

DEC-London Human Factors methods for IVD and POC devices

Dr Simone Borsci, Prof. Peter Buckle, Prof. George Hanna



- Introduction to human factors in the in-vitro diagnostics DEC (Borsci)
- Introduction to workshop activity (Buckle)
- Stakeholder mapping (All)
- Feedback (Group leader)
- Other human factors approaches used in the DEC (Borsci)
- Summary (Buckle)

One of four national centres of expertise funded by the National Institute of Health Research

Based at Imperial College, St Mary's Hospital Campus and is led by Professor George Hanna, Head of the Division of Surgery

The overall aim of our Centre is to develop world-class methods for Point of Care (POC) diagnostic test validation and facilitate efficient integration of these technologies into clinical practice



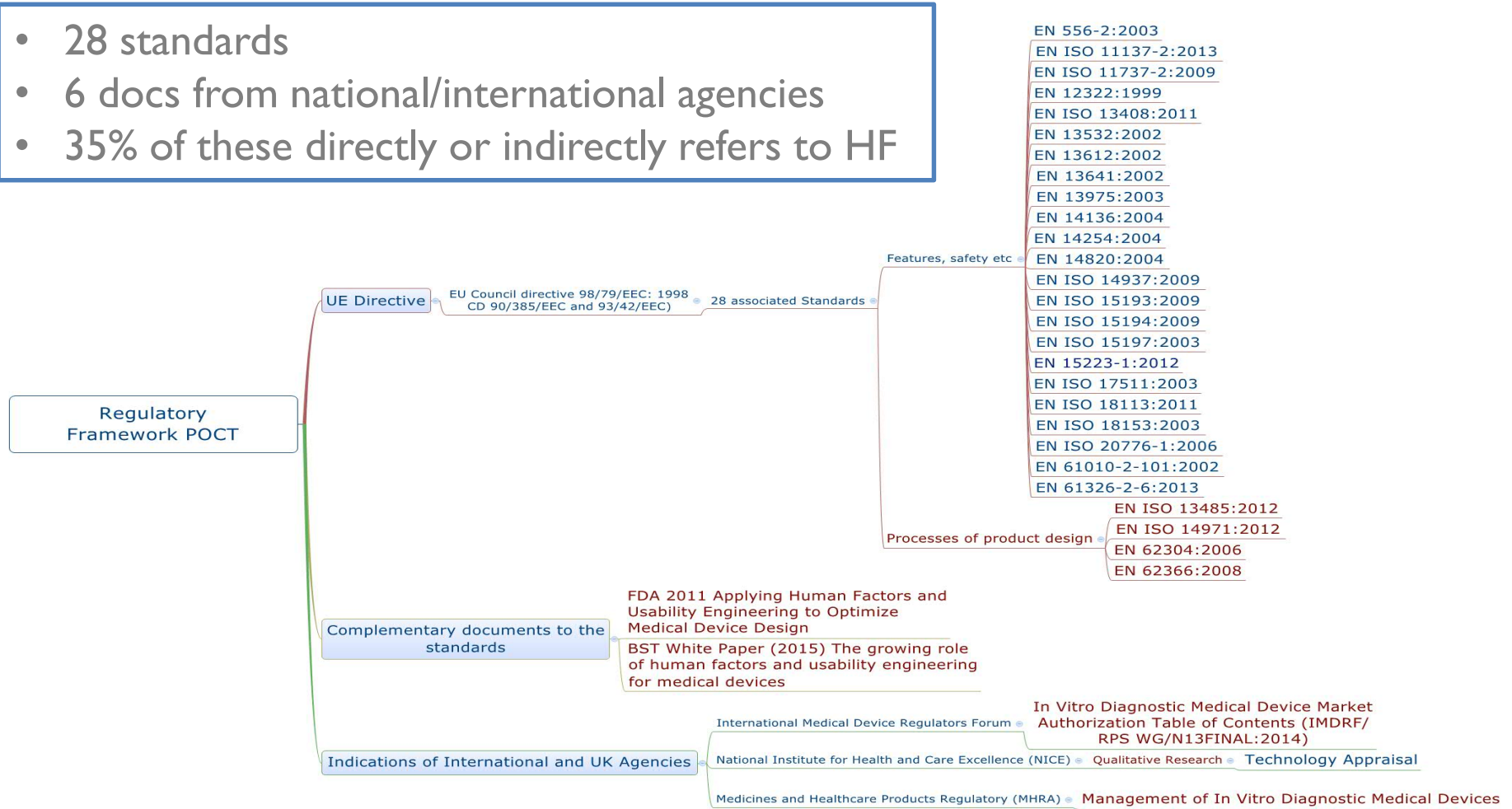
Medical device design is a challenging task



