THE IMPATIENT PATIENT
FROM ANGER TO ACTIVISM

A systematic review of the history, working models, relevance and perspectives of the European Community Advisory Board
List of acronyms and abbreviations

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<th>Acronym</th>
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<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
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<td>CAB</td>
<td>Community Advisory Board</td>
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<td>Community Clinical Consultancy Groups</td>
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<td>Data Safety Monitoring Boards</td>
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<td>European AIDS clinical society</td>
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<td>European Association for the Study of the Liver</td>
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<td>ECAB</td>
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<td>European AIDS Treatment Network (FP 7 project)</td>
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<td>Non-Governmental Organization</td>
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<td>People Living With HIV and AIDS</td>
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The institutional review of the European Community Advisory Board (ECAB) looked at the history, working models, past and present relevance, and future perspectives of the organisation.

While ECAB and its work remain relevant, there has been a substantial change in the epidemic and the social discourse around it: There is a contradiction between the discourse of the epidemic and the lived reality of the disease. Hence there is a clear tension between the necessary need for and role of expert patients, and the image that expert patients communicate to the outside world.

One of the key strengths and legitimating factors of ECAB has been the accumulated knowledge of its membership. The informal structures of advocacy work in the civil sector allow for flexibility, speed and non-conventional tools in the negotiation of interests, however, professionalization and standardization of certain knowledge elements and procedures are inevitable if ECAB is to remain a key player and a role model for other patient organisations. More conscious and proactive contacts with academia are suggested. Target oriented mapping and monitoring of the membership’s skills and knowledge are proposed alongside a flexible and high-quality training/education program for existing and current ECAB members. The concept of a ‘school of excellence’ for HIV patients and supporters is proposed in order to allow for the discovery and institutionalization of the immense informal knowledge that exists within the organisation. Finally, proactive recruitment of new members with specific skills is suggested.

Abstract

“Being united makes you stronger as advocates”
(ECAB member)
The European Community Advisory Board (ECAB) was established in 1997 as a forum for interaction between the community of people living with HIV and AIDS (PLWHA) and the pharmaceutical industry. ECAB operates as a working group of the European AIDS Treatment Group (EATG), a European voluntary patient organisation for PLWHA.

The European AIDS Treatment Group (EATG) was established in Berlin, Germany in 1992. The mission of the EATG includes: “To achieve the fastest possible access to state of the art medical products and devices, and diagnostic tests that prevent or treat HIV infection or improve the quality of life for people living with HIV, or at risk of HIV infection”, which it has been pursuing since its establishment. ECAB has retained a certain degree of independence from the EATG.

In a former study, one of the members provided a thorough description of the early history of HIV/AIDS activism in Europe. He points out: “From the streets and from public action patient pressure has over time been transferred to the meeting rooms of Community Advisory Boards (CAB’s) in numerous forms. Originally coming from the U.S. (where communities largely mean ethnic or socially defined groups), CAB’s have become the model of choice to channel patient pressure and to turn aggressive attack into more constructive dialogue”. The initially politically motivated process of activism transgressed into, pressurized and then infiltrated the world of pharmaceutical research.

The original roots of the European Community Advisory Board are to be found in the so-called Community Constituency Groups (also referred to as Community Clinical Consultancy Groups [CCCG]) that were mostly established or called by pharmaceutical companies or national regulatory agencies. These entities were attached to a trial site, attached to a specific study, or a specific company.
One founding member tells the story: “Since its implementation in 1992, EATG has had meetings with pharmaceutical companies to receive information on research / drugs in the pipeline, discuss trial designs, and (partially) also marketing strategies.” This knowledge and information was soon distributed to the community in the form of the European AIDS Treatment News (EATN), a pre-internet newsletter that was sent out to the readers via fax and mail.

An important milestone in the establishment of ECAB was the meeting held in Bergen, Norway on 11-13 April 1997. Originally devised as a discussion about the ethics of patient involvement and the representativeness of community advisory boards, the meeting held and the report approved in Bergen set the foundation for the current work of ECAB. The report instructs EATG to start working with national and European regulatory authorities to “improve the drug approval process in terms of making promising new drugs available at the appropriate time”.

**Key achievements and milestones include:**

- Putting a lower limit of CD4 cell count to one important trial in treatment naïve patients.

