Session: Integration of people with diabetes into society

ADNEC, Abu Dhabi, 7th December 2017

Ethics and Diabetes

The Diabetes Challenge: From Human and Social Rights to the Empowerment of People with Diabetes

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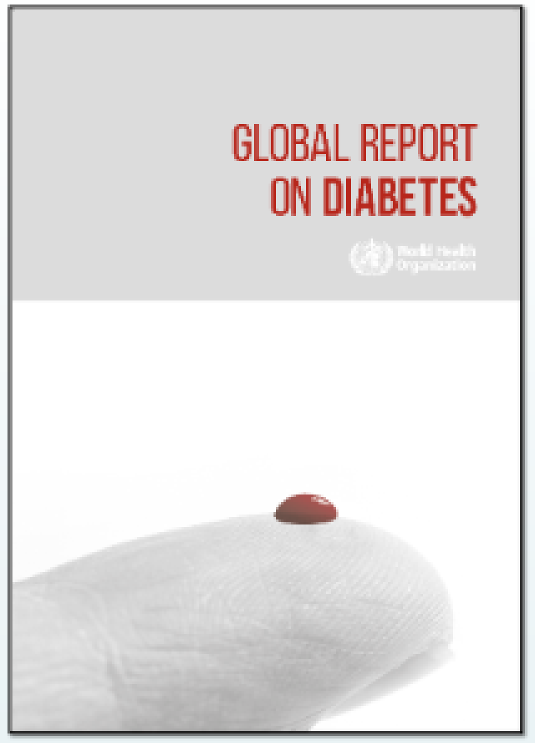
The Burden of Diabetes

http://www.who.int/diabetes/global-report/en/

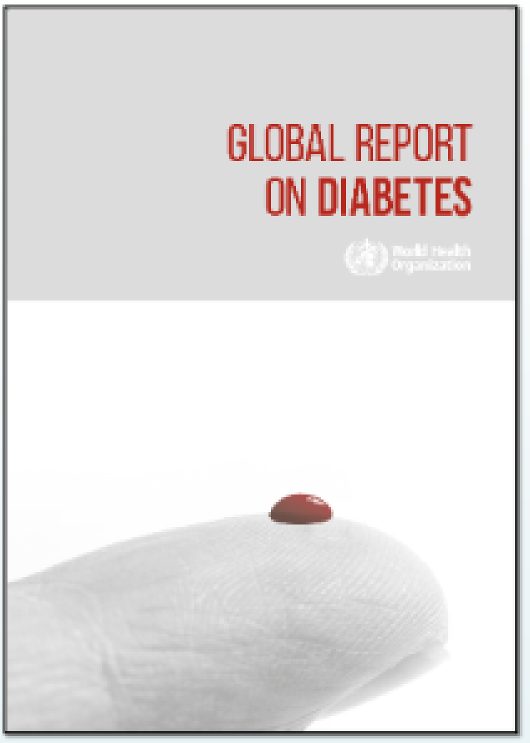


According to the WHO GLOBAL REPORT ON DIABETES (2016):

- 422 million adults were living with diabetes in 2014
- The global prevalence (age-standardized) of diabetes has nearly **doubled** since 1980 (from **4.7% to 8.5%** in the adult population)
- This reflects an increase in associated **risk factors** e.g. being overweight or obese
- Over the past decade, diabetes prevalence has risen **faster in low and middle-income countries** than in high-income countries
- Diabetes caused **1.5 million deaths in 2012**
- Diabetes and its complications bring about **substantial economic loss** to people with diabetes and their families, and to health systems and national economies through direct medical costs and loss of work and wages

Preventing Diabetes

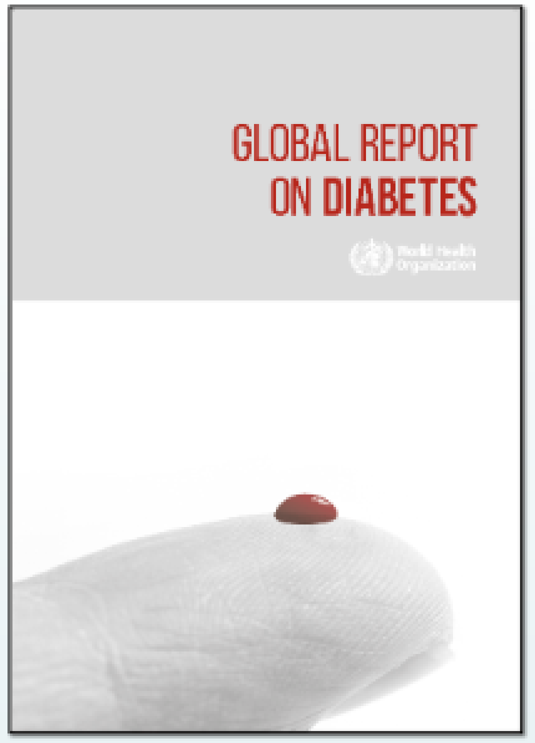
http://www.who.int/diabetes/global-report/en/



- Type 2 diabetes is largely preventable
- Multisectoral, **population-based approaches** are needed to reduce the of modifiable diabetes risk factors in the general population e.g.:
  - Overweight
  - Obesity
  - Physical inactivity
  - unhealthy diet
- Diabetes can be delayed or prevented in people who are overweight and have impaired glucose tolerance (IGT)
- Diet and physical activity interventions are more effective than medication
- A combination of f**iscal policies, legislation, changes to the environment and raising awareness** of health risks works best for promoting healthier diets and physical activity

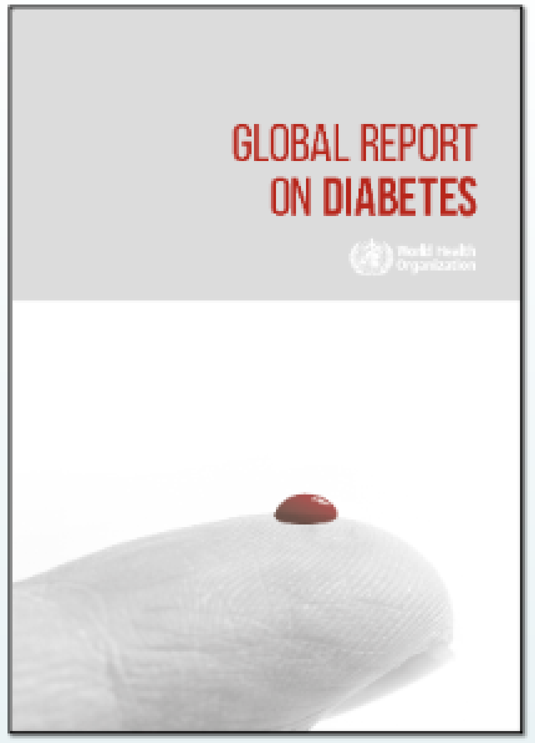
Managing Diabetes

http://www.who.int/diabetes/global-report/en/



- The starting point for living well with diabetes is an **early diagnosis**
- For those who are diagnosed with diabetes, a series of **cost-effective interventions** can improve their outcomes
- Efforts to improve capacity for diagnosis and treatment of diabetes should occur in the context of **integrated non-communicable disease (NCD)** management to yield better outcomes

Key WHO Recommendations = link to ethical values


GLOBAL REPORT ON DIABETES

- Strengthen the **health system response to NCDs**, including diabetes, particularly at primary-care level
- Implement guidelines and protocols to **improve diagnosis and management** of diabetes in primary health care
- Establish policies and programmes to ensure **equitable access** to essential technologies for diagnosis and management
- Make essential medicines such as human insulin available and **affordable** to all who need them
- Address key gaps in the diabetes **knowledge** base
- Outcome evaluations of innovative programmes intended to **change behaviour** are a particular need
- Strengthen national capacity to **collect, analyse and use representative data** on the burden and trends of diabetes and its key risk factors
- Develop, maintain and strengthen a **diabetes registry**

Tackling the Diabetes Epidemics within NCDs

- A combination of fiscal policies, legislation, changes to the environment and raising awareness of health risks works best for promoting healthier diets and physical activity
- The political basis for concerted international action to address diabetes is provided by the following references::
  - Sustainable Development Goals
  - United Nations Political Declaration on NCDs and
  - WHO NCD Global Action Plan

