No innovation about us without us

Francesco De Lorenzo
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Disclosure statement

Nothing to disclose
ECPC: "Nothing about us, without us"

- Representing 403 cancer patient groups in 44 countries
- All cancers – common and rare
- Run and governed by patients
- Promoting *timely access* to appropriate prevention, screening, early diagnosis, treatment and care for all cancer patients
- Reducing *disparity* and inequity across the EU
- Encouraging the *advance of cancer research & innovation*
- Increasing cancer patients' *influence* over European health and *research policy*
European Cancer Patient Coalition’s Activities

- Position papers and policy studies
- Awareness-raising events
- EU institution advocacy

- Working Groups
- ECPC Masterclass
- General Assembly
- Education & Courses
- Advocacy Training

- CANCON
- Members of the EC Expert Group on Cancer Control
- Members of the European Initiative on Breast Cancer
- JARC
- Health Policy Forum
- EMA’s Patients’ and Consumers’ Working Party
- CDDF
- EAPM
- ECC
- EORTC
- ESMO/ECCO
- OECI
- UICC
- EAU

- EurocanPlatform
- eSMART
- RARECAREnet
- InSup-C
- BenchCan
- Transcan 2
- Project on Mesothelioma
ECPC as a partner of EU institutions

ECPC represents cancer patients within:

- **European Commission**
  - Joint Action on Cancer Control – CanCon;
  - Joint Action on Rare Cancers and ERN;
  - European Commission’s Expert Group on Cancer Control
  - mHealth Code of Conduct and Working Group

- **European Medicines Agency**
  - Patients’ and Consumers’ Working Party

- **Strong relationship with the European Parliament**
  - 4th February 2015 Declaration: 160 MEPs signed
  - Written Declaration 30/2015: 260 MEPs endorsed
  - EU Regulation 726/2004 AMENDED
  - General Data Protection Regulation: APPROVED with ECPC proposal
The power of innovation in cancer
A good example: Immuno-Oncology

• ECPC is on top of innovation in cancer
• Our mission: empower patients across Europe, providing them key info on new treatments
• Example: ECPC Immuno-Oncology Portal, Europe’s first patient-oriented, scientifically validated information hub on immuno-oncology

• 9 EU experts involved
• Funded by unrestricted grants from 7 different companies
• Composed of 2 modules
• Translated in Italian
• To be translated in 6 languages
Patients’ questions
Can we truly access innovative treatments?

- Why “access”?
  Innovation is not effective if not made available to all patients who need it!!

- Cancer research achieved impressive results in many cancers, but not in all cancers

- Patients needs related to innovation:
  - **Timing**: the best innovation which arrives too late is of no use to the patients
  - **Inequalities**: innovation should decrease level of inequalities in cancer care
  - **Sustainability**: innovation must be available to all who need it
  - **Safety**: patients cannot compromise on safety, but also cannot compromise on timing!

- Conclusion: patients’ perspective is not taken enough into consideration

  **Our suggestion:**
  Better integrate patients in all steps of innovation

  From prioritisation of research to reimbursement and pricing decisions
RESEARCH
Biobanks and Patients
A mutually beneficial partnership

• Biobanks
  o Crucial role in clinical research
  o There is no safer place to store information on patients!
  o BBMRI – ERIC is the future: added value of European aggregated data!

• Patients
  o Benefit of cancer research ran on biobanks data
  o Patients have strong political voice
  o Biobanks would not exist without patients’ donations
  o Reciprocity – diagnostics: giving back to the patients
Creating an alliance with patients: Reciprocity

*Biobanking is not only about research!*

Scientific community has to **establish a dialogue to inform** and **empower** the patient on the advantages related to the donation

**HOW?**

- New **TRULY informed consent forms** shall inform the patient of the personal advantages of donating:
  - Receive relevant information on the results of researches made on their samples
    - Need to share relevant information to the patient and their relatives!
  - Be granted access to the sample
    - Importance as diagnostic tool (particularly liquid biopsy)
    - The patients should have access to the sample in case of relapse
  - *It is possible under the new GDPR, lobbied also with the support of ECPC + ESMO + BBMRI-ERIC*
TUTTI I TUMORI - ESCLUSI I TUMORI NON MELANOMATOSI DELLA CUTE
ALL TYPES BUT SKIN NON-MELANOMA

