



South London  
Commissioning Support Unit

Programme Briefing

# Commissioning for Quality

A programme supported by South London Commissioning Support Unit and the Good Governance Institute

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# Commissioning for Quality

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## Background

Working with South London CSU and their client Clinical Commissioning Groups (CCGs), the Good Governance Institute (GGI) has developed the 'Commissioning for Quality' programme to help clinical commissioners address their post-Francis quality responsibilities. A core tenant of this work has been raising awareness and confidence amongst those on governing bodies in CCGs around the quality assurance processes within NHS providers.

The role of internal and clinical audits within NHS providers has emerged as a potential resource for CCGs ensure quality in commissioned services. A key aspect of the Commissioning for Quality programme is to identify opportunities to use existing quality assurance activities to inform commissioning decision-making and secure quality assurance knowledge. At present, commissioners are largely unsighted on provider conducted audit programmes and their results. GGI believes that the post-Francis duty of candour is a game-changer in encouraging greater grip on quality issues by commissioners.

As part of the 'Commissioning for Quality' programme, GGI, along with South London CSU and their clients, have analysed the concept of whether the more joined-up use of resources devoted to all audit activity across a healthcare economy (internal and clinical audit programmes) can better add to the assurance around the quality of care. To date, GGI have acquired feedback from key stakeholders across the healthcare sector, including commissioners, auditors, representatives of quality schemes and others. Outputs of the programme include a Board Assurance Prompt tracing commissioner interaction with audit activity which can be access on the GGI website [www.good-governance.org.uk](http://www.good-governance.org.uk).

Audit hold the potential to provide commissioners with a right seam of validated insight into key care and management processes. Audit reporting considers whole systems of internal control, and as such can offer crucial insight around effective risk management by providers for commissioners. A key actor in the provision of clinical audit in the UK is the Healthcare Quality Improvement Partnership (HQIP), while internal audit services are provided by a range of professional auditing firms. Engagement across the healthcare environment is crucial to ensure quality for patients, as well as meeting business and performance objectives by challenging existing processes and identifying innovative solutions.

# Internal and clinical audit

## Clinical Audit

### The Healthcare Quality Improvement Partnership (HQIP)

[www.hqip.org.uk](http://www.hqip.org.uk)

The Healthcare Quality Improvement Partnership (HQIP) was established in April 2008 to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. HQIP is led by a consortium of organisations, including the Academy of Medical Royal Colleges and the Royal College of Nursing.

Foremost among the audit programmes run by HQIP is the National Clinical Audit and Patient Outcomes Programme (NCAPOP). NCAPOP audits are commissioned and managed on behalf of NHS England by HQIP. These are a set of national clinical audits, registries and outcome review programmes which measure healthcare practice on specific conditions against accepted standards. In this sense, the role of quality review bodies under examination in the adjoining strand of the 'Commissioning for Quality' programme is complemented by these broader clinical audits.

These projects give healthcare providers (and potentially commissioners) benchmarked reports on their performance, with the aim of improving the care provided. Most of these projects involve services in England and Wales; some also include services from Scotland, Northern Ireland and other regions. On a local level, NCAPOP audits provide local trusts with individual benchmarked reports on their compliance and performance, feeding back comparative findings to help participants identify necessary improvements for patients.

As well as the 30-plus national clinical audits, NCAPOP also encompasses the four Clinical Outcome Review Programmes (CORP). These aim to assess the quality of healthcare and stimulate improvement by enabling clinicians, managers and policy makers to learn from adverse events and other relevant data.

## Internal Audit

A range of professional audit firms provides Internal Audit services across the NHS. Internal audit is fundamental to overall good governance, and to the nature of quality assurance reporting more specifically. The Department of Health publishes NHS Internal Audit standards, aimed primarily at the providers of internal audit services, but also relevant to Accounting Officers, Audit Committees, and a range of other stakeholders in the healthcare environment.

The Institute of Internal Auditors define internal audit as:

"An independent, objective assurance and consulting activity designed to add value and improve an organisation's operations. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control and governance processes<sup>1</sup>."

It is important to understand that while internal audits examine an organisation's financial controls, the wider system and processes of internal control and good governance also come under consideration. In this way, the internal audit can act as an important source of quality assurance information for NHS commissioners. Examples of internal audit activity relating directly to the quality of patient care would be of the processes surrounding incident and near-miss reporting, complaints, data quality and patient care records.