- In Europe: Errors in design and use cause 8-12% of hospitalizations
 - In US (2012) 26.5 millions of units withdrawn from the market
- in UK alone (2012-2013) 13,549 patients were involved in Device-Induced Adverse Events

Map HF in the Regulatory framework for in vitro devices

- 28 standards
- 6 docs from national/international agencies
- 35% of these directly or indirectly refers to HF



Introduction to workshop activity

- Example from the telecare industry



EMERGENCY
DEPT

DAY
HOSPITALS

AMBULANCE

SPECIALIST
DOCTOR
HEALTH VISITOR
PLANNING/COORD

OOH
GP SERVICE

GP

Nurse/OT/
Physio/Chiro

McM Nurse/
Hospice at
home

GP reception

CASE
MANAGER

MEDICATION
REVIEW

COMMUNITY
REWARDS
TERMS

Mem/falls
clinic

INFO/
ADVICE
LINES

Voluntary
sector/group

Social worker

COMMUNITY
TRANSPORT

Pharmacy
delivery

Initial
Assessor

ASSESSORS
INITIAL
REVIEW

RESPONDER

Telecare user

EXERCISE
CLASSES

DAY
CENTRES

Meals on
wheels+

Home care
asst.

PLANNED
SUPPORT

Housing
Officer

SHELTERED
HOUSING
WARDENS

COMMUNITY
GROUPS

FAITH
GROUPS

Tradespeople
(visiting)