The legal Framework: the Right to Health

- The right to health is enshrined in numerous international and regional human rights treaties:
  - The 1948 UN Universal Declaration of Human rights (Article 25) firstly recognized to every human being "**the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services**"
- The notion of right to health is globally conceived as **inclusive of all the socio-economic and environmental determinants** of health and expands to various dimension that are strictly dependent upon the realization of other fundamental human and social rights

The legal Framework: Human and Social Rights of People with Diabetes

- The interdependence between the right to health and the other human and social rights is evident in the unfortunate occurrence of *disability*:
  - the respect of the **principle of non-discrimination** is key to ensuring the highest attainable standard of health
- Building upon previous legislative instruments, the UN General Assembly has adopted the **Convention on the Rights of Persons with Disabilities in 2006**, a human rights instrument that provides explicit social development goals:
  - *"persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability"*

IDF Charter of Rights and Responsibilities of People with Diabetes

- The vision of the Charter is to:
    - *"optimize health and quality of life, enable people with diabetes to have as normal a life as possible, reduce or eliminate the barriers which deny realization of full potential as members of society"*
- The Charter specifies that the fundamental human and social rights of people living with diabetes include:
    - the right to **health care**
    - the right to **information**
    - the right to **education**
    - the right to **social justice**
    - People with diabetes **Responsibilities**

Cross-border health care

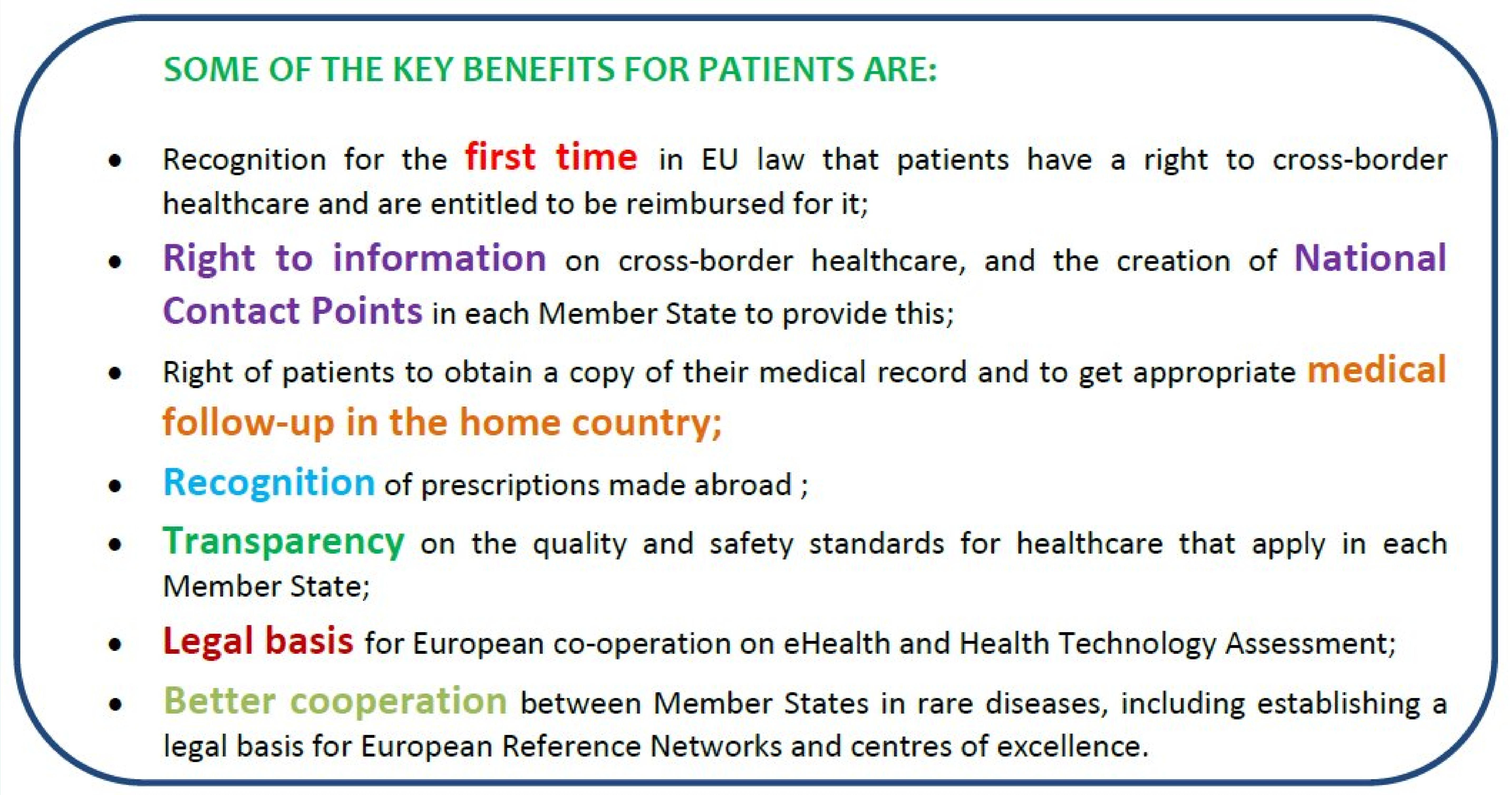
EU CASE STUDY

- *EU Directive 2011/24/EU on the application of patients' rights in cross-border healthcare came into force on 25 October 2013.*
- The Directive covers all healthcare services, including **diagnosis, treatment, prescription and dispensation of medicines and medical devices** (but not reimbursement) and **including eHealth services** (Article 1(2), recital 26).
- The Directive **does not apply to:**
    - **long-term care** or support for people in their daily routines (such as in care homes).
    - allocation of **organs for transplants** or **national vaccination** (Article 1(3)).
    - **Member States' laws and regulations** relating to the organization and financing of healthcare (Article 1(4)).
- The Directive is based on the **principle of non-discrimination**: healthcare providers that provide cross-border healthcare are **not allowed to charge higher fees** for overseas patients than for domestic patients. Member States are also not allowed to treat overseas patients differently from domestic patients (Article 4(3) and 4(4)).

Cross-border health care

http://www.eu-patient.eu/globalassets/policy/cross-borderhealthcare/2013-11-18_cbhc_guidance-final.pdf

EU CASE STUDY



SOME OF THE KEY BENEFITS FOR PATIENTS ARE:

- Recognition for the **first time** in EU law that patients have a right to cross-border healthcare and are entitled to be reimbursed for it;
- **Right to information** on cross-border healthcare, and the creation of **National Contact Points** in each Member State to provide this;
- Right of patients to obtain a copy of their medical record and to get appropriate **medical follow-up in the home country;**
- **Recognition** of prescriptions made abroad ;
- **Transparency** on the quality and safety standards for healthcare that apply in each Member State;
- **Legal basis** for European co-operation on eHealth and Health Technology Assessment;
- **Better cooperation** between Member States in rare diseases, including establishing a legal basis for European Reference Networks and centres of excellence.