Driving value from the joined-up use of such assurance operations is a key aspect that the 'Commissioning for Quality' programme seeks to examine. Including commissioners within this assurance framework is an opportunity to instil and safeguard the continuity of quality care for patients across the NHS.

## The role of Audit Committees in relation to clinical standards

‘Because the core business of every NHS organisation is healthcare, the Audit Committee should, and must, spend time reviewing the healthcare aspects of the business. In particular, it falls to the Audit Committee to consider the clinical objectives and risks in the Assurance Framework and to report to the Board on the controls and assurances in relation to these. Provider trusts will be concerned with the clinical care provided within their organisations whereas commissioners need to take account of the arrangements made by their providers and the extent to which their Clinical Quality Review Groups can obtain confirmation of assurances.

There may be a perceived concern of duplication in the Audit Committee looking at such matters but its role in relation to clinical services is clearly distinguishable. Its role, at all times, is to satisfy itself that the same level of scrutiny and independent audit over controls and assurances is applied to the risks to all strategic objectives, be they clinical, financial or operational. As with financial and operational objectives, the Assurance Framework is the foundation for the Audit Committee’s work in addressing risks to clinical objectives and satisfying itself that controls are adequate and assurances are sound and sufficient.’ (From NHS Audit Committee Handbook, HFMA 2011, Amended at italics to reflect new structures)

## Quality Schemes

A core tenant of the Commissioning for Quality programme has been raising awareness and confidence amongst those on governing bodies in CCGs around the quality assurance processes within NHS providers.

While the Care Quality Commission (CQC) is positioned as an overarching regulator of health and social care services in England, a range of other quality review bodies operate throughout the healthcare sector. Many of these schemes relate to practice-specific quality assessment, and as such can offer detailed and timely insight. Indeed, in constructing their quality and risk profiles, CQC incorporate the data provided by these quality review schemes.

The structure of assessment methods implemented range from voluntary self-assessment processes, to on-site inspections by bodies with the power to suspend licensing and accreditation.

As part of the ‘Commissioning for Quality’ programme, GGI, along with South London CSU and their clients, have examined how these small-scope quality assurance schemes that exist within healthcare providers can add value to the assurance around care quality for commissioners. In the course of this research, we have identified a number of such quality review schemes that may be useful in contributing to a framework of greater quality assurance (appendix attached).

As a means of organisation, and following initial feedback from a variety of stakeholders, we have focused primarily on schemes that exhibit the following traits:

- Use of standards
- Incorporate an element of external review
- Lead to a published report
- Have their own quality assurance process

A key part of the attraction of such schemes is that they can provide aggregated information on the state of practice within an organisation or field. The outputs of these schemes can act as an easily accessible and clearly communicated touchstone for both the legacy and current environment of quality across the healthcare landscape.

We feel that these schemes provide a rich but often underused source of assurance for the boards of provider organisations, and commissioners too could gain a valuable insight into the quality issues in the providers they work with through imaginative use of the outputs from these various schemes. The most productive benefits would be gained from building constructive relationships between providers and commissioners to make better use of the sometimes detailed insight into patient care that comes out of these schemes.

## Appendix: Quality Review Systems

### Human Tissue Authority (HTA)

[www.hta.gov.uk](http://www.hta.gov.uk)

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, patient treatment, education and training, and public display. HTA also give approval for organ and bone marrow donations from living people. The organisation licenses establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met. HTA licences more than 800 organisations. Their remit extends to Scotland in relation to tissues and cells used in patient treatment. HTA publish annual reports, which are publically available on the HTA website, as are HTA inspection reports of specific premises.

HTA has recently moved from a fixed-term to a continuous licensing system. Fixed-term licences will now only be issued in exceptional cases, for example to temporary mortuaries, temporary exhibitions and establishments that are deemed to be a high risk. The continuous licensing system is supported by a sector-specific compliance monitoring framework that involves the collection of regular compliance updates from licensed establishments.

