PATIENT PERSPECTIVE AND ENGAGEMENT IN REUSING HEALTH DATA FOR RESEARCH

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Realising the Value from Health Data ~ Improving Care and Research

Joint Event

September 21-22, 2017
Madrid, Spain

“ A STRONG PATIENTS’ VOICE TO DRIVE BETTER HEALTH IN EUROPE ”
About EPF

- European Patients’ Forum
  - Independent & non-governmental
  - Umbrella organisation
  - Active since 2003
  - EU patients’ voice

- Our members
  - 74 patients’ groups
  - EU disease specific organisations & National patient coalitions
Funding sources
European Commission – 80% of operating budget + co-funding of projects (PHP, FP7, CIP, IMI-JU)

Unrestricted grants from commercial sector – 19% of operating budget + project portfolio co-funding

Membership fees – 1.4% – annual fee structure ranging from 100-1000€ based on organisation's annual turnover

Principles of Transparency and Good Governance
Commitment to diversity of funding – not relying on any one source

Transparency and independence in all aspects of our work: Code of Ethics and Framework for working with funding partners

Full details of EPF's funding available at our website:
http://www.eu-patient.eu/About-EPF/Transparency/

EPF is a registered NGO on the European Commission’s Transparency Registry
Our Vision!

“All patients in the EU have equitable access to high quality, patient-centred health and social care.”

Our Mission!

“To ensure that the patient community drives health policies and programmes that affect them.”
There is an increasing drive to improve collection, sharing and use of patients’ data in order to achieve better, more sustainable healthcare and advance health research. The only way to do this in a meaningful and valuable way is together with patients.

EPF’s remit:

Patients living with chronic or long term conditions

Our focus: towards the application of technology that supports the management of chronic diseases for patients and ethical secondary use of health data to advance health research
Distinction between *patients* and *citizens*

Patients – generally **comfortable** and **willing** to share health data for research purposes and recognise that this is of **vital importance to advance health research**, help other patients and ultimately benefit society.

- **Trusted environment** – healthcare and research setting
- To help peers – general community and **peer support**
- To help future generations
- Looking for **solutions to unmet needs**
- Have lived through the experience of diagnosis and hospitalisation
- Have already **experienced** the benefit of research, through therapy or management of their disease
- Patients learning from their own data - **self-management, empowerment**
Distinction between patients and citizens

However, views of citizens may well be different

- Need for trust building
- Lack of awareness, information
- Understanding, education
- Health literacy
- Confidence
- All stakeholders have a role to play

That being said, Patients have privacy and data security concerns

- Unauthorised disclosure of personal health or genetic information could negatively impact on an individual patient’s personal and professional life, this is why informed consent and transparency on the use made of data is essential.
Patients’ privacy concerns

• Patients’ fundamental right to protection of their data is vital in diverse contexts: healthcare, eHealth, cross-border care, clinical trials,…

• Fear of discrimination on the grounds of health/genetics: in the field of employment, insurances

• Ownership of data e.g. clinical trials

• New technologies offer opportunities to collect, use and share health data more efficiently

... but set new challenges for privacy and data security
Our data, our privacy, our health: Patient involvement

- Patient participation in decisions regarding health and genetic data is a matter of good governance.
- Involvement at policy and programme level on questions of privacy in healthcare and health research
- Empowering patients as owner of their health and genetic data to make decisions about their personal information

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• 2013 - Roche launches new process for accessing clinical trial data
• Independent body to grant access to patient-level data for scientific review
• This body will evaluate and approve requests to access anonymised patient-level data
• And will support the release of full clinical study reports (CSRs) for all its licensed medicines via regulatory authorities and make available any CSRs that cannot be provided by these authorities upon a researcher’s request.
What EPF is doing

1. Gathering patients’ views and Building patient group’s capacity
3. Influencing the legislative process
4. Training patients - EUPATI

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EPF’s Work so far

- **Position Statement** on the EC’s proposal for a General Data Protection Regulation – December 2012

- **Position Statement** on informed consent in clinical trials – May 2016


- **eHealth Position Paper** – December 2016

- 2017: **Briefing on big data** - aim of ensuring the capacity of patient communities to provide meaningful input to policy discussions in this highly technical area

- 2017-2018: **Patient survey** on electronic health records and data sharing
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4. Training patients - EUPATI
Being health literate empowers people

Being health literate enables people for example:

- To understand information about their health
- To evaluate information for its quality and trustworthiness
- To reflect on and explore alternative options
- To make more informed decisions

- HL is a key dimension of patient empowerment (EMPATHIE, 2014)
- HL is essential for health systems that are equitable, high quality and patient-centred (WHO, 2013)

Right of Access to one’s own data:
- in EU still obstacles for patients to access their health information
- and data stored in silos rather than in interoperable systems

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Empowering patients

Right of Access to one’s own data:
• in EU still obstacles for patients to access their health information
• and data stored in silos rather than in interoperable systems

Right to information:
• Transparent policies in place
• Informed consent
• Information about their right as data subjects

Right to be forgotten/ to object/ to rectification

Any restriction to these rights should be limited and justified
Informed consent and Information to Patients

- **Informed consent**: not simply a process of providing information to the patient. Neither is it about obtaining a signature on a form. From a patient’s perspective, informed consent should be seen as a process a kind of “decision aid” that should enable a patient to make an enlightened decision.