Monitoring
centre

SECURE
SOCIAL
NETWORK

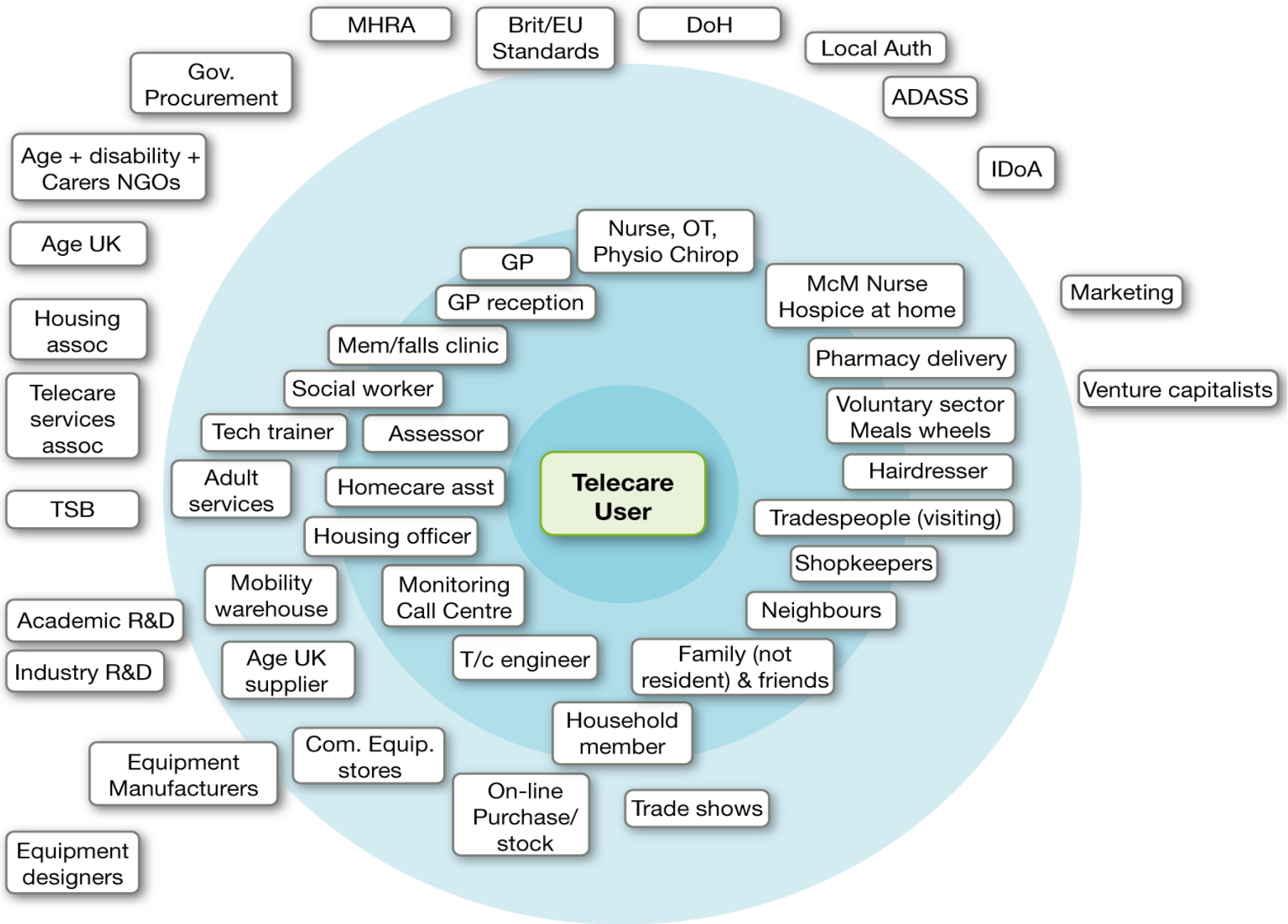
Household
member

Family (not
residents) &
friends

Shopkeepers

T/C engineer

Neighbours



Feedback from group leaders



Section 2

OTHER HUMAN FACTOR METHODS

Overview of DEC London HF methods



System overview

- Stakeholder identifications
- System/Process Mapping
- Preliminary Clinical pathways

Context analysis

Context of use envisaged by:
designers, clinicians, end users



Common Evaluation Scales (before and after the interaction)

- Expectations/preferences
- Trust
- Likelihood to use
- satisfaction



System review and interaction analysis

- Expert review: Cognitive walkthrough, task analysis
- Focus group with stakeholders
- Usability and experience assessment

Example of end-users feedbacks

Portability of POCT is not always a good solution!

- Devices often disappear from hospital!
- Portable tools like to dive onto the floor more than non portable tools!
- Portable tools are quite often left near the patients' beds



Professionals often ask:

- “We have to clean POCT after each use...Why do companies never explain in their guidelines which kind of products we can, or cannot, use to clean a device?”

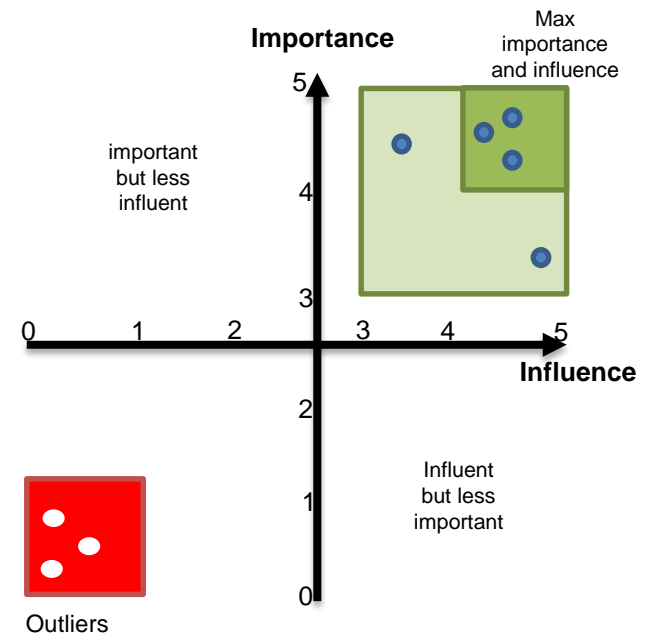
Stakeholder tool

Three phases:

1. Manufacturers rank all the possible stakeholders in terms of influence and Importance through the ST.
2. Stakeholders are recruited
3. Stakeholders rank all the possible stakeholders through the ST.

Example of Table

| Stakeholders | Influence 1=Little/No influence 2=Some influence 3=Moderate influence 4= Significant influence 5= Very influential | Importance 1=Little/No influence 2=Some importance 3=Moderate importance 4=Very important 5=Critical player |
|---------------|---|--|
| 1. Paramedics | 5 | 5 |
| 2. GP | 3 | 4 |
| 3. End-users | 3 | 5 |
| | | |





Section 3
EVALUATION SCALES

Common Evaluation Scales



There are several reliable scales to assess different factors related to usability and user experience:

- Expectations and preferences
- Overall trust and trust in a specific tool
- Satisfaction
- Likelihood to use

No studies on these scales for the specific case of POCT.



Common Evaluation Scales: Expectations and preferences (1/4)



Aesthetics and usability are related.

- Before the use products with high aesthetics are seen as products with high usability
- After the use, the perceived usability affects the perceived aesthetics.



Trust in a technology is a set of beliefs toward the use of technology

- Before the use of a tool: “propensity” to trust (Overall trust)
- After the use of a tool: Trust in the specific device.

