

## Cross-border flow of health information: is 'privacy by design' enough? Privacy performance assessment in EUBIROD

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**Background:** The EUBIROD project aims to perform a cross-border flow of diabetes information across 19 European countries using the BIRO information system, which embeds privacy principles and data protection mechanisms in its architecture (privacy by design). A specific task of EUBIROD was to investigate the variability in the implementation of the EU Data Protection Directive (DPD) across participating centres. **Methods:** Compliance with privacy requirements was assessed by means of a specific questionnaire administered to all participating diabetes registers. Items included relevant issues e.g. patient consent, accountability of data custodian, communication (openness) and complaint procedures (challenging compliance), authority to disclose, accuracy, access and use of personal information, and anonymization. The identification of an *ad hoc* scoring system and statistical software allowed an overall quali-quantitative analysis and independent evaluation of questionnaire responses, automated through a dedicated IT platform ('privacy performance assessment'). **Results:** A total of 18 diabetes registers from different countries completed the survey. Over 50% of the registers recorded a maximum score for accountability, openness, anonymization and challenging compliance. Low average values were found for disclosure and disposition, access, consent, use of personal information and accuracy. A high heterogeneity was found for anonymization, consent, accuracy and access. **Conclusions:** The novel method of privacy performance assessment realized in EUBIROD may improve the respect of privacy in each data source, reduce overall variability in the implementation of privacy principles and favour a sound and legitimate cross-border exchange of high quality data across Europe.

### Introduction

Healthcare information systems offer crucial advantages for improving public health. The integrated availability of health data promotes optimization of health systems, efficiency savings, increased safety and health benefits.<sup>1</sup>

Although the European Union has taken steps to improve the availability of quality data across Europe, health information is still not homogeneous and often not efficiently used for policy making.<sup>2</sup> A major obstacle to the use of data for international

comparisons is the lack of harmonization of international privacy policies, which has sometimes posed unnecessary legislative constraints on the processing of data for public health purposes.

Health information systems, which strongly rely on advanced IT solutions, pose technical challenges to existing privacy/data protection legal frameworks.<sup>3</sup> Opportunity and risks arise from the increased hardware capacity (storage, processing speed), more powerful software (data management systems and data mining) and the easier interconnection and interoperability across different

systems, which facilitates the secondary use of health data and data linkage.

However, legislative barriers to the implementation of efficient health information systems can be overcome by adopting appropriate safeguards and privacy protective solutions. Targeted legislative instruments are needed to reconcile the conflicting interests of the right to privacy/data protection with those of the right to health/health care.

The right to privacy, recognized in many international treaties,<sup>4–7</sup> became legally binding for Member States (MS) with the entry into force of the Lisbon Treaty in 2009, which incorporated the Charter of Fundamental Rights of the European Union.<sup>8</sup> While Article 7 of the Charter recognizes the fundamental human right to privacy, Article 8 specifically protect personal data as an autonomous human right, different from, but closely linked to the right to privacy. Furthermore, the Lisbon Treaty introduced a new legal basis to establish a comprehensive and coherent Union legislation through Article 16 of the Treaty on the Functioning of the European Union.<sup>9</sup>

On this basis, the Commission is undergoing a revision of the EU Data Protection Directive (DPD).<sup>10</sup> Accordingly, a ‘Communication on a comprehensive approach on personal data protection in the European Union’<sup>11</sup> has been enacted in 2010 to address the new technological challenges for data protection and to overcome pitfalls in the implementation of the DPD across MS. The Communication acknowledges that privacy and data protection rights should not unnecessarily limit other fundamental rights enshrined in EU Treaties, including the right to health/health care. It also highlights that, despite of a common EU legal framework, there is a lack of harmonization among the legislation of MS on different aspects of data protection, including data processing for public health purposes. The divergent implementation of the DPD across MS may produce both an inadequate protection of the right to privacy/data protection and unnecessary legal constraints. In the health-care sector, the direct impact of these practices produced a substantially lower capacity of conducting effective research in specific MS.<sup>12</sup>

The new DPD is expected to be enacted in 2012. Among the means to promote harmonization, it will foster the use of privacy enhancing technologies (PETs), privacy by design and privacy impact assessment (PIA) in specific cases and particularly when sensitive data is to be processed.<sup>11</sup> Privacy by design and PIA are systems engineering methodologies embedding privacy/data protection throughout the entire life cycle of technologies.<sup>13</sup>

The BIRO<sup>14</sup> project built a transnational ‘Shared Evidence-Based Diabetes Information System’ to automatically deliver quality indicators for international comparisons on a regular basis. The project defined a European common dataset and a template for routine reporting, realized through the development of an *ad hoc* database/statistical software. In line with the Commission Communication, the system architecture was identified through a novel method of PIA,<sup>15</sup> which ensured complete privacy protection without hampering the information content for public health. The resulting technology operates on top of distributed databases and the transmission of aggregate data to a central server, which delivers EU indicators.

