

Accreditation of Point of Care Testing (ISO 22870) – addressing the practicalities:

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Agenda

- A brief history of everything!
- ISO 15189 and 22870.
- Addressing some practical issues
- Community POCT



The first test

- The oldest known diagnostic test was performed before 400 B.C.
- Urine was poured out onto the ground and carefully observed.
- If the urine attracted insects the patient was immediately diagnosed with 'boils'.
- Turn around time is believed to have been only minutes!



The first S.O.P.

- In about 300 B.C. Hippocrates advocated a diagnostic protocol that involved tasting patients urine.
- Over the next century 'water casting' became so common place that the urine flask was adopted as the emblem of medieval medicine.
- In AD 900 Isaac Judaeus devised guidelines for the use of urine as a diagnostic aid – because urine could then be shipped for examination diagnosis at long distance became common.
- Turn around time is thought to have become a little more erratic at this point.



Early Accreditation

- The first attempt at Accreditation seems to have come some 200 years later.
- The Jerusalem Code of A.D.1090 laid out 'standards' for the analysis of urine against which physicians were examined.
- Non-conformance issues appear to have exposed the physician to public beatings.
- It is believed this may have resulted in the reticence of early medical practitioners to 'buy-in' to any form of accreditation process.



Advances in Accreditation

- In 1896 what is generally recognised as the first hospital based clinical lab opened in Johns Hopkins Hospital, Baltimore, U.S.A.
- In 1923 an American Medical Association survey found that 48% of U.S. hospitals had clinical laboratories.
- In 1918 the American College of Surgeons attempted to accredit hospitals based on a single page standard which included a requirement for '***adequately staffed and equipped laboratories***'.
- Out of 671 hospitals 81 passed on first inspection and 100 more passed upon re-inspection after non-conformances had been resolved.



Modern Times

- During the 1990's accreditation became central to progressive laboratory medicine.
- In 1996 early drafts of ISO 15189 were being circulated for discussion.
- CPA (UK) published the first version of Standards for the Medical Laboratory in 2000.



Current Irish Laboratory Accreditation Status

- Majority of Irish labs which have achieved Accreditation are accredited by CPA (UK).
- E.U. legislation will require that all future accreditation of Medical Labs in Ireland will have to be performed by an Irish national body e.g. INAB.
- > 40 Irish hospital labs are already accredited by INAB to ISO 15189.



Point Of Care Testing

- POCT has evolved rapidly over the last 50 years from semi-quantitative glucose analysis in the 60's to today's portable analysers capable of measuring a broad range of Clinical Chemistry and Haematology parameters.
- Major advances in micro-fluidics and microelectronics continue to result in the development of ever more compact and complex analytical platforms.
- The worldwide POCT market is expected to double in value over the next 5 to 7 years.



Irish POCT Guidelines

- POCT Consultative Group – AMLS, ACBI, IMB & RCPI.
- Guidelines for the Safe and Effective Management and Use of Point of Care Testing published in 2007.
- Guidelines for the Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care launched this year. (Consultative group and IPS)



Irish POCT Survey Results

- 49% response rate (27/55).
- 37% of respondents (10/27) accredited – 9 to CPA and 1 to ISO.
- 44% had a defined QMS.
- 56% had a POCT Policy.
- Blood Gas analysis well supported by labs with glucose next best supported.
- Little or no support for other parameters.



POCT and Accreditation

- ISO 22870:2006 POCT – Requirements for Quality and Competence published early '06 as an annex to ISO 15189:2003.
- CPA published 'Additional Standards for POCT facilities' in April 2010.
 - In the introduction to the standards CPA direct the reader to '*purchase and read ISO 22870 in preparing for accreditation of their facilities*'.
- No Irish or British hospital is yet accredited for POCT although some labs are accredited to perform certain tests such as Blood Gas analysis having included these tests in the scope of their application to CPA.



ISO 22870:2006

- Requirements apply when POCT is carried out in hospital, clinic and by a healthcare organisation providing ambulatory care. The standard can be applied to transcutaneous measurements, the analysis of expired air and in-vivo monitoring of physiological parameters.
- Patient self-testing in a home or community setting is excluded.



ISO 22870:2006

- Standard is broken into 2 sections:
 - Management Requirements
 - ‘The management of laboratory services shall plan and develop the processes needed for POCT.’
 - Technical Requirements
 - ‘The organisation shall determine and provide the human resources needed...’