Common Evaluation Scales: Satisfaction (3/4)



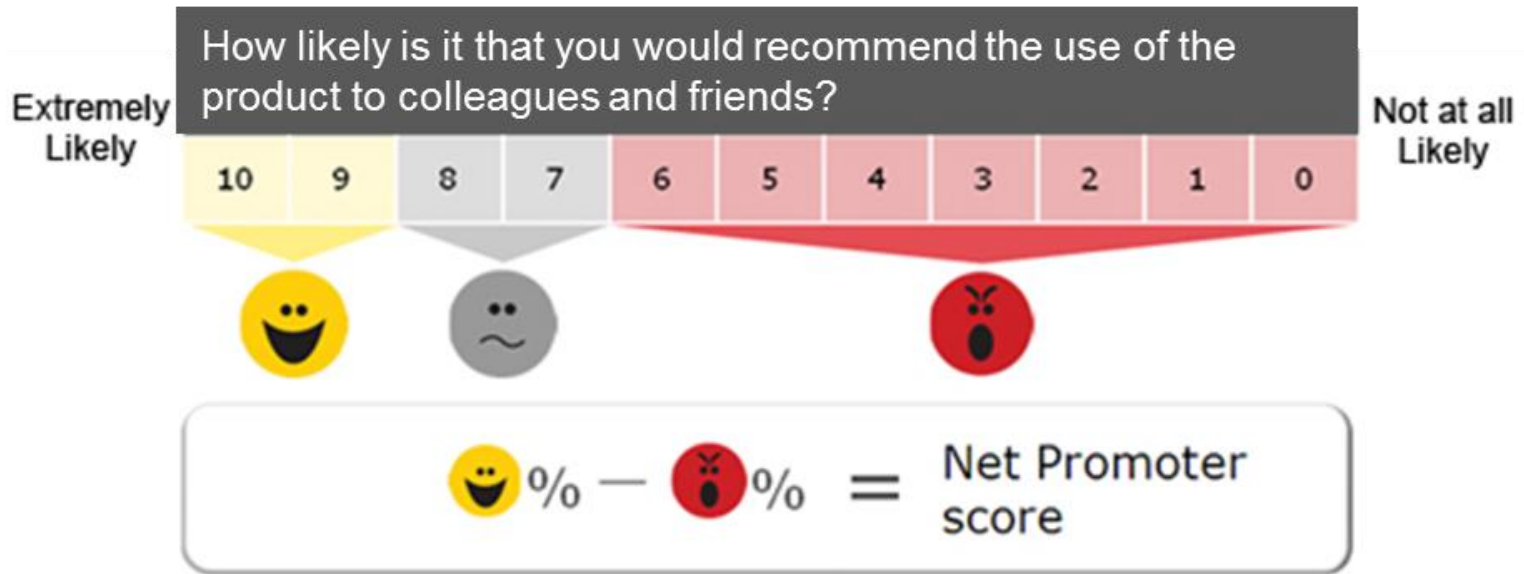
Satisfaction is one of the main usability dimensions

There are several scales to assess people satisfaction, the most interesting quick and dirty scales are:

- SUS – 10 items
- UMUX – 4 items

Common Evaluation Scales: Likelihood to promote (4/4)

Reichheld, F. (2003). *One Number You Need to Grow.*



Originally created for marketing, Net-Promoter Score is composed of one single question

Evidences show a strong relationship between Likelihood-to-use and SUS (satisfaction)



Section 4

SYSTEM REVIEW AND INTERACTION ANALYSIS

Participatory design review (1/2)



The distance between manufacturers and stakeholders point of view.

- To reduce this distance it is necessary to show to manufacturers and to stakeholders the other perspective.

Participatory design review (2/2)

Mix together design review and participatory approach in four phases:



1. Identification of design uncertainties
2. Interview to explore uncertainties
3. Scenarios of use to test the uncertainties
4. Usability and user Experience test

Summary: Integration for the HF analysis



Each HF evaluation protocol on IVD and POC at DEC-London has:

- A phase of stakeholder identification and modelling
- A specific methodology associated to the device development stage
- A set of common scales
- A set of product related questions

Diagnostic Evidence Co-operative London

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Simone Borsci, PhD Research Fellow in Human Factors and user experience NHIR DEC, Imperial College of London.

s.borsci@imperial.ac.uk



Peter Buckle research professor, at Helen Hamlyn Centre for Design, Royal College of Art, Methodologist at NHIR DEC.

peter.buckle@rca.ac.uk



George Hanna professor of surgical sciences, and head of surgery division and director of NHIR DEC, Imperial College of London. g.hanna@imperial.ac.uk