**Pool of Italian Cancer Registries - 1 January 2010**

**COMPLETE PREVALENCE BY YEARS SINCE DIAGNOSIS**

<table>
<thead>
<tr>
<th>YEARS</th>
<th>≤ 2</th>
<th>(2 - 5)</th>
<th>(5 - 10)</th>
<th>(10 - 15)</th>
<th>(15 - 20)</th>
<th>&gt; 20</th>
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<tbody>
<tr>
<td>No.</td>
<td>493 439</td>
<td>550 376</td>
<td>625 093</td>
<td>370 198</td>
<td>218 987</td>
<td>329 254</td>
</tr>
<tr>
<td>%</td>
<td>19%</td>
<td>21%</td>
<td>24%</td>
<td>14%</td>
<td>8%</td>
<td>13%</td>
</tr>
<tr>
<td>PROPORTION PER 100 000</td>
<td>866</td>
<td>969</td>
<td>1 102</td>
<td>653</td>
<td>385</td>
<td>583</td>
</tr>
</tbody>
</table>

MALE 44% | FEMALE 56%

**COMPLETE PREVALENCE BY SEX, MACRO-AREA, AND AGE**

**PROPORTION PER 100 000**

**ALREADY CURED at 1 JANUARY 2010**

**704 648 (27%)**

**COMPLETE PREVALENCE AND PROPORTION OF ALREADY CURED SURVIVORS BY SEX**

**MALE**

**FEMALE**

**PROPORTION PER 100 000**

**MALE ALREADY CURED**

**FEMALE ALREADY CURED**

**COMPLET EPREVALENCE**

**OVERALL NUMBER (OR PROPORTION) OF CANCER SURVIVORS.**
RESEARCH
Survivorship – tertiary prevention

22% of all cancer patients can be considered CURED = same life expectancy as average population
SURVIVORSHIP IS A TICKING BOMB!

We need innovation in survivorship!

• Not enough research is done to innovate:
  o Supportive care and rehabilitation
  o Socio-economic issues related to survivorship and rehabilitation
  o More data should be collected from large cohorts of patients on follow-up and long-term survivorship.
    ❑ cost estimation of the different options
    ❑ stratify patients according to the risk of recurrence and sequelae
    ❑ Patient-reported outcomes
    ❑ This is the only way to truly enhance knowledge!
  o Biomarkers in survivorship settings: not only early detection but also tertiary prevention/late effects
Inequalities in cancer care: an economic problem

Example: avg. cancer expenditures per citizen in the EU

€/citizen

Europe: 102
Bulgaria: 16
Romania: 20
Poland: 37
Portugal: 53
UK: 85
Spain: 94
France: 110
Italy: 114
Germany: 182

INEQUALITIES
Disparities (survival) in cancer care: a European reality

The example of colorectal cancer

Rising cost of cancer medicines

Global Oncology Market Forecast

- US
- EU5
- Japan
- Pharmerging
- ROW

Global Spending US$Bn

- 2009: $75Bn
- 2014: $100Bn
- 2018: $117-147Bn

CAGR 2010-2014: 7%
CAGR 2014-2018: 6-8%

Source: IMS Health MIDAS, Dec 2014; IMS Health Market Prognosis, March 2015
Patients’ paradox
Can we truly access innovative drugs?

An exploratory analysis of the factors leading to delays in cancer drug reimbursement in the European Union: The trastuzumab case

Felipe Ades a, Chistelle Senterre b, Dimitrios Zardavas c, Evandro de Azambuja a, Razvan Popescu c, Florence Parent d, Martine Piccart a,a

Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.
A new engine in an old frame
Updating organisation of care, radiotherapy and surgery

Innovation in oncology means also innovating radiotherapy, surgery and organisation of care

- **Radiotherapy capacity in Europe:**
  - Dramatic under capacity in Eastern EU
    - In Romania, more than 65% of patients who should receive radiotherapy do not have access to it!
  - Problems also in UK, Spain, Portugal, Italy
A new engine in an old frame
Updating organisation of care, radiotherapy and surgery

Surgery

• Key component of multidisciplinary care!
• Inequalities in quality of surgery exist across Europe. One example: EUROCARE 4 data
  o How much is the surgical standard of care applied in breast cancer?
    • France: 78%
    • Estonia: 9%

• Our recommendations
  o Establishing benchmarking standards for surgical oncology (for example: EURECCA)
  o *Inform patients about centres with high volume of cancer surgeries*
    • High volume = experience = BETTER OUTCOMES
    • Model: Oncoguida (Italy)
A new engine in an old frame
Updating organisation of care, radiotherapy and surgery

eHealth/mHealth

• For mHealth to deliver results to cancer patients, it has to be implemented at **all stages and in all health care delivery activities**.