HTA also conducts inspections to check that licensed establishments maintain good standards and follow appropriate procedures. The HTA defines inspection as a process encompassing desk based assessment, on-site assessment and analysis of information to evaluate compliance with the conditions of a licence and HTA licensing standards. Site visit inspections are conducted based on the findings from a desk based assessment and any other relevant information.

The focus during a site visit inspection is on reviewing operational policies and procedures, inspection of premises, scrutiny of practices which involves review of documentation, and in some cases interviews with a range of staff at the establishment. Through his process, HTA aim to identify any shortfalls in relation to the standards and the conditions of a licence, assess whether the HTA is satisfied with the suitability of an establishment to carry out one or more of the activities regulated by the HTA, offer advice on improvements which are required to be made and identify areas of good practice.

### Clinical Pathology Accreditation (CPA)

[www.cpa-uk.co.uk](http://www.cpa-uk.co.uk)

The clinical pathology accreditation service (CPA) is a wholly owned subsidiary of UKAS. The scheme implements medical laboratory accreditation through internationally recognized standards (ISO 1581), with a structure of peer assessment. While accreditation is voluntary, the majority of UK medical laboratories are enrolled, and the Department of Health requires that all medical pathology laboratories register with CPA.

Organisations wishing to register for CPA accreditation provide information on the scope of their activity, any current in-house calibration services, and general system documentation and procedures. This forms the basis of a gap analysis before the assessment team is organised.

The role of the CPA Peer Assessor is to provide specific medical laboratory expertise for the assessment of applicant and accredited laboratories. The CPA Assessment Teams are normally composed of a full-time CPA Regional Assessor, acting as Lead Assessor, supported by peer assessors who assess the validity of systems, appropriateness of equipment, facilities and resources, competence of staff, internal quality control, external quality assessment and patient needs and requirements. These peer assessors are trained in assessing against ISO 15189:2012 and to UKAS requirements.

Assessment findings are discussed at the time they are identified and recorded, with potential corrective actions also discussed and specified. A summary of findings is provided at the end of inspection before the main report is prepared. This report is the basis for the UKAS implemented recommendations, timescales and mechanisms for clearing findings. Laboratories are assessed every two years and have to renew their registration annually, confirming that they are continuing to operate according to CPA guidelines and standards.

On-site assessments lead to a report, however CPA does not currently publish these. The report may recommend accreditation, identify conditions that must be met before accreditation is granted, or recommend that accreditation be refused and the applicant advised to reapply at a later date.

The Assessment Manager will consider the recommendations and issue a decision. The final decision about accreditation status rests with CPA. CPA currently assesses approximately 1250 Laboratories. Most laboratories are in the UK, but CPA has also accredited laboratories in Europe, Middle East and the USA.

## General Medical Council – Medical schools and Deaneries inspection visits & Emergency Medicine Checks

[www.gmc-uk.org](http://www.gmc-uk.org)

The General Medical Council (GMC) sets standards for medical education and training. As part of its quality assurance processes to ensure that medical schools, postgraduate deaneries and local education providers are complying with these, GMC conduct visits to review education and training. In formulating its annual Regional Review reports, GMC visit all of the medical schools and deaneries in a geographical region (or country) to make judgements about each individual organisation and to get a picture of education and training in that area. This includes visits to local education providers (LEPs) providing clinical placements for medical schools and delivering the postgraduate training managed by postgraduate deaneries. The 2012-13 Regional Review focused on London, while the 2013-14 process will review the quality of medical education and training across the North West.

GMC also implements a programme of Emergency Medicine Checks to review the delivery of training in emergency medicine. As part of the review, site-specific reports detail local findings while a summary report draws together key themes from the small sample of checks completed.

## Medical Deanery Research

Complementing the GMC inspection and review framework around medical education is the research of Medical Deaneries. These Deaneries are hosted by Health Education England. Since 1 April 2013, Local Education and Training Boards (LETBs) have been responsible for workforce planning and development and education and training of the healthcare and public health workforce. In this sense, the functions of Postgraduate Medical Deaneries have come within the remit of LETBs, but continue to exist and work with Health Education England in providing training and professional development for doctors and dentists.

The research of Medical Deaneries has been identified as a potentially useful resource for supporting commissioning quality assurance. An area of particular insight is the framework around Junior Doctor Exit Interviews. While the standardization of exit interviews by Medical Deaneries is underdeveloped, the approach of the North Western Deanery provides a potentially valuable scheme for helping clinical commissioners discharge their quality responsibilities.

