KING'S College LONDON

Department of Social Science, Health & Medicine www.kcl.ac.uk/sshm

CRISPR Genome Editing Technologies: Bioethics and Biopolitics in the UK and US

Dr Silvia Camporesi

April 28th, 2016

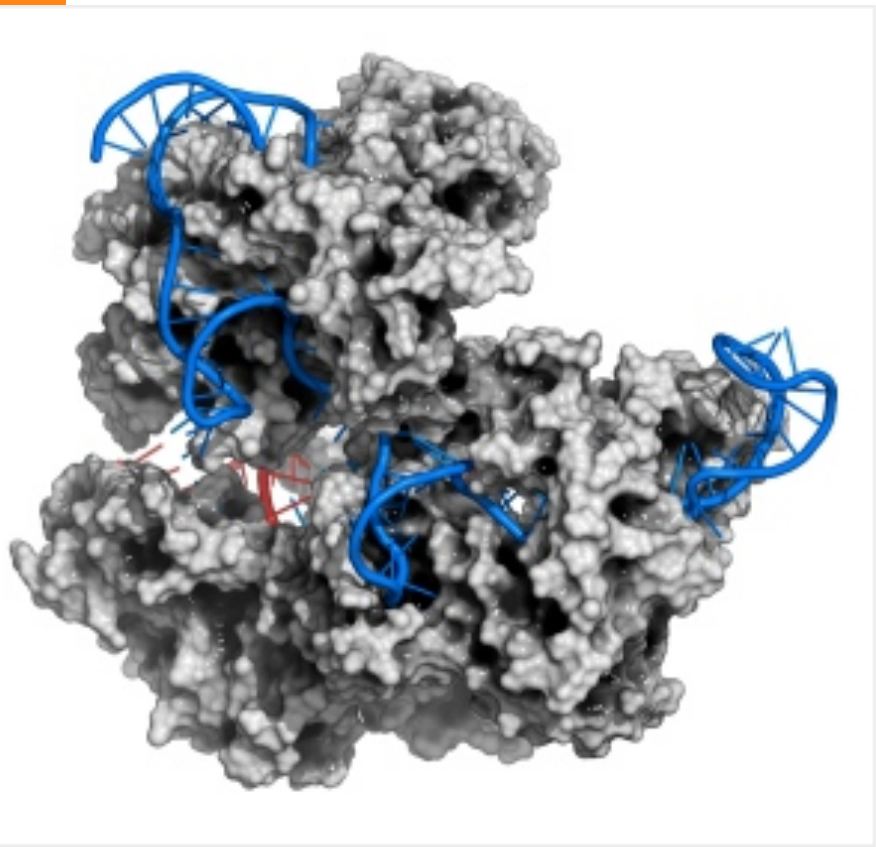
Ethics at Noon Seminar Series

Markkula Centre for Applied Ethics at Santa Clara University

Outline

- Presentation of CRISPR bioethics debate in UK and US
- Regulation of Embryo Research in the UK
- Ethical and political significance of somatic-germ line distinction in UK/US and challenges thereof
- Way forward in ethics and policy making?

CRISPR mediated genome editing



MOLEKUUL/SCIENCE PHOTO LIBRARY

The gene-editing technique CRISPR uses an enzyme (white) and RNA guides (blue) to cut DNA at a point specified by a DNA fragment (red).

- **Very efficient, highly versatile, cheap and ubiquitously used in labs worldwide**
- RNA-guided **genome editing tool** consisting of naturally occurring clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated (Cas) nucleases
- The nucleases (i.e. molecular scissors) can **target to a specific locus** in genome and generate DNA **double-strand breaks** at high efficiency in numerous sites in all eukaryotic genomes

CRISPR Applications:

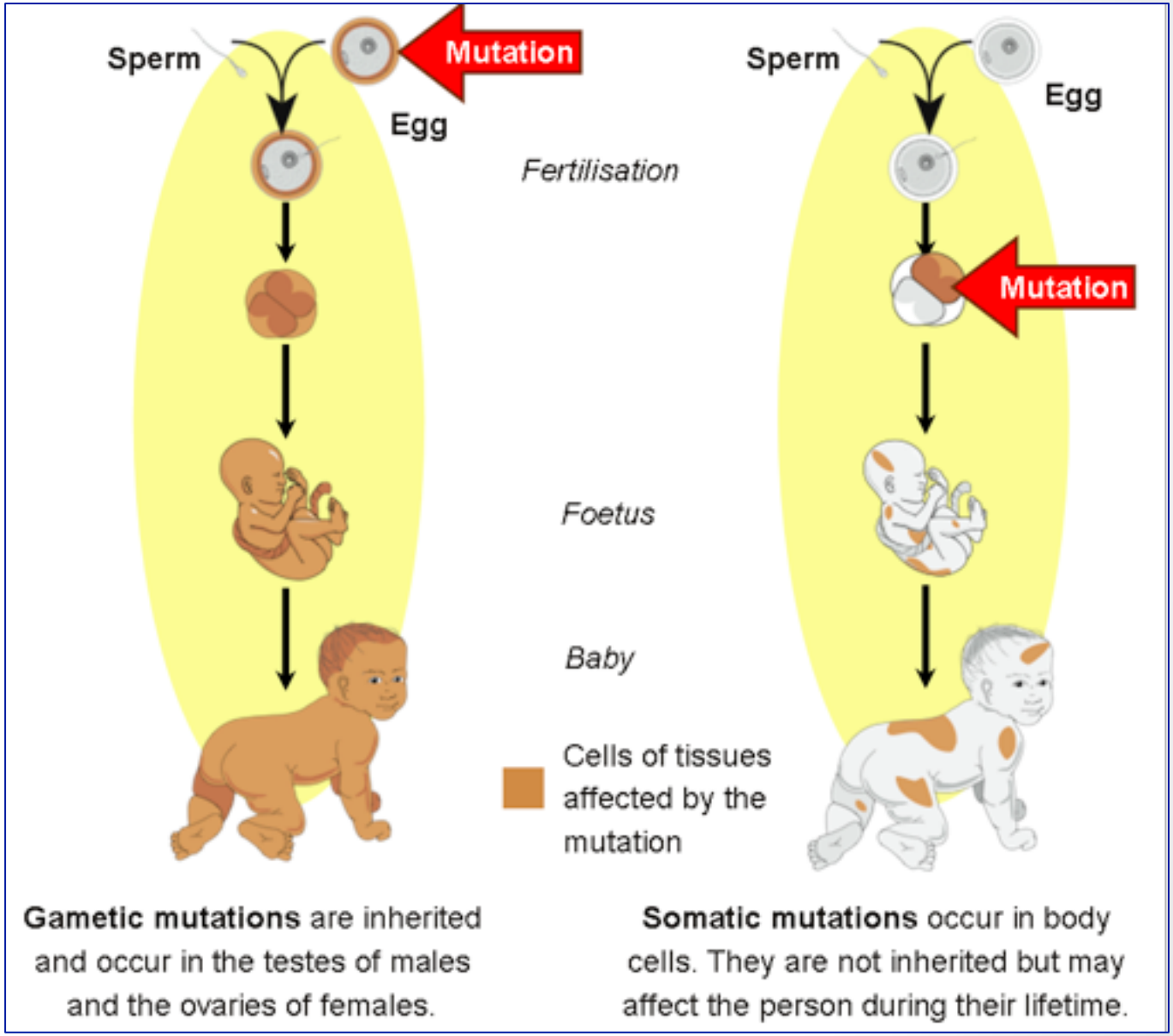
a. *Red Biotechnology: Gene Therapy (Somatic/Germ-Line) to cure genetic disorderers, combined with Induced Pluripotent Stem cells (iPSc) ; humanised animal models for organ transplant*

b. *Green Biotechnology: Engineered crops for food consumption; engineered mosquitos to eradicate diseases*

Somatic vs germline genome editing

In **somatic editing**, altered DNA sequence would only affect the treated individual.

