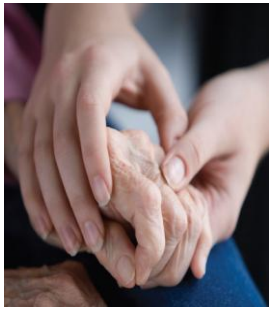

ECDC PPS of HAI and AM use: pilot validation study

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Institute for Applied Health Research

"Making a difference to the health and health care of individuals and communities"

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Overview

- **Overview of the pilot study**
  - Participants, Deliverables and Timetable
- **The ECDC PPS validation protocol**
  - Methods
  - Implementation of the pilot
- **Deliverables to date**
- **Interim feedback**
- **Next steps**
- **Key issues for discussion**

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Overview of the pilot study

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Background -Pilot validation project 2011

- Test a number of methods for PPS validation (Se, Sp) and inter-rater agreement (reproducibility/repeatability/ concordance) in 2011

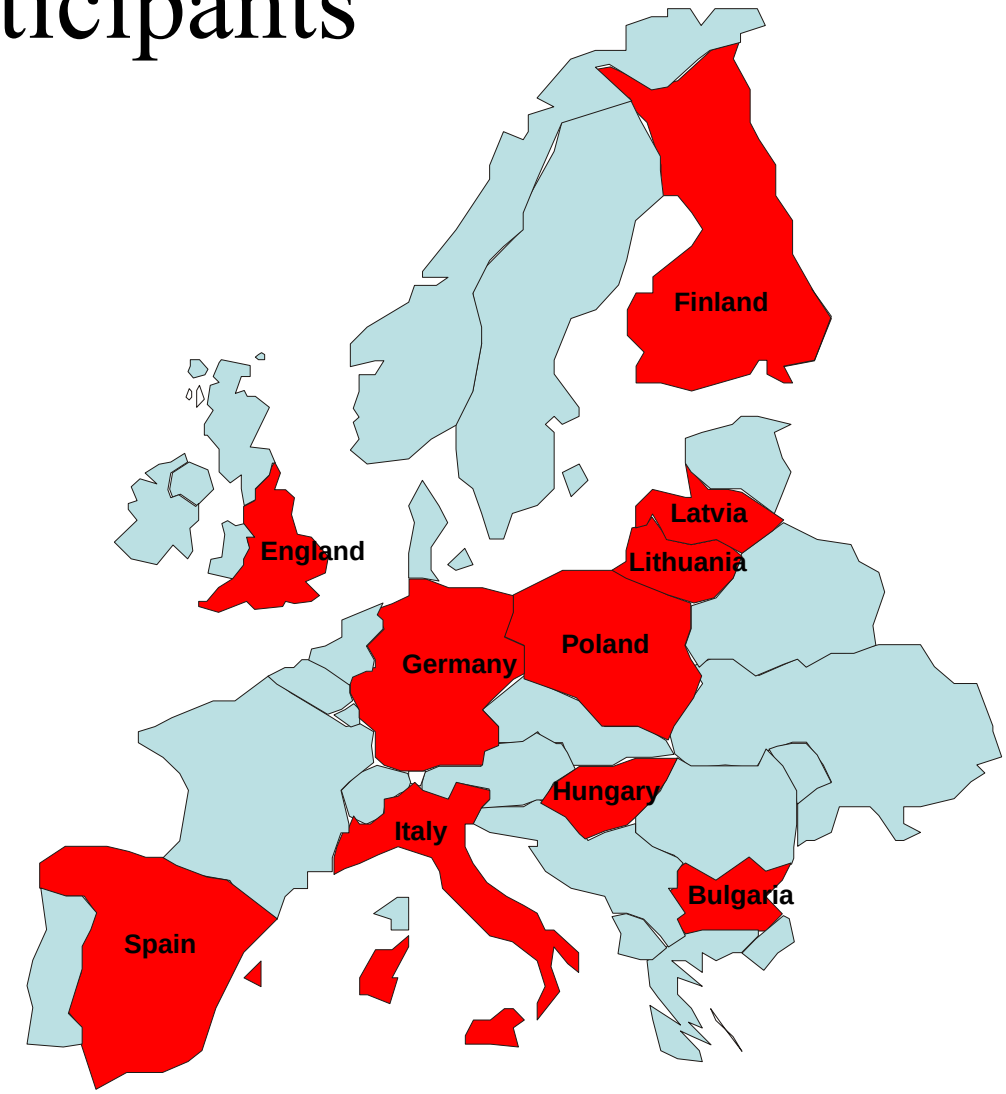
  $\Rightarrow$ Propose final validation dataset for May-June 2012 and beyond

- ECDC invited countries to participate
- Pilot validation protocol discussed at expert meeting, 29-30 August, London