The EUBIROD project<sup>16</sup> implemented the BIRO technology in 19 countries to automatically produce a European Diabetes Report including 81 quality and outcomes indicators. Sections of the report include: demographics, clinical characteristics and risk factors, health system structures and processes, population (prevalence rates), risk-adjusted intermediate and terminal outcomes and paediatrics.

A novel method of ‘Privacy Performance Assessment’ (PPA) was conceived to respond to the following questions:

- how heterogeneous is the implementation of privacy requirements/principles among participating centres?

- which are the key areas of concern requiring advice and guidance? and
- how can the consistency of registers with privacy requirements be improved?

In this article we explain how PPA can be used as a practical solution that can help respond to the new privacy challenges in the design of transnational health information systems.

## Methods

### *Privacy performance assessment*

The PIA method originally developed in the BIRO project focused on the system as a whole.<sup>15</sup> The EUBIROD PPA explored privacy issues at the level of systems’ users, assessing the variability of data processing procedures in 19 countries and their deviation from EU privacy standards. Summary measures of privacy performance were automatically provided back to users for an independent evaluation of local policies. The PPA methodology involved the following steps:

- identification and definition of key elements of data protection (privacy factors) in the management of diabetes registers;
- adoption of a targeted tool (questionnaire) to collect data on procedures used across the Consortium;
- analysis of privacy factors and variability of approaches at the European level and
- creation of a dedicated tool to improve the management of privacy issues.

The questionnaire adopted in EUBIROD was a revised/updated version of the one included in the Canadian PIA Guidelines.<sup>17</sup> Key elements of data protection (factors) were selected to ascertain the compliance/non-compliance with privacy principles/norms of data processing operations occurring in EUBIROD registers.

The following eleven privacy factors were included as separate sections in the questionnaire:

- ‘accountability of personal information’: for example, questions on the custody and control of personal information and third parties involvement;
- ‘collection of personal information’: on the authority to collect, the necessity of the information collected (minimality principle), the use of information for secondary purposes, and the provision of anonymization for planning, management and/or evaluation purposes;
- ‘consent’: on the necessity to gather informed consent for the collection and processing of data in the registry, if it is obtained from the individual, if it is clear/unambiguous and if the capacity to give consent has been taken into account;
- ‘use of personal information’: on the authority to use information, if the use is in compliance with the purpose specification principle and if personal identifiers are used for data linkage;
- ‘disclosure and disposition of personal information’: on the consent/authority to disclose personal information and/or personal identifiers;
- ‘accuracy of personal information’: on the possibility for individuals to access, assess, discuss or dispute the accuracy of his/her record;
- ‘safeguarding personal information’: on security measures and processes;
- ‘openness’: on the provision of communication processes and the way personal information is managed/protected;
- ‘individual access to personal information’: evaluating the practical implementation of access rights;
- ‘challenging compliance’: on the availability of complaint procedures and mechanisms to ensure accountability and
- ‘anonymization process for secondary uses of health data’: analysing the compliance with international technical standards and principles.

The EUBIROD PPA questionnaire, including a total of 57 questions, is available as an official project deliverable.<sup>18</sup>

### Study population

The target population of the EUBIROD PPA included 19 participating diabetes registers: Healthgate Styria (Austria), IPH Survey Belgium, Diabetes Register of Croatia, Larnaca (Cyprus), Hillerod (Denmark), Rheinland-Pfalz (Germany), GPMSSP Hungary, Tallaght (Ireland), Umbria (Italy), Administrative Data Luxembourg, Mater Dei (Malta), West Friesland (the Netherlands), Diabetes Register of Norway, Silesia (Poland), Bucharest (Romania), DARTS Tayside (Scotland), Type 1 Childhood Diabetes Register of Slovenia, Malaga (Spain), Skaraborg (Sweden). The details of participating institutions are available on the EUBIROD website.<sup>16</sup>

### Data collection

Partners were asked to complete a Word document and return it by email to the Coordination Centre. Continuous legal advice was provided to ensure correctness and completeness of answers and avoid any potential misunderstanding in the interpretation of questions. Various rounds of submissions/corrections were undertaken to complete the process and allocate all answers correctly.