- Working out and maintaining an access template for all drugs of the companies working in the field. The database informs about the registration status, availability and reimbursement of drugs in every European country.

- Participation of ECAB members in different data safety monitoring boards (DSMB) attached to clinical trials.

- Achieving amendments to protocols that were not in the best interests of study participants.

- Formal cooperation and communication with the European Medicines Agency.

- Voice of patients in the EU with several formally held positions in institutions.

- ECAB as a part of EATG is collaborative organisation to WHO Europe.

- Maintaining close relationships with important research groups and consortia.

- Recognised and involved in pan-European structures - European conferences, guideline panels, EU panels and conferences (EACS, EASL, IAS etc.).

- Leading role in helping promote ECAB-like working models in different European countries (UK-CAB, Spanish CAB, Portuguese CAB, Russian CAB, Ukrainian CAB), and strengthening the empowerment of PLWHA in the field of treatment and research.
“Initially it was about speed, that the drugs are registered as fast as possible. At one point more members, more issues, more drugs [were there] as well; we could look into ethics, representation of specific populations in clinical trials, inclusion of IDUs, human rights issues...”

(ECAB former chair)
At the end of 2012 ECAB had 101 regular members, of which 70 are EATG members, 2 list-only members (who are participating with varied frequency in discussions and communication on the organisation’s mailing list), and 29 guests/candidate members. The membership covers a total of approximately 30 countries in Europe.

1 The relationship between the scientific community and the pharmaceutical industry is beyond the control, but not necessarily beyond the scope of influence of ECAB. More conscious interaction with the scientific/academic community and outreach to scientists working at pharmaceutical companies can strengthen the representation of the patients’ interests in biomedical research.

2 Currently there is no formal relationship between the EATG/ECAB and the scientific community. The establishment of more formal structures is suggested with the involvement of ECAB in the form of joint research projects with universities or independent researchers, memoranda of understanding accompanied by more active outreach to the scientific community.

3 ECAB does not control the relationship between the scientific community and public and international institutions, but it can influence that relationship indirectly. Treatment activists can exert pressure on governments and international institutions to achieve universal access to treatment. This requires better and cheaper drugs that are available faster, which in turn requires more research.

4 Relationships between public and international institutions and the EATG are partly formalised. These relations contain a lot of potential that can be exploited through more conscious involvement of ECAB and its members. ECAB does not shy away from the political dimension if it comes to promoting the core objective: assisting the biomedical research processes of HIV/AIDS to ensure accessible, good treatment for all.

5 The relationship between public and international institutions and patient organisations is not within the scope of control of ECAB. However, ECAB is capable of exerting some influence on it through lobbying and spreading the know-how amassed in EATG/ECAB over the years. The EATG organises regular training sessions for fellow activists all around Europe, and the lessons learned from its 25-year long experience are available to all other patient organisations.

6 The relationship between patient organisations (CABs) and ECAB is partly formalised. More work and the strengthening of these relations are needed. ECAB has assisted in the establishment of several country and disease

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1 For financial reports and disclosures of the EATG: www.eatg.org/aboutus/Finances
specific community advisory boards. Certain aspects, points and methods of the work ECAB does are relevant and useful more universally for all patient organisations.

7 The relationship between ECAB and the pharmaceutical industry is strong. This particular aspect of the relationship involves not only the flow of support and information from the industry to ECAB, but also a reciprocal flow of information, skills and know-how. However, the funding of ECAB needs to be diversified in order to improve its independence and credibility.

8 The relationship of patient organisations and pharmaceutical companies can be influenced by ECAB strongly and in a concerted way through lobbying and leveraging on the role of EATG/ECAB as a leading patient and advocacy organisation in Europe. ECAB realizes and takes very seriously its responsibility associated with its leading role in the field of organised patient involvement.

9 The reverse relationship between ECAB and the pharmaceutical industry entails the flow of information from ECAB to the companies, and is currently seen as being weaker than it could or should be. This aspect of the relationship needs conscious development and targeted work.
Methodology

“I think for the patients it’s clear: The interest is to have better drugs faster, and with better clinical information early on.”

