KONINKLIJKE NEDERLANDSE
AKADEMIE VAN WETENSCHAPPEN

Amsterdam, 25 June 2014

KNAW-debate on Gain of Function

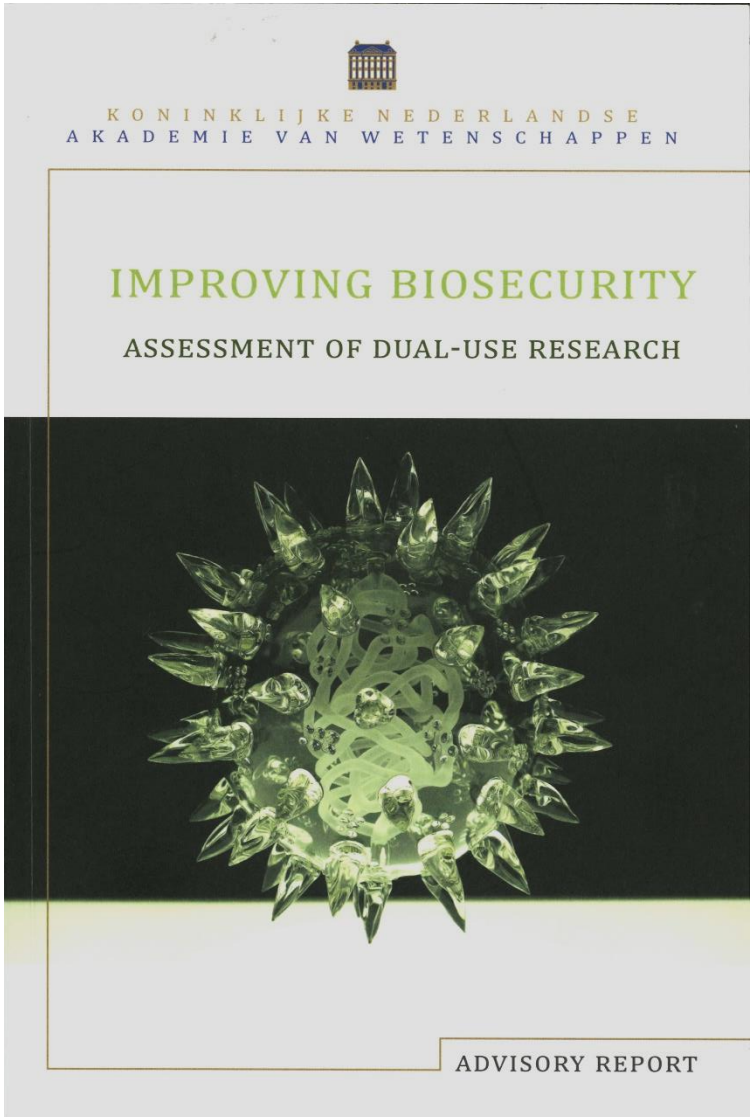
Giorgio Palù, M.D.

Professor of Microbiology and Virology
President, European Society for Virology
University of Padova, Italy

EUROPEAN SOCIETY for VIROLOGY

Anatomical Theatre – University of Padova

Royal Netheralands Academy of Arts and Sciences



EUROPEAN SOCIETY for VIROLOGY

Noel Tordo

Dimitri Lavillette

Otto Haller

Ben Berkhout

Bernhard Fleckenstein

The European Society for Virology provides a forum for scientists active in all aspects of Virology.

The stated aim of the Society is to advance the art and science of Virology and to promote and stimulate the exchange of information and collaboration among individual scientists as well as among national and international associations of Virology throughout Europe.

These goals are achieved by organizing regular scientific meetings, promoting virological education at all levels and by representing the science and profession of Virology to governmental and regulatory institutions of the European Union, the media and the general public.

Corporate Members of the ESV

- Gesellschaft für Virologie e.V.
- Società Italiana di Virologia
- Association des Journées Francophones de Virologie
- Sociedad Espanola de Virología
- Hungarian Society for Microbiology
- Society of Microbiology of Czech Republic, Section Virology
- Swiss Society of Microbiology, Section Virology
- Israel Society of Microbiology, Section Virology
- European Society for Veterinary Virology
- European Society for Clinical Virology
- Virology Division, Society for General Microbiology
- Polish Society of Virology

?????


