EUBIROD

EUropean Best Information through Regional Outcomes in Diabetes

The Policy Framework

Disease Registers and Privacy Protection: the case of Diabetes in the EUBIROD Project

Concetta Tania Di Iorio
Serectrix

Special BIRO Academy Meeting
"Coordinated Information Delivery from Diabetes Registers to improve quality and outcomes in Europe"
Rome 4-5th June 2010

Directorate-General for Health & Consumers

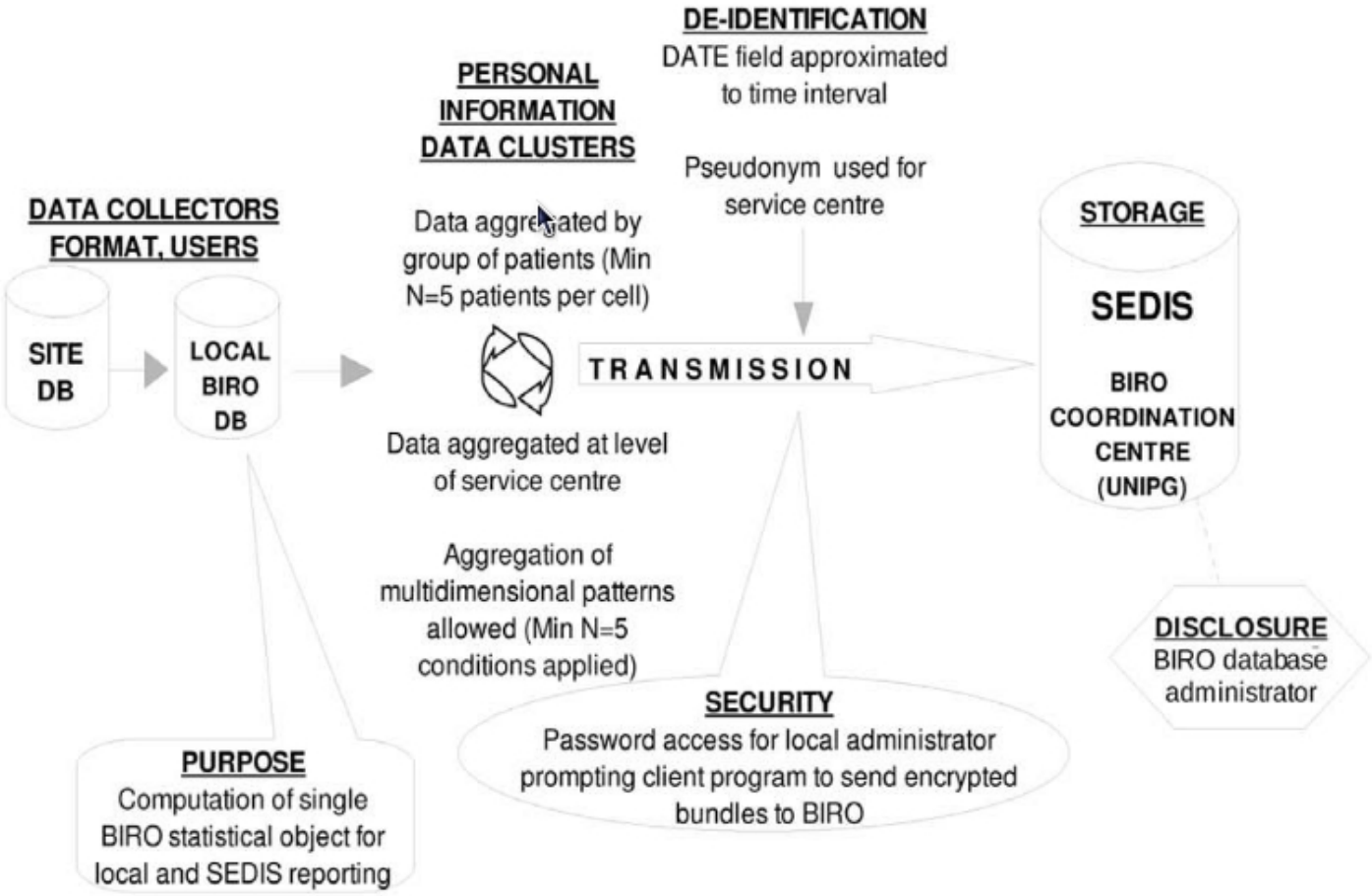
Executive Agency for Health and Consumers

Why Privacy is Important?

