Guy's and St Thomas' NHS
NHS Foundation Trust

Operational Policy

Point of Care Testing

Policy Summary
In order to assure patient safety, all Point-of-Care Testing (POCT) performed within Guy's and St. Thomas' NHS Foundation Trust (GSTFT) shall comply with standards set by the International standard "Point of care testing (POCT) – Requirements for quality and competence" and the Trust's Medical Devices Policy.

Document Detail	
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Approved by, date	Medical Devices Management Group
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Relevant external law, regulation, standards	ISO standards 15189:2007 & 22870:2006. CPA standards, v2.00 (Sept 2007)

Change History		
Date	Change details	Approved by

Policy
The standards to be achieved.

Traditional examination of patients' samples is generally carried out in the controlled and regulated environment of accredited medical laboratories. Advances in technology have resulted in compact, easy to use *in-vitro* diagnostic devices that make it possible to carry out some examinations at, or close to, the location of the patient.
Guy's and St. Thomas' NHS Foundation Trust (henceforth called the "Trust") is committed to providing patients with the best quality care and recognizes that point of care testing (POCT) may be of benefit to both the patient and the Trust.
To this end the Trust shall, for all POCT devices within Trust premises, implement a quality management system that complies with relevant national quality standards.

This shall include:[1]

- Evaluation of new or alternative POCT instruments and systems.
- Evaluation and approval of end-user proposals and protocols.
- Purchase and installation of equipment.
- Maintenance of consumable supplies and reagents.
- Training, certification and recertification of POCT system operators.
- Quality control and quality assurance of devices, systems and processes.

The Trust shall achieve this by:

- Appointing a multidisciplinary POCT management group with representation from laboratories, administration and clinical programmes including nursing to advise on the provision of POCT. This group shall report to the Trust Executive via approved channels.
- Appointing an operations manager to have overall responsibility for management of the POCT quality management system.
- Appointing sufficient staff to enable compliance with the quality management system.
- Undertaking regular audit of the quality management system and processes. These audits shall be both internal and external in nature.
- The making and storing or records to demonstrate compliance with this policy.
- Empowering those groups or individuals with responsibility for POCT to remove from service any device or system that fails to meet the required standard in order to safeguard patients' health.

Rationale
Why the policy is necessary.

This document outlines the principles and procedures for the practice of POCT for Guy's and St. Thomas' NHS Foundation Trust (GSTFT). In following these principles and procedures, POCT groups shall ensure that all POCT services used within the Trust are well managed; produce good quality and accurate results and contribute to excellence in patient care

Scope
To whom it applies and where and when it should be applied.

This Code of Practice applies to all aspects of the delivery of POCT services at GSTFT, irrespective of whether the services have clinical or research applications, or have been purchased, hired, loaned or received as a donation.

It shall apply to all stages of a POCT device's life cycle within the Trust: from initial request for introduction of a device; through procurement; introduction into service; training; use; quality assurance; audit; preventive and corrective actions; and finally, disposal.

Definitions
POCT covers a wide range of both pathology and non-pathology testing. POCT, in this context, can be defined as an analytical test undertaken by a member of the healthcare team or by a non-medical individual in a setting distinct from a normal hospital laboratory.[2] This definition can also vary depending upon test and equipment and may comprise of:

- Non-instrumental systems: disposable systems or devices that vary from reagent test strips for a single analyte to sophisticated multi-analyte reagent strips incorporating procedural controls
- Small analysers: usually hand or palm held devices
- Desktop analysers: larger devices including systems designed for use in clinics or a small laboratory

Principles
The underlying aims, beliefs, statutes, regulation etc. upon which the policy is based.

Compliance with national standards
Guidance can originate from international standards or from national regulatory or advisory organisations.
All processes relating to POCT devices shall be comply with the relevant British Standards and guidance from the national regulatory authority.**Error! Bookmark not defined.** [2 3]

Monitoring and assurance of this Policy
How will compliance with this policy be assured, and to whom?

Compliance with the national standards will be assessed by both external and internal assessment teams:

- The United Kingdom Accreditation Service (UKAS) has delegated the external assessment to the national accreditation body for medical laboratories: Clinical Pathology Accreditation (UK) Ltd (CPA).[4]
- Internal assessment will be undertaken by the Pathology Directorate, as described in the supporting document …. This specifies that serious issues pertaining to POCT devices will be raised with the Trust's Medical Director for action.
- The POCT committee, a sub committee of the Medical Devices Management Group (MDMG), also monitors compliance with this policy and reports to the Medical Director via the MDMG. Its terms of reference are available on the Pathology intranet site.[5]

Supporting documents

How the policy standards will be met through working procedures, protocols, guidance, standards.

The associated documents will not form part of the policy but will be listed here with links to their intranet location.

This policy is met by following the Code of Practice Point of Care Testing: Introduction of Devices.[5]

List:
Point of Care Testing: Introduction of Devices. GSTFT-COP-POCT0801

References

1 Point of care testing (POCT) – Requirements for quality and competence. BS EN ISO 22870:2006.

2 *Management and Use of IVD Point of Care Test Devices* MDA DB2002(03) Medicines and Health Regulatory Authority. March 2002.

3 Medical laboratories –Particular requirements for quality and competence. British Standards Institute. BS EN ISO 15189:2003

4 http://www.cpa-uk.co.uk/

5 Pathology POCT intranet page