The FOUNDATION for VACCINE RESEARCH
WORKING TO SECURE OUR CHILDREN'S FUTURE
OUR WEBSITE IS IN DEVELOPMENT.
IT WILL BE FULLY OPERATIONAL BY SPRING 2014.
601 Pennsylvania Ave NW, Suite 900, South Building, Washington, DC 20004
Tel +1 202 220 3008 • Fax +1 202 639 8238 • www.vaccinefoundation.org

"It's an exciting time to advance vaccine research and development to prevent humankind's most wretched diseases….However, scientists must have the resources. We need leadership and further political commitment worldwide. I am pleased that finally someone **will be advocating and campaigning for increased funding for vaccine research**"

Founding Board Director Prof. Robin Weiss of University College London on the Foundation for Vaccine Research, June 8 2011

EUROPEAN SOCIETY for VIROLOGY

www.eurovirology2013.eu

5th European Congress of Virology

Centre des Congrès de Lyon France

September 11-14, 2013

Secrétariat d'organisation

Setting the scene

Late 2011: worldwide discussion on the work carried on by Fouchier's and Kawaoka's groups on H5N1 influenza virus

March 2012: the U.S. National Science Advisory Board for Biosecurity advices in favor of publication of the papers

May 2012: the work of the Kawaoka's group is published in Nature

June 2012: the work of Fouchier's group is published, after Fouchier obtained an export license (under protest)

End of September 2013: the Dutch district Court rejected Erasmus MC's appeal against the government's opinion, based on Council regulation EC 428/2009

…The story continues: H7N9, H7N1, H5N1 (JVI, Cell….2014)

October 2013*: The ESV, with the mandate of the European Society for Clinical Virology, writes to the President of the European Commission Mr. Barroso*

The ESV's letter

«*As European Society for Virology we clearly understand the* ***legal*** *and* ***ethical*** *aspects about research on potentially dengerous pathogens. But we also believe that this case clearly shows that it is time to* ***initiate a debate within Europe****, with the involvement of all* ***relevant institutional bodies and stakeholedrs****, to elaborate common and agreed lines to take on issues related to freedom in Science, dissemination of results, and protection of sensitive data in the research area*»

Mr Barroso's answer

Ref. ARES (20..13)3656560 06/11/20..13

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

The Director-General

Brussels, 25 NOV. 2013
RTD/DDG3/F3/LM/IP/tj
rd.ddg3.f.3(2013)3656374

Dr Giorgio Palù
President
Department of Molecular Medicine
Padova University
Clinical Microbiology and Virology
Padova University Hospital
Via A. Gabelli, 63
I-35121 Padova
Italy

Dear Professor Palù,

I would like to thank you for your letter of 16 October 2013 related to 'dual use research' and addressed to President Barroso, who has asked me to reply on his behalf.

In your letter, written on behalf of the European Society for Virology (ESV), you describe in detail the recent Dutch court decision of 25 September 2013 on the licensing of H5N1 export. I agree that the H5N1 court case touches on sensitive issues such as academic freedom and freedom of publication. However, it has also created a window of opportunity for a debate on dual use research, export control regulations and the need to take account of security considerations within the scientific community and with policy makers.

The control of 'export' of dual-use goods and technologies is regulated under Council Regulation 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items, adopted on 5 May 2009[1]. Dual use goods and technologies are defined in the regulation as products and technologies which are normally used for civilian purposes but which may have military applications, including in particular in relation to the proliferation of Weapons of Mass Destruction. Controls apply not only to the export of goods, but also to intangible transfers of technology, which may, in certain circumstances, concern dual use research.

In this context I would like to underline that export controls do not aim at preventing 'trade' or in this case, research. Controls are defined in such way as to minimise disruptive effects on legitimate activities, including research activities. This approach is illustrated by the clear exemptions provided in the above regulation for 'basic scientific research' and information 'in the public domain'. Moreover, as mandated under Regulation 428/2009, the Commission is currently conducting a review of its export control policy, and has recently adopted, on 16 October 2013, a report to the Council and European Parliament on the implementation of the export control regulation

[1] published in the Official Journal of the European Union on 29 May 2009, L 134

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: CDMA 02/152 - Tel. direct line +32 229-52883

Ine.matthiessen@ec.europa.eu

(COM(2013) 710 final). This review process will be an opportunity for adjustments and improvements to the current EU export control policy thus also providing an opportunity to address dual use research related matters. On the basis of this review process the Commission will adopt in 2014 a communication with options for a new EU export control strategy.