The North Western Deanery exit interviews form part of a continual collection mechanism in conjunction with the GMC, and have a response rate of 96%. These trainee surveys can offer a wealth of information on institutional culture across the NHS. The Deanery research is collated in reports, which are currently targeted at Trust Boards. Based on our experience throughout the 'Commissioning for Quality' programme, Deaneries would largely welcome commissioners having access to such information as part of a broader framework of quality assurance.

## Joint Advisory Group on Gastrointestinal Endoscopy (JAG)

[www.jagaccreditation.org](http://www.jagaccreditation.org)

The Joint Advisory Group on Gastrointestinal Endoscopy (JAG) was established in 1994 under the auspices of the Academy of Medical Royal Colleges. Endoscopy services that sign up to the JAG Accreditation Pathway are part of an ongoing annual programme of quality improvement, accreditation and maintenance. JAG Accreditation is awarded annually on evidence of satisfactory standards. Once application to the system is in place, all endoscopy services are required to complete two online Global Rating Scale (GRS) self-assessment censuses, in April and October each year. The GRS examines the following domains of endoscopy services: quality of patient experience; clinical quality; workforce; and training.

GRS Accreditation requires the maintenance of GRS scores at level A for timeliness and B across all other domains. If an accredited unit does not maintain the required levels for the GRS in April they will be contacted by JAG to inform them that they will not be eligible for the annual accreditation process unless a satisfactory GRS score is achieved. JAG offers support and a Quality Improvement visit to help sites address relevant issues. Clinical quality

The JAG scheme is supplemented by a JAG Endoscopy Training System (JETS). This provides the endoscopy community with a system to book and evaluate endoscopy training courses and an e-Portfolio to support the JAG trainee certification process. JAG also publish a range of annual reports, covering a national census of endoscopy units in England, strategic improvement reports, as well as how to track progress through the GRS scores.

## Imaging Services Accreditation Scheme (ISAS)

[www.isas-uk.org](http://www.isas-uk.org)

The Imaging Services Accreditation Scheme (ISAS) is run in conjunction with the Royal College of Radiographers and the Royal College of Radiology. The scheme is delivered and managed by United Kingdom Accreditation Service (UKAS) on behalf of the Royal Colleges. Accreditation is an independent attestation of an organisation's competence to provide diagnostic imaging services.

The ISAS standard has been developed by both of the royal colleges. The standard covers key aspects of an imaging service's performance across four quality domains: clinical; patient experience; safety; and facilities, resources and workforce. Across these four quality domains are 33 'standard statements' that address aspects necessary for the provision of an independently recognised, high quality diagnostic imaging service. Each standard statement is accompanied by detailed professional guidance that provides advice on meeting it.

Accreditation can be achieved via two routes, either a staged pathway with recognition for progress along the route, or a direct pathway whereby all documentation is submitted and assessed in one stage. Initial gap analyses at the registration stage are followed by further desk analyses of policies and procedures. This leads to an on-site assessment consisting of observation of practice and interview of staff. Improvement actions can then be recommended before accreditation can be granted based on annual self-assessment.

ISAS assessment teams are made up of trained assessors, external peers and a layperson led by a UKAS assessment manager. The scheme is entered into voluntarily, with results contributing to annual reviews published by the Royal Colleges.



## Accreditation for Inpatient Mental Health Services (AIMS)

[www.rcpsych.ac.uk](http://www.rcpsych.ac.uk)

AIMS is a standards-based accreditation service implemented by the Royal College of Psychiatrists. The scheme is designed to improve the quality of care in psychiatric wards. The work of AIMS is separated across five branches; wards for working-age adults, wards for older people, psychiatric intensive care units, inpatient learning disability services, and inpatient rehabilitation units. Compliance is measured by self- and peer-review. Accreditation is valid for up to 4 years, subject to an annual self-review.

During phase 1 of the accreditation process, the service will undertake a series of surveys, including staff, carer and ward/unit manager questionnaires, a service user feedback tool, a review of case notes and an audit of the environment. This allows the service to review their local procedures and practices against the standards set by AIMS and, if necessary, to make the changes required to achieve accreditation. A summary of the results from the self-review forms the basis of the discussion of the peer-review visits.