In **germ-line editing**, the individual's gametes (reproductive cells, sperm cells and oocytes) would carry the modified sequence as well, which would therefore be transmitted to offspring/ future generations



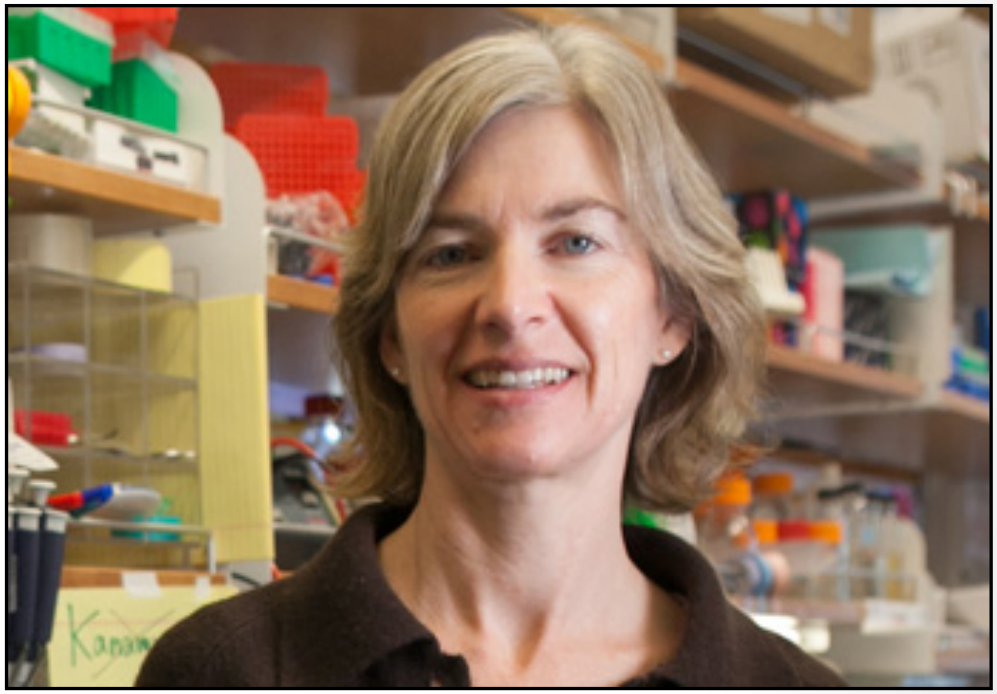
In the US: The actors involved (1)

rna.berkeley.edu

THE DOUDNA LAB

Exploring molecular mechanisms of RNA-mediated gene regulation

DOUDNA RNALAB



November 2014: **Jennifer Doudna** and **Emmanuelle Charpentier** receive $3 million *Breakthrough Prize* for developing CRISPR technology

In the US: The actors involved (2)

In the past few years, the use of CRISPR has exploded. On Wednesday, all five of the scientists announced as winners of the 2016 Canada Gairdner International Award—a prestigious $100,000 prize that's often called a precursor to winning the Nobel—worked on CRISPR's development: the others were Jennifer Doudna, Emmanuelle Charpentier, Philippe Horvath and Rodolphe Barrangou. (Anthony Fauci received the

McGovern
Broad MIT

Research Team

Feng Zhang, Ph.D.
Principal Investigator
zhang_f at mit.edu

http://linkis.com/motherboard.vice.co

Where and when the debate started:

1st publication of CRISPR/Cas9 application in (non-viable) human embryos in China, April 2015

Protein Cell 2015, 6(5):363–372
DOI 10.1007/s13238-015-0153-5

CrossMark Protein & Cell

RESEARCH ARTICLE

CRISPR/Cas9-mediated gene editing in human tripronuclear zygotes

Puping Liang, Yanwen Xu, Xiya Zhang, Chenhui Ding, Rui Huang, Zhen Zhang, Jie Lv, Xiaowei Xie, Yuxi Chen, Yujing Li, Ying Sun, Yaofu Bai, Zhou Songyang, Wenbin Ma, Canquan Zhou✉, Junjiu Huang✉

Guangdong Province Key Laboratory of Reproductive Medicine, the First Affiliated Hospital, and Key Laboratory of Gene Engineering of the Ministry of Education, School of Life Sciences, Sun Yat-sen University, Guangzhou 510275, China
✉ Correspondence: hjunjiu@mail.sysu.edu.cn (J. Huang), zhoucanquan@hotmail.com (C. Zhou)

Received March 30, 2015 Accepted April 1, 2015

NATURE | NEWS

Chinese scientists genetically modify human embryos

Rumours of germline modification prove true — and look set to reignite an ethical debate.