- **Disparities across the EU** - both in terms of the quality and quantity of the information provided to patients, and the effectiveness of the informed consent process.

- **Consent** is still often regarded as a ritual or a box-ticking exercise, rather than a crucial means by which patients are able to **fully comprehend** and **evaluate the risks** and potential benefits (of taking part in a clinical trial for e.g.).

- See EPF recommendations for meaningful informed consent.
Rules for consent

The new Regulation establishes rules to strengthen citizen’s rights as regards the process of consent for the collection, use and sharing of their personal data.

• consent must be explicit and unambiguous, that is to say it needs to be given through a clear affirmative act, it has to be freely given, and be an “unambiguous indication of a data subject’s agreement to the processing of their personal data”. This can be written, electronic or oral. Silence or inactivity (a pre-ticked box for example) cannot be considered as consent (Recital 32).11

• Data controllers –that is to say persons or entities that collect data from people – have to be able to demonstrate that a person has given consent. In other words, the burden of the proof is with them (Article 7 para. 1).

• Consent has to be informed: It has to be demanded in intelligible and easily accessible forms, using clear and plain language, and be distinguishable from other matters (Article 7 para.2).

• In addition, patients should be informed on how to withdraw consent prior to giving it (Article 7 para.3)

• For children below 16, parental consent is necessary for the processing of data to be lawful– Member States may decide to lower that age, but not below 13 (Article 8)

• Limited exemptions to consent for sharing data needed, with safeguards in place
What EPF is doing

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In March 2014 the European Parliament adopted a first reading position of the data protection regulation for stricter rules on consent for research.

If implemented, this Regulation would have harmed health research by creating an obligation to seek specific consent when personal data was used.

And so, EPF joined the European Data in Health Research Alliance which brought together academic, patient and research organisations from across Europe to ensure the final Regulation allowed vital research that has taken place for many years to continue, whilst keeping appropriate/proportionate safeguards.
The ‘Data Saves Lives’ Campaign

The European Data in Health Research Alliance - ensuring the Data Protection Regulation allows vital research to continue

I trust health research to use my data for society’s benefit

#DatamattersEU

www.datasaveslives.eu

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EUPATI: an innovative training model

Focuses on **education and training** to increase the capacity and capability of patients to understand and contribute to **medicines research and development** and also improve the availability of objective, reliable, patient-friendly information for the public.

- Consortium of 33 organisations – led by EPF
- Funded by IMI (PPP between EC and EFPIA)
- Launched Feb 2012 - Jan 2016 and will continue as an EPF project

Develop & disseminate **objective, credible, correct and up-to-date information** on medicines R&D in 7 European languages

Building **competencies & capacity** among patients & public to get involved

Facilitate patient involvement in R&D to support academia, industry, authorities and ethics committees

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Making Progress and Moving Forward

• **Patients’ role** has evolved over the last decades
  - informed and engaged actors, a source of expert information, participating and leading research
• **Traditional silos breaking down**
• **Forward thinking** of health professionals
• **Space for opportunity** in determining health priorities and driving the research agenda
• **Partnership and cooperation** in research

=> leading to a new clinical research ecosystem
To conclude

1. The **right balance** needs to be reached between ensuring confidentiality of data while allowing their availability and sharing for public health, healthcare and research purposes.

2. **Ethical** secondary use of health data and **confidentiality**

3. **Interests and attitudes of patients** towards the use of their data for research across Europe is generally **favourable**

4. **Together with patients and patient organisations**
THANK YOU FOR YOUR ATTENTION!

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More information
www.eu-patient.eu
info@eu-patient.eu

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Further Information

- EPF Position Statement on the EC’s proposal for a General Data Protection Regulation
- Position Statement on informed consent in clinical trials
- The new EU Regulation on the protection of personal data: what does it mean for patients? A guide for patients and patients’ organisations
- EPF Position Paper on eHealth
- EPF Position Statement on the Patients’ Rights In Cross-Border Healthcare Directive
- EPF Patient Empowerment Roadmap
- EPF Campaign on Access to Healthcare