Data from the questionnaire were recorded in an Excel spreadsheet, saved in Comma-separated Value (csv) format and submitted to the statistical routine for reporting.

### Statistical analysis

Scores for privacy factors were derived by re-coding the original values of each question (0: No, 1: Yes, 2: Not Applicable/Not Determined, 9: Missing—Blank or Comment Only) to '1' for a positive, privacy protective conduct, and '0' for a non-privacy compliant procedure. The overall score for each factor (section) was computed as the sum of re-coded values. Standardized factors for each register were computed as a percentage of the factor score on the total attainable overall score for each factor. The overall level of privacy protection was computed as a composite indicator corresponding to the average of all standardized factors for each participating register.

Statistical analysis included descriptive analysis of questions, factors and overall scores with the associated 95% confidence intervals (CIs). The median, range for overall factor scores were computed to take into account the skewed distribution of responses. A variety of graphs were produced to display results from the questionnaire relative to single questions, factors, and the overall questionnaire (histograms, boxplots, starplots and dotplots). *Ad hoc* software written in the R statistical language<sup>19</sup> was developed specifically to produce all results.

### IT platform

The IT platform includes an electronic version of the questionnaire and a complete management system allowing new users to submit their questionnaires, validated by the IT platform administrator. A csv file is extracted and directly submitted to the R source code to update the report and produce all graphical outputs. Results delivered by the R program are then included in a user interface through which each register can browse own results of privacy performance against those obtained by others, whose identity is never disclosed. The IT platform is directly available from the EUBIROD website.<sup>16</sup>

### Results

A total of 18 out of 19 EUBIROD registers returned the questionnaire.

Table 1 presents the main summary results for all standardized privacy factors.

Over 50% of the registers recorded a maximum score (100%) for the following factors: accountability, openness, anonymization and challenging compliance. Questions related to 'collection of personal information' highlighted that 44% of the registers make secondary use of registry data. Only 22% of the registers collect information from public databases and 33% from multiple sources using a common patient identifier. Consent to collect and process personal data in the registry is required by 61% of the centres. In the remaining cases, registers are built without patient consent by authority of law, which also meets privacy requirements.

The factor 'use of personal information' highlighted that data linkage is performed by 50% of the registers.

Median values showed that the most problematic privacy factors are:

- disclosure and disposition (40%) and
- individual access (50%)

However, factors e.g. consent, use of personal information and accuracy are also of concern, with a median of 75%.

A high variability of scores was found for the following factors (standard deviation, range):

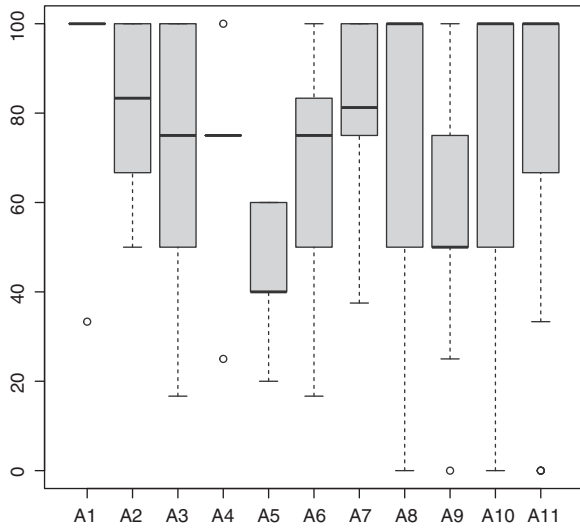
- challenging compliance (39%, 0–100%); anonymization (35%, 45–100%); openness (30%, 0–100%); consent (28%, 17–100%); accuracy (26%, 17–100%) and individual access (25%, 0–100%).

Figures 1–3 summarize the results in a graphical format.

At the end of the study, each register was provided with a privacy performance report deployed on the IT platform in de-identified format. Privacy reports present average results in tabular and graphical display, showing own median scores (overall and for each factor) against those attained by the entire sample, along with the relative 95% CI.