David Cyranoski & Sara Reardon

22 April 2015

The US reaction to Chinese experiment

Don't edit the human germ line

Heritable human genetic modifications pose serious risks, and the therapeutic benefits are tenuous, warn **Edward Lanphier**, **Fyodor Urnov** and colleagues.

http://www.nature.com/news/don-t-edit-the-human-germ-line-1.17111

A self-imposed moratorium?

A prudent path forward for genomic engineering and germline gene modification

By David Baltimore,[1] Paul Berg,[2] Michael Botchan,[3,4] Dana Carroll,[5] R. Alta Charo,[6] George Church,[7] Jacob E. Corn,[4] George Q. Daley,[8,9] Jennifer A. Doudna,[4,10] Marsha Fenner,[4] Henry T. Greely,[11] Martin Jinek,[12] G. Steven Martin,[13] Edward Penhoet,[14] Jennifer Puck,[15] Samuel H. Sternberg,[16] Jonathan S. Weissman,[4,17] Keith R. Yamamoto[4,18]

Recommendations:

1. ***Strongly discourage*** clinical application of this technology
2. Create forums for education and discussion
3. Encourage open research to evaluate the utility of CRISPR-Cas9 technology for both human and nonhuman model systems.
4. Hold an international meeting to consider these issues and possibly make policy recommendations.

In the US: federal ban on CRISPR research on human embryos

Statement on NIH funding of research using gene-editing technologies in human embryos

April 29, 2015

Genomic editing is an area of research seeking to modify genes of living organisms to improve our understanding of gene function and advance potential therapeutic applications to correct genetic abnormalities. Researchers in China have recently described their experiments in a nonviable human embryo to modify the gene responsible for a potentially fatal blood disorder using a gene-editing technology called CRISPR/Cas9.

NIH will not fund any use of gene-editing technologies in human embryos. The concept of altering the human germ-line in embryos for clinical purposes has been debated over many years from many different perspectives, and has been viewed almost universally *as a line that should not be crossed.*

http://www.nih.gov/about/director/04292015_statement_gene_editing_technologies.htm

Dissenting voices: UK (1)

Robin Lovell-Badge
robin.lovell-badge@crick.ac.uk
+44 (0) 20 8816 2126

https://www.crick.ac.uk/research/a-z-researchers/researchers-k-o/r

"I disagree with such a moratorium, which is in any case unlikely to be effective. ***I am fully supportive of research being carried out on early human embryos in vitro****, especially on embryos that are not required for reproduction and would otherwise be discarded. If the techniques work, there are many interesting questions that could be asked about the role of specific genes in early human embryo development"*
http://www.bionews.org.uk/page_519962.asp

Dissenting voices: UK (2)

Director of the Oxford Uehiro Centre for Practical Ethics
Professor Julian Savulescu

*"Far from being wrong, the research by Huang and colleagues is **ethically imperative.** [It] has the potential to provide **permanent cures** for genetic diseases, it also holds the **potential to correct** the genetic contribution to common diseases like diabetes".*

Protein Cell 2015, 6(7):476–479
DOI 10.1007/s13238-015-0184-y

Protein & Cell

PERSPECTIVE

The moral imperative to continue gene editing research on human embryos

Julian Savulescu[1,2], Jonathan Pugh[1✉], Thomas Douglas[1], Christopher Gyngell[1]

[1] Uehiro Centre for Practical Ethics, University of Oxford, Oxford OX1 1PT, UK
[2] Queensland University of Technology, St Lucia, Brisbane, QLD 4072, Australia
✉ Correspondence: jonathan.pugh@st-annes.ox.ac.uk (J. Pugh)

http://blog.practicalethics.ox.ac.uk/2015/04/press-release-the-moral-imperative-to-research-editing-embryos-the-need-to-modify-nature-and-science/

“Round 2” CRISPR in Human Embryos

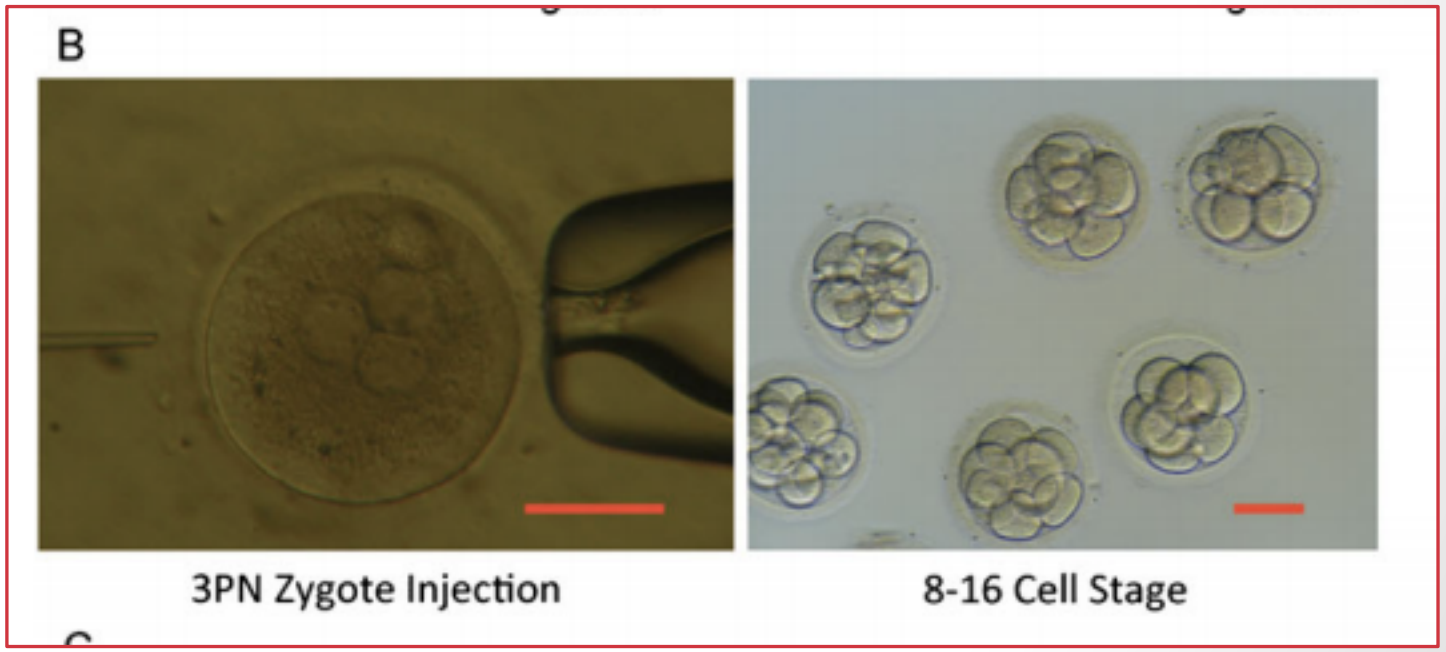
J Assist Reprod Genet
DOI 10.1007/s10815-016-0710-8

TECHNOLOGICAL INNOVATIONS

Introducing precise genetic modifications into human 3PN embryos by CRISPR/Cas-mediated genome editing

Xiangjin Kang[1] · Wenyin He[1] · Yuling Huang[1] · Qian Yu[1] · Yaoyong Chen[1] · Xingcheng Gao[1] · Xiaofang Sun[1] · Yong Fan[1]

April 2016



"Round 2" CRISPR in Human Embryos: Sweden?

- In a Cell paper published in April 2016, Lanner's team (Karolinska Institute) analysed gene expression in 88 early human embryos and is using those data to identify genes to disrupt in embryos using CRISPR–Cas9.
- Lanner will discuss the work at a meeting on human gene editing organized by the US National Academy of Sciences and National Academy of Medicine in Paris (April 28th).

Fredrick Lanner, Karolinska Insittute, interviewed in April 2016

http://www.nature.com/news/gene-editing-research-in-human-embryos-gains-momentum-1.19767#

CRISPR Regulation in Europe

FEAM
Federation of European Academies of Medicine

The Academy of Medical Sciences

Académie Nationale de Médecine