As regards your suggestion related to the establishment of an independent scientific advisory body for biosecurity including dual use research, similar to the U.S. NSABB, I recognise the need to develop outreach and guidance for the scientific community, and would like to assure you that these issues will be considered in the context of the on-going export control policy review.

Finally, I fully agree with you on the need to avoid negative consequences for individual European scientists and to avoid the risk that European research loses its competitive edge. Horizon 2020, the new EU Framework Programme for Research and Innovation for the years 2014-2020 plans to provide practical guidance through a 'dual use toolkit' accessible via the Participants Portal when the first Horizon 2020 calls for proposals are launched. In addition, and as mentioned above, the current review of the EU export control system should be an opportunity to revisit the role of research under this regime. Taken together, these measures represent an important step towards our common goal of ensuring the best possible conditions for research and innovation in Europe.

Yours sincerely,

Robert-Jan Smits

For the Director General absent
W. BURTSCHER
Deputy Director General

Copy: Mr John Ryan, DG SANCO
Mr Germain Thinus, DG SANCO
Ms Ditte Juul-Joergensen, DG TRADE
Mr Stephane Chardon, DG TRADE
Ms Ruxandra Draghia-Akli, DG RTD

From the letter

«…I would like to underline that export controls do not aim at preventing «trade» or in this case research

The Commission is currently conducting a review of its export control policy and has recently adopted, on 16 October 2013, a report to the Council and European Parliament on the implementation of the export control regulatio (COM(2013) 710)

This review process will be an opportunity for adjustments and improvements to the current EU export control policy thus also providing an opportunity to address dual use reasearch related matters.

On the basis of this review process the Commission will adopt in 2014 a communication with options for a new EU export control strategy….»

The Royal Society meeting on GOF

- Date: 16 December 2013

- Participants: Sir Roy Anderson, Professor Hans Dieter Klenk, Lord Robert May FRS, Professor Thomas Mettenleiter, Professor Tony Minson, Professor Richard Moxon FRS, Professor Giorgio Palù, Professor Philippe Sansonetti, Sir John J. Skehel FRS, Professor Simon Wain-Hobson

- Main recommendations:
  - The term «gain of function» is not appropriate
  - Regulation of experiments should be considered during initial stages of application for support….
  - Greater discussion and debate….would generally be welcomed.
  - Influenza is only one field which must deal with these issues

Regulating dual-use research in Europe. Science. 2014 Jan 24;343(6169):368-369

Palù G.

ESV's position stems from **the concern** that results from scientific work carried out in Europe on these organisms would require **an export permit before they can be published in international scientific journals.**

This prospect raises a number of serious issues. Under what circumstances should this EC regulation be applied to biomedical research? **Who is going to decide when the EC regulation does or does not apply**? What should be considered "basic scientific research," **and who is going to judge this criterion**? (This is not a trivial question, especially in the European Union context, where, in theory, there might be 28 different interpretations of the same regulation.) Does this create the potential for discrimination among scientists working in different European States and between European scientists and those in the rest of the world? Does this decision apply only when specific results are going to be published in journals outside Europe, or does it apply universally?

It may be that controversial questions **related to this issue were ignored for too long**, allowing a precedent to be set prematurely. We are overdue for discussions on **how to regulate the dissemination of "sensitive" data in a way that does not compromise biosecurity, while maintaining the principle that acquiring important and meaningful knowledge cannot simply be stopped. ESV believes that export control does not represent the best way to deal with this issue.**

Our **intention is not to criticize or to disregard the work of jurisprudence experts.** We believe that the **European Commission should take steps to promote a common understanding of the current regulation by existing working groups or by a new advisory committee** created to deal with the dual-use research in a harmonized and balanced way throughout Europe. In the meantime, we have expressed our willingness to provide law officers with proper scientific advice, making available the expertise of our many European scientists.

