design indicators that focus on how well the system of internal control is functioning. For example, an indicator might be the rate at which risk treatments are implemented or the board's previous awareness of cases where claims are filed. This is a vital component as it is not just the identification of isolated processes that will drive change, but the mechanism by which risk is communicated; how it is dealt with and how effectively changes are implemented. Guidance for Directors on the Combined Code provides further guidance on the information boards should consider when assessing the effectiveness of its control system and ,therefore, system indicators could be derived from these requirements.

At a national level, in the UK, there has been “*a drive to incorporate not only structures and processes into an assessment model, but also to take account of outcomes in any review of service quality, since it is essential to know what is achieved*”<sup>18</sup>. An example of an outcome indicator might be the rate of hospital acquired infection amongst inpatients. Differences in focus between performance and risk management mean that the latter is more concerned with ‘why is there a higher rate of hospital acquired infection?’ in order to strengthen the system of internal control, so that risk can, if appropriate, be minimised.

Once system failure has occurred the organisation can only analyse events in order to ascertain the underlying causes that led to the occurrence. This analogous to the wave ‘breaking’, leaving the organisation to ‘ride the surf’ as best it can. Isolated or system factors can be monitored and reviewed on a continual basis using structure or process based indicators. Whilst it is comforting to see improvements in a particular outcome, the reason for the increase or decrease in rate of occurrence and the likelihood that the result will be sustainable will not be known, unless there is a good understanding of the related interweaving processes. As internal control focuses on prevention, considerable effort should be directed at developing triggers that highlight deficient processes as early as possible, rather than reacting after the event.

## 2.3 Rates, thresholds and trends

Structure, process and outcome indicators can be used to identify risks and evaluate control mechanisms within an NHS environment. To be useful in reflecting the frequency of the event under study the indicator is best expressed as a ratio with a numerator and denominator<sup>19</sup>. The numerator can be the number of times the event occurred, with the denominator being the total population under study. It is important to define the denominator clearly, as it provides the basis of which to calculate the percentage of cases in which the event occurred<sup>20</sup>. For example, if there was concern that mandatory reporting to the Health and Safety Executive was not being sufficiently undertaken, a structure indicator might be:

The number of work place injuries reported to the Health and Safety Executive  
The number of reportable events to the Health and Safety Executive for a defined time period

If there was concern regarding the level of inappropriate discharge from the Accident and Emergency Department, an outcome indicator might be:

Number of patients admitted for inpatient treatment of an acute problem within 12hrs following discharge from A&E after being seen for the same complaint  
Number of patients discharged from A&E during the relevant period<sup>21</sup>.

Commonly used indicators include sentinel event and rate based indicators. Sentinel event indicators are undesirable events, which are infrequent in nature and are not easily amendable to statistical or comparative analysis<sup>22</sup> i.e. a maternal death or a breach of security in a maternity unit. Rate based indicators are utilised for those events which have a relatively high frequency and lend themselves easily to statistical analysis. Rate based indicators are expressed as a ratio with the number of occurrences divided by the total population under study<sup>23</sup> (as shown above). Whilst sentinel event indicators only need one case to act as a trigger, rate based indicators often incorporate a tolerance threshold, which could show a persistent or undesirable trend. For example, the ACHS suggests 'if a post-operative cholecystectomy rate of 5% is quite usual, 5% may be established as the 'threshold' level. A percentage higher than this may 'flag' or alert a facility to potential problems. Alternatively, a result much lower than the threshold level may indicate problems with data collection<sup>24</sup>.

The second, less common approach, for rate based indicators, originates from Continuous Quality Improvement (CQI). Statistical Process Control (SPC), which can be traced back to the work of Shewhart and subsequently Deming, is "*generally accepted to mean management control of the process through the use of statistics or statistical methods*"<sup>25</sup>.

The four main uses of SPC are as follows:

- “To achieve process stability
- To provide guidance on how the process may be improved by the reduction of variation
- To assess the performance of a process
- To provide information to assist with management decision making<sup>26</sup>”

Statistical Process Control (SPC) does not wait for a threshold to be breached, rather it is proactive in nature, focusing on the entire output of the process. This enables organisations to 1) reduce the variability in the process and /or 2) shift the process in the desired direction. It centres on common cause variation (*a regular rhythm of a process which means the process is stable or ‘in control’*) and special cause variation (*irregular rhythm of a process which means the process is unstable or ‘out of control’*)<sup>27</sup>. In terms of understanding variation it is extremely useful as it provides a ‘dynamic display’. As Carey and Lloyd (1995) suggest, “*whereas static displays of data can be compared to taking a snapshot with a camera, dynamic displays on the other hand, are more like a moving picture obtained with a camcorder*”<sup>28</sup>. For detailed information on statistical process control applications, readers are recommended to read Lloyd & Carey 1995.

## 2.4 Features of an Indicator

The indicator must be relevant to enable the identification of key financial, operational or compliance risks and reproducible i.e. accurate and precise (not open to different interpretations by individuals and remains reliable over time). Essential attributes of indicators have been published by a number of sources. These include:

Attributes of Indicators	NHSE 1998 <sup>29</sup>	ACHS 1999 <sup>30</sup>
<b>Importance / Significance</b> (addresses an issue which is high cost, high priority, high risk, high volume)	√	√
<b>Valid / Attributable</b> (the <u>clinical</u> indicator must have evidence to support the validity of it as a measure of quality)	√	√
<b>Usefulness</b> (relevance to practice. In particular, the indicator identifies areas where deficits occur and improvements are possible)		√
<b>Definable</b> (the data elements of the indicator must be clearly defined without ambiguous or subjective terms)		√
<b>Readily Available / Accessible</b> (the data elements are able to be collected from existing or data collection systems within a reasonable timescale)	√	√

<b>Reliable / Robust</b> (the data elements are accurate and reproducible)	√	√
<b>Identifiable</b> ( the data elements of the indicator event and the denominator are readily identifiable and measurable)		√
<b>Meaningful</b> (the frequency of occurrence of the indicator should not be prone to floor and ceiling effects. The indicator event should be sizeable enough to adjust for known measurement errors and allow for random variation.		√
<b>Avoid Perverse Incentives</b>	√	
<b>Responsive / Potential to Improve</b> (the potential of the indicator to induce change)	√	√

## 2.5 Developing and Monitoring Internal Control Indicators

The organisation will need to decide, based on its own assessment of risk (from various sources of information), in which areas it needs to design indicators and how long it wishes to monitor them. Clearly, there will be some internal control areas which are so vital in meeting the organisations objectives (financial, operational and compliance), that it would monitor related indicators indefinitely. Other indicators may be monitored for a period of time, until the board is reassured that the issue has been resolved.

## 3 Local and National Indicators – The Rationale

It is clear from the development of indicators around the world that whilst indicators centrally imposed are considered ideal, in reality organisations cannot accurately deliver the requirements because of a lack of the right information systems. It is now generally held that indicators need to be kept within the realm of the possible and should be developed and allowed to evolve over time<sup>31</sup>. As Controls Assurance intended from the outset for organisations to develop indicators that represented their own risks, it remains important for these indicators to be locally defined. There may be, however, common risks which run throughout the NHS and therefore CASU will serve as a library for indicators. In order to achieve this, it is vital that organisations send their indicators to CASU for inclusion.

Whilst locally defined indicators are needed for boards to assess the effectiveness of their own system of internal control, it must be recognised that there may be some macro-measurement of whether the NHS is getting better or worse at managing risk. It is possible that a limited number of outcome measures will be developed, which the centre wishes to monitor. If this is the case, then emphasis will be based on trusts' ability to collect the required information.

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