

National Consultative Ethics Committee

Review of Bioethics Law

France : 2018/2019

Process and Public Consultation

<https://www.ccne-ethique.fr/en>

Prof. Jean-François Delfraissy (CCNE)

CPP Annual Conference

Montpellier, June. 20 2019

FRENCH ETHICAL LANDSCAPE

- **CCNE : National Consultative Ethics Committee on Life sciences and health**
- **Regional Ethics Committees (ERER)**
- **Ethics committees of research agencies (Inserm, CNRS, ...) Academy for Sciences, Academy for Medicine.**
- **CPP : Ethics committees for clinical research**

The National Consultative Ethics Committee



Le Comité Consultatif National d'Éthique

- Independent institution created in 1983
- Its mission is « to give opinions on ethical problems and societal issues raised by progress in the fields of biology, medicine and health » (Law of August 6, 2004)



Pr Jean-François Delfraissy
President of the CCNE

39 members – the « plenary committee » - engaged in activities concerned with bioethical issues (medicine, research, philosophy, law, religion...)

130 published opinions and reports

The CCNE :

A unique experience of reflection on bioethical issues

Last published opinions :

- **Opinion 125** : « Biodiversity and health: a new Relationship between Humanity and the Living World? » (March 2017)
- **Avis 126** : « Societal Requests for Medically Assisted Reproduction » (June 2017)
- **Avis 127** : « Migrants' Health and Ethical imperatives » (October 2017)
- **Avis 128** : « The Ethical Issues of Ageing » (March 2018)

- **Avis 129** : « Contribution of the CCNE to the revision of the bioethics law » (September 2018)
- **Report CERNA** : « Health and digital. What ethical issues for which regulations ? » (November 2018)
- **Avis 130** : « Big Data in Health » (May 2019)

Work in progress:

- New technics in genomic engineering
- Neurosciences and education
- Ethics and access to Medical Innovation

Regional ethics committees : Les ERER

- Regional committees are in close contact with university hospital centres and come under the responsibility of the Regional Health Agencies in each region and some overseas territories
- **Mission : to spread an ethical culture among health professionals and the general public :**

