Putting science into standards: Evidence-based quality assurance. An example for breast cancer

20-21 October 2015, Ispra

'How standardization can address social needs: ANEC experience'

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Raising Standards for Consumers
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ANEC – The European consumer voice in standardisation

Since 1995 - Independent non-profit association
Funded by EU & EFTA, members paying in kind

Represent & defend European consumer interest:

- Standardisation (European, international)
- Use of standards (e.g. market surveillance)
- Laws related to standards & consumer protection

Ensuring that in European Single Market all products and services – including newest technologies – are safe, interoperable & accessible to all, with their impacts to the environment and health minimised
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ANEC Services sector - priorities

- Horizontal service standardisation & policy
- Health, care & support services
- Tourism, leisure & sports services
  - Safety of accommodation services
- Services of general interest (Postal, CCCs,...)

Service guide help care support quality
But also... Reducing hazardous chemicals in consumer products

ANEC suggests EU regulatory strategy to close gaps:

- Food & water contact materials
- Textiles
- Toys, Child use & care articles
- Tattoo inks
- Packaging
- Emissions to indoor air
- Nanomaterials in various products

- Participation in relevant standardisation activities
- CEN SABE project on tailored approach on chemicals in standards

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Experience in health care services related standardisation

- CEN Workshop 68 on quality criteria for health checks
- CEN TC 403 ‘Aesthetic surgery services’
- CEN TC 412 ‘Indoor UV exposure’
- CEN TC 385 ‘Sheltered housing services for elderly’
- CEN TC 431 ‘Services chain for social care alarms’
- Draft CEN Strategy on health care services
Consumer expectations – Where can standards help? (I/II)

- Full access of consumers/patients to healthcare standards development
- Provide appropriate information esp. on risks
- Patients consent to treatment – incl. vulnerable consumers
- Medical records accessible to patients & doctors (abroad)
- Recognition of role of patients as partners in their health
- Address preventative & public as well as clinical health
Consumer expectations – where can standards help? (II)

- Support for health literacy and self-management of conditions
- Support for promotion of healthier behaviours and lifestyles
- Clarify responsibilities of different healthcare providers
- Allow record of outcomes of clinical intervention
- Address needs for follow-up of medical intervention
- Separation of diagnosis & treatment (avoid false diagnosis for provider’s financial benefit)

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‘Consumer’ vs. ‘Patient’

Terms often used as interchangeable, however:

Before being a patient, person considering/choosing to undergo a medical treatment (or seeking health info) will require quality & safety criteria to reflect general consumer needs.

ANEC sees distinction between what patient “wants” - which defines him/her as a consumer - and what a patient “needs” defines him/her as a subject for clinical intervention.

Patients’ associations represent concerns of people with particular conditions or diseases.
CEN Workshop 68 on ‘Quality criteria for health checks’ - achievements

Consumer & patient requirements:

- Informed consent on health checks
- Communication on risks
- Written contracts to include full details (costs, risks, complaints procedures,..)
- Protect from adverse effects
- Tackle distortion of health checks
- Objective follow-up information
CEN TC 403 ‘Aesthetic surgery & aesthetic non-surgical medical services’

Consumer concerns in the area:

• Increasing surgery tourism

• Disparities in service quality & safety across Europe

• High risks associated with surgical procedures often downplayed when services marketed to consumers.
New European Standard on Aesthetic surgery services (EN 16372)

ANEC welcomes it satisfactorily included:

• Psychological assessment of patients
• Importance of sufficient cooling-off period
• Clear information on risks, costs & further health & financial consequences of treatments
• List of treatments listed as suitable for patients <18.

BUT

Numerous A-Deviations & some divergences in TC show need for overall strategy
CEN draft Strategy on health care standards – ANEC input

• Need to consider current challenges (demographic & economic)
• Greater engagement & involvement with patients
• Not only specific health needs,
• Healthy lifestyles,
• Need for overall increases in health literacy
• Service elements that are key for consumers (inclusiveness, responsibility, ...)
• ...

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ECIBC scheme – what would a standard need to consider?

- Related wider context
- Breast cancer services as example
- Focus on people access to and use of health services (incl. data)
- Existing guidelines and standards - not overlap
- Increased access to services
- Attention to service provision
- Communication with patient
  - requirements for objective & comprehensive info
  - individual consultation to reflect all potential risks
ECIBC scheme – what role for standards?

- Consumer and patients organisations involved
- Need European added value
- Clinical health remains out of scope
- Initiative in support of clinicians in changing service frameworks where:
  - patients are more informed
  - increased need for self-management
  - Remote services, e.g. tele-health, telemedicine
Standards as tools for better services

- Voluntary
- Complement legislation or industry codes
- Developed & written by consensus in technical committees with relevant stakeholders
- Can increase assurance of compliance with regulatory requirements
- Can achieve better quality in service provision
  - e.g. complaints handling, consumer information templates, customer care...

Support for Directive 2011/24/EU on application of patients’ rights in cross-border healthcare provisions?
Thank you
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ANEC is supported financially by the European Union & EFTA

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