The peer-review visit takes place four to eight weeks after a service has completed self-review. A team, generally of four people and comprising staff from other member services and a service user and/or carer representative, will undertake a peer-review visit. In addition to validating the self-review, the peer-review provides an opportunity for discussion, sharing of ideas and for the visiting team to offer advice and support.

Information from the self- and peer-review is compiled into a summary report that is verified by the lead reviewer and the service before being submitted to the Accreditation Committee (AC). The Committee makes a recommendation about the service's accreditation to the Special Committee on Professional Practice and Ethics (SCPPE), as the awarding body.

There are four categories of accreditation status:

- accredited as excellent;
- accredited;
- accreditation deferred;
- not accredited.

Services that cannot achieve accreditation at the point of review but are expected to be able to do so in the near future are deferred for a time-limited period in which they must meet the necessary standards.

The Royal College of Psychiatrists' Centre for Quality Improvement (CCQI) publishes national reports based on the accreditation programme. Currently, the *2007-2009 National Report for Working Age Acute Wards* and *2008-2011 Inpatient Mental Health Services-Older People's Services* reports have been published and are available online.

## National Peer Review Programme

[www.nationalpeerreview.nhs.uk](http://www.nationalpeerreview.nhs.uk)

The National Peer Review Programme is a quality assurance programme that is aimed at reviewing clinical teams and services to determine their compliance against national measures, as well as the assessment of quality aspects of clinical care and treatment. The scheme reviews approximately 2000 NHS clinical and service teams annually.

Care services in this scheme include:

- **Cancer** – annual self-review with peer-review site visits if significant scope for improvement is identified. Standards are based on the Manual for Cancer Services. Both individual team reports and national summary reports are published.
- **Paediatric Diabetes** – structure under review (A redeveloped diabetes peer review scheme to be implemented mid-2014)
- **Stroke** – structure under review

## Safe Effective Quality Occupational Health Service (SEQOHS)

[www.seqohs.org](http://www.seqohs.org)

SEQOHS Accreditation is the formal recognition that an occupational health service provider has demonstrated that it has the competence to deliver against the measures in the SEQOHS Standards. The scheme is managed and governed under the Royal College of Physicians (RCP).

The standards for accreditation have been developed in conjunction with the Faculty of Occupational Medicine (FOM), and were pilot tested with 17 different providers of occupational health services from various sectors. SEQOHS produces an annual report for the FOM to reflect the performance outcomes achieved through each year. The standards are grouped into six domains: Business Probity, Information Governance, People, Facilities and Equipment, Relationships with Purchasers and Relationships with Workers.

Accreditation is a voluntary cyclical process that provides independent validation that an occupational health service has demonstrated competence measured against the standards and is considered to be fit for purpose. Occupational health services seeking

accreditation complete a pre-qualification questionnaire to analyse their compliance with current laws and best practice guidelines. A customer satisfaction survey is also implemented as part of the accreditation process. These questionnaires are further supplemented by an online assessment, the information from which informs the on-site assessment visit. Occupational health services seeking accreditation or re-accreditation undertake self-assessments in years when an external audit is not performed.

SEQOHS note that a number of major reviews and audits of occupational health in the NHS, notably the Boorman Review in 2009, have highlighted inconsistencies in the provision of occupational health to NHS staff.

Domain G has been introduced to set a minimum standard in the NHS in aspects not covered by the other SEQOHS domains. Domain G covers four key areas:

1. The delivery of a common range of Core Services;
2. Business Standards to ensure services are costing out services and trading profitably, and are working to a business plan which sets out their key work activities and improvement plans;
3. Delivery standards to ensure that they are meeting their NHS commissioners expectations around waiting and access times to the service for NHS staff;
4. Clinical standards to ensure services are undertaking local clinical audit annually to identify and establish clinical improvements.

## Patient-Led Assessment of the Care Environment (PLACE)

[www.hscic.gov.uk/PLACE](http://www.hscic.gov.uk/PLACE)

Patient-Led Assessments of the Care Environment (PLACE) are a self-assessment of a range of non-clinical services which contribute to the environment in which healthcare is delivered in the both the NHS and independent/private healthcare sector in England. Participation is voluntary. All hospitals with in-patient facilities are eligible to participate, as are NHS Treatment Centres, whether they have inpatient beds or not.