- Information
- Training course
- Documentation

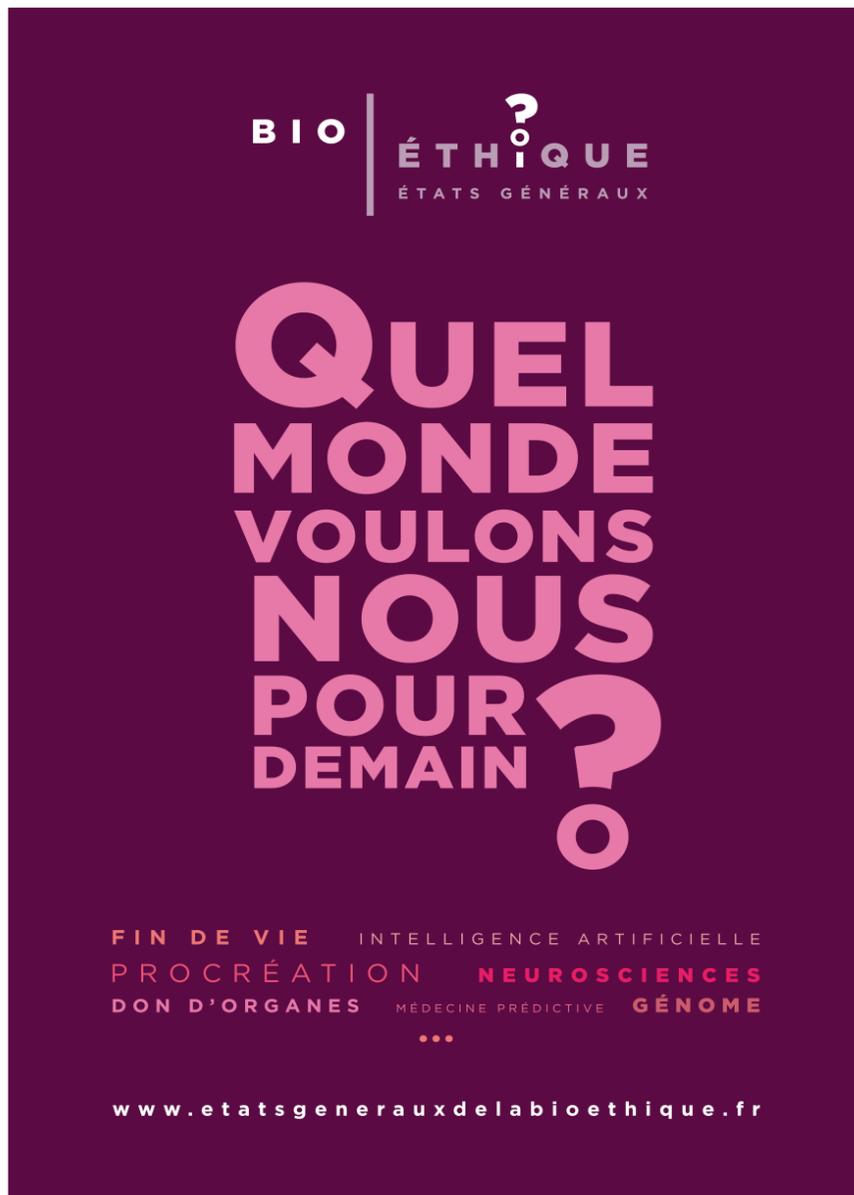


Organisation of gatherings and debates



- Great deal of latitude for the organisation of the debates (methods and debating themes)
- In close cooperation with the CCNE (each ERER delivers a report to the CCNE)

→ What kind of cooperation(s) between the CCNE and the ERER after the National consultation ?



2018 Public Consultation on Bioethics



États généraux de la bioéthique

Law on bioethics n°2011-814 / 7 July 2011

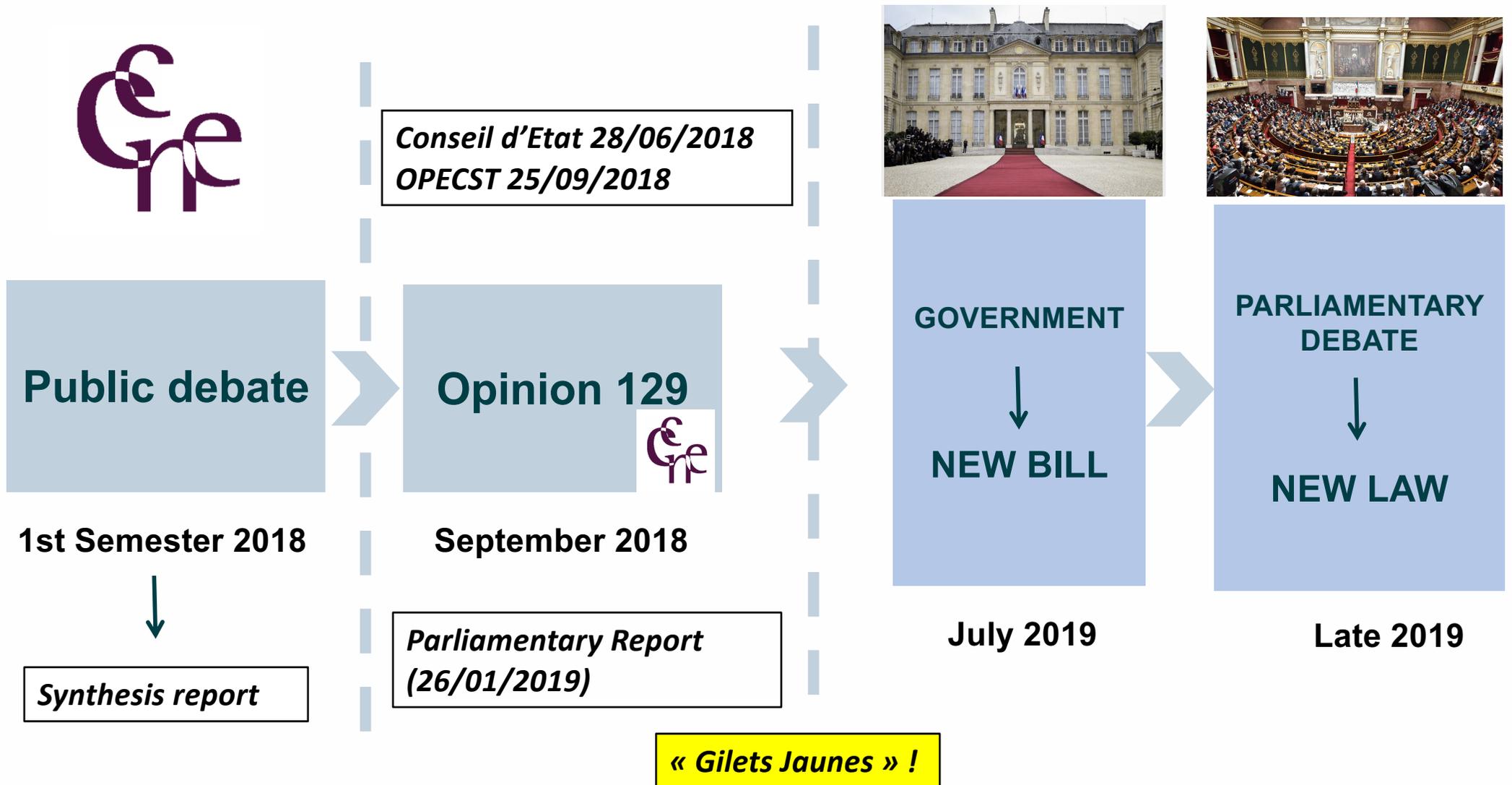
Article 46 :