Cross-border health care

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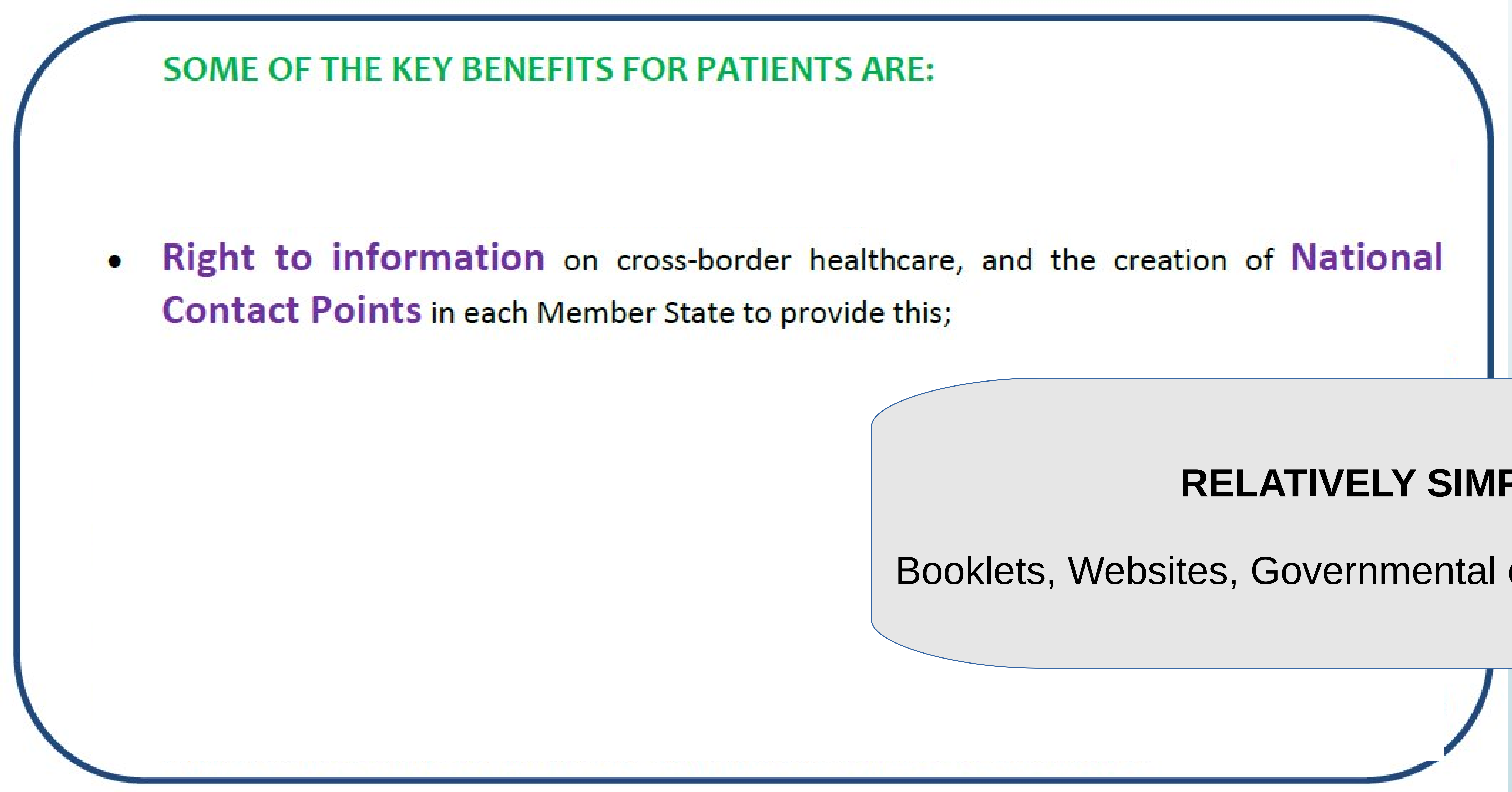
EU CASE STUDY

EPF European Patients Forum



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RELATIVELY SIMPLE

Booklets, Websites, Governmental offices, Info points...

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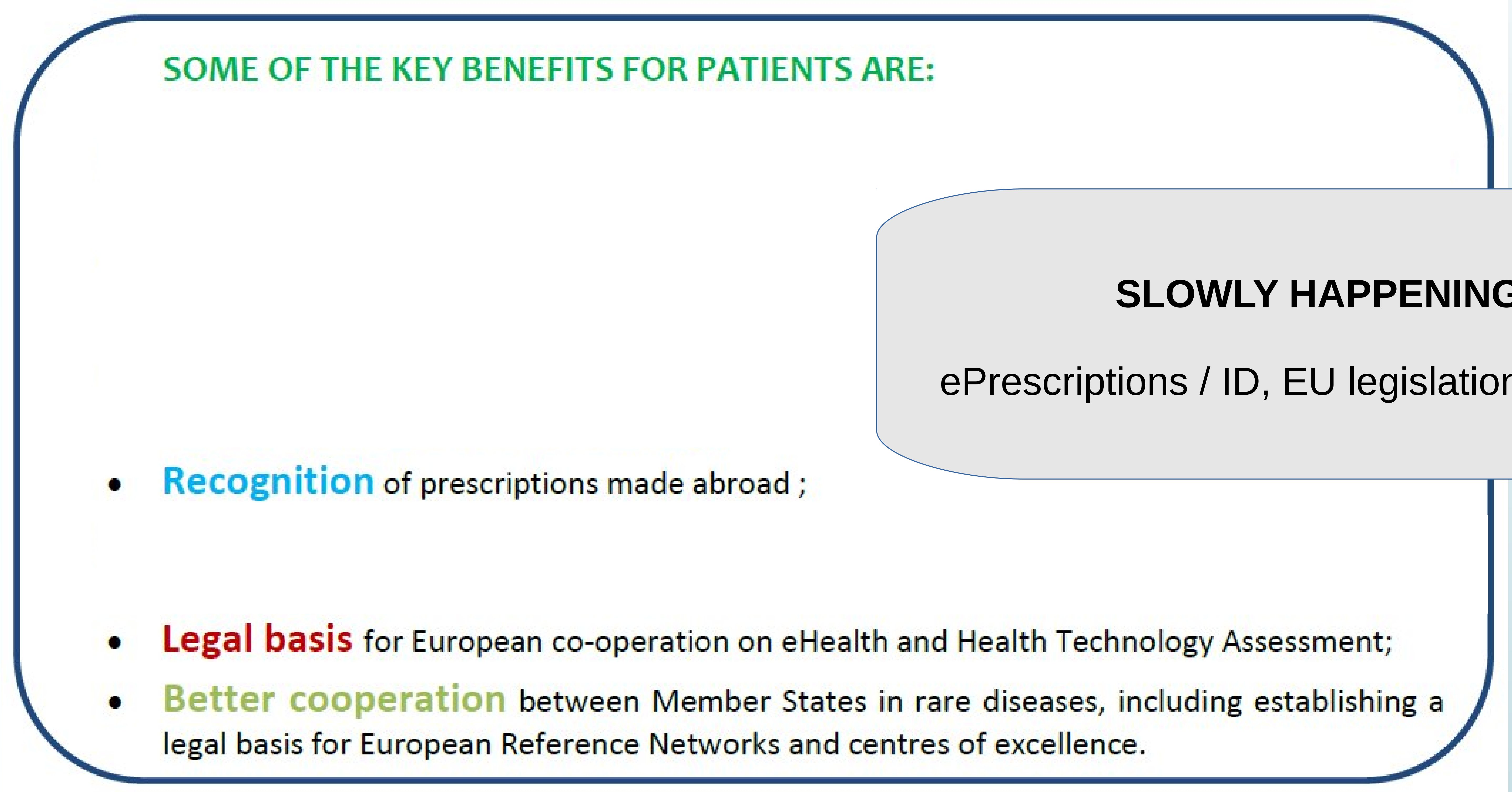
EU CASE STUDY



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SLOWLY HAPPENING

ePrescriptions / ID, EU legislation, ERNs….