(ECAB member)

Funded by NEAT ², a pharmaceutical manufacturer, and ECAB itself, the review was performed in order to support the patient organisation’s work in the promotion of biomedical research and pharmaceutical development in the fields of HIV/AIDS and related co-infections and diseases. A mixed-method quantitative and qualitative research was conducted with organisation members, stakeholders, and pharmaceutical industry representatives. Members of the organisation (n=36) and industry representatives (n=13) were polled through different questionnaires. A SWOT analysis of the functioning of ECAB was followed up by semi-structured interviews with members (n=27). Interviews were analysed for meaning and key concepts, and contrasted against the questionnaires. Different internal and publicly available documents were also reviewed in order to reconstruct the history and work of ECAB.

2 The European AIDS Treatment Network (www.neat-noe.org)
Theoretical background

“The core values [of ECAB] to me became the need of ensuring better treatment options, better care, faster delivery, equal access irrespective of groups of countries. There are still many unmet medical needs. Moving forward the good standards of care.”

(ECAB member)

The concept that patients are actively involved in the process of pharmaceutical development and biomedical research not only as passive participants of clinical trials but active advisors and consultants is still relatively new but no longer unusual. Although historical data are scarce and somewhat contradictory, there is strong pride in the community of PLWHA that research in the field of HIV/AIDS was the first where this kind of involvement of the patient community was admitted and even solicited by academia and industry in the middle of the 1990’s.

One particular study points out the importance of recognizing patients as informed consumers of health care services – a concept that is increasingly present in western health care approaches. It also points to the fact that “the addition of everyday knowledge to the communication process between patients and health professionals would contribute to more realistic patient participation in conversations about their health care and a more informed decision-making process” 3. The same study states also admits that the knowledge of the patient is not considered when making decisions about their health care, which may lead to dissatisfaction, and ultimately, weaker results in care.

The emancipation of the patient is key, the recognition of the fact that the person living with HIV/AIDS is more than the patient sufferer of their disease and medical interventions: they are an active participant, a more or less conscious partner in the construction of their disease and its progression.

A research paper from the UK 4 points out that patient involvement in biomedical research is not very widely discussed in scientific literature. The authors nevertheless concede, “consumers (including patients) should be regarded as an expert resource and equal members of the research team. Their inclusion encourages a closer patient focus within health research, and adds depth to data interpretation”. The ECAB has been in the forefront of this kind of involvement since 1997.

When faced with a life-long (and potentially stigmatizing) disease, there may be different pathways towards integrating it into the identity, and different outcomes of the process. One of the alternatives is the way of the “expert patient” 5. Expert patients in our case are people living with HIV/AIDS who become highly educated about their disease and work as active contributors to the provision of health care services,
psychosocial support, advocacy and policy services to other patients.

All of these key factors: combination therapy; the lived reality of the disease with longer life expectancy and relative health; the emergence of the concept of the emancipated expert patient points to the need for change in interventions and research. This is exactly where patient organisations and expert patients are and should be involved in the biomedical research and health care processes in various disease areas including HIV/AIDS.

Some organisations focus primarily on providing emotional support and information to patients. Others use their collective voice to embrace an advocacy agenda. Yet others define themselves as medical research organisations and focus aggressive fundraising efforts entirely on a translational research agenda that addresses critical gaps in diagnostic and therapeutic interventions. The EATG is a patient organisation that actively covers all three key areas described here.

Peer helpers can (and should) play an important role in providing support to other PLWHA. Through shared and similar experiences, peer helpers and expert patients bring to the equation the added value of credibility and authenticity towards other PLWHA. Their involvement in the provision of various services could ease the increasing burden on health care systems. Also, their visibility and work can implicitly contribute to the erosion of stigma and discrimination against PLWHA.

Treatment activists, prevention advocates and expert patients in fact work in the “grey zone” between the dominant/fear-laden, and hidden/spectral frames of HIV/AIDS. While firmly rooted in the highly medicalised and rational tradition of scientific research and evidence-based treatment, expert patients who live with HIV/AIDS are also the embodiment of the disease, and the success of their work is often dependent on how far they are able to balance between the strategy of calm and composed “survivorhood”, and “haunting” the audience in order to get the message across. Thereby expert patients, through their presence, become active vehicles of the fight against stigma and discrimination, and also actively, even if not consciously, use their empowerment to overcome the “victim-blaming” frames in the discourse of HIV/AIDS. Patient organisations like ECAB epitomize this process of “positive transition”.