Any planned reform on **ethical problems** and **societal issues** raised by **progress in the fields of biology, medicine and health** must be preceded by a **public debate** (Etats généraux). These are organized **on CCNE's initiative**.

Following the public debate, **CCNE draws up a report to be submitted to the Parliamentary Office for Scientific and Technological Choice (OPECST)**, which then makes its assessment.

In the absence of any planned reform, CCNE is required to hold a National consultation at least once every five years.

2018 – 2019 Bioethical law's reviewing timeline



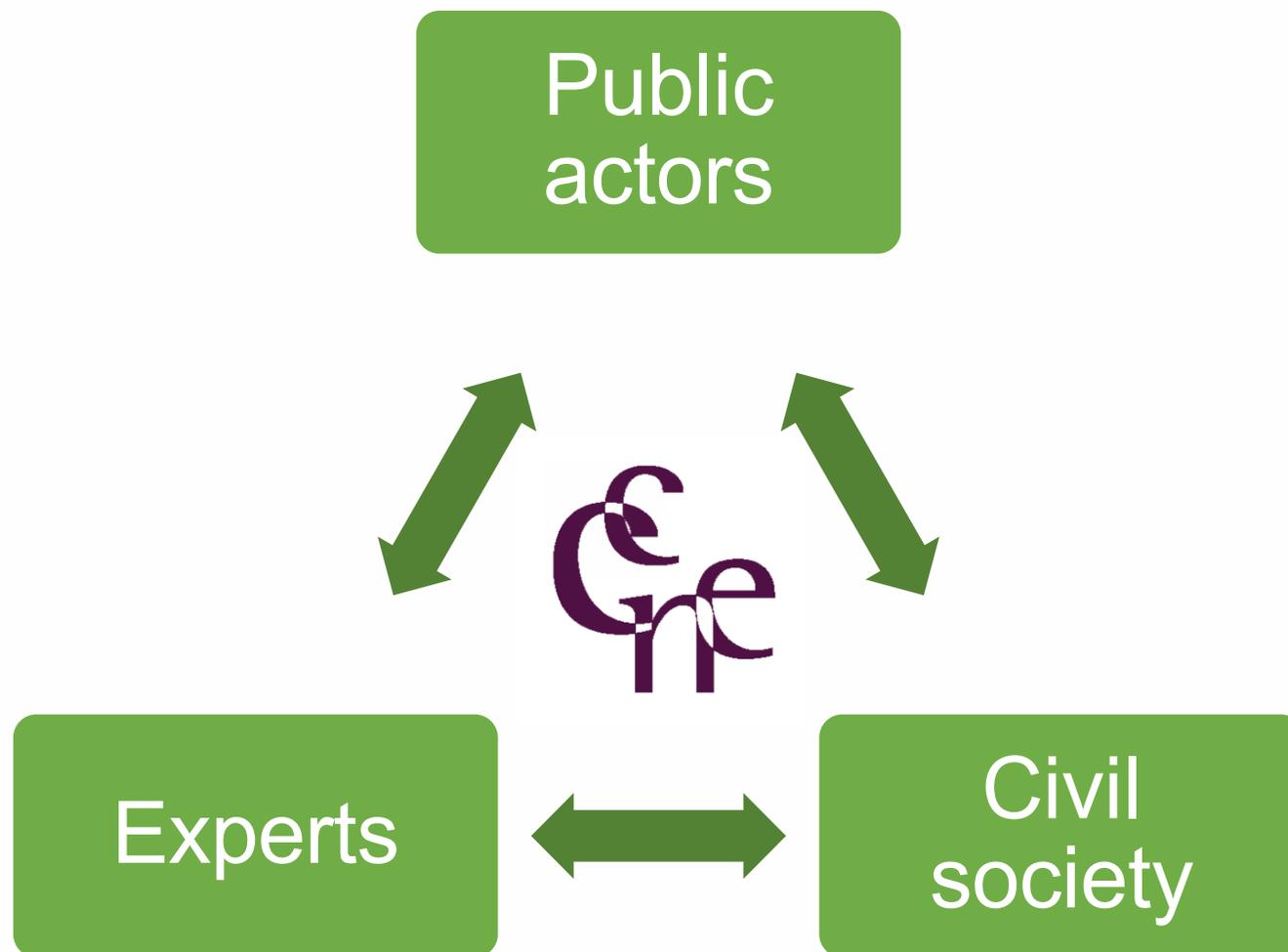
Consultation report (June 2018)