- The provision of complete information on quality of care and outcomes is essential to improve health systems
- Analytical systems may deliver more precise indicators by using micro-data, including health records at the subject level
- These data are readily available in **disease registers**, but their possible use in identifiable form may raise conflicts with the right to privacy
- Privacy norms should be interpreted consistently with the goals of scientific investigation and health research, including the attainment of complete data

The BIRO System

Di Iorio CT et al., Privacy impact assessment in the design of transnational public health information systems: the BIRO project, J Med Ethics. 2009 Dec;35(12):753-61.



Using BIRO on a Broad Scale

- The EUBIROD project must take into account the **impact of privacy issues** on the routine use of the BIRO system
- Rolling out the system on a European level involves a wider and more **heterogeneous context** where different approaches may impact on data completeness and comparability of results
- Regional frameworks with a more balanced approach between the public interests and privacy protection can safely use **data linkage**, creating a repository where more parameters and more indicators are made available

EUBIROD
Privacy Impact Assessment

- "Privacy Impact Assessment" in the EUBIROD project focuses on:
  - Identification of the key elements of **data protection** in the management of diabetes registers
  - Creation of a targeted tool (**questionnaire**) to collect data on procedures used across the EUBIROD Consortium
  - Definition of main **factors** in the evaluation of privacy issues
  - Analysis of the **variability** of approaches at the European level
  - Creation of a tool to improve management of privacy issues through the **privacy performance self-evaluation** of disease registries

EUBIROD Privacy Questionnaire

- **Sections identified by main "items"** referring to specific EU and/or international data protection principles or norms
  - e.g. accountability, anonymity, collection of personal information
- **Items include a series of questions (sub-items)**
  - e.g. are secondary uses contemplated for the information collected?
- **Each answer is given a mark according to an ordinal scale**:
  - 0=Not Compliant with privacy requirements
  - 1=Compliant with privacy requirements

Sections (Items)

A1. Accountability of personal information
A2. Collection of Personal Information
A3. Consent
A4. Use of Personal Information
A5. Disclosure and Disposition of Personal Information
A6. Accuracy of Personal Information
A7. Safeguarding Personal Information
A8. Openness
A9. Individual Access to Personal Information
A10. Challenging Compliance
A11. Anonymization Process for Secondary Uses of Health Data

Online Data Entry

B.I.R.O. Online Data Questionnaire

Welcome Serectrix LOGOUT

Questionnaire | P.I.A. | Data Manager | Table Manager | Admin | User Guide (PDF)

Privacy Impact Assessment (PIA) Questionnaire

P.I.A. | Section 1 | Section 2 | Section 3 | Section 4 | Section 5 | Section 6 | Section 7 | Section 8 | Section 9 | Section 10 | Page 11 | Summary

You are currently in section 1

PLEASE NOTE:
For each question not answered, a value of "Missing" will be automatically applied

If you want to save this section **without answering any of these questions**, you can do so by simply clicking on the "Save" Button. Be Aware that by doing so, each question will be given the value of "Missing"

Accountability for Personal Information

Code	Question for Analysis	Answer	Provide Details
1.1	Has the custody and control of personal information been determined?	(•) YES ( ) NO ( ) ND/NA	
1.2	Has the accountability of the registry/database custodian of personal information been documented?	( ) YES (•) NO ( ) ND/NA	
1.3	Are third parties involved in the custody or control of the personal information?	(•) YES ( ) NO ( ) ND/NA	
1.4	If third parties are involved, do you have an agreement in place that establishes privacy requirements?	( ) YES (•) NO ( ) ND/NA	
1.5	Are there any requirements in registry/database legislation or policies on the management of personal information that affect the EUBIROD project?	(•) YES ( ) NO ( ) ND/NA	