Work packages

- Call for Tender: outsourced
  - Coordination, participate in preparing study material, hosting teleconferences and communications
  - Contracts with participating countries: max 10000 euro per country (10) against data for at least 2 hospitals
  - Data collection & analysis
  - Production of a technical report and recommendations for future PPS validation studies by ECDC

The participants



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Timetable

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Sample size in pilot validation study

- Goal: acceptable sample size at EU level, eg:
  - 2000 patients in 20 hospitals (10 countries) = 100 patients per hospital
- Minimum 2 hospitals per country
- May be spread over >2 hospitals

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The PPS pilot validation protocol

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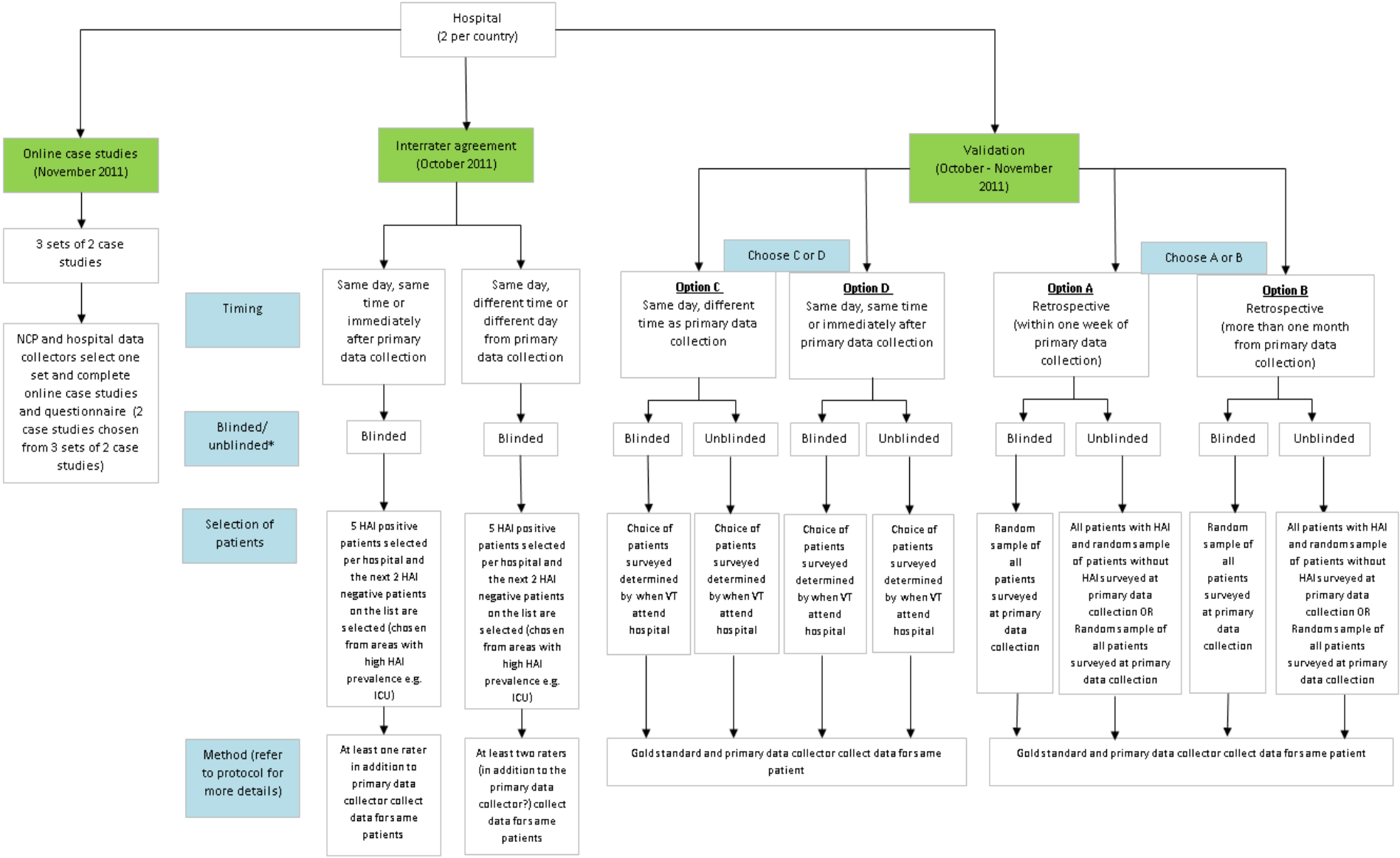

Instructions for Validation in Participating Hospitals

- Hospitals are free to choose the validation method most suitable for their setting
- A validation timing method should be chosen using the flowchart above. (C or D) AND (A or B)
- Recommended that two timing scenarios should be alternated between wards in the same hospital
- The blinded and unblinded aproaches should be alternated in consecutive wards