The funding structure of ECAB

“All meetings start with a minute of silence to remember those who could not benefit from the advances of science. A lot of my friends died from AIDS, and I found the minute’s silence an important way to remember and respect them and to focus on the meeting goals.”

(ECAB former Chair)

Being part of the EATG, ECAB is integrated into its budget. Pharmaceutical companies contribute to the funding of ECAB in different forms: Through core funding in the form of unrestricted grants, through support for ECAB meeting in ECAB meetings, and through sponsoring specific projects (conferences, information campaigns etc.). With the changing legislative environment in the European Union and a ban on direct to consumer advertising of pharmaceuticals, this form of funding has become a matter of controversy.

EATG and ECAB stand firm in saying that interaction with the pharmaceutical industry in ECAB meetings is

• rigorously scientific;
• confidential;
• targeted at information exchange between the community and industry;
• organised on the highest possible level between patient advocates and researchers;
• outside of the scope of usual interactions between industry and consumers;

and therefore cannot be seen as direct to consumer marketing of drugs.

Nevertheless, there has been intensive work done at EATG/ECAB to ensure diversification of funding, especially through the involvement of non-pharmaceutical and public funders.

7 For financial reports and disclosures of the EATG: http://www.eatg.org/aboutus/Finances
8 For a summary of the debate: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2661977/
General working model

“ECAB tries to make sure that the community speaks in one voice”

(ECAB member)

This is where ECAB works

ECAB can be seen, and positioned as, a novel vehicle of innovation

Wienold, M., Community Participation in Clinical Research, Hanover, 1997 and Derbyshire, J., Patient groups - Do they have anything to say?, in: European AIDS Treatment News, Spring 2011, 8-9
The work of ECAB is composed of several elements: regular meetings, substantial back-office work by the Scientific Officer and the Hepatitis Officer, and several lively e-mail lists keep the daily work of the organisation going.

**ECAB meetings** are structured according to a certain ‘choreography’ that was set up in the early days of the organisation and still survive today. They provide a reliable structure, reflect professionalism, and also are a source of pride. Most ECAB meetings are held over weekends: from Friday morning until Sunday noon. Meetings are usually divided into five units, app. 3.5 hours each. Companies and other presenters can reserve one or two units (which means either a half or a full day). ECAB holds 5 to 6 meetings a year in Brussels, Belgium.

Meetings with companies are conducted under strict confidentiality. Meeting participants are not allowed to disclose confidential materials and information outside the meetings, but they can use this information to make informed recommendations and to give advice to community members in their own constituencies. Sunday morning meetings are reserved for the discussion of internal ECAB. Training sessions cover current or general scientific and policy related topics.

A full-time staff of the EATG, the **Scientific Officer** has the task of supporting the development and strengthening of EATG’s activities in the key area of science and research. The Scientific Officer coordinates science-oriented projects where EATG is a partner, and supports the work of ECAB. He is responsible for the content development and also administrative support of the organisation and its leadership. He organises meetings with external stakeholders, prepares the scientific agenda and makes sure that the administrative aspects (logistics etc.) are taken care of. The Scientific Officer also organises training sessions for ECAB and evaluates the needs of the membership on an ongoing basis, while also liaising with the pharmaceutical industry.

**Hepatitis C Virus** (HCV) co-infection is one of the leading causes of death for PLWHA in Europe. After an extensive consultation with the community and scientific advisors, ECAB decided in 2007 to add HCV to its portfolio, and its work now extends to the monitoring and scrutiny of the development and research of viral hepatitis drugs. Dedicated ECAB meetings are organised with pharmaceutical companies engaged in the field of viral hepatitis. In addition a series of specific scientific and policy meetings, the so called “Sitges Meetings” are organised by EATG and ECAB – five meetings were held in Sitges and Brussels between 2007 and 2012. While the main focus of ECAB is co-infection with HIV and HCV, the Sitges meeting sustain close cooperation with advocacy groups of mono-infected populations in Europe and the United States as well.