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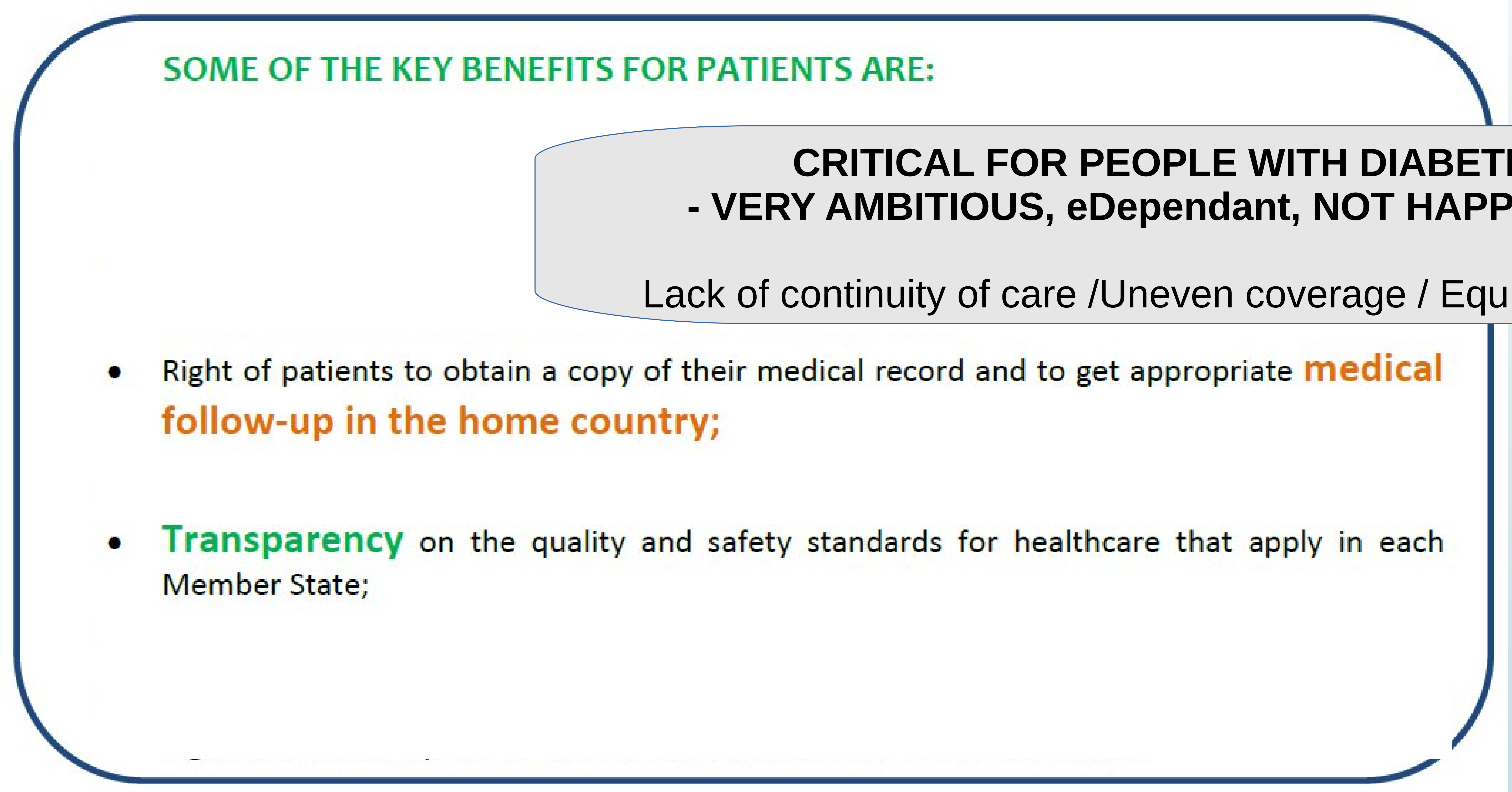
EU CASE STUDY



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CRITICAL FOR PEOPLE WITH DIABETES
- VERY AMBITIOUS, eDependant, NOT HAPPENING -

Lack of continuity of care /Uneven coverage / Equity Issues /

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NEED OF:
Electronic Health Records, Unique ID broadly applied,
Standardized Performance Indicators routinely calculated
European Diabetes Register

EPF European Patients Forum

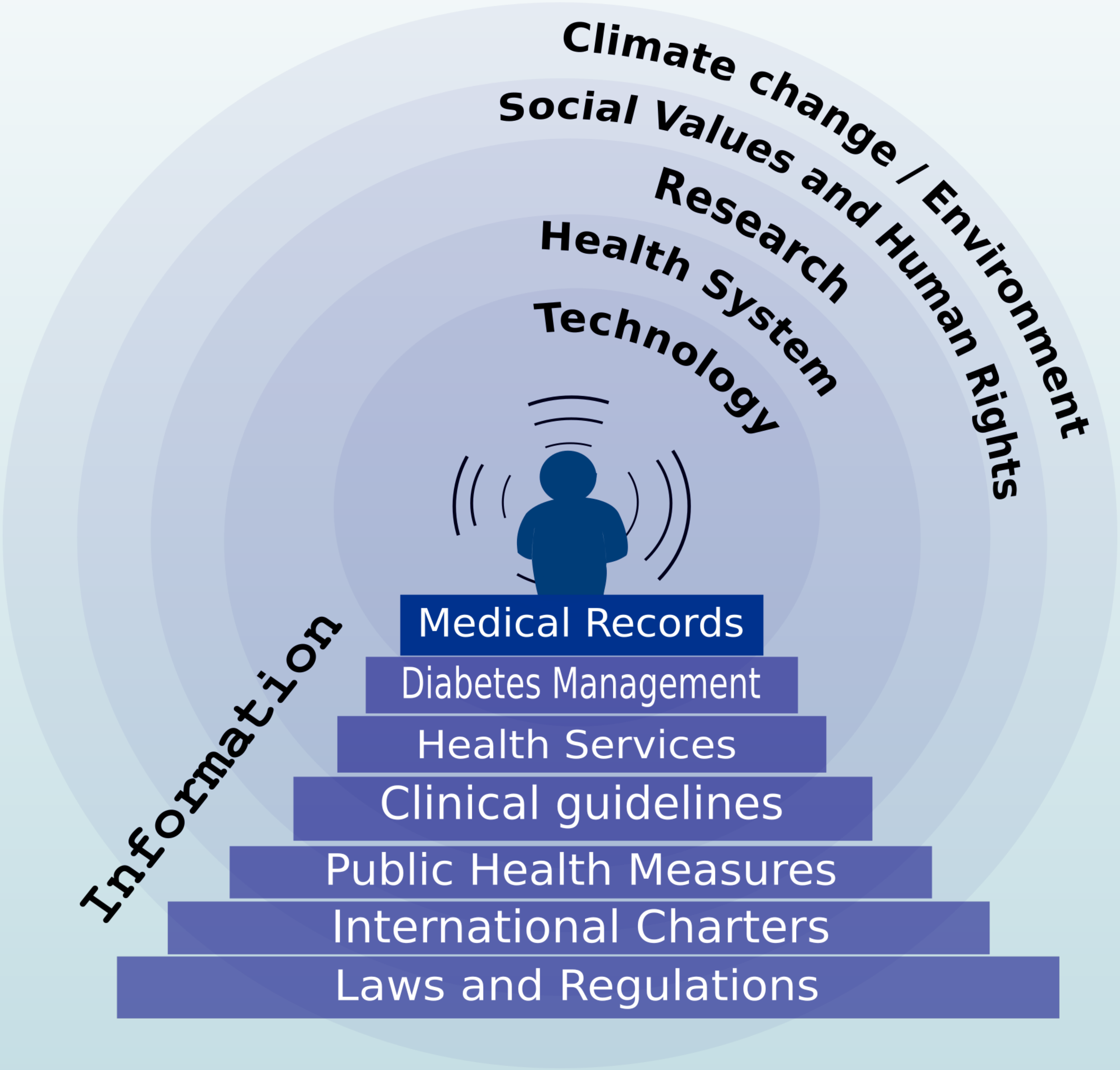
Ethics and diabetes: playing an active role

- Ensuring the respect of ethical values in diabetes is both a **right and a precise responsibility of the person with diabetes (and related organizations)**
- **Playing an active role implies:**
  - **influencing the legislation and ensuring sustained funding for implementation**
  - **strictly monitoring its implementation**
  - **providing guidance and recommend immediate corrections**
- The increased attention towards **Person Reported Measures (Outcomes: PROMs, Experiences: PREMs, Activation: PAMs, Incident: PRIMs)** provides an ideal basis for the recognition of such an active role
- The role of people of diabetes is at the center of a complex network of interrelated political, social and economic components
- **INFORMATION IS A KEY ETHICAL REGULATOR THAT SHALL BE PROPERLY MANAGED BY THE PERSON WITH DIABETES**