- **CCNE organized the consultation jan 2018 – may 2018 in collaboration with ERER.**
- **CCNE defined nine themes for debate, not all the topics will be covered in the upcoming law.**
- **A synthesis report : factual and impartial account of the opinions that had been expressed by citizens**

Opinion 129 (Sept 2018)

- **Provides guidelines to the policy-makers: government, parliamentarians and the state bodies on bioethics**

Public debate : a multipolar debate

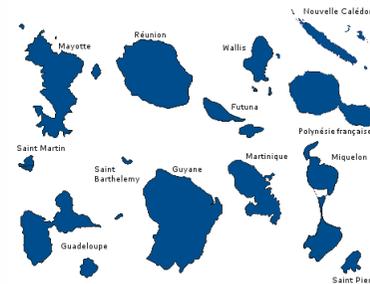
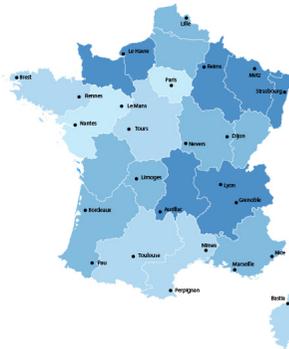


A broad consultative process

- Website
- Citizen committee
- Regional events

- Hearings
- Meetings with institutional ethics committees

MAINLAND



**OVERSEAS
TERRITORIES**

Reaching out to individuals and organizations :
Citizens with and without internet access, students, healthcare professionals, members of local ethics committees, medical societies and citizen associations

Key players

CCNE

- Oversees and organizes the consultation
- Scientific committee

Steering Committee

Louis Schweitzer, mediator

Former director of the French Equal Opportunities and Anti-Discrimination Commission (HALDE)

- Responsible for receiving and responding to complaints about the consultation process.

Citizen committee

22 members reflecting the diversity of French population

- Issued an independent, critical assessment of the consultation
- Issued an opinion on end-of-life and genomics

Regional Ethics Committees ERER

(Espaces de réflexion éthique régionaux)

- ERER are independent committees
- In charge of the regional gatherings

The consultation's figures

Website:

183 498 single visitors

29 032 participants

64 985 contributions, including 3

755 newpropositions

832 773 votes

Regional debates:

271 events

21 000 participants

1/3 students

Hearings:

154 organizations: 88
associations ; 36 medical
societies ; 9 faith communities
and philosophical groups ; 18
institutions ; 3 firms or corporate
unions

Citizen Commitee :

22 members

4 week-ends

3 opinions

9 topics : CCNE responsibility

End-of-life



Reproduction & society



Artificial intelligence & robotization



Health & environment



Stem cells and embryo research



Genetic testing & genomic medicine



Organ donation & transplantation



Neuroscience



Health data



10th theme raised by the participants : organization of healthcare, the patient involvement in the healthcare system

Monde
L'accord
sur le nucléaire
iranien en péril P. 8-9

Économie
Les finances
des Français
très aisés P. 11



Culture, le pari des régions
L'Isère réconcilie
ville et campagne
P. 26-27

éditorial
Guillaume Goubert

Un débat
à poursuivre

Fin de vie, génome, PMA La bataille des arguments

Le Comité consultatif national d'éthique
a livré hier un compte rendu
des états généraux de la bioéthique
P. 2-3



Bioéthique, ce qui est en jeu



CCNE organized a 3 days formation for +50 journalists

Bioéthique : les enjeux de la future loi

- ▶ Les Etats généraux de la bioéthique s'ouvrent le 18 janvier, alors que l'exécutif doit déposer un projet de loi à l'automne afin d'actualiser la législation
- ▶ Les évolutions de la science dans certains cas et de la société dans d'autres font naître de nombreuses questions sur leur traduction dans la loi
- ▶ La question de l'ouverture de la PMA aux femmes seules et aux couples de femmes sera centrale. Macron s'y est dit favorable, mais reste prudent
- ▶ Diagnostic préimplantaire, tests génétiques et médecine prédictive, édition du génome, fin de vie... autant de sujets qui seront débattus d'ici à l'été
- ▶ Un collectif de 110 signataires, dont Irène Théry, Elisabeth Badinter et Pierre Rosanvallon, défend une GPA éthique