These assessments were introduced in April 2013 to replace the former Patient Environment Action Team (PEAT) assessments. Inspections are conducted annually, with the 2013 process involving visits to 1,359 assessment sites. Assessments cover key non-clinical areas – cleanliness; the condition, appearance and maintenance of healthcare premises; the extent to which the environment supports the delivery of care with privacy and dignity; and the quality and availability of food and drink for patients.

A key component of PLACE is encouraging and facilitating the involvement of patients, the public and other bodies with an interest in healthcare (e.g. Local Healthwatch) in assessing providers. The aim is for this to occur in equal partnership with NHS staff to both identify how they are currently performing against a range of criteria and to identify how services may be improved for the future. The Health and Social Care Information Centre (HSCIC) publish PLACE reports containing the results of inspections. Hospitals are required to publish the results of their inspections, along with a local action plan.

## Anaesthesia Clinical Services Accreditation (ACSA)

[www.rcoa.ac.uk/acsa](http://www.rcoa.ac.uk/acsa)

Anaesthesia Clinical Services Accreditation is a voluntary scheme for NHS and independent sector organisations that offers quality improvement through peer review. The scheme has been developed by the RCoA Quality Management of Service Committee and the Professional Standards Directorate. Assessment is based on a self-assessment process and on-site review. When an organisation achieves 100% compliance with the ACSA standards and their compliance is tested during an on-site review, they become accredited. RCA aims to construct benchmarking resources for quality improvement using ACSA data. The ACSA programme is supplemented by the RCA's 'Guidelines for the provision of anaesthetic services 2014' publication, which outlines professional standards and is of relevance to commissioners.

This scheme is currently being updated.

## Improving Quality in Physiological Diagnostic Services (IQIPS)

[www.ukas.com](http://www.ukas.com)

Improving Quality in Physiological diagnostic Services (IQIPS) is a programme hosted by the Accreditation Unit of the Royal College of Physicians with support from the Department of Health. Accreditation is awarded by the UK Accreditation Service (UKAS) under contract with the Royal College of Physicians.

UKAS has been licensed by the Royal College of Physicians to manage and deliver an assessment and accreditation service for the following eight physiological diagnostic specialisms: audiology, cardiac-physiology, gastro-intestinal physiology, neurophysiology, ophthalmic and vision science, respiratory and sleep physiology, urodynamics and vascular science.

The entry point for IQIPS Accreditation is a the Self Assessment and Improvement Tool (IQIPS-SAIT) which can be used by services to assess their level of performance in relation to established standards and to improve the service delivered. IQIPS service accreditation involves a peer assessment process that validates adherence of a service to the standards providing assurance of quality to patients and commissioners.

When a service is obtaining level B for most measures in the SAIT (approximately 95%), they are eligible to apply for accreditation. This section of the process involves uploading evidence to demonstrate that the service meets set standards, and can be measured and observed by the UKAS assessment team. The UKAS team will review the evidence and once approved, an on-site assessment visit will be carried out.

The IQIPS model is a four-year Accreditation cycle with an annual self-assessment and improvement process. RCP have published reports based on these assessments, however census reports only exist for 2012 and 2013. These reports provide aggregated data across the eight physiological diagnostic specialisms, and do not identify organisation or institution specific outcomes. The census reports are used to identify strengths and weaknesses in the provision of service and to guide the development of support interventions.

## Telecare Services Accreditation (TSA)

[www.telecare.org.uk](http://www.telecare.org.uk)

Telecare Services Accreditation (TSA) is contracted with Insight Certification Ltd, a UKAS accredited independent inspection body, to undertake inspections for Telecare service providers seeking formal accreditation to the Telecare Code of Practice. TSA currently have over 350 member organisations, including some from outside the UK.

An updated TSA Code of Practice was launched in 2009. There are 9 Process Modules and 11 Standards Modules for the Integrated Telecare and Telehealth Code of Practice. Telecare and/or Telehealth service providers can seek accreditation to any or all of the 9 Process Modules depending on the activities being delivered.