The issue

*How to regulate the dissemination of "sensitive" data in a way that **does not compromise biosecurity**, while maintaining the **principle that acquiring important and meaningful knowledge cannot simply be stopped***

*ESV believes that **export control does not represent the best way to deal with this issue***

GOF applied to potential pandemic pathogens is a case of potential «**Dual Use Research**»

Dual use research of concern

Dual use research: “research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment, or materiel’’ (National Science Advisory Board for Biosecurity 2008)

- Research on «Potential Pandemic Pathogens» is assessed in the context of DURC
- Council Regulation (EC) No 428/2009: «setting up a Community regimen for control of export, transit, brokering of dual use items»
- This regulation deals with the **post-experimental phases** and cannot be exhaustive

Dual Use Dilemma

Should I, as a scientist, perform a certain experiment whose results might be misused? ⇨ An (inherently) *ethical* dilemma concern with values, benefits, harms, duties

Ethics is also dual

Pursuing GOOD can produce HARM. It is intended that pursuing HARM is not allowed

Ethical questions and answers can change (different stakeholders, different social and historical setting….)

Dual use dilemma is an ethical dilemma

Promoting good in the context of potential harm

- **For researchers**: potential «malevolent» actions of *others*
  - Intended outcomes
  - Unintended but forseen outcomes
  - Unforseen outcomes
- **For private and public institutions**: academic freedom, dissemination of research findings, funding
- **For private companies**: free enterprise, profit
- **For military services** (NBACC ➡ offense vs defence)
- **For international bodies (**WHO, EU ➡ policy, funding**)**

From Ethics…

Socrates (αρετη, σοφια), Plato (ἀγαθόν εἶδος), Aristoteles (εὐδαιμονία)

Saint Agostine (responsability , charity)

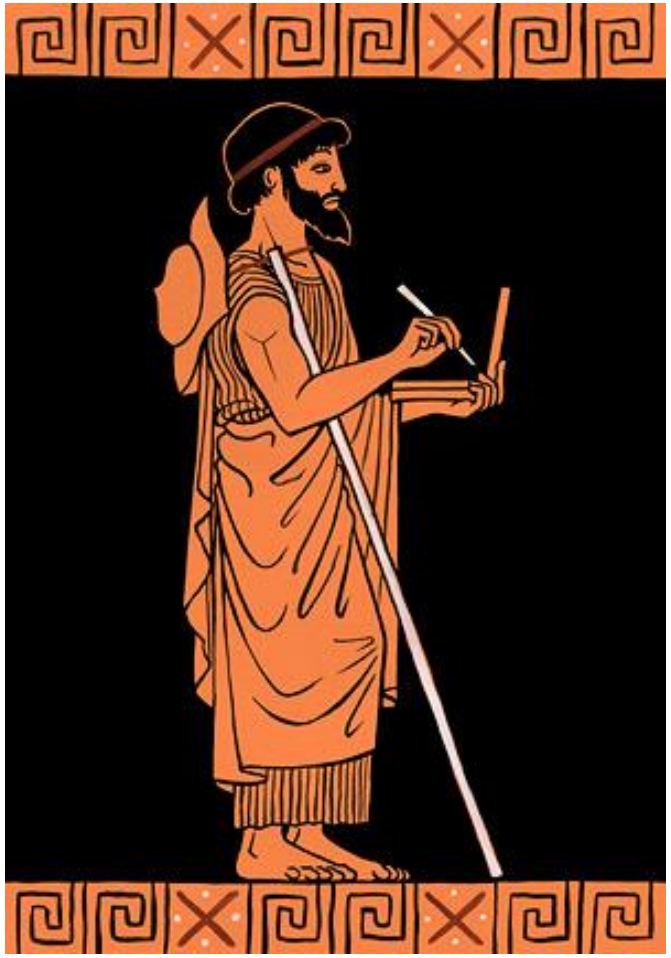
Kant and illuminism

> Humans are bound, from a knowledge of their duty as rational beings, to obey the categorical imperative to respect other rational beings

Utilitarianism (Mills)