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Twitter trends - National Launch

1	#Riverdale
2	#LOSCSRFC
3	#Berguita
4	#JeudiConfession
5	#TFCFCN
6	#SoixanteHuit
7	#EtatsGenerauxBioethique
8	#FCMASSE
9	#BIS2018

Regional debates

A close collaboration
between ERER &
CCNE

271 events in
mainland and
overseas territories

Over 21 000
participants



Diversified approach

- Lectures
- Group discussions
- Coffee-clubs, cine-clubs
- Focus groups...

Diverse audience

- General public
- **Students (one third)**
- Health professionals
- Clerics

Each of the 271 events organized by the Regional Ethics Committees (ERER) was the subject of a report to CCNE to serve as material for the consultation report

CCNE Hearings

154 organizations representing millions of French citizens

88 associations
36 medical societies
18 institutions
9 faith communities
and philosophical groups
3 firms or corporate
unions



1-hour, 4 CCNE members per hearing.

Most popular themes:
Procreation, End-of-life,
Genomics, organization of
healthcare.

Their contributions consisting in a few pages of text outlining the points they would like to have modified in the future law were systematically posted online.

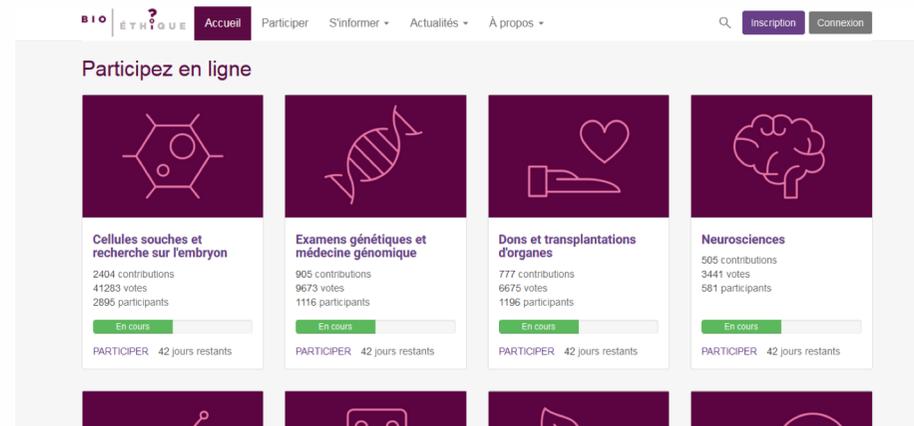
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Most popular themes :

1. Reproduction & society (45% of total contributions)
2. End-of-life (24%)
3. Stem cells and embryo research (11%)
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Led by an independant service provider



345 contributions moderated

The Mediator received 152 requests from claimants during the consultation and 11 letters of response were published.

Citizen committee

- Led by an independent service provider
 - 22 members reflecting the diversity of France
 - Remained anonymous until the end of the consultation
- Met over four weekends and heard some twenty experts.
 - Asked CCNE representatives to respond to their queries regarding the consultation procedures.

Submitted three opinions to the CCNE :

- citizen consultation process
- end-of-life
- Genomics in general populations.

Meetings with institutional ethics committees and experts

1st national forum led by the CCNE on November 29th 2017

- 15 institutional ethics committees (CNRS, INSERM, CEA, CNES...)
- Closing speech by Frédérique Vidal, Ministry of Research

Three workshops on Health and digital ; genomics ; the patient of tomorrow

Several experts' workshops in 2018

(i) Embryo and embryonic stem cell research ; (ii) genomic medicine and genetic testing development ; (iii) neurosciences

Temporary working group on Health and digital, leading to the publication of a report CCNE-CERNA (November 2018)

A new forum to be organised in June 2019

The CCNE at the center of a new network between the institutional ethics committees ?

Hearings of foreign ethics committees

*Prior to formulate its Opinion 129, the CCNE has **consulted a number of foreign ethics committees** between July and September 2018.*

*Indeed, the CCNE was convinced that **better understanding of the reflections conducted in these countries** was necessary and would enrich its own reflection.*

*During these hearings, **various topics were discussed**: organization of public debate, links between ethics and politics, but also some specific bioethics issues such as Big Data, genomic medicine, end-of-life, procreation...*

Were consulted members from the ethics committees of the following countries :

Canada, Switzerland, Belgium, Japan, Mexico, Germany, Portugal, and United Kingdom.