**Table 1** Results of EUBIROD PIA for standardized factors and overall average as a percentage of the maximum attainable score

Factor	Description	No. Questions	Mean (SD)	95% CI	Median	Range
A1	Accountability	3	96.3 (15.7)	89.0–100.0	100.0	33.0–100.0
A2	Collection	6	83.3 (15.1)	76.3–90.3	83.3	50.0–100.0
A3	Consent	6	71.3 (28.5)	58.1–84.4	75.0	16.7–100.0
A4	Use	4	73.6 (13.5)	67.4–79.8	75.0	25.0–100.0
A5	Disclosure	5	44.4 (11.0)	39.4–49.5	40.0	20.0–60.0
A6	Accuracy	6	69.4 (25.7)	57.6–81.3	75.0	16.7–100.0
A7	Safeguarding	8	80.6 (18.8)	71.9–89.2	81.2	37.5–100.0
A8	Openness	2	80.6 (30.3)	66.5–94.6	100.0	0.0–100.0
A9	Access	4	55.6 (25.1)	44.0–67.1	50.0	0.0–100.0
A10	Compliance	2	75.0 (39.3)	56.8–93.2	100.0	0.0–100.0
A11	Anonymization	3	79.6 (34.6)	63.7–73.5	100.0	44.5–100.0
	OVERALL		73.6 (11.1)	68.5–78.8	74.8	68.5–78.8



**Figure 1** Distribution of factor scores in the EUBIROD sample. Boxplots represent the median, upper and lower quartiles, with whiskers at 1.5 times the interquartile range, plus any outlying values. Factors are coded A1–A11 according to the order they have been presented in the methods section

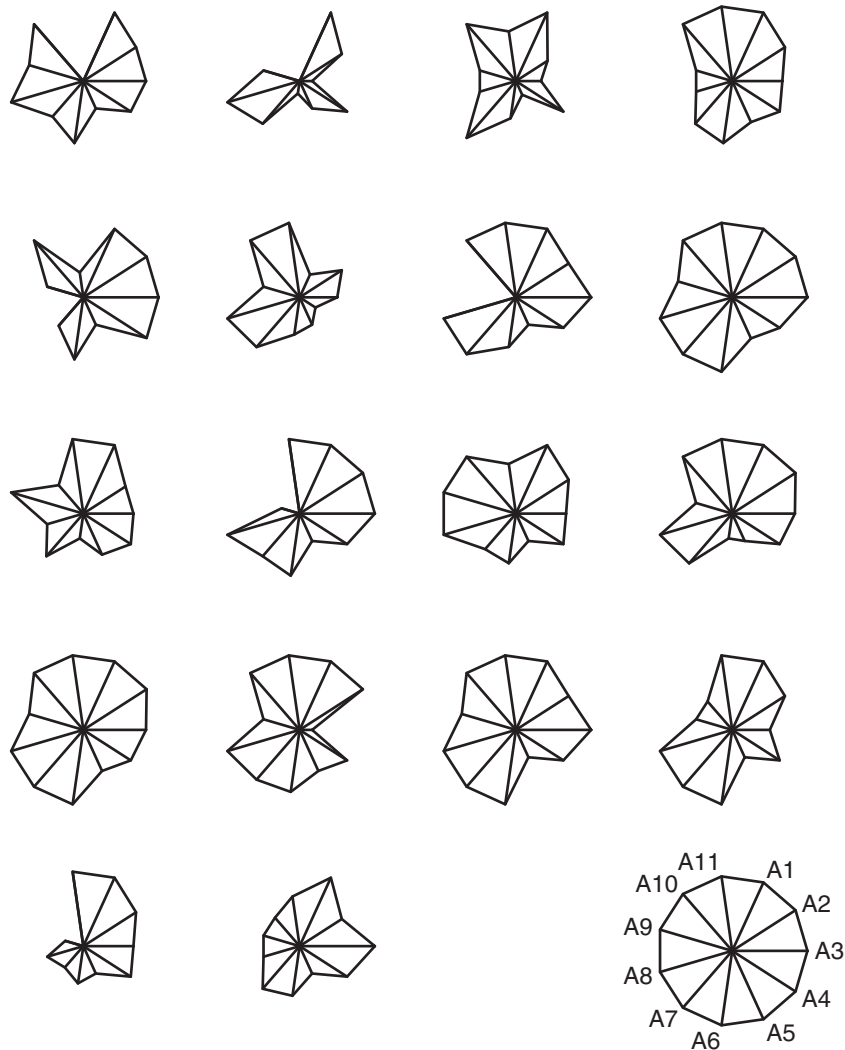
## Discussion

The completeness of information available from disease registers is paramount for making best use of data for research, monitoring, surveillance, quality improvement and efficient planning of healthcare systems. Understanding the nature and causes of potential information loss may help avoiding wrong decisions based on unreliable results (e.g. organizational changes following clinical audits where high-risk groups have been systematically excluded).