….To Bioethics

Van Potter 1970



Herodotus, c.500 BC

Ancient Sages' Wisdom

"A decision was wise, even though it led to disastrous consequences, if the evidence at hand indicated it was the best one to make; and a decision was foolish, even though it led to the happiest possible consequences, if it was unreasonable to expect those consequences"

Risk/Benefit analysis…but what is «risk» and what is «benefit»

Risk: *ρισικον (chance), riscus or ριθα (rish)*

➡ *Dissemination of highly pathogenic microrganisms*

➡ *Harm*

Benefit: *bene facere* ➡ *Aids for health (vaccine, drugs, pandemic preparedness, diagnostic tools)*

➡ *Knowledge itself (Ulixes myth from Dante's Divine Comedy)*

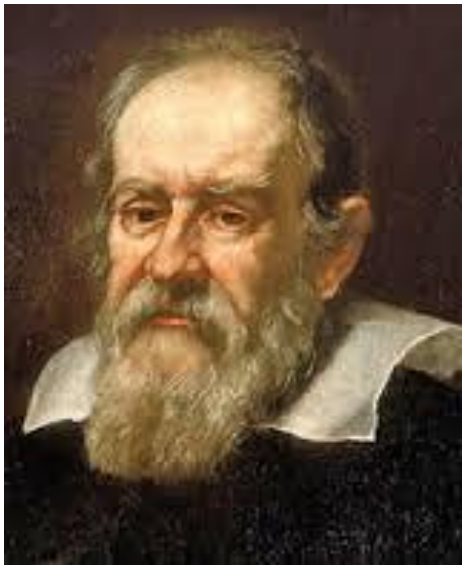
➡ *Good*

From Philosophy
to Natural Philosophy
to Science

Science derives from the late latin «Scientia» = «Knowdledge»

used to be «τα φυσικα» or «de rerum natura»

New Knowledge ➡ controversy



Galileo Galilei introducing the scientific method in natural philosophy dissertation

From the Dialogue Concerning the Two Chief World Systems:
«*Philosophy is written in this grand book, the universe, which stands continually open to our gaze. But the book cannot be understood unless one first learns to comprehend the language and read the letters in which it is composed. It is written in the language of mathematics, and its characters are triangles, circles, and other geometric figures... Without these, one wanders about in a dark and obscure labyrinth*»

The Galileo's podium at the University of Padova

Universa Universis Patavina Libertas: the Academic freedom motto

When applied to Microbiology….

From «The Betrothed» of A. Manzoni, Don Ferrante about the Plague

*«The plague contagium is not **substance** nor is it **accident**, it is not **matter** nor **spirit**, thus it cannot exist»*

***Formal logics** according to Aristotele*

But prevention needs knowledge

"When meditating over a disease, I never think of finding a remedy for it, but instead, a means of preventing it" ***L. Pasteur (1884)***

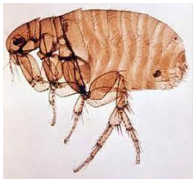
Prevention in place before vaccines

The Plague doctor

"*The nose half a foot long, shaped like a beak, filled with perfume with only two holes, one on each side near the nostrils, but that can suffice to breathe and to carry along with the air one breathes the impression of the drugs enclosed further along in the beak. Under the coat we wear boots made in Moroccan leather (goat leather) from the front of the breeches in smooth skin that are attached to said boots and a short-sleeved blouse in smooth skin, the bottom of which is tucked into the breeches. The hat and gloves are also made of the same skin… with spectacles over the eyes*”

Prevention in place before vaccines

Lazzaretto and quarantine



Plague epidemics in Venice, 1630

The «Lazzaretto» island (the quarantine island)

Controversial scientific topics

Some examples in «Biology»

Genetic modified microorganisms → Recombinant DNA technologies: ONGOING DEBATE

Gene Therapy → the case of Jesse Gelsinger and of insertional oncogenic transformation: ONGOING DEBATE

Embryonic stem cells research: ONGOING DEBATE

Human genome cloning: ONGOING DEBATE

Syntetic biology: ONGOING DEBATE

Gain of function experiments ACCEPTED FOR MANY FIELD OF RESEARCH, **under debate** for understanding pathogens' virulence, transmissibility, fitness…. OUR DEBATE

Ongoing debate around human cloning

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General Assembly ban on all human cloning to be reconsidered by UN ethics panel

13 October 2008 – The permissibility of therapeutic cloning will be the focus of a United Nations ethics panel later this month when it considers whether a non-binding General Assembly declaration calling on Member States to ban all forms of human cloning should be reassessed in light of scientific, ethical, social, political and legal advances.