LESSONS LEARNED (I)

The outcome of this consultation is and constitutes a « collective property » shared with French society, the scientific community and the CCNE itself

1. Public debate supported by a diversity of tools

- Plurality of expression do not provide a true representation of public opinion
- Some difficulties with « so-called » societal issues
- Difficulties of including the more vulnerable populations

No tool is perfect : It is all the tools, in their complementarity, that can comprehend correctly public opinion

LESSONS LEARNED (II)

2. Points of convergence, divergence and tension

- Several major topics with few discussions : blood donation, addictions, access to costly new drugs ...
- Interconnections between the themes : genomic, big data
-> Modification of the corpus of bioethics
- Queries and even disquiet seem to be emerging in France on the actual concept of scientific and medical progress (and their actors)
- The essential need for public information
- Role and responsibility of Research

LESSONS LEARNED (III)

3. Reaffirmation of ethical principles

- **Respect for each and every person's liberty and autonomy**
- **Social dimension of health, human relationship
+++**
- **Right to be different and protection of most vulnerable citizens. Equality for access to health care**

This French version of bioethics is strongly rooted in France culture, together with a health system based on solidarity.

LESSONS LEARNED (IV)

4. A new theme: what civil society expects from the health care system and from medicine ?

- Health care is not just technology**
- A new medicine with AI, genomics : role and place of the patients ?**
- Access to health care is an essential right**
- Economic considerations have a bioethic counterpart**
- Questions about the ethics of physicians (MD) and researchers**

The media: major/complex tools for public debate

Journalists are an essential medium for engaging in debate with the public. Bioethical issues can sometimes be very complex for them to understand though. What's to be done?

- **Encourage the training** of journalists to improve the debate
- **Help them by proposing angles on the subject**
- **It's okay if they draw public attention to one or two issues only**, rather than the whole issue, especially if it's complex

The public can tackle a complex problem after being sensitized to one or two issues through the media.

- **Combine public awareness through the media with the implementation of debate tools** to enable the public to deepen the subject and participate.

QUEL MONDE
QUELLE ÉTHIQUE

VOULONS-NOUS

AUJOURD'HUI ?
POUR DEMAIN

AVIS¹²⁹

CONTRIBUTION
DU COMITÉ CONSULTATIF
NATIONAL D'ÉTHIQUE
À LA RÉVISION DE
LA LOI DE BIOÉTHIQUE



COMITÉ CONSULTATIF NATIONAL D'ÉTHIQUE

AVIS 129

CCNE OPINION

SEPTEMBER 25. 2018

*« Orientation board for
politicians »*

CCNE Opinion n°129

« Considerations on the new bioethical law »

- A special opinion issued from anterior opinions and citizen consultation.
- Dedicated to ministries, health and research administrations, stakeholders, parliamentarians
- 11 meetings of Plenary CCNE between june and september 2018.
- Four parts :
 - What is new since 2011
 - Ethical principles and ethics improvement
 - Opinions on the 9 topics
 - A vision for the future

A vision for the future

1. **Bioethics laws should be revised every 5 years,**
2. **More debate between the revisions of the law**
3. **A role of oversight and early warning regarding new ethical questions in partnership with the EREER.**
4. **More research in the human and social sciences on major social questions (procreation, end of life)**
5. **Development of the teaching of ethics for healthcare professions**
6. **Strengthening the international dimension**
 - Several interviews with foreign NECs already led in September 2018 (Germany, UK, Japan...)

EGB/Research

1. Very few research teams. No french visibility in H20-20.
2. Very few research productions in social sciences and humanities, public health and major societal issues (assisted procreation, end of life...)
3. Good interactions with institutionnal ethics commitees and learned societies, few with ITMOS.
4. 3 subjects in discussion :
 - **Neurosciences**
 - **AI and Health**
 - **Genomics / preconception**

Opinion 129 : Embryos and embryonic stem cells

1. The CCNE considers justified the **authorization of research on supernumerary embryos**, including genetic modifications, provided there is no embryo transfer.
2. The CCNE reiterates the ethical relevance of **the ban on the creation of embryos for research purposes**.
3. The CCNE proposes using **different legal regimes for embryo research and for research on embryonic stem cell lines**, as the ethical issues associated with these two types of research are different.