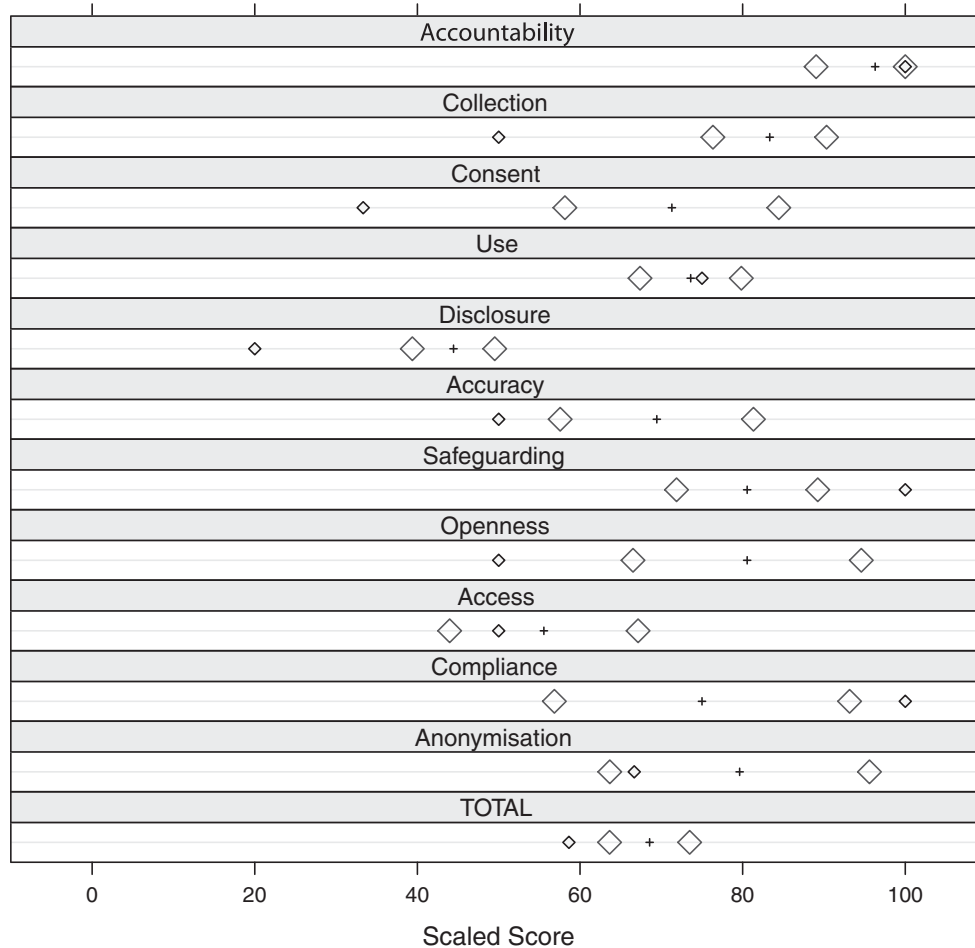
Sustainable strategies to rapidly improve data quality, e.g. policies to reduce the variability of unexplained cultural barriers, can be highly convenient, particularly in a time of financial pressure. Our survey highlighted that database administrators of diabetes registers normally do not have access to personal information stored in routine databases and/or across multiple sources, perform data linkage only in half of the cases and can hardly use data for secondary purposes.

These findings may be due to structural limitations e.g. lack of a personal identifier or scarce resources. However, registers involved in EUBIROD are well established in countries where these conditions are usually met.