In 2005 the Assembly declared all cloning incompatible with human dignity and protection of life, voting 84 in favour, 34 against, 37 abstaining and 36 absent, after a decade of work on reproductive cloning by the International Bioethics Committee (IBC) of the UN Educational, Scientific and Cultural Organization (UNESCO).

Now the IBC will debate the issue anew at a two-day meeting at UNESCO headquarters in Paris beginning 28 October, noting that some people, mainly scientists, are urging a different approach to therapeutic cloning.

"Recent technological developments and new prospects for the use of stem cells in the therapy of human diseases have once again raised the issue of adequacy of international regulations governing this research," an IBC working group set up at the request of UNESCO Director-General Koïchiro Matsuura said in a report in September.

The report noted that the main point of contention in the 2005 Declaration was the question of linking the issues of reproductive and non-reproductive cloning, which was not agreeable to many States who abstained or voted against.

"Scientists have an obligation to do no harm. They should always ***take into consideration the reasonably foreseeable consequences of their own activities***" **The Nuremberg Code**

"The experiment should be such as to ***yield fruitful results for the good of society****, unprocurable by other methods or means of study, and* ***not random and unnecessary in nature***" **The Nuremberg Code**

Who is going to decide?

Examples of DURC research

- The mousepox virus experiments (JVI 2001)
- The project Jefferson (*B.cereus-anthracis* September 2001)
- The sequence of the SPICE protein of the small pox virus (PNAS 2002)
- Accidental generation of a virulent form of *Mycobacterium tubercolosis* (PNAS 2003)
- Smallpox-Ebola chimera (US Biodefence)
- Entire sequence of *B.anthracis* (Nature 2003) and of 1918 H1N1 (Nature 2005)
- «Resurrection» of 1918 H1N1 by reverse genetics (Science 2005) (the NSABB evualuated the paper before publication and concluded that the scientific benefits far outweighed the potential risk of misuse)
- Synthetic syntesis of a poliovirus (Science 2002)

Experiments of concern: not only GOF on H5N1!

- How to render a vaccine ineffective
- Confer resistance to abtibiotics and antiviral agents
- Enhance the virulence of a pathogen, or render a non-pathogen virulent
- Increase the transmissibility of a pathogen
- Alter the host range of a pathogen
- Enable the avasion of diagnosis and/or detection
- Enable the weaposization of a biological agent or toxin
- Genetic sequencing of pathogenic microrganisms
- Synthesis of pathogenic microrganisms
- Experiments with smallpox virus
- Attemps to recover/revive past pathogens

From Miller & Selgelid Sci Eng Ethics, 2007 13:523-580

The Ebolavirus paradox in the GOF debate at the Royal Society (December 2013)

- Hans Dieter Klenk: Ebola already weaponised for military purposes

- John James Skehel: GOF applied to Ebola might still be useful if one could predict natural emerging variants by NGS

RISK? BENEFIT?

Who is going to decide?

These different controversial scientific topics rise the same ethical questions and need the same answers?

Is human cloning comparable to GOF applied to potential pandemic pathogens?

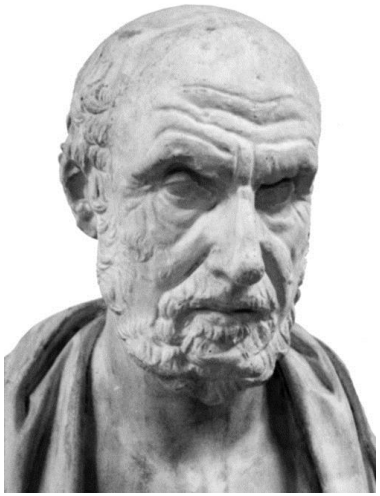
Who is going to decide?