* Blinded-VT do not know the hospital data collectors decision, unblinded-VT know the hospital data collectors decision

ECDC Protocol defined methods for validation study-1

- **Validation**
  - Validation by reevaluation of files included in primary data collection
  - Validation and accurateness of denominator data and more subjective variables in the protocol as well as HAI
  - Measurement of Se and Sp against gold standard
  - Gold standard = protocol, applied by highly trained “reference persons” in same way in all countries => inter-country comparison of Se and Sp
  - Large sample size needed, both positive (Sp) as negative (Se) files

ECDC Protocol defined methods for validation study-2

- **Inter-rater agreement**
  - Several surveyors (2 or more) involved un data collection examine the same files
  - Mainly for HAI, rating of same cases by different hospital PPS staff
  - Kappa statistic, smaller sample size
  - But: difficult comparison of results between countries (e.g. problems if “national” deviations from ECDC-PPS protocol)

ECDC Protocol defined methods for validation study-3

Other “validation” methods

- Case studies sent to hospital staff via national contact points
- Feasibility/ lessons learned debrief survey of national contact points

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Survey and case studies- further details (not in the protocol)

- Some ID variables (country level only)

Case studies

- 3 sets of 2 case study questions (with 10 data points) made available in an online survey – available to all hospitals via national contact points
- Translation necessary – Back-translation
- Report given to each country and overall European results to be looked at
- May be used for “accreditation” of survey staff in the future, e.g. Certificate “ok to perform PPS”

Survey

- Debrief on line survey of national contact points: ‘what went well, what did not go well….’

Deliverables to date

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Work packages

√ Coordination, participate in preparing study material, hosting teleconferences and communications

√Contracts with participating countries: max 10000 euro per country (10) to deliver data for at least 2 hospitals (two contracts outstanding)

√ Data collection (about half way there!)

√ Analysis (plan commenced)

- Production of a technical report and recommendations for future PPS validation studies by ECDC

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Interim feedback

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Interim update on data collection

Email survey to all participants in November 2011:

- **100% (10 of 10) participant countries responded**
- **Validation**
  - 90% (n=9) completed data collection
  - Good coverage of all approaches to be tested in pilot: retro, simultaneous, blind and 'unblind'
  - 50% (n=5) have tested all approaches, some only retrospective
  - 60% (n=6) have completed data entry
- **IRR**
  - 50% (n=4) have completed IRR collection (one country has not carried this out)
  - Data entry underway (data entry process now agreed)

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Interim update on key issues identified

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Most difficult/ challenging aspects of data collection

- **Time**
  - Organising and finding dates to discuss cases with data collectors
  - Ward staff and clinician availability
  - Time for the validation data collection team
  - Organisation at ward level to ensure records available (multiple sources)
- **Retrospective**
  - Availability of patient records and data
- **Concurrent**
  - Access to notes/ interference with clinicians in wards
  - Patients at x ray or other places with their notes within minutes of data collection

Factors which may affect data quality

- **Understanding what was available at the time of original data collection**
  - Timing not always known
  - Different clinicians available give different answers on McCabe and AM to PPS team and validation team
- **Missing data**
  - Availability of records retrospectively: not in ward but not archived, therefore not accessible
  - Missing data in patient records e.g., device insertion and removal dates
  - Lack of knowledge of local hospital systems by ‘gold standard’
  - Time of AM changes not recorded
  - Clinicians not available for verification (McCabe score and AM issues)

Fields in the validation protocol considered least useful?

- Patient demographics
  - Age, sex etc
- Device data (CVC, PVC, urinary cath, intub)
  - status may differ at different points in time
  - time consuming
  - ‘too much pain not enough gain’
- Surgery
- AM in notes
- Validation start time
- Consultant/ specialty

HAI most commonly discordant?

- Pneumonia and BSI identified by 3 countries
- Others were different in each response, but included:
  - SSI (O and D difference)
  - C-SEP
  - GI-IAB
  - CRI

Next steps

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ECDC future validation study- next steps

- Report with recommendations to ECDC (Jan 2012)
- Production of ECDC PPS validation protocol
- Invitation from ECDC for full-scale validation in 2012 for those participating in PPS in May/June

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Key issues for discussion

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Key issues for discussion

- Do we need criterion based HAI forms to enhance IRR and feedback?
    - Do these criteria need to be collected in the future to further enhance our understanding of definitional issues?

- Are there some fields which are not useful to collect?
- Should we only focus on HAI data and AM use for validation?
- Issues of practicality- real world validation vs scientific gold?

Acknowledgements

With many thanks to the coordinators in each of the 10 countries participating

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