Management Requirements (1)

- The lab shall comply with the std. when carrying out work in its permanent facilities or at sites other than the permanent facilities for which it is responsible.
- ISO requires that a 'health professional grouping shall be responsible to the governing body for defining the scope of POCT to be made available.'
 - Define clinical need for POCT.
 - Financial implications.
 - Technical feasibility.
 - Ability of the organisation to fulfil the need.
- Requirement for a POCT Mgt Group which would be directed by the Steering Group
 - Define and communicate responsibility and authority for POCT.
 - Evaluate and select POCT devices and systems.
 - Consider all proposals to introduce any product device or system for POCT.



Management Requirements (2)

- Quality Management System
 - Quality Policy
 - Quality Manual
 - Measureable POCT Quality Objectives
 - Identification and control of non-conformances
 - Annual Management Review

- ‘Policies, processes, programmes, procedures and instructions shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.’



Technical Requirements (1)

- The organisation shall determine and provide the human resources needed to:
 - Implement and maintain the POCT QMS and continually improve its effectiveness.
 - ensure that required training is provided to personnel from all services, programmes and departments.
 - Enhance healthcare provider/patient/client satisfaction by meeting customer requirements.
- ‘Overall responsibility for the provision of POCT may be delegated to an appropriate laboratory specialist.’



Technical Requirements (2)

- The manager shall develop, implement and maintain an appropriate theoretical and practical training programme for all POCT personnel.
 - Only personnel who have completed the training and demonstrated competence shall carry out POCT.
 - Retraining intervals and a continuing education programme shall be established by the management group.
 - POCT operator performance shall be monitored as part of the quality assurance programme.
 - Records of training/attestation and of retraining and re-attestation shall be retained.



Technical Requirements (3)

- The organisation shall determine and manage the work environment needed to achieve good working conditions as well as conformity to POCT requirements and the device manufacturers recommendations.
- Procedure manuals for each POCT system shall be available to all users.
- The organisation shall ensure identification of the sample and its clerical traceability to the patient.
- The management group shall recommend that any POCT device or system be withdrawn from service if critical requirements are not met or safety becomes an issue.



Technical Requirements (4)

- EQA programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.
- POCT results shall be permanently recorded in the patient's medical record.
 - The identity of the person performing the test should be recorded.
- The record shall distinguish between POCT results and those from the central laboratory or its satellites.



Achieving conformance

- **Organisation-wide ‘buy-in’ and support in the form of written policies are essential.**
- **Connectivity platforms are essential.**
- **E-learning and virtual teaching tools are essential.**
- **Dedicated resources are essential.**



The cost of Medical Laboratory Accreditation

- As per INAB schedule of fees for accreditation of Medical Testing Laboratories to ISO 15189;
 - Application fee = €1,260
 - Pre-assessment fee = €2,795
 - Initial assessment/annual mgt fee = €6,640
 - One lead assessor for 1 day – each additional assessor = €2,795 per day on site.
- Minimum total excl. VAT = €10,695
- Of course these figures do not account for staff time in preparing for and maintaining accreditation.



The value of Accreditation

- Provides us with a benchmark for performance and quality to determine if our organisation is fit to meet the requirements of an internationally recognised standard.
- Provides confidence to users of our services as regards the quality and reliability of the test results we produce.
- Accreditation is an effective marketing tool and a passport to submit tenders to contractors that require independently verified laboratories.



POCT in the community

- Failure to lead has seen an explosion of non fit-for-purpose services in hospitals and communities.
- Pharmacies are keen to provide POCT services.
 - 1,500 community pharmacies in Ireland.
 - The average person in this country visits a pharmacy 23 times each year.
- Imperative to devise a system to licence/accredit community based POCT which is cost appropriate.



A practical approach to Accrediting Community POCT?

- Hospital based Laboratories strive toward accreditation to ISO 22870.
- Cost prohibitive for individual community based POCT providers to attain accreditation.
- Could Accredited Labs provide governance and oversight for local community based POCT?
 - The lab shall comply with the std. when carrying out work in its permanent facilities or at sites other than the permanent facilities for which it is responsible.
- Lab might issue a 'renewable licence' in the form of an SLA to the community provider to perform specified POCT.
- Licence only granted if conditions of testing satisfy the requirements in ISO 22870.



‘Fast is good but accuracy is everything!’ – Wyatt Earp



Questions?