Too limited attention so far to the ethics of scientific experiments that might be risky but do not immediately involve **human participants** (Nuremberg Code)

Council Regulation (EC) No 428/2009 cannot be the only answers ➡ **code of conducts? Hippocrates oath for scientist?**

Lessons from Medical Science

- Long history/experience with codes of conduct:
  - Hippocratic Oath
  - Codes of Medical Associations (e.g., AMA and WMA)
  - Nuremberg Code
  - Declaration of Helsinki
    - →Extremely influential
    - →Largely effective guide to action



Hippocrates

Gain of function based experiments

"Gain of function experiments, the logical counterpart of knockouts, are performed to finely establish the function of a specific gene"

- Are they needed?
- Are they useful?

- Mechanisms of oncogenesis (Ras, cMyc, Src, p53, p63…)
- Embryogenesis
- …..

Gain of function or gain of pathogenicity?

The «special» case of pathogens

Any time we manipulate a microbial genome we could potentially alter the microrganism's pathogenicity (i.e. Shimono et al, PNAS 2003)

Even «wild-type» pathogens handled under controlled and high standard biosafety and biosecurity conditions might pose risk (**June 2014 possible anthrax exposures of 75 CDC staff members**)

The problem is not confined to influenza virus (Ebolavirus, HIV….), and is not confined to Virology (*Clostridium botulinum*….)

HOWEVER

The risk might be higher for studies aimed at the development of predictive parameters for assessing:

- the risks associated with emergent virus strains
- the outcome of vaccination

The risk might be higher when the experiments are conducted on **Potential Pandemic Pathogens**

GOF on PPPs: open questions

- Are these studies useful?
- Are there methodologies alternative to GOF to understand virulence, transmissibility, pathogen fitness and adaptation?
- Can we design universal vaccines and efficient therapeutic strategies without this knowledge?
- What could tell us a risk/benefit analysis and who should carry it on?
- Should we wait for an highly aggressive pathogen to emerge in the human population or should prepare ourself to fight it?
- **Key question**: HARM for humankind?

- Scientific, regulatory and ethical questions (not only for scientists)

Risk-benefit analysis

- **GOOD:** useful to «prevent» or «foresee» the onset of pandemics; useful to develop vaccines; useful to develop drugs???? If there is not a clear demonstration of these «benefits» there is not a prove against them

- **HARM:** dissemination of highly pathogenic viruses intentionally by «others» or by mistake ??? Reproduction of these data by bioterrorists??? These events are possible (as in the case of previously published DURC researchs) but …. the generated H5N1 is really highly pathogenic????

Who is going to decide?

Some answers

Cell

Volume 157, Issue 2, 10 April 2014, Pages 294–299

Essay

Peering into the Crystal Ball: Influenza Pandemics and Vaccine Efficacy

Matthew S. Miller[1,] , Peter Palese[1, 2,]

- *Understanding how factors such as virulence, transmissibility, and viral fitness intereconnect will require GOF experiments*

- *GOF experiments are (AND HAVE ALWAYS BEEN) fundamental pillar of scientific inquiry and are essential to the rigorous execution of scientific method*

- *Ironically the only way to address the uncertainty is* ***to move forward with GOF studies*** *that will serve to contextualize how adaptations that mediate mammalian transmissibility affect other property of the virus (such as the dramatic reduction in virulence observed by Fouchier group)*

Alternative approaches to studying human adaptation of influenza A viruses, and more generally to improving vaccines and therapeutics.