Empowerment of People with Diabetes

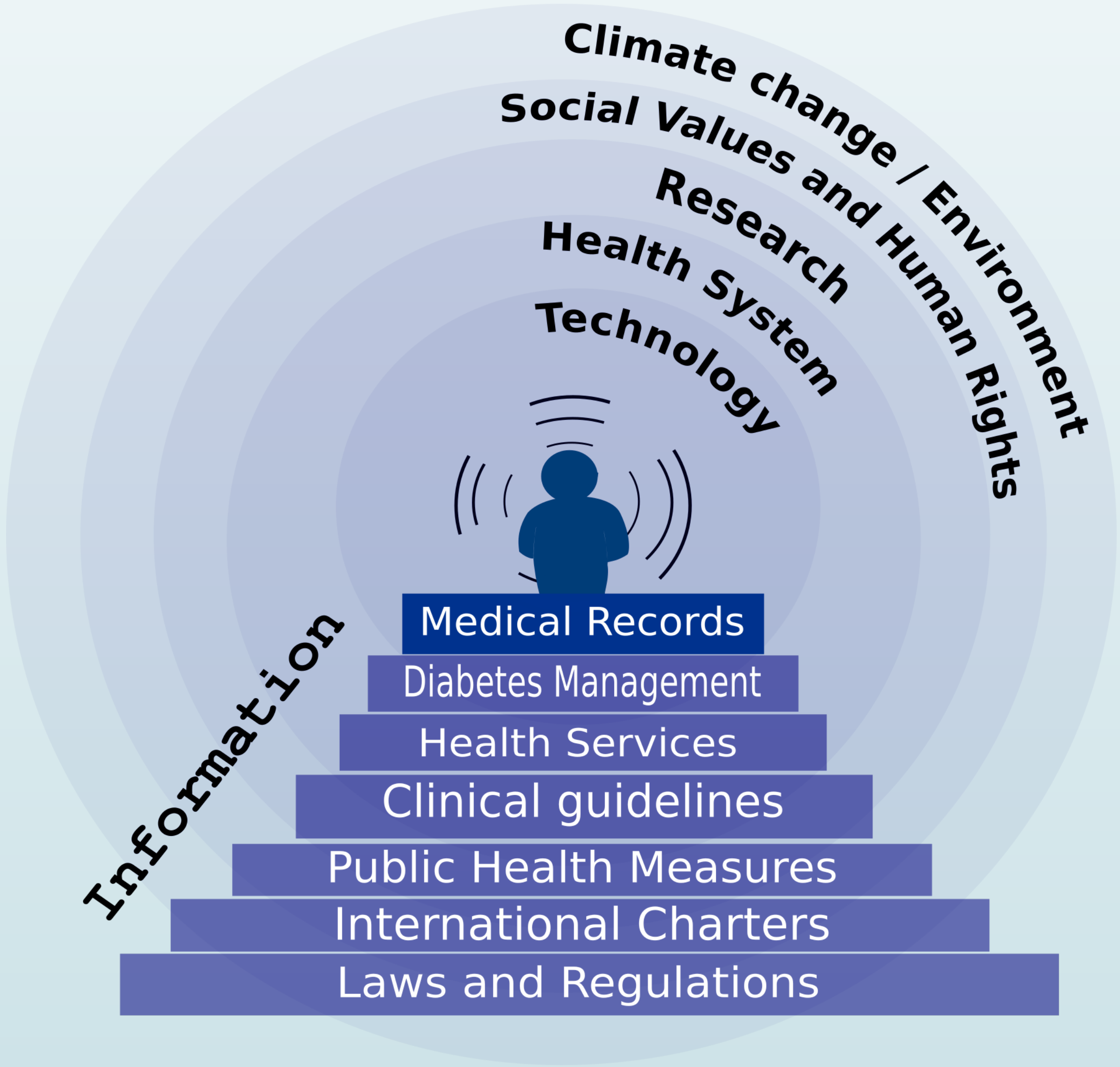
- **Empowerment** can be defined as “**the ability of a person affected by a disease to be an active member of his/her management team**”
- It addresses different dimensions of care management, e.g.:
  - the ability of a person to make **decisions** on treatments
  - the **education** on both medical and health conditions
  - the consciousness of the **emotional impact** of the disease
- In diabetes, patient empowerment translates into **improving the adherence to agreed self-care regimens**
- The Charter of Rights and Responsibilities of People with Diabetes fosters patient empowerment through the recognition of the rights to information and education and the identification of people with diabetes’ responsibilities
- The notion of **empowerment** should include the possibility for people with diabetes to have access to reliable and comparable data

The “Pyramid of Empowerment” of people with diabetes



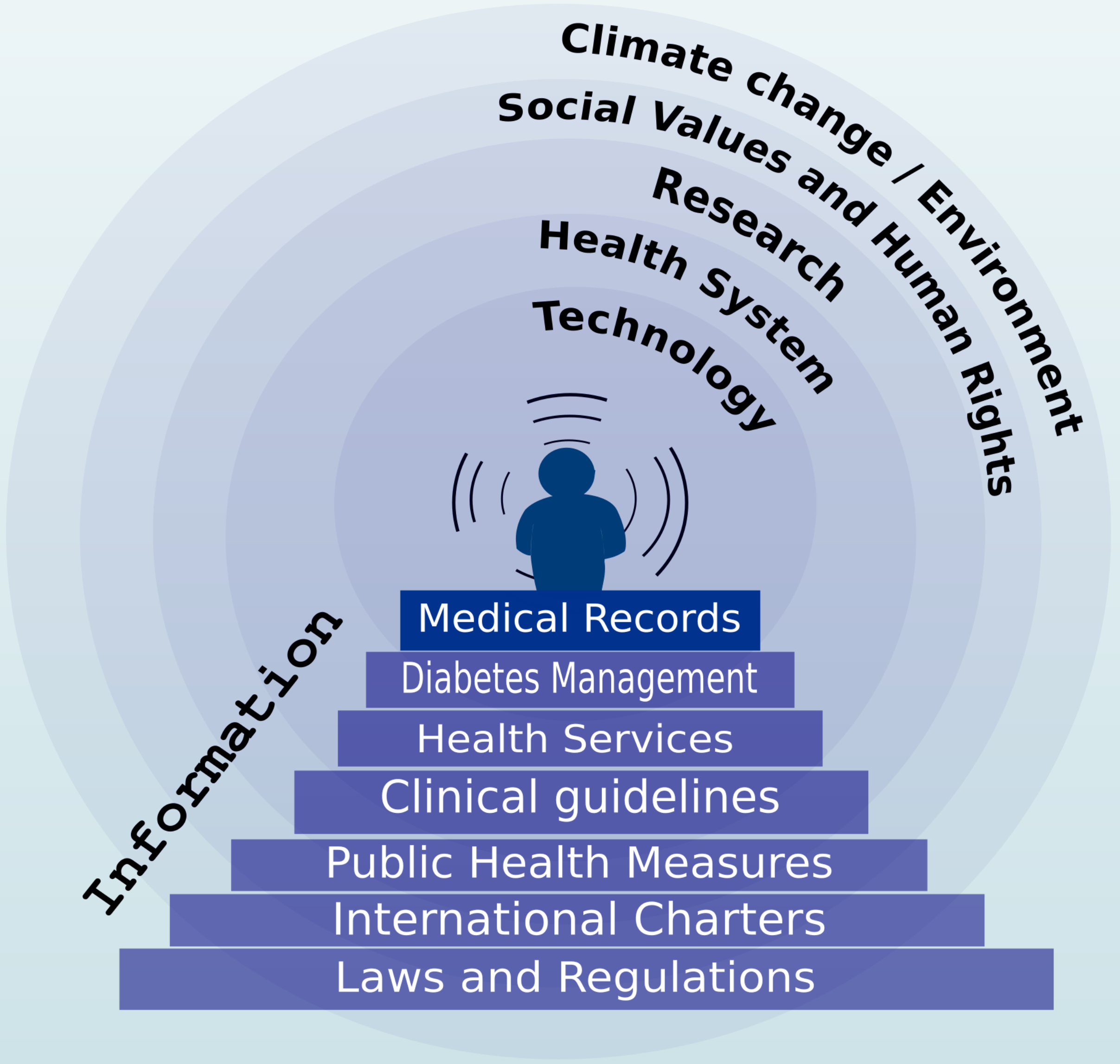
The "Pyramid of Empowerment" of people with diabetes

- People with diabetes stand at the top of a "pyramid of empowerment" composed by blocks of human actions, organized to respond to problems that originate from a series of **connected domains (nested circles)**
- The **social and natural environment** directly influences the adoption of ***laws, charters and public health measures*** e.g. prevention policies and health promotion campaigns, whose content is based on the evidence produced by **research**, which in turn provides the basis for the preparation of ***clinical guidelines***
- The availability of guidelines ensures the provision of appropriate ***health services*** and regulates the related market within ***health systems*** that can be differently organized.