On the other hand, these shortcomings provide an empirical estimate of the potential effect of the heterogeneous implementation



**Figure 2** Privacy profiles of EUBIROD registers. Each starplot represents the profile of a single EUBIROD diabetes register. Rays represent the level of each factor according to the legend located in the lower right corner. Registers are displayed anonymously (the order does not correspond to the presentation order in the main text)



**Figure 3** Privacy performance self-evaluation chart. A chart is produced for each EUBIROD centre to benchmark its level of adherence to privacy principles against the general results. For each factor and overall, the register score (small diamond) is plotted against the average (plus sign) and the computed 95% confidence limits (large diamonds). In this example, a register presents optimal levels of accountability, safeguarding and compliance, but low levels for anonymization, access and exceedingly low levels of collection, consent, disclosure, accuracy and openness. Overall, the centre is an outlying privacy under-performer

of the DPD across MS, one of the aspects at the basis of recent developments in EU privacy legislation.<sup>12</sup> As conflicts of interests exist between the needs of privacy protection and those of public health, targeted solutions should be implemented to achieve an optimal balance between the two interests.

The 1995 DPD<sup>10</sup> imposes specific conditions and limitations for the legitimate processing of personal information (Articles 7 and 8), unless data is to be considered anonymous.

The DPD strongly encourages the recognition and implementation of the right to privacy and data protection, but clearly recognizes the need of societies to attain better healthcare by providing several exemptions to the prohibition of processing sensitive data when health improvements are involved; e.g. Article 8(3–4). Article 8(3) justifies the processing of health data, without patients' consent, for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment and the management of healthcare services. Consent would be necessary to process the same data for any secondary purpose; e.g. Article 8(4). MS can provide additional exemptions to those laid down by the DPD for reasons of substantial public interest. According to Recital 34 of the DPD, public health is included in the notion of substantial public interest. Nonetheless, only very few MS have translated this possibility into national laws/regulations; while some others have adopted specific exemptions only for selected activities.<sup>20</sup> As a matter of fact, MS who have not used the possibilities of Article 8(4), have made data processing for public health purposes more difficult, differently from what was originally envisaged by the EU legislator.

The implementation of the DPD at national level should be carefully monitored to assess if, how and to what extent a balanced approach has been achieved in practical national settings, particularly in the field of public health. Therefore, it is crucial to identify factors presenting the largest heterogeneity in the implementation of privacy principles and to highlight the key areas of concern in privacy protection.

The EUBIROD PPA addressed these problems through a qualitative assessment of the level and variability of implementation of privacy norms/requirements across MS and the direct identification of privacy principles that need targeted actions to be fully complied with.

Furthermore, PPA includes an IT platform that allows participating centres to identify their position in the distribution of overall privacy results, and to identify the main areas of concern by benchmarking scores for each factor against either average values or specified targets.

The creation of a dedicated tool to improve the management of privacy issues in diabetes registers may represent a practical solution to feed privacy results back to individual centres and improve their privacy performance. The PPA platform, preserving the identity of registers, may favour the consolidation of collaborative models in a sensitive area of legal inquiry. The PPA tool may also help improving the quality of information required for the production of public health indicators by targeting factors e.g. the 'accuracy of personal information', where the observed low scores may relate to difficulties in using additional sources and data for secondary purposes.

To overcome this issue, both privacy protection and data accuracy should be ensured by enforcing appropriate safeguards for data processing operations posing privacy risks.<sup>21</sup> In addition to the novel solutions proposed in BIRO and EUBIROD, other means could be safely used to improve data quality. For instance, data linkage is a crucial area where solutions e.g. trusted third parties could be implemented to guarantee the respect of privacy norms. However, targeted survey instruments should be explored to test the robustness of these solutions in detail.

Finally, some limitations of our study must be outlined.

The identification of privacy factors in the questionnaire was internally performed by the EUBIROD Consortium. Nevertheless, the direct reference of each question to EU and international legislation/guidelines is fairly evident and transparently reflected in our results.

Results are based on a sample of diabetes registers. However, the study includes a large number of countries, whose centres are all highly regarded internationally in a field e.g. diabetes, which involves managing large databases and using highly standardized electronic health records.

The scoring system applied for analysing privacy factors is based on a simple linear sum of the individual questions. The overall level of privacy protection assumes that all factors weigh equally. These assumptions should be properly tested in a targeted study.