Approach	Examples	Scientific Benefits
Molecular dynamical modeling of influenza proteins and interactions with inhibitors and receptors	Analysis of adaptive changes in HA of H1N1pdm [74], lipid tail protrusion as a determinant of HA–membrane fusion [75], and identifying determinants of inhibitor-resistant NA [76]	Biophysical basis for complex phenotypes
In vitro studies of specific properties required for human adaptation, using single proteins	Studies of H5 or H7 receptor binding to mammalian versus human sialic acids [50,77]; studies of genetic determinants of optimal pH of fusion by comparing properties of natural isolates [11]	Higher throughput than in vivo studies; can study more sequences and define motifs required for binding, beyond individual mutations; ability to assess generality of hypothesized determinants [54]
In vitro studies of genetic interactions between loci in one or several viral proteins using replication-incompetent viruses	Studies of epistatic interactions in nucleoprotein [51] or between nucleoprotein and polymerase [78] based on in vitro expression of markers and stability measurements of proteins	Higher throughput; ability to link structure to function; ability to test combinations of mutations
Sequence database comparisons of genetic properties of human- and avian-adapted viruses	Identify amino acid markers of host adaptation and quantify the extent of adaptation to a particular host [79,80]; search for markers of human adaptation (established from earlier studies without PPP production) in H7N9 viruses [63]	Very high throughput; future studies could use novel analytic methods [81] to systematically identify new markers associated with human adaptation, which could then be tested experimentally; focus on naturally viable mutations
Sequence and in vitro phenotypic comparisons of human seasonal influenza isolates, zoonotic isolates from infected humans, and avian isolates	Comparison of human and avian isolates of H7N9 [82]; comparison of viral shedding in ferrets of human seasonal and pandemic versus avian H5N1 viruses [83]	Focus on naturally viable variants; higher throughput; ability to test a wide range of phenotypes
Experimental production and evaluation in animal transmission models of reassortants or mutants of seasonal influenza to identify genetic components required for transmissibility, maintaining surface proteins to which human immunity exists	Replacing M segment of H3N2 and H1N1 strains with one from H1N1pdm to assess effect on guinea pig transmission [84]; ferret transmission assays of recombinant H1N2swine × H1N1pdm viruses to determine role of HA-NA balance [85]	Human transmissibility of parent viruses provide "natural" validation of animal model
Universal or broadly neutralizing influenza vaccine research	HA stalk vaccines [86,87]; enhancing responses to conserved proteins [88]; T cell vaccination and improved adjuvants [89]; targeting universal NA epitopes [90]	Successful vaccine could eliminate need for rapid production of pandemic-specific vaccine and seasonal revaccination; complementary technology to other approaches
Studies of host factors using naturally occurring viruses	Identification of host factors restricting pathogenicity in animal models, in vitro, and via human genetics [91]	Potential therapeutic targets identified
Accelerating vaccine production	Sequence-based design and cell culture manufacture of influenza vaccine [92]	More rapid manufacture

HA, hemagglutinin; NA, neuraminidase.
doi:10.1371/journal.pmed.1001646.t002

Lipsitch M, Galvani AP (2014) Ethical Alternatives to Experiments with Novel Potential Pandemic Pathogens. PLoS Med 11(5): e1001646. doi:10.1371/journal.pmed.1001646
http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1001646

PLOS | MEDICINE

The route to biomedical research: a case of responsability

- Writing a scientific proposal
- Discussing risk/benefit when pertinent
- Assessing biosecurity & biosafety issues according to current legislation (GMO, BSL, Council Regulation 428/2009)
- Having approval from local/regional/national authorities
- Having approval from a peer panel

- Risk of accidental or deliberate release, risk of misuse of the results: how big are these risks? How can they be avoided?
- Once again GOF on PPPs is a complex issue which should be **OPENLY discussed and APPROPRIATELY regulated**

Options for the regulation of dual-use experiments

- Complete autonomy of the individual scientist
- Institutional Control
- A dual system: Institutional and Governamental Control
- An independent Authority
- Governamental Control

From Miller & Selgelid Sci Eng Ethics, 2007 13:523-580

ESV's proposal

- Quantitative risk–benefit analysis carried on by an **ad hoc independent board**

- Setting up of an European National Science Advisory Board for Biosecurity with the involvement of:
  - Scientists
  - Policy makers
  - Biosecurity and biosafety experts
  - Civil servants
  - Civil society

From Mr. Barroso's answer to ESV

"…As regards your suggestion related to the establishment of an independent scientific advisory body for biosecurity including dual use research, similar to the U.S. NSABB, I recognise the need to develop outreach and guidance for the scientific community and would like to assure you that these issues will be considered in the context of the ongoing export control policy review.

Finally I fully agree with you on the need to avoid negative consequences for individual European scientists and to avoid the risk that European research loses its competitive edge.

Horizon 2020,……., plans to provide a practical guidance through a «dual use toolkit» accessible via the Participants Portal……."

Conclusions

Medicine (and Biomedicine) will always be funded on a dual nature, Science and Humanism, which are reciprocal in essence