The "Pyramid of Empowerment" of people with diabetes

- Effective solutions for the prevention of diabetes complications e.g. integrated ***disease management*** may be variously organized and supported by powerful ***technology*** e.g. apps
- As for many other aspects of modern society, being able to manage own rights strictly depends from the competent use of all **information** flowing across the different levels of the pyramid
- Using **medical records** effectively is essential to close the loop of the empowerment cycle, which can directly influence the respect of ethical values and improve the **social values and human rights** towards new achievements



EU CASE STUDY

The challenges of Big Data

EUROPEAN DATA PROTECTION SUPERVISOR

Opinion 7/2015

Meeting the challenges of big data

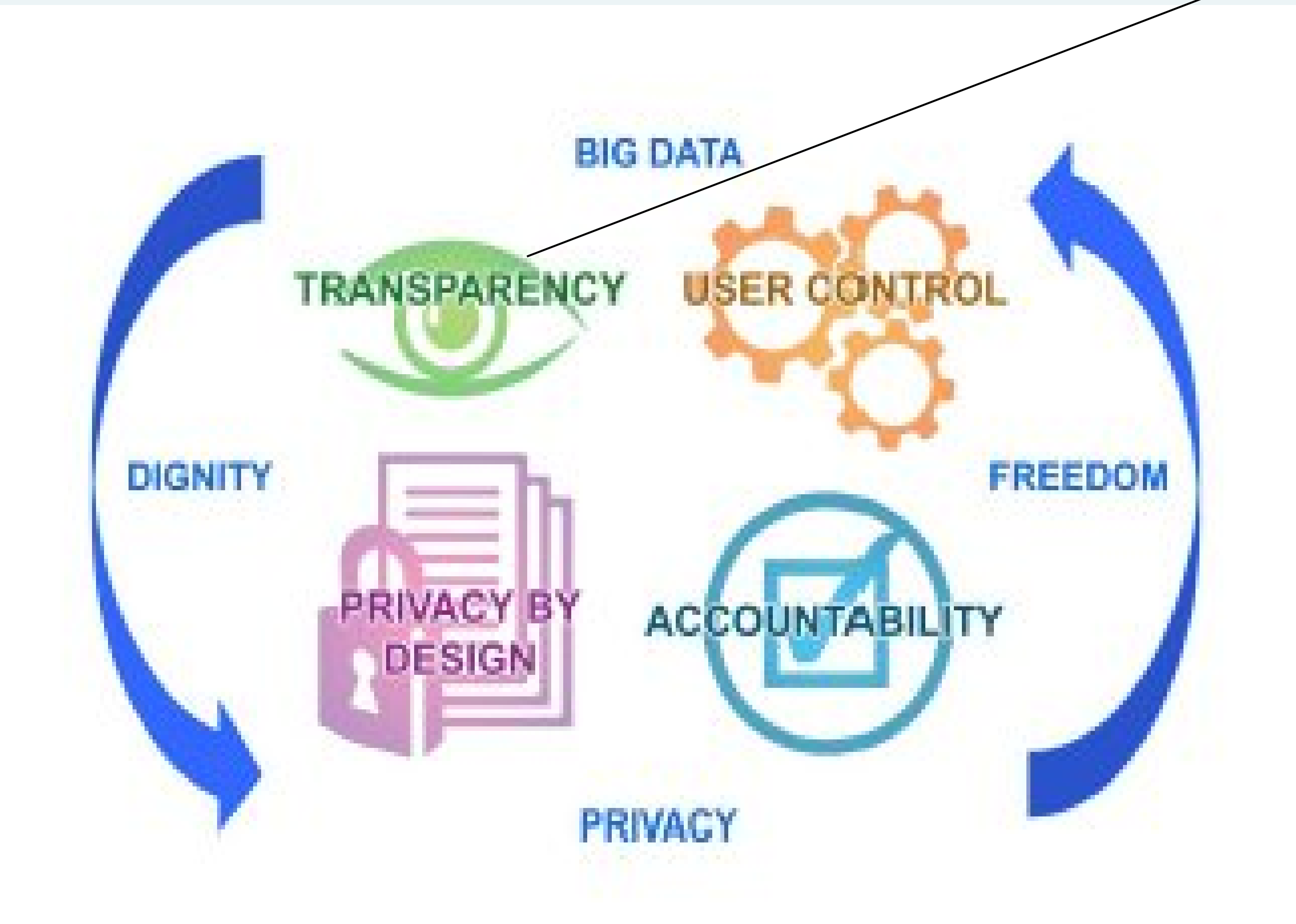
A call for transparency, user control, data protection by design and accountability

EDPS

19 November 2015

The challenges of Big Data

EU CASE STUDY



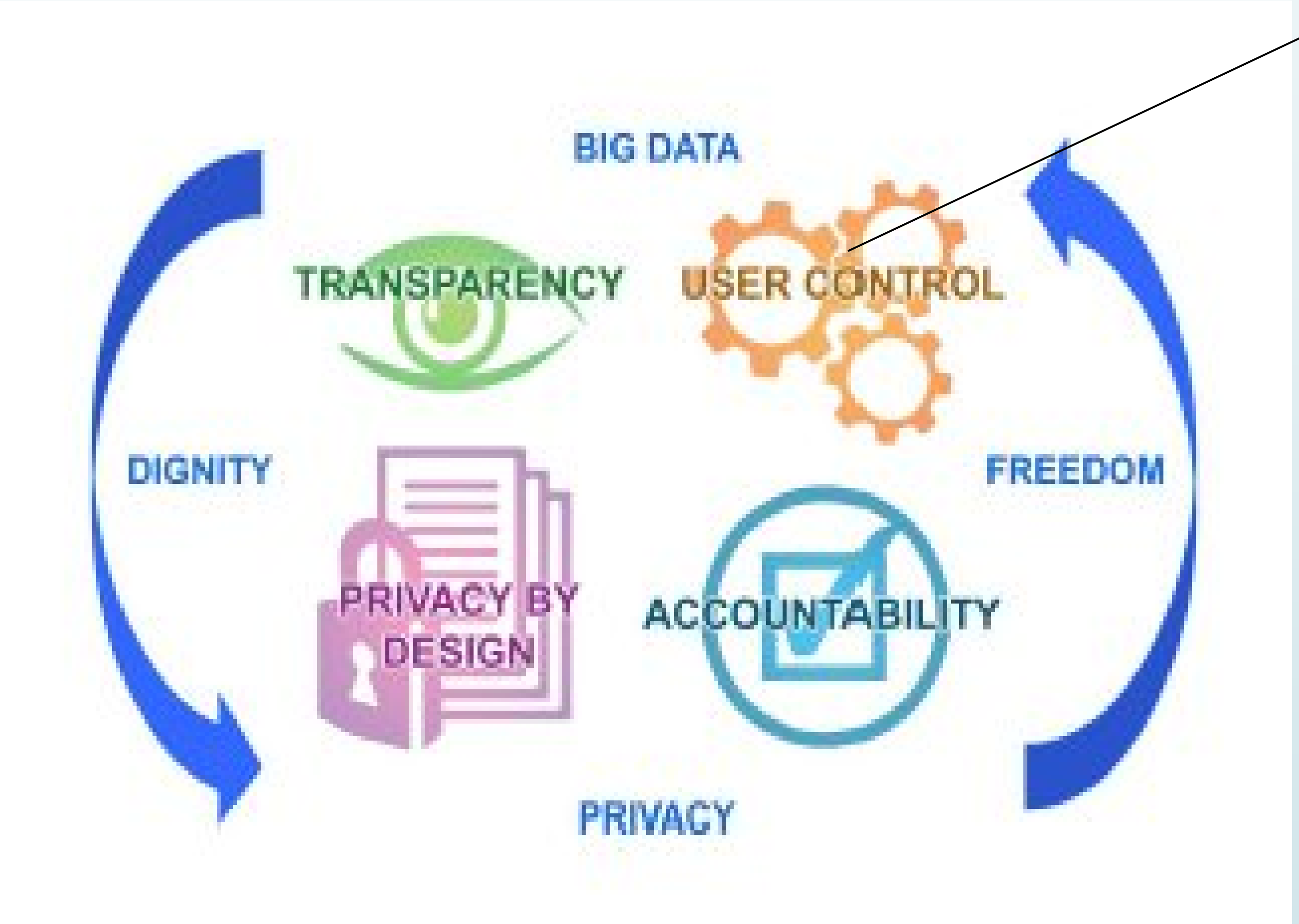
Transparency: end covert profiling

Disclosing the logic involved in Big Data analytics. Organisations shall disclose the logic of the ‘black box’ of big data analytics in order to ensure that any particular application can be safely deployed to all.