Opinion 129 : Procreation (1)

1. The CCNE reiterates its proposal to **make ART (assisted reproductive technology) available to female couples and single women.**
2. The CCNE considers it essential to anticipate how making ART more available will affect the capacity of centers for the study and storage of oocytes and human sperm to meet this new demand for donated sperm.
3. The CCNE favors **maintaining the ban on surrogacy.**

Opinion 129 : Procreation (2)

1. The CCNE favors the possibility of **proposing, without encouraging, storage of oocytes for all women** who wish (the only restrictions being minimum and maximum ages), following medical advice.
2. The CCNE proposes **lifting of anonymity for future sperm donors**, for the children resulting from these donations.
3. The CCNE favors **the availability of ART post mortem**, ie, the *in utero* transfer of a cryopreserved embryo after the death of the man, provided the spouse receives medical and psychological support.

Opinion 129 : Digital technology and health

1. The CCNE considers the dissemination of digital technologies in the health sphere a priority and wishes to **minimize enforceable rights**.
2. The CCNE proposes that the legislation should include the **fundamental principle of guaranteed supervision** of all use of digital technologies in human health.
3. The CCNE considers that any person using artificial intelligence in the care pathway should be **informed** beforehand so that he or she can give **free informed consent**.
4. The CCNE does not want the digital revolution to penalize **citizens without digital technologies**, who are often in a precarious situation, particularly in terms of health.

Social participation / International : work in progress



Organisation
mondiale de la Santé

1. WHO – April 16-17 2019



« Face-to-Face Meeting of the Social Protection Technical Network SPTN to Support the Development of the WHO Handbook on Social Participation »

- Platforms to engage populations in policy-making processes (Iran / Tunisia / Thailand)
- Démocratie sanitaire and public participation in health sector decision-making (France)
- Issues to consider in engaging populations, communities, and civil society (Guidelines on Social participation / November 2019)

2. Strasbourg / Council of Europe – June 4 2019

« High-level-seminar on public debate as a tool for the governance of new technologies »

- Public debate in action at the national level – why, what and when?
- Public debate at the international level – shaping human rights norms and governance arrangements for new technologies in biomedicine
- Governance of new technologies and public debate - what strategic action for the Council of Europe? medicine?

The French « Great national debate »



1st Trimester 2019



*The « Grand débat national » and the « Etats généraux de la bioéthique » : two public consultation with different purposes and topics...
... but using the same methods to organize the debate (same website, regional gatherings...)*

Two major conclusions about bioethics emerged from the GND :

- 1. Bioethics is not a priority for the participants (it was not the subject of the consultation though)*
- 2. Conversely, as it has been the case for the EGB, inequalities of access to healthcare unexpectedly turned out to be a great concern for the citizens*

And now ?

France should discover soon (July 2019) the bill submitted by the government.

There's a good chance that **the provisions of the bioethical law won't be exactly :**

- *The conclusions of the public consultation (citizens and experts)*
- *The conclusions of the several institutional reports (CCNE, Conseil d'État, OPECST...)*

In that case ... : ***what the added value of the public consultation?*** *What is ultimately the link between democratic debate and the construction of the law? What consequences will there be for the « Etats généraux de la bioéthique » and more generally for the CCNE?*

LE COMITE CONSULTATIF NATIONAL D'ETHIQUE

Président :

Honorary presidents:

5+1 appointed by the President of the French Republic

(Jean-François Delfraissy)
Abdenour BIDAR
Cynthia FLEURY
Marion MULLER-COLARD
Dominique QUINIO
Frédéric WORMS

Secretary

Marie-Hélène MOUNEYRAT, G. Secretary
Marie-Christine SIMON, Head of Comm.

Marc BONGIORNI Louise BACQUET
Maxime CHIAPPINI Djamila RAHMANI
Joseph EYRAUD Jean-Luc RENAUDON

Jean-François DELFRAISSY

Jean Claude AMEISEN
Jean-Pierre CHANGEUX
Alain GRIMFELD
Didier SICARD

15 appointed by MoH (Research)

Gilles ADDA
Mounira AMOR-GUÉRET
Régis AUBRY
Jean-François BACH
Thomas BOURGERON
Marie-Germaine BOUSSER
Monique CANTO-SPERBER
Laure COULOMBEL
Claude DELPUECH
Pierre-Henri DUÉE
Anne DURANDY-TORRE
Catherine PATRAT
Francis PUECH

Pending appointment of 2 members

19 appointed by MoH (bc of their interest in Ethics)