To gain accreditation, organisations must undergo an audit from Insight Certification Ltd, who implement the inspections to assess if an organisation meets the relevant criteria for accreditation. Having achieved accreditation, service providers are inspected annually thereafter, to ensure compliance. On every third anniversary, members will be required to undergo a full inspection to verify they still meet the standards set out in the Code of Practice.

Having achieved accreditation, service providers are inspected annually thereafter, to ensure compliance. On every third anniversary, members are required to undergo a full inspection to verify they still meet the standards set out in the Code. Individual assessments involve a report document, however this is not published by TSA.

GGI has recently developed a good practice whole-service standard for telehealthcare services, which includes as an element this work of the TSA.

## Medicines and Healthcare products Regulatory Agency (MHRA)

[www.mhra.gov.uk](http://www.mhra.gov.uk)

The MHRA is a government body involved in the regulation of medicines and medical devices and equipment used in healthcare as well as in the investigation of harmful incidents. While the MHRA is concerned mainly with manufacturers and distributors, the body conducts sampling through pharmacies, and investigates complaints from the public and healthcare professionals. MHRA produces regulatory guidelines, and publishes Public Assessment and other reports on its website.

As part of the overall quality assurance objectives, MHRA have developed best practice guidelines for the areas of manufacturing, distribution, clinical, laboratory, pharmacovigilance, and medicines testing. MHRA commenced its Good Clinical Practice (GCP) Inspection programme in May 2004, in accordance with the UK Statutory Instrument 2004/1031 (the Medicines for Human Use (Clinical Trials) Regulations 2004) and subsequent amendments.

The Lead Inspector allocated decides on the type of inspection to be performed. There are three types of GCP Inspections. The first is a risk-based approach. This uses a combination of information provided to the MHRA on the Compliance Report, internal information about previous inspection history, organisational changes and other compliance reports with the results of intelligence gathering to determine an organisation's control of their risk. The majority of GCP inspections conducted by the MHRA are conducted under the Statutory GCP risk-based inspection programme, these are either systems-based (examination of systems implemented across a number of clinical trials) or study specific (assessing a particular clinical trial which has been completed and reported).

The second type of inspection is a triggered inspection process. These are ad-hoc inspections that may be triggered as a result of MHRA licensing requests or reports received by the MHRA on suspected violations of legislation relating to the conduct of clinical trials. In rare circumstances the organisation may not be notified of these inspections in advance and a plan may not be shared with the organisation.

The third inspection process occurs when the Committee for Medicinal Products for Human Use (CHMP) requests inspections in relation to marketing authorisation applications made using the EU centralised procedure. The European Medicines Agency (EMA) coordinates these inspections, which are conducted by inspectors from the EU Member States.

MHRA publish a wide range of regulatory and safety guidelines to industry on the regulation of devices and medicines. Public Assessment Reports, a scientific assessment report on new licenses granted after 30 October 2005, are made available by the MHRA. The organisation is also responsible for issuing consumer information on the safe use of medicines and medical devices, including communicating recalls and alerts.

## Clinical Negligence Scheme for Trusts (CNST)

[www.nhs.uk](http://www.nhs.uk)

The NHS Litigation Authority (NHSLA), established in 1995, indemnifies English NHS bodies against claims for clinical negligence through CNST, and aims to promote effective risk management to minimise harm to patients and the cost of claims.

NHS LA has assessed NHS trusts against its risk management standards. Trusts at Level 1 are assessed once every two years and those at Levels 2 and 3 at least once in any three year period, although organisations may request an earlier assessment if they wish to move up a level. Trusts that fail an assessment are re-assessed within a year. Assessment factsheets are available on the NHS LA website.

The NHS LA has decided that it will no longer implement an assessment programme from March 2014. Instead, NHS LA is developing a Safety and Learning Service. A key aspect of this is the provision of a safety and learning library of materials which are a combination of good practice, how to guides, policy reports and new knowledge from in-depth analysis of claims. While this claims based learning information is not directly available to non-members, NHS LA aim collaborate with partners and professional bodies, together with the organisation's panel solicitors and clinicians in particular focused specialities, to produce learning materials for other stakeholders who will not access the extranet, such as clinicians.

You can find out more details about this work by contacting Donal Sutton, Researcher, GGI at [donal.sutton@good-governance.org.uk](mailto:donal.sutton@good-governance.org.uk)



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