Better tools for informing individuals. Any information relating to the processing of personal information must use clear and plain language, tailored to the relevant audience, allowing individuals to make sense of complex information, and be easily accessible.

The challenges of Big Data

EU CASE STUDY



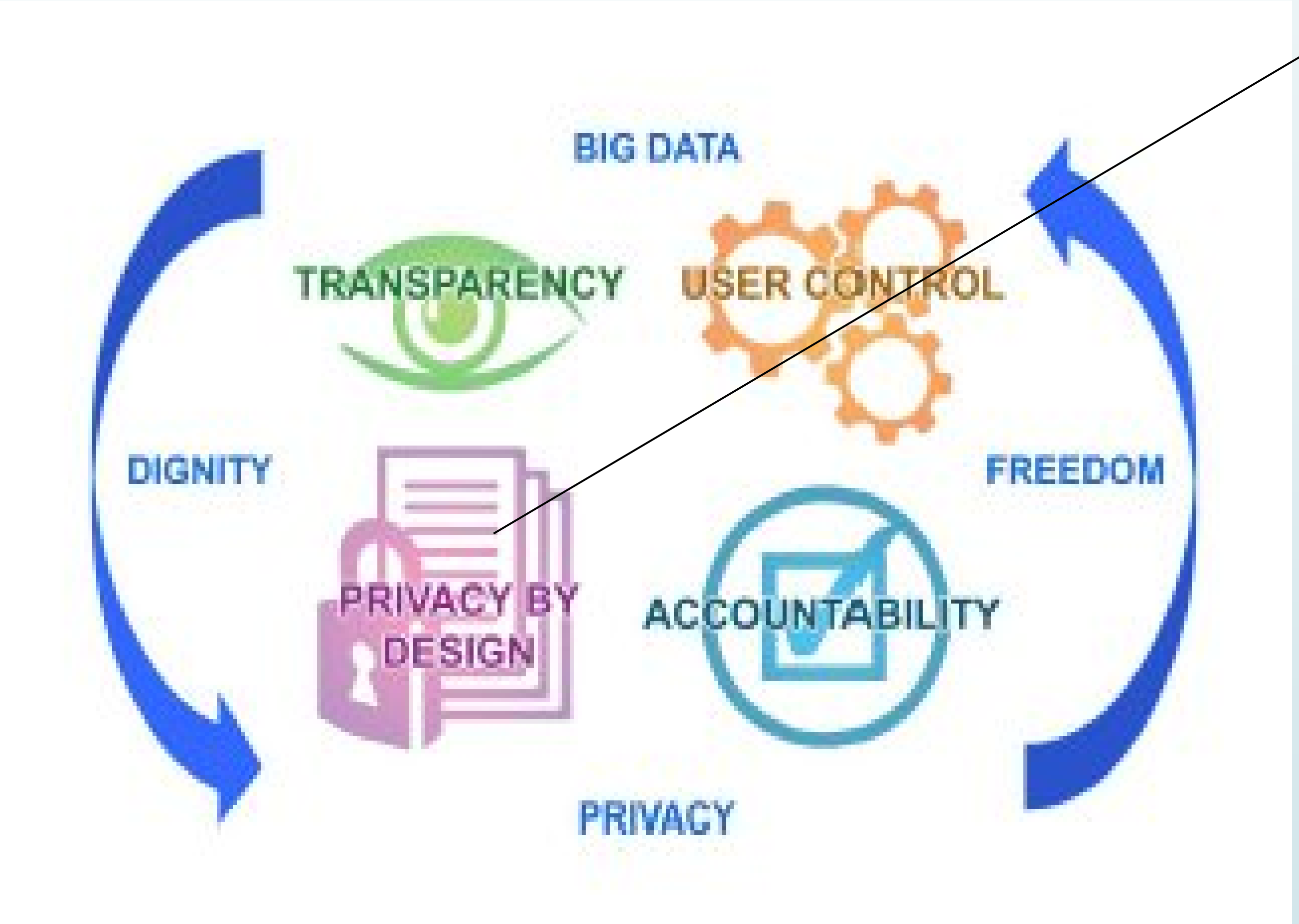
User control and shared benefits

'No questions-asked' opt-out.
Distinguish data processing whose benefits are general/societal, from those that merely provide economic benefits to those processing the data.

Right of access and data portability.
Data portability would require that organisations: provide individuals with access to their own data in portable format.

The challenges of Big Data

EU CASE STUDY

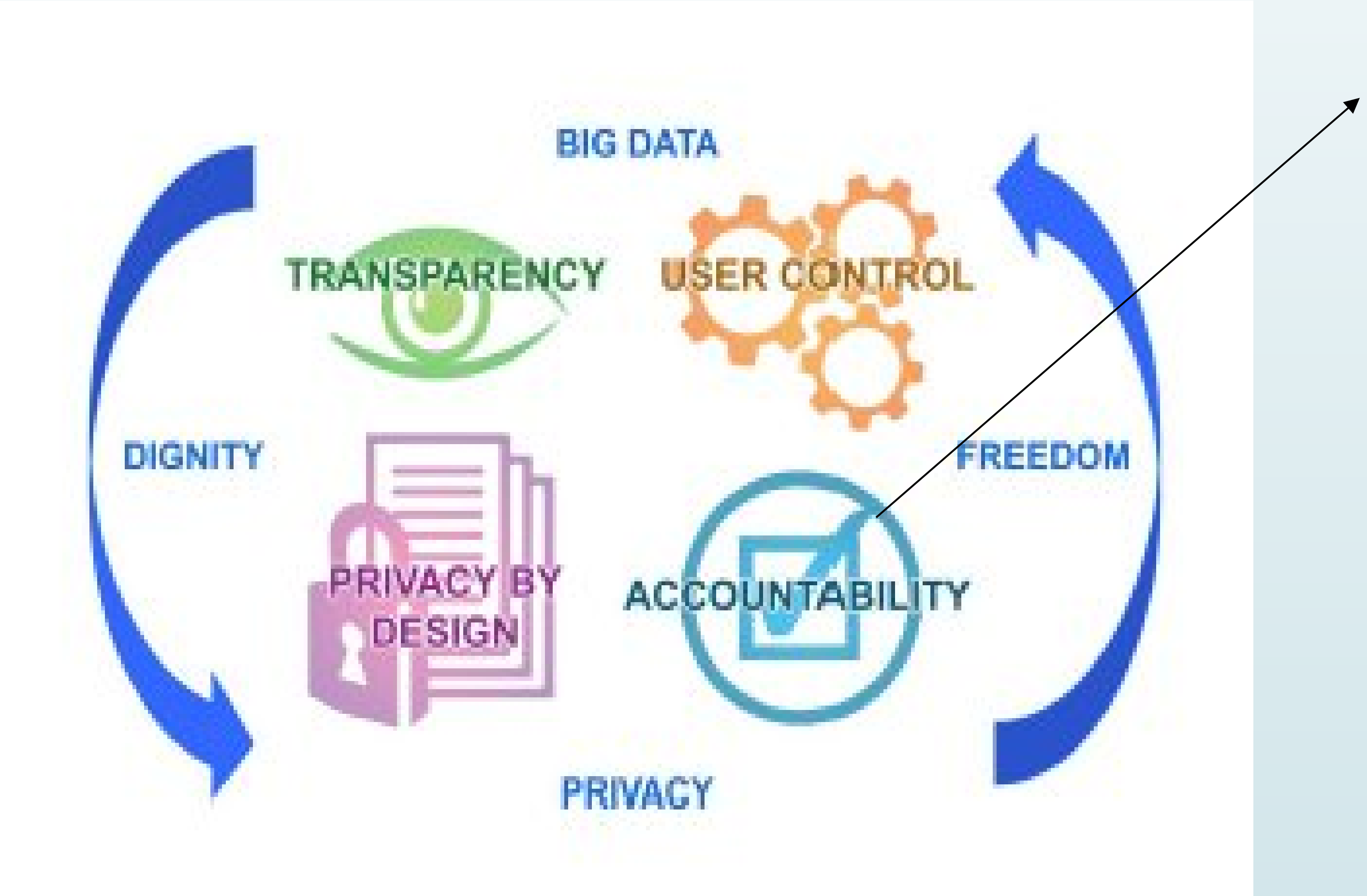


Privacy by design

Innovative and privacy-friendly engineering.
Privacy-friendly organisational arrangements and business practices.