François ANSERMET
Christiane BASSET
Alexandra BENACHI
Carine CAMBY
Yves CHARPENEL
Sophie CROZIER
Marc DELATTE
Pierre DELMAS-GOYON
Florence GRUAT
Claire HÉDON
Corinne IMBERT
Florence JUSOT
Claude KIRCHNER
Karine LEFEUVRE
Martine LE FRIANT
Caroline MARTIN
Jean-Pierre MIGNARD
Lionel NACCACHE
Michel VAN-PRAËT

BACK UP

Opinion 129 : Neurosciences

1. In light of current knowledge, the CCNE firmly opposes the use of the **functional MRI in the legal field**.
2. The CCNE advises against use of **functional MRI in "social" applications** such as neuromarketing.
3. The CCNE is opposed to the use of **functional MRI in selection of job applicants or in insurance practices**.
4. The CCNE suggests the general public to be given **more information** on techniques of cognitive enhancement concerning non-medical devices.

Opinion 129 : Genetic testing and genomic medicine

1. The CCNE suggests **preconception genetic diagnosis** to be offered to everyone of childbearing age who wishes, following genetic counseling. As a preventive medicine procedure, this would be covered by the national sickness insurance fund.
2. The CCNE wishes to examine in greater depth the **possibilities of extending genetic testing to the general population**. It urges rapid initiation of a pilot study in several regions and for various age ranges so as to assess the consequences in terms of public health, psychological impact, and cost.
3. The CCNE favors the authorization of genetic tests on samples taken from a **deceased patient**, except if he or she expressed refusal when alive.
4. The CCNE proposes the creation in France of a **status of genetic counselor**, including non-physicians, in response to the exponential growth in genetic tests.

Opinion 129 : Organ donations and transplants

1. In terms of the collection of organs from dead patients:

- The CCNE wishes **current regional inequalities** in transplant availability to be reduced.
- The CCNE wants **continued information campaigns on organ donations**.

2. Regarding organ transplants from living donors:

- The CCNE insists that professionals should be vigilant when overseeing the **procedure for collection of the donor's consent**, in view of potential family pressure in favor of donation.
- The CCNE proposes the **creation of a donor "status"** in respect of the principle of fairness among patients on the waiting list, and highlights the need to accelerate reimbursement of costs advanced by the living donor.

Opinion 129 : Health and environment

1. The CCNE proposes “health and environment” to be the object of **interdisciplinary reflections**, the results of which would support ministerial actions.
2. The CCNE proposes inclusion of this ambition in the preamble to the bioethics law and favors **modification of the corporate purpose of companies** that take into consideration the social and environmental consequences of their activities.
3. The CCNE would like companies to present each year to their shareholders and their economic and social committee **an ethics document**, outlining their policy for inclusion of environmental concerns in their functioning and their strategies for development.

Opinion 129 : End-of-life care

1. The CCNE does **not propose any change to the existing end-of-life law** (Claeys-Leonetti Law) and underscores the pressing need for this law to be better known, applied, and respected.
2. The CCNE suggests funding for a **new governmental development plan for palliative care**. This plan should seek to reduce regional inequalities and to expedite local organization of palliative care.
3. The CCNE wants **descriptive and comprehensive research work** to be done **on exceptional situations not dealt with by the law** and which could possibly advance the legislation.

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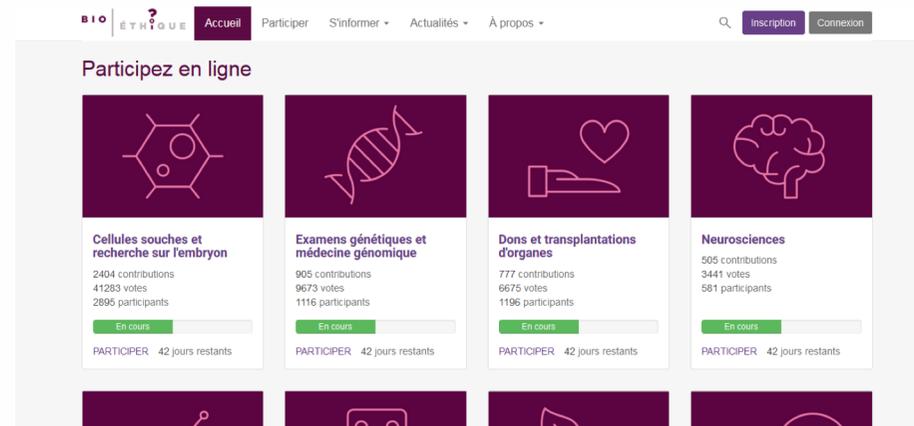
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