• Patients need to be involved at the design phase, to ensure usability and patient-friendliness

• **Regulation is there, but implementation is lagging behind**
Cancer patients are key stakeholder to develop **Code of Conduct** and mhealth Assessment Guidelines

• **Training and awareness**
  • Patient organizations can be the drive for policy change at national level
ECPC: leverages on European institutions for a solution to delays in access to cancer drugs

• **World Cancer Day 2015 declaration**: 160 MEPs supported ECPC to fight inequalities in cancer care

• **Debate in Plenary, European Parliament September 2015**: MEPs ask the Commissioner for more sustainable healthcare systems & denounced problem of access to innovative treatments

• **Written declaration 30/2015**: ECPC & 19 MEPs ask the European Parliament to take a position on sustainability of healthcare, requesting the Commission to do more to harmonise HTA process at EU level

• **Amendments to the EMA regulation 726/2004**: ECPC supported the amendments to the regulation to pave the way for the EMA to centralise the HTA assessment at the EU level and increase harmonisation

**APPROVED BY ENVI - EU PARLIAMENT**
Europe of Disparity in Cancer (EoDiC) 
ECPC’s solution to tackle inequalities

- ECPC policy strategy, presented at ECC2015
  - Covers all the inequalities in cancer patients’ journey, from early detection to survivorship

- Patient-friendly, scientifically validated recommendations to tackle inequalities in cancer care

- **EoDiC is already making a difference!**
  - CanCon WP5 will use it as a starting point for their policy paper on equity (2016)
  - EoDiC’s principles are at the base of the Written Declaration 30/2015, supported by ECPC and promoted by 19 MEPs
Europe of Disparities Launch event
European Parliament – 27th January 2015
Can we truly access innovative treatments?

• Issues:
  o Research has been underfunded for decades
  o Efficacy vs Cost/Effectiveness
    ❑ The EMA evaluates new drugs only on the base of the clinical outcomes;
    ❑ Reimbursement is based on national/regional/local HTA, including
      o Cost/effectiveness
      o Relative efficacy

• Consequences:
  o EMA newly authorised drugs are not timely available to patients by Member States;
  o Reimbursements arrive with huge delays, or at all!
A possible solution:
Cut the time from bed to lab
Harmonize HTA relative assessment at EU level

• EU HTA bodies shall agree to produce one relative efficacy assessment for all Europe
  o This would cut part of the delay in accessing drugs

• Strengthen the collaboration of network of European HTAs within the EMA
  o Institutionalise the EUNetHTA into a new body and formalise its collaboration with EMA

• Start a new debate on pricing and reimbursement policies
HTA as a tool to ensure faster access
Measuring what matters to patients

- HTA is not a purely technical process, but includes economic, ethical, political and societal aspects

- *It is necessary to embed patients in all level of HTA, including in EU reference relative efficacy assessment*

- NICE is an example:

  - Decision at NICE
  - Cost-Effectiveness
  - Clinical effectiveness
  - Innovation
  - End of life
  - Other Health Benefits
  - Extent of Uncertainty
  - Equity & Diversity
  - Social Value Judgment

  Patients & clinical experts, consultation comments
PREFER

- Funded by the Innovative Medicines Initiative
- Duration: 5 years (2016 – 2021)
- Coordinated by Uppsala University
- More than 30 partners, including patients, industry and academia

**Main objective:**

*Strengthen patient-centric decision making* throughout the life cycle of medicinal products by *developing evidence-based recommendations* to guide *industry, Regulatory Authorities, HTA bodies, reimbursement agencies, academia, and health care professionals* on how and when *patient-preference studies* should be performed.
PREFER

The role of ECPC

• Create and lead the Patient Advisory Group comprising the other patient organisations involved (EPF, IAPO, MDUK)

• Provide feedback on patient preference elicitation issues and approach

• Support in the drafting of the final project recommendations

• Take on dissemination activities
Thank for your attention

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