**The Hepatitis Consultant’s** main responsibilities include supporting the implementation of EATG hepatitis co-infection activities as...
part of the global EATG mission. The Hepatitis Consultant will support the hepatitis related work of the European Community Advisory Board. He works closely with the Scientific Officer, the ECAB Chair(s) and Steering Committee, and supports them in further developing the ECAB hepatitis strategy and work plan including budget, priorities and evaluation in collaboration with the ECAB chair(s) and the Scientific Consultant; organising ECAB meetings with special focus on hepatitis; establishing collaboration with networks, peer organisations and international organisations involved in hepatitis research; establishing and maintaining contacts with pharmaceutical industry and other partners; monitoring and analysis of developments and trends of hepatitis research with specific attention to co-infections with HIV issues; organising training sessions for ECAB members; and some additional administrative tasks. The Hepatitis Consultant is a paid position, and a member of EATG/ECAB currently fills it.
ECAB, i.e. the community sets the agenda of the meetings. Setting the agenda and taking the initiative in the community’s own hands are cornerstones of the organisation’s work and success. ECAB includes clinical trials and compounds in its agenda from phase II trials upwards to phase IV. Topics suggested by the companies are completed with the proposals and questions of the community, which are collected and collated by the company liaisons and the Scientific Officer.

The company liaison responsible for the company invited will start working with the representative of the company several weeks ahead of the meeting. A pre-meeting precedes the company meeting, which is confidential and private to ECAB members and EATG staff. New or inexperienced members are briefed in the pre-meeting, but questions are always welcome also during the meeting. All meetings are minuted, and the minutes are shared with the companies concerned.
The emancipation of the “patient” (the person living with HIV/AIDS) is key. Empowerment yields more conscious citizens who will be able to take better care of themselves and their peers. This research argues for more inclusive scientific projects where PLWHA are not only the subjects of research but also active participants that are involved from the stage of study design through assessment to evaluation. This concept has been working very well in biomedical research for many years – and it is spreading to the field of social sciences.

EATG/ECAB argues for the use of the patient community and peer helpers in areas like prevention, adherence, psychosocial support to other patients, outreach to hidden and difficult-to-reach populations, education and training for the medical profession, or study design. This utility of the organised patient movements has already been recognized by the pharmaceutical industry. We suggest using this resource more consciously. Doing so is also empowering for the patients.

**General**

- ECAB will turn even more towards science and research.
- There is a need to build new contacts/relationships with the scientific/academic community.
- That the procedures of ECAB will be simplified. Background work, day-to-day liaising with members and companies should become smoother and more transparent.
- Access/policy must remain an integral part of ECAB’s work.
- ECAB will retain the concept of “advisory board” to industry. When approached by industry for advice, responses are quick and efficient, and advice is proactively offered.

“ECAB has a collective knowledge and memory which far surpasses many of those doctors who come and meet with us. That’s why ECAB can be very useful to them. This is what [pharmaceutical companies] benefit from. They also want to meet the people who take their drugs!”

(Former ECAB chair)
**Capacity building**

- ECAB is working continuously to increase the level of knowledge of the membership about HIV and treatment, and related science.

- Regular training sessions are organised about relevant topics.

- Training materials are developed in a format that can be reused in future sessions (video tutorials, webinars, podcasts, slide decks with voice tracks).

- The establishment/development of an “Academy of advocacy excellence” is proposed for the continuous training and development of ECAB members.

- Active outreach and recruitment policy is proposed in order to ensure that additional skills, capacities and constituencies are involved.

- The value of training is considered and consciously used as an incentive to members.

- ECAB’s experiences and know-how are available for transfer to other patient organisations and NGO’s.

**Specific activities**

- Other, new, related and relevant disease areas are continuously being integrated into the remit of ECAB.

- Cure/eradication

- Immune-based therapies

- Psychosocial aspects

- HIV and ageing

- Co-infection management

- Treatment as prevention etc.

- Thus, ECAB is able to propose research initiatives in cooperation with the scientific/academic community.
The publication of the ECAB review/and or corresponding scientific work/ has been possible thanks
to funding received from EC in the Project: The European AIDS Treatment Network, (NEAT) with
contract number LSHP-CT-2006-037570, which is a FP 6 network of excellence- project within the
“Integrating and Strengthening the European Research Area”
The EATG is a nongovernmental organisation that defends the interests of people living with HIV by focusing on treatment activism and treatment advocacy. We promote legislative changes that will help increase access to HIV treatment and care, and we monitor the development, testing and approval of new HIV treatments with respect to the needs and rights of people living with HIV.