Anonymisation techniques.
Anonymisation of data cannot be achieved by just stripping a dataset of some directly identifying attributes.

The challenges of Big Data



Accountability

Internal mechanisms and control systems that ensure compliance and provide evidence.

Regular verification that internal control systems continue to be fit and any data processing continues to comply with the law.

Need for a comprehensive solution: Population-based Registries

- The availability of medical records should be matched with the ability of health systems to **integrate all sources and produce information that can be easily interpreted by anyone (e.g. infographics of health indicators)**
- This requires implementing automated procedures that can provide **secure regulated** access to population data in real time
- ***Population-based registers*** may represent a pragmatic solution that empowers the person with diabetes and works in the public interest:
    - Registers are population-based when an indicator for a specific category of subjects (e.g. people with diabetes experiencing a complication) can be compared against a more general population, through a unique identifier ideally within a determined geographical area

Projects BIRO+EUBIROD+BRIDGE-HEALTH (2005-2017): “Best Information through Regional Outcomes in Diabetes”

EU CASE STUDY

- End users:
  - People with diabetes, national/local decision makers, health care administrators, health professionals, research institutions and all citizens
- Continuously designed in three sequential EU-funded projects:
  - “Best Information through Regional Outcomes” - 7 partners

  (BIRO: http://www.biro-project.eu)

  - “European Best Information through Regional Outcomes in Diabetes” - 21 partners (EUBIROD: http://www.eubirod.eu)
  - Bridging information and data generation for evidence-based policy and research (Task 8.2) – 14 partners (Bridge Health: http://www.bridge-health.eu)

The BIRO System

Di Iorio CT et al. Privacy Impact Assessment in the design of transnational public health information systems: the BIRO project, Journal of Medical Ethics, 2009 35: 753-76, http://jme.bmj.com/content/35/12/753

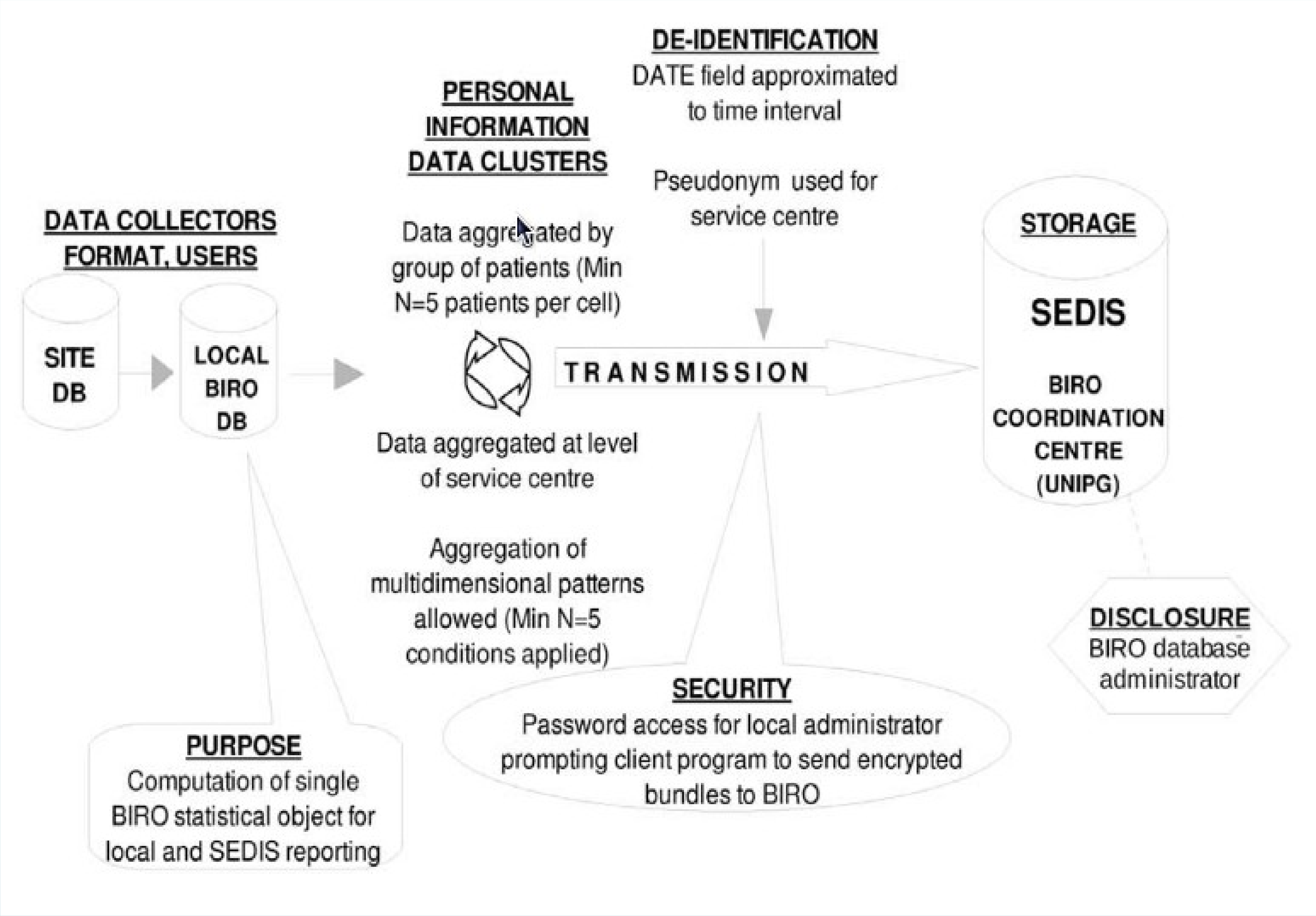
EU CASE STUDY

- The BIRO system implemented an open source architecture, based on the concept of "privacy by design"
- Allows the cross-border flow of information across diabetes registers in Europe
- The system is structured on a data model that regards each element (a regional/national government, the single care provider, or even a person with the disease) as a potential data source contributor
- The same software, including advanced statistical routines, runs safely on the database stored at each node, using a predefined set of standardized criteria
- **Only aggregate data are transmitted to produce the pooled results**
- As the system is general, it delivers a wide range of quality and outcome diabetes indicators, compiled into a final common report template that can be used to inform all the above mentioned categories of users

BIRO Privacy by Design

EU CASE STUDY

Di Iorio CT et al. Privacy Impact Assessment in the design of transnational public health information systems: the BIRO project, Journal of Medical Ethics, 2009 35: 753-76, http://jme.bmj.com/content/35/12/753



EU CASE STUDY

EUBIROD+BRIDGE HEALTH
Addressing (not resolving) implementation

Di Iorio CT et al. Cross-border flow of health information: is ‘privacy by design’ enough? Privacy performance assessment in EUBIROD. Eur J Public Health 2013 Apr;23(2):247-53, https://academic.oup.com/eurpub/article/23/2/247/679307

- Application of the BIRO principles in sites from twenty countries
- Information: demographics, clinical characteristics, risk factors, health system structures and processes, population rates and risk-adjusted estimates of intermediate/terminal outcomes
- EUBIROD also delivered an interface through which each data source can independently assess the level of adoption of privacy and data protection principles, including issues of data quality and access rights (“Privacy Performance Assessment”)
- Moving from prototypes to permanent systems will allow strengthening the level of participation of the entire community, empowering each individual through the direct access to relevant data and the independent assessment of trusted sources of information

Conclusions

- Ethical values are recognized by relevant international laws, charters and regulations
- The respect of ethical values is a right as well as a responsibility of the person with diabetes
- The complex principle of empowerment may be a driving force towards ethical improvement. Information is a key element in a complex network of interrelated components.
- People with diabetes (and related associations) shall be on the frontline in the design and implementation of key solutions e.g. population-based registries
- The realization of these achievements require strict monitoring and a strong financial commitment from national governments and international organizations.

Reference

C.T. Di Iorio, F. Carinci and M. Massi Benedetti.

Chapter 76. The diabetes challenge: from human and social rights to the empowerment of people with diabetes.

In: DeFronzo, R. A., Ferrannini, E., Zimmet, P. and Alberti, K. G. M. M. (eds), **International Textbook of Diabetes Mellitus 2015**, John Wiley & Sons, Ltd, Chichester, UK.