



Putting Science into standards

Session 3:

Stakeholder's view

Gian Luca Salerio,
Rapporteur Session 3



Clinical guidelines and experience in Norway

Clinical guidelines are used as a framework for the development of technical standards that may get useful for a better interpretation and implementation of concepts specified in these guides.

*In other words,
technical standards can describe the technicality of
many concepts of clinical guides in an operative way*



Clinical guidelines and standards: what is different and what is in common?

- Standards are based on consensus
- Guidelines are based on evidence



But standards are studied keeping in mind the definition of what standards shall be (according to CEN/CENELEC Internal Regulation Part 3):

Standard shall be based on the consolidated result of science, technology and experience and aimed at promotion of optimum community benefit

*However, it is clear to all that standards **does not/shall not** describe any kind of medical treatment (this is not the scope of standardisation)*



The role of Consumer

Consumer representation in the European standardisation related to healthcare services succeeded in including several needs that were interpreted as technical solutions by standards writers.



Consumer's view is..

Standardisation *can play* in facilitating the implementation of guidelines resulting from the European Commission Initiative on breast cancers.



Colonoscopy screening

It remains the definitive investigation for colonic cancer and the faecal immunochemical test for haemoglobin (FIT) is the preferred test according to the EU guidelines on quality assurance in colorectal cancer screening

(successful test ... no standards in this field!)



This is a test without standard...but

«hemoglobin is unstable in solution»...

«probes used for testing are different»...

«do we have same results with all devices?»

*So standardisation can play an important role
in this field!*



Introduction of definition of «breast cancer unit»:

«Organised team of dedicated specialists and appropriate clinical centre»

...this issue could become a subject for standardisation (for example.. description of what the team and clinical center should be..)



Accreditation/certification for high quality care services:

-happy to work with guidelines groups and ECIBC and JRC but...

box of requirements to be filled, (with support of standardisation?)



Experience of NHS in England:

- 10 years experience (documents, results, questions pending,..)
- importance of team role,
- lots of feedback..

All this would be useful and important for standardisation work...



Thank you

**Gian Luca Salerio,
Rapporteur Session 3**

(UNI , Italian Standards Body, Member of CEN)