Save | Clear Answers for this Section

EUBIROD

Directorate-General for Health & Consumers

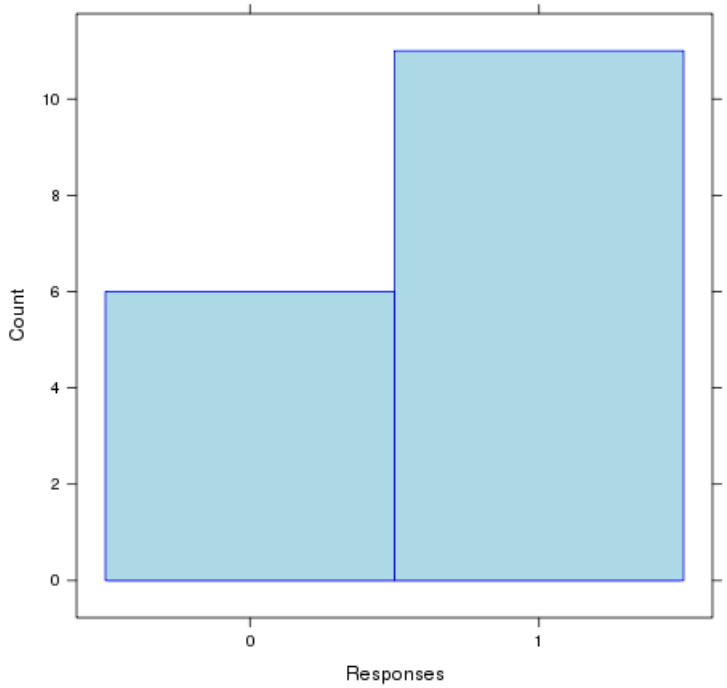
Executive Agency for Health and Consumers

Results (1)

- N=17 registers provided detailed answers
- Most fields were filled in, missing data frequently including comments
- A re-coding matrix was specified by the analyst to assign marks in terms of compliance/not compliance to privacy
  - Examples:
    - single question 0=>1; 1=>0; (reverse meaning)
    - multiple questions q2.1=0;q2.2=1 => q2.1,2=1 (merged questions)

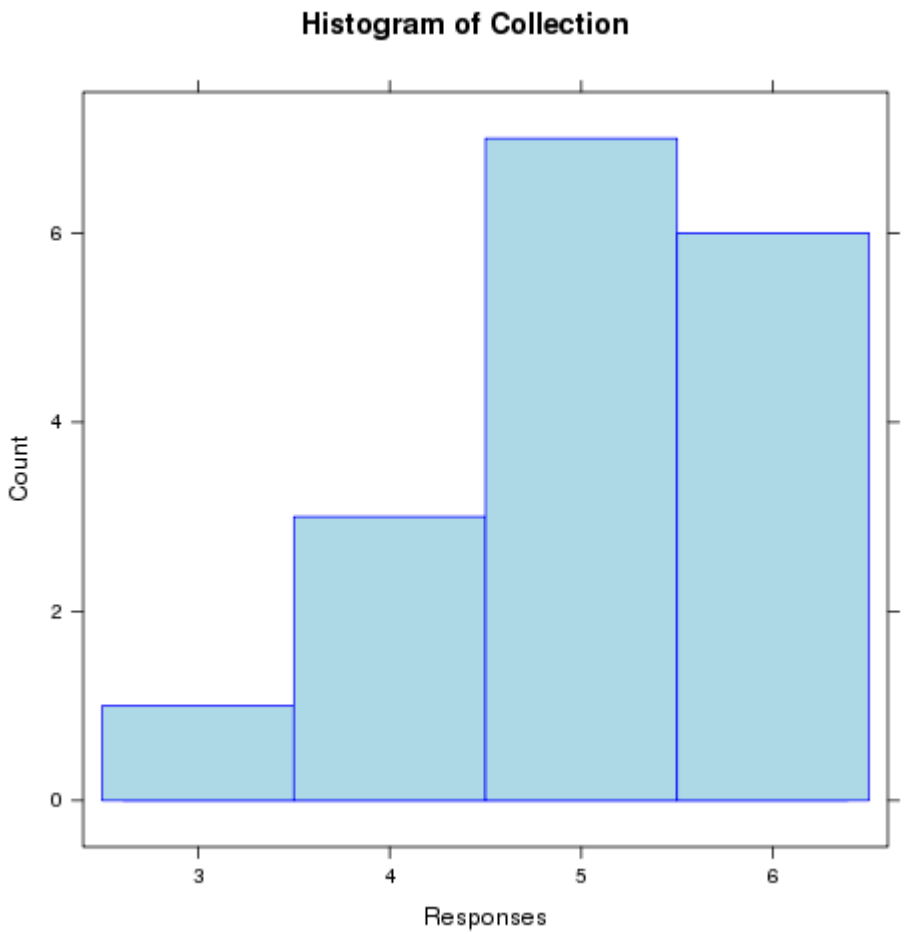
Results (2)

- Example of single question result:
  - Is personal information being collected directly from the individual?
    - Coding:
      - YES=1
      - NO/NA/ND=0



Privacy Items Scoring

- **Factors** provide summary results that are easy to interpret for all questions included in <u>each section (item)</u>
  - Example:
    - A2=Q2.1+Q2.2+Q2.3 +Q2.4+Q2.5,6,7+Q2.8



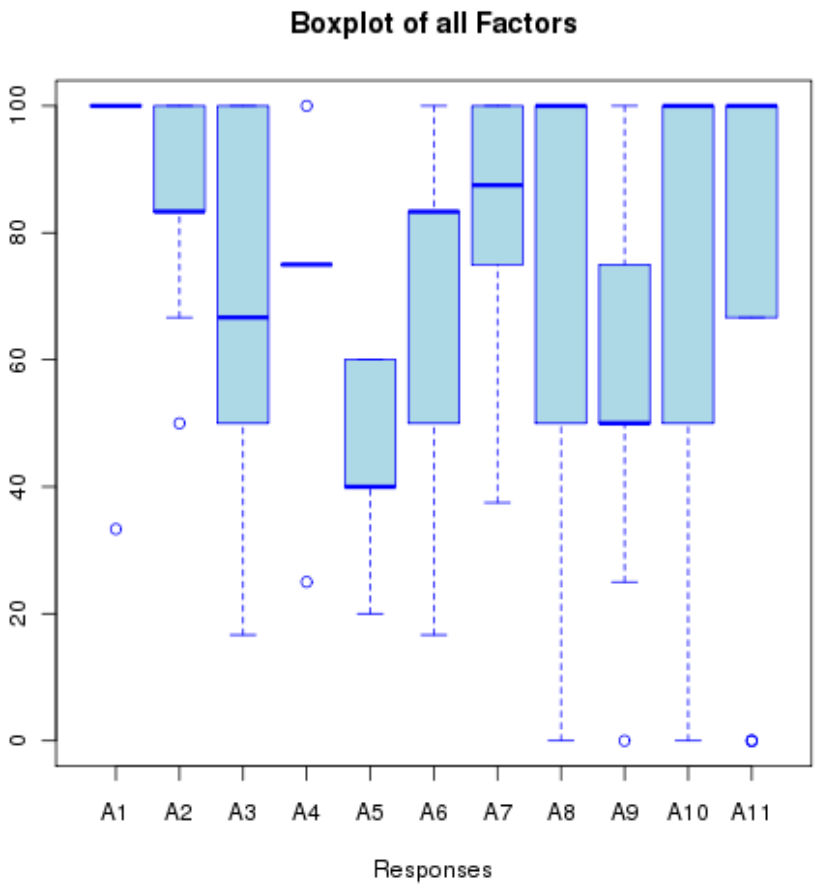
Privacy Factors and Overall Scoring

- **Scaled factors for each register** are computed as a percentage of the factor score on the total attainable score
- The **overall score** of privacy protection for each participating register is computed as a **composite indicator:**

OVERALL = Average of All Scaled Factors

- **The resulting composite indicator assigns equal weights to all privacy factors**
- Descriptive statistics are produced by specialized R software developed ad hoc for the project. Results are displayed by question, item, factor, register, and for the overall sample to show the variability across the EUBIROD Consortium
- **Scoring of individual centres is never disclosed**

Results (3): Privacy Factors

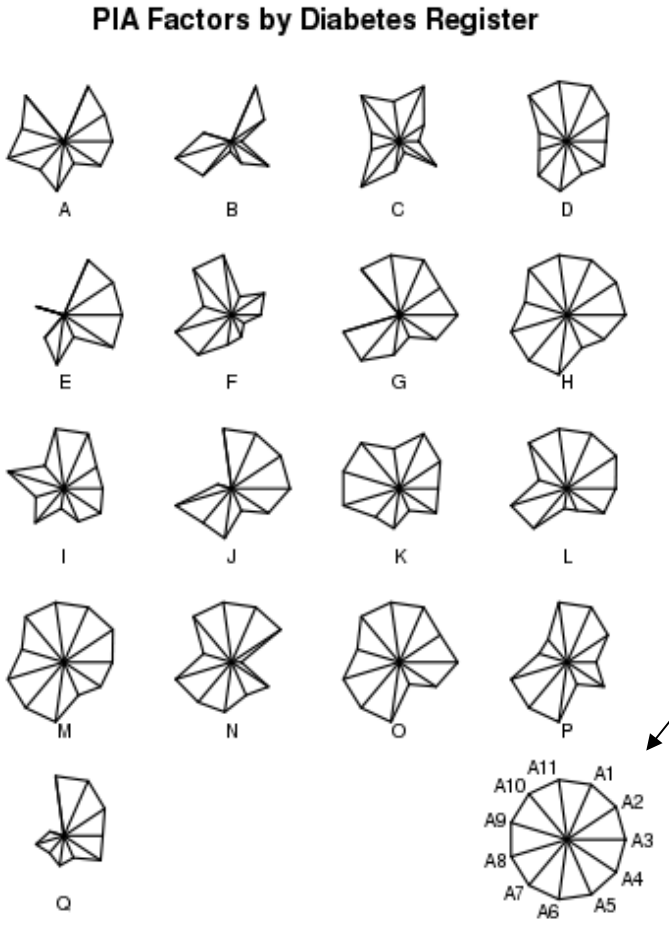


- **Boxplots highlight key areas of concern in the implementation of the Data Protection Directive**

Main Results:

- EUBIROD Registers show an average of:
  - Accountability, Openness, Challenging compliance and Anonymisation at the highest attainable level
  - Consent close to 65%
  - Disclosure, Disposition and Access rights between 40%-50%
- The variability of factors across the EUBIROD Consortium:
  - is High for Consent, Openness, Challenging compliance
  - Mild for Accuracy and Access

Results (4): Analysis of Variability across Registers

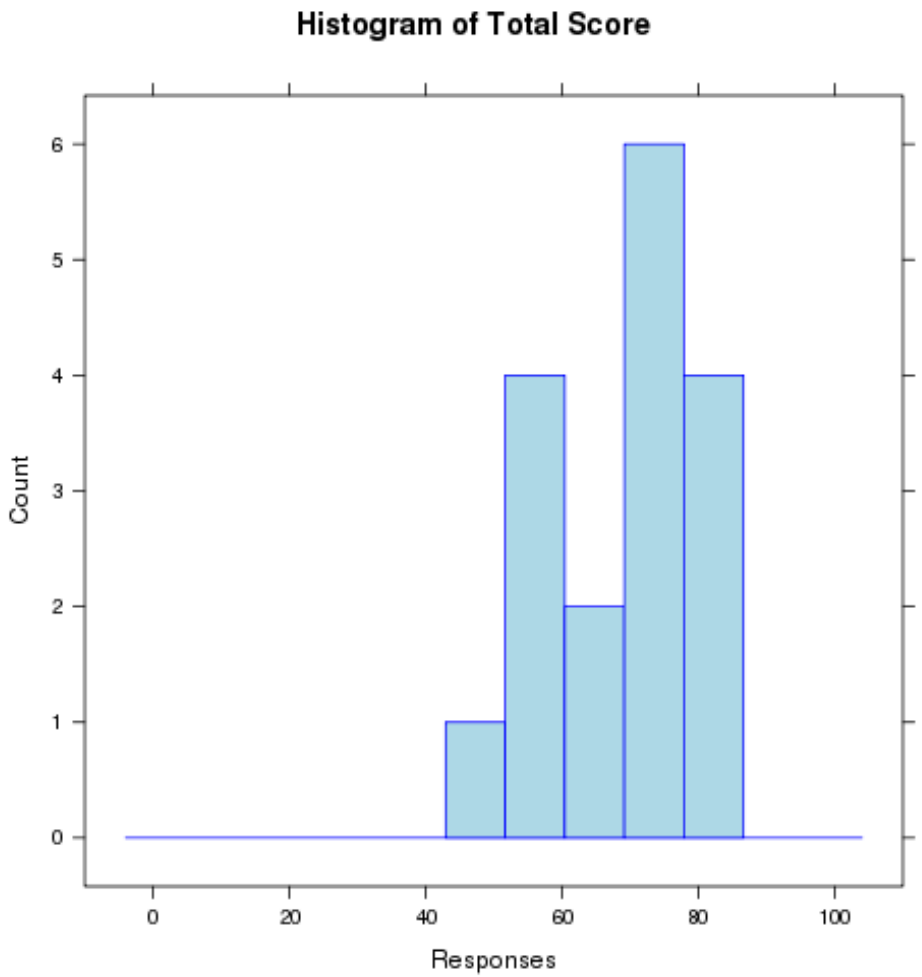


- Starplots summarize the "Privacy Profile" of each EUBIROD register included in the database

(Factors Legend)

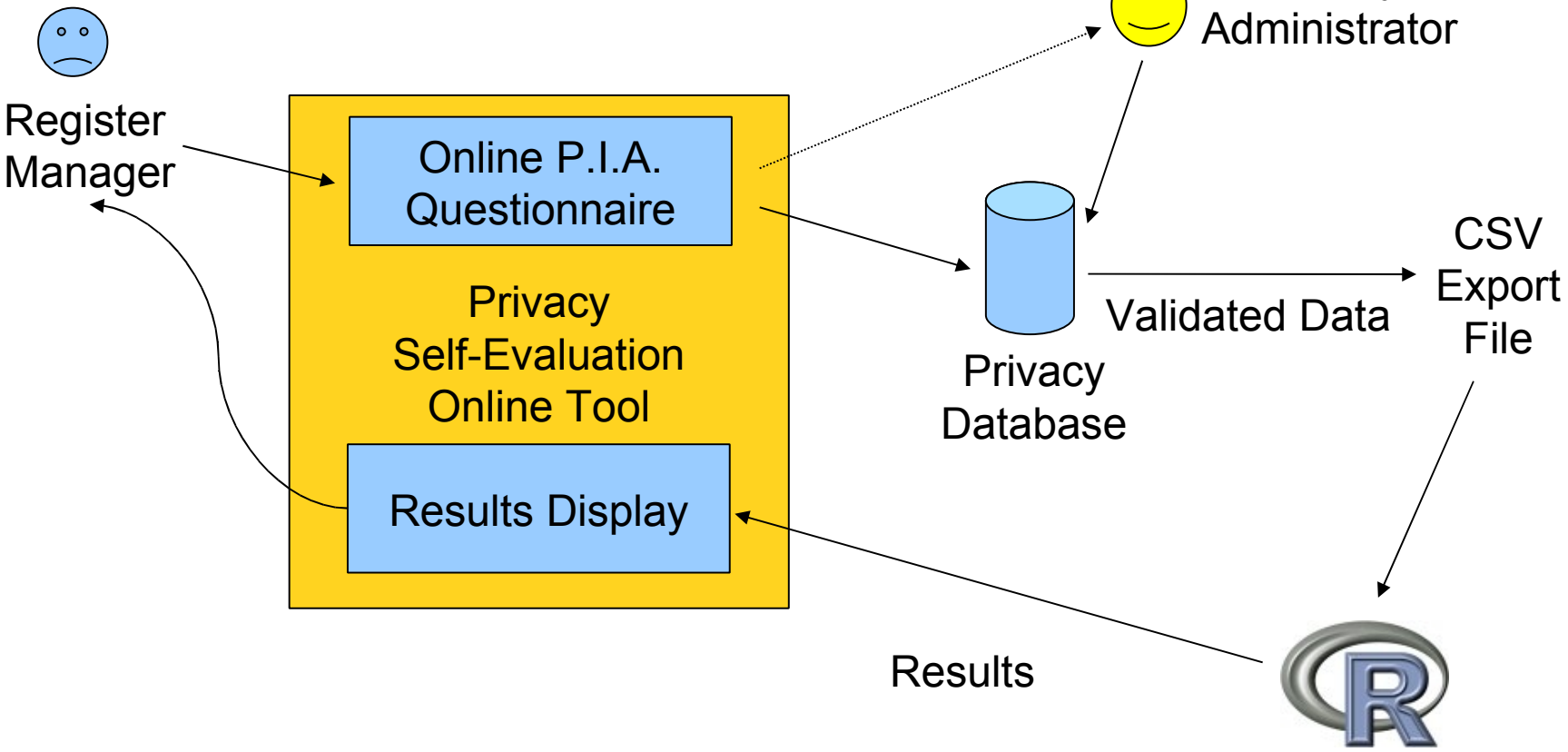
- The larger the area of the polygon, the better the privacy profile

Results (5): Overall Privacy Performance

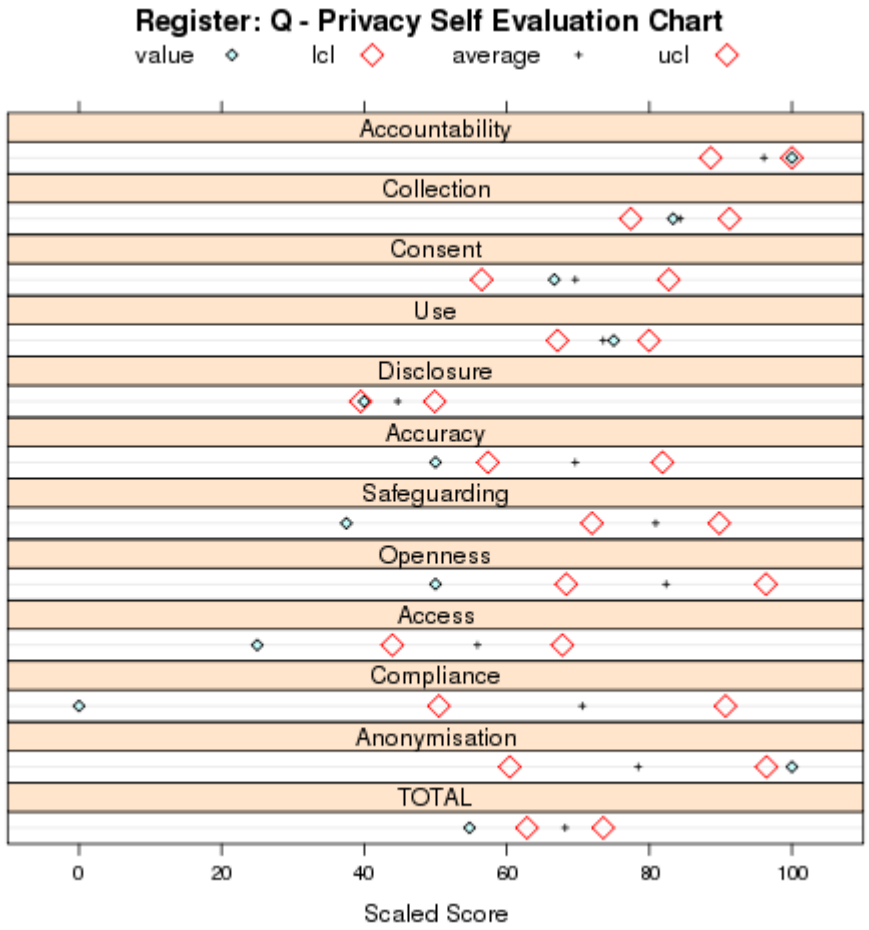


- **Overall level of privacy protection attained by diabetes registers in EUBIROD:**
  - N=4 registers: **78%-85%**
  - N=6: 70%-78%
  - N=2: 60%-70%
  - N=4: 50%-60%
  - N=1: 50%

Improving Privacy by Self-Evaluation: the EUBIROD PIA IT Platform



Privacy Performance Self-Evaluation



Each register can compare own practice against the average of the overall sample and the maximum attainable score

Example:

- Maximum score in terms of accountability and anonymisation
- Acceptable levels for collection, consent, use and disclosure
- All other factors show poor privacy performance

Conclusions (1)

- **Average Level of Privacy Protection:**
  - no Register in EUBIROD is perfectly compliant with privacy requirements
  - factors showing the **lowest scores** are:
    - Disclosure and disposition of personal information
    - Use of personal information
    - Individual Access to personal information
- **Variability in the Implementation of the Data Protection Directive is:**
  - High: Consent, Openness, Challenging compliance
  - Mild: Accuracy and Access

Conclusions (2)

- A **general model of privacy performance evaluation** can help identifying the main areas of concern that can impact on the quality of information
- Collaboration, rather than “privacy league tables” must be pursued to generate **quality improvement loops** that can increase data accuracy and completeness
- The **self-evaluation tool** realized in EUBIROD can be used as a general model of collaborative Privacy Performance Evaluation to improve the quality of any disease register