## Conclusions

The model of PPA developed in EUBIROD proposes a new method that allows measuring the level of implementation of privacy principles/norms as well as identifying the key areas of concern that require targeted actions at both the national and European level. At the level of disease registers, it makes possible to identify key areas of concern, including those influencing data quality, and apply appropriate corrective measures. At EU level, it allows performing a sound assessment of the variability in the implementation of the DPD across MS, highlighting privacy principles/factors that need to be strengthened.

The overall model is designed to foster the uptake of privacy/data protection principles and generate local quality improvement loops that would result into more solid transnational information exchange for public health.

A concerted action at both the legislative level and point of care provision is overtly needed to achieve the right balance between privacy/data protection and better health.

## Funding

The EUBIROD project has been co-funded by the Health Information Strand of the European Public Health Program, DG-SANCO, European Commission, Contract no. 2007115.

*Conflicts of interest:* None declared.

## Key points

- Diabetes registers from 18 countries normally do not have access to personal information from routine databases and/or multiple sources; they perform data linkage only in half of the cases and rarely use data for secondary purposes.
- The 'Privacy Performance Assessment' platform supports privacy protection and quality improvement on a routine basis.
- The overall model of the 'Privacy Performance Assessment' may favour the homogeneous implementation of the DPD, while enabling more solid transnational exchange of public health information.

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*European Journal of Public Health*, Vol. 23, No. 2, 253–257

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 doi:10.1093/eurpub/cks037 Advance Access published on 8 August 2012  
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## Factors associated with delayed tuberculosis diagnosis in China

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**Background:** Delays in the diagnosis of tuberculosis reflect a lack of access to care, and contribute to ongoing tuberculosis transmission in the community. The objective of this study was to evaluate the delay in tuberculosis testing and the associated risk factors in Shanghai, Shandong and Sichuan provinces in China. **Methods:** A prospective cohort study of 765 culture-positive pulmonary tuberculosis patients registered between December 2006 and December 2008. The delay between the onset of symptoms and tuberculosis diagnosis testing and patient information were recorded in a questionnaire and analysed. **Results:** The median delay was 36 days and was significantly shorter in patients from Shanghai compared with other places (30 vs. 42 days,  $P < 0.001$ ). Multivariate analysis revealed that cough in Shanghai patients, lowest income level, being married and presenting expectoration in Shandong and Sichuan patients, were associated with a delay in the diagnosis testing of tuberculosis of >30 days. The only factor associated with a delay of >90 days was, in Shandong and Sichuan provinces only, female gender. The presence of other pulmonary symptoms like haemoptysis and loss of weight, fever and chills could shorten these delays. **Conclusion:** Efforts to shorten delays in the diagnosis of tuberculosis must target vulnerable populations. The non-specific symptom of cough is a risk factor associated with longer delays. Training for healthcare workers in areas with a high incidence of tuberculosis, where a delayed diagnosis in coughers may enhance tuberculosis transmission in the community, is of paramount importance.

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## Introduction

Tuberculosis (TB) is a major global health burden with more than 9 million people developing the active disease annually. The World Health Organization's (WHO) global targets for reducing the burden of disease attributed to TB are to halt and to begin to reverse the high incidence of TB. To meet these targets, the proportion of new TB cases detected should be 84% of all infected cases globally by 2015.<sup>1</sup> Between 2000 and 2005, the case detection rate for new smear-positive cases in China increased from 31 to 73% but remained stable in 2008.<sup>1</sup>

TB control can be effectively achieved if individuals with the disease are diagnosed in a timely manner and receive adequate and timely treatment. A delay in diagnosis reflects a lack of access to TB care that delays treatment for the individual patient, as well as increasing the risk of TB transmission in the community until the

patient is treated.<sup>2,3</sup> In most Chinese studies, low-income, female and rural TB patients are at a high risk of receiving a late diagnosis.<sup>4–9</sup>

In China, beginning in the early 1990s, huge efforts and resources have been aimed at strategies involving short courses of directly observed treatments (DOTs) that emphasize passive case-finding that would otherwise result in delayed diagnoses. The incidence rate of TB decreased from 113/100 000 in 2003 to 96/100 000 in 2009 with an estimated 1.3 million new cases and 160 000 deaths attributable to TB in 2009.<sup>1,10</sup> In our study areas, patients may go to any general hospital, community health centre or countryside health care facility. If the patient has TB symptoms such as cough for  $\geq 2$  weeks, weight loss or fever, a chest X-ray will be done for screening. Patients suspected of having TB are referred to a TB hospital for definitive diagnosis and free treatment.