



Patients' voices: International cooperation
within patient groups. Why, Who and How

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**REASON SETS US APART FROM ALL
OTHER ANIMALS BUT DIGNITY
MAKES US PEOPLE**

PATIENTS' VOICES:INTERNATIONAL COOPERATION WITHIN PATIENT GROUPS

WHY?; Patients and experts are few and geographically scattered, Research is fragmented, Reliable information is scarce, Resources are limited, Sustainability is an issue.

WHO?; All parties involved should support collaboration=Patients, families, patient advocacy groups, public authorities, companies, representatives of industry, clinicians, academics....

HOW?; Become aware, gain trust , gain strength in their capacity to act, make choices and transform choices into actions, gain more power to take control of their life, their rights, and their social, economic and political conditions. Ultimately, in defending their dignity

Human Rights

Human Rights are the rights that one has simply because one is human, do not require a large recognition or greater legal implementation

- Why research, treatments, orphan drugs? Right to life and Right to the integrity of the person.
- Why protection of personal data? Right to privacy.
- Why accessibility? Right to freedom of movement.
- Why should children with rare diseases not have limits on their education? Right to education...
- Right to health includes of freedom of research and scientific production

LEGAL ASPECTS

We should use the international tools;

- International Courts; for example, The jurisprudence of the European Court of Justice has helped to change the mindset within the European governments with respect to the cross-border healthcare. At this moment, it is an important issue in European Reference Networks.
- For example; UN Committee on the Rights of Persons with Disabilities (CRPD).
- General rule= should have used all the remedies in the State concerned that could provide redress for the situation you are complaining about . It is often very costly and long.

LEGAL ASPECTS

DIRECT COMPLAINTS;

- **Special Rapporteur on the right to education**
- **Special Rapporteur on the rights of the child**
- **Special Rapporteur on the rights of person with disabilities**
- ***Working Methods of the Committee on the Rights of Persons with Disabilities adopted at its Fifth Session (11-15 April 2011)***, UN Doc. CRPD/C/5/4, 2 September 2011; “ K.Early-awareness and urgent-action procedures; These special procedures are aimed at preventing existing problems within States parties from escalating into full-fledged conflicts or preventing the revival of pre-existing problems. They will also be used to consider issues that may require immediate attention in order to avoid serious violations of the Convention or to reduce the number or degree of such violations.”
(But this procedure has never been used in the world)

LEGAL ASPECTS

- When an International Human Rights Treaty is ratified by a country, the Treaty is directly applicable in this country.
- Declarations are non-binding instruments but nevertheless of great value and sets out criteria to follow:

Universal Declaration of Human Rights

Universal Declaration on Bioethics and Human Rights

International Declaration on Human Genetic Data

Universal Declaration on the Human Genome and Human Rights

...

INTERNATIONAL DECLARATIONS OF PRINCIPLES

INFORMED CONSENT

- A patient has the right to be given full information about their health
- Right to decide whether or not to be informed about their health or research results
- Respect the patient's freedom of choice
- People without the capacity to consent should be involved to the greatest extent possible in the decision-making process of consent
- The opinion of a minor should be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity.

INFORMED CONSENT

- The right to genetic counselling
- Equity in access to the genetic analysis
- Prior, free, informed and express consent should be obtained for the collection of human genetic data, human proteomic data or biological samples

CONFIDENTIALITY OF THE INFORMATION

- The confidentiality and privacy of all patients should be safeguarded
- Observe the obligation of professional secrecy, even after they have left the service
- Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family

DATA PROTECTION

- Patients have the right to safeguard their privacy in the field healthcare actions.
- Data linked to an identifiable person and Data unlinked to an identifiable person are personal data
- Data irretrievably unlinked to an identifiable person is not personal data
- Genetic data collected should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned
- Right of access, rectification, cancellation and opposition
- The family should be informed about any issues that could affect their health
- Protect future generations (genetic analyses)



**CODE OF ETHICS of
FEDER (Spanish Federation for Rare Diseases)**

FUNDRAISING

- Greater diversification should be the key for sustaining the organizations
- Model dominated by public financing
- Model dominated by private financing
- Mixed model; public financing and public financing
- It is not possible to transform society without financing = It is a means to an end, and never an end in itself

FUNDRAISING

- Objectives of the fundraising= Code of Ethics= our responsibilities as organizations
 - a.- Transparency*
 - b.- Credibility*
 - c.- Independence*
 - d.- Confidentiality*

CODE OF ETHICS

(General objectives)

- Identify the ethical principles and values of our organization
- Develop and implement a complete set of clear ethical standards that must be followed in our activity
- Include measures to avoid conflicts of interest
- Take responsibility for the community. That will also contribute to greater transparency and consistency
- The organizations should bring a unique voice

CODE OF ETHICS

(Specific objectives with the companies)

- Regulate the network between FEDER and the companies
- Establish a mutually agreed framework which should be accepted in good faith by both parties.
- Be ethical, responsible and transparent when planning and performing actions

CODE OF ETHICS

(Pharmaceutical industry)

- Do not give personal data
- Act as interlocutor between all parties (patients and pharmaceutical industry)
- Should not promote the use of specific treatments
- Refuse donations for a specific treatment
- Provide access to information on new and current clinical trials to patients which should be always verified

These principles constitute the structure of our ethical code

- FEDER= An independent, non-political organization
- Any financial support will be recognised
- The diversification of funding sources is very important; a company can collaborate with FEDER up to 34% increase of its annual budget.
- Do not support the commercial promotion of company's products
- Sponsor activities should be austere and appropriate

Work together
and learn from each other
Thank you!