Considerations for Infectious Disease

POCT Clinical Testing.

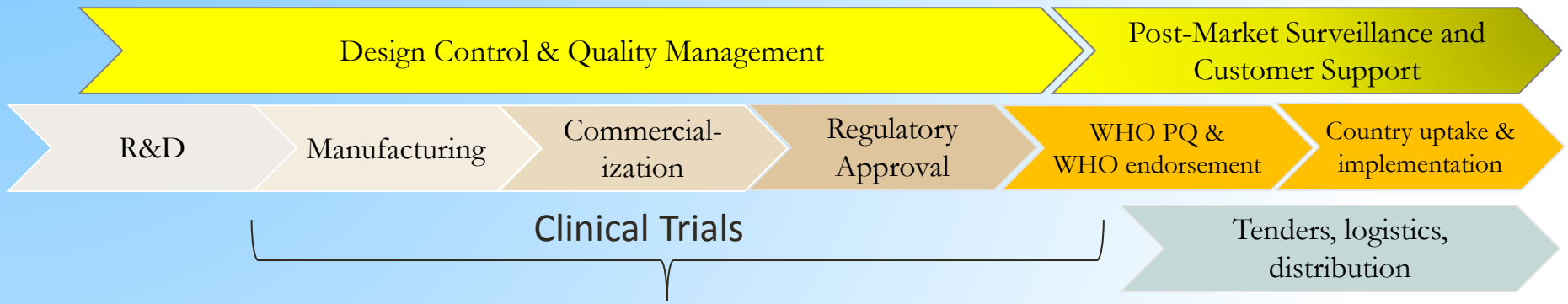
J. P. Hays

Erasmus University Medical Centre Rotterdam (Erasmus MC)

Rotterdam, The Netherlands

(j.hays@erasmusmc.nl)

Design Process



Study Design

- Observational
- Interventional
- Screening (MRSA)
- Diagnostic (URTI)

Geographical Location

- Europe
- USA
- China
- India
- Low & Middle Income Countries

Context

- Hospital
- Family Doctor
- Care Homes
- At Home (online/hospital)
- Remote Villages
- Battlefield
- In Space

- Know Your Cohort
- Implementation
- Ethics

Know Your Cohort: Initial Considerations

- Is there a need (or want !) for POCT in a particular market

  - POCT is financially viable for its market - at home / insurance / health authority

  - user is a doctor, nurse, technician, patient

    - complexity / ease of use (at home versus hospital)

    - educational level of user

Know Your Cohort: Multi-organism POCT

- Is POCT test - a single organism or multi-organism device ?

….. complex validation issues

- prevalence / incidence of each target organism ....

endemic, seasonal, epidemic e.g. mycoplasma, RSV, influenza

- will ‘significance’ be reached for the intended target(s) in this population

- rates of healthy carriage in the community

(S. pneumoniae / S. aureus / S. pyogenes)

Know Your Cohort: Antibiotics

- If ‘sales pitch’ relates to better targeted antibotic prescribing practices ……

  - how frequently antibiotics are used (incorrectly)

  - development of antibiotic resistance

  - reduced morbidity / mortality

  - reduced side-effects of antibotics e.g. microbiota

  - financial savings

  - time-to-result

Know Your Cohort: Reporting and Storage

- Expert panel required - to assess if disease criteria have been met e.g. sepsis

- End user and complexity of reporting
  - result only e.g. presence / absence
  - suggest antibiotics to use
  - suggest an action e.g. 'Make an appointment with your family doctor'

- Feasibility of .....
  - specimen storage (re-testing, future clinical trials)
  - data protection – anonimity / encryption
  - data communication / storage (computer, wifi connection)

Implementation: Regulations

- Test conforms with regional and national regulations

  e.g. the Medical Devices Directive 93/42/EEC

- Authorised by local / national Medical Ethical Committee(s) ….

- Potential conflicts of interest documented e.g. sponsors, institutional affiliations etc

- Trained personnel available in all study centres (hospital versus home ?)

Implementation: Risk

- 'Risk Analysis' completed by the manufacturer
- Liability Insurance
- (Serious) Adverse Event – (prolongation of) hospitalization; disability; birth defect, death; related (in time) to the use of the product
- Serious Adverse Device Effect - an SAE with a causal relationship with the medical device

e.g. During an interventional study for a POCT test that indicates a cesarean section e.g. HSV, HIV

e.g. During an URTI POCT screening trial at home

Implementation: Multi-National / Multi-Centre ?

- Which centre takes the lead
- The same ‘gold standard’ methods being used in all centres
- Trained personnel in all centres - standardised training video or literature
- Standardised Quality Control and Quality Assurance
- Standardised adverse event reporting criteria

- Different Languages
  - standard operating procedures
  - training material
  - patient information forms

Implementation: Low and Middle Income Countries

- ’Unburdened’ Equipment – Electricity Supply !
- Protective equipment e.g. EBOLA, SARS – goggles, aprons etc
- Supply Chain, Correct Storage e.g. temperature considerations
- Availability of QC and QA reference materials
- Data collection and monitoring (via wifi ? – internet access !)

Cultural Issues

- Cultural Acceptance of Testing – Stigmatisation of Patients
- Gender Issues e.g. female testing via females
- Intermediary (community representative)

Emergency Planning

- POCT implementation plan already available

  e.g. emergency legislation during disease outbreaks ?

- Enough kits – increase manufacture if an outbreak occurs

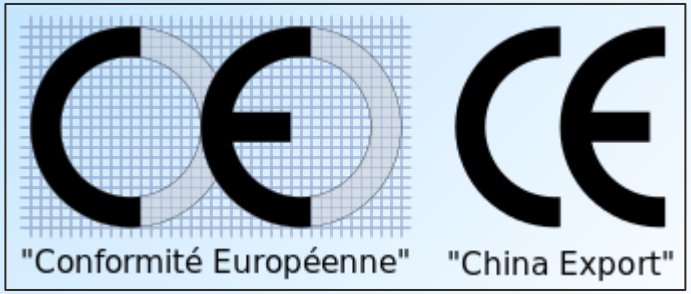
Corruption !

Implementation: Clinicians and CE mark

- a CE mark is often falsely assumed to be a mark of quality

- the CE marking - applies only to the ‘intended use‘ of the device

<u>as defined by the manufacturer</u>



- Quality Assurance and Quality Control plan

Ethics

- Trial must be performed under ethical regulations e.g. 'Declaration of Helsinki 2015'.

Manufacturer

- Care
- Reliability
- Verifiability
- Impartial
- Independent

Researcher

- Respect
- Care
- Impartial
- Responsible

- Health of the patient outweighs any other factor !

Ethics

- Target Age Group - suitability ?
- Mentally impaired (dementia) ?
- Burden of extra samples ?
- Burden of reporting ?

- *The right to publish scientific data !*

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Patient Preference and Adherence

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ORIGINAL RESEARCH

Perceptions of point-of-care infectious disease testing among European medical personnel, point-of-care test kit manufacturers, and the general public

This article was published in the following Dove Press journal:
Patient Preference and Adherence
18 June 2013
Number of times this article has been viewed

Wendy E Kaman[1]
Eleni-Rosalina Andrinopoulou[2]
John P Hays[1]

Background: The
requires knowledg
determine the curre
in the field of medi
was established.

Future MICROBIOLOGY

OPINION

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Current problems associated with the microbiological point-of-care testing of respiratory tract infections in primary care

"...healthcare providers may need to consider giving incentives to general practitioners if sufficient numbers are to adopt and utilize these 'first-generation' devices."

Wendy E Kaman[1], Gijs Elshout[2], Patrick JE Bindels[2], Konstantinos Mitsakakis[3,4] & John P Hays[*,1]

Future Microbiology Opinion Article - Title Page

Title: Pre-implementation guidelines for infectious disease Point-of-Care testing (ID-POCT) in medical institutions.

Authors: A. A. van der Eijk[1], A. N. Tintu[2] and J. P. Hays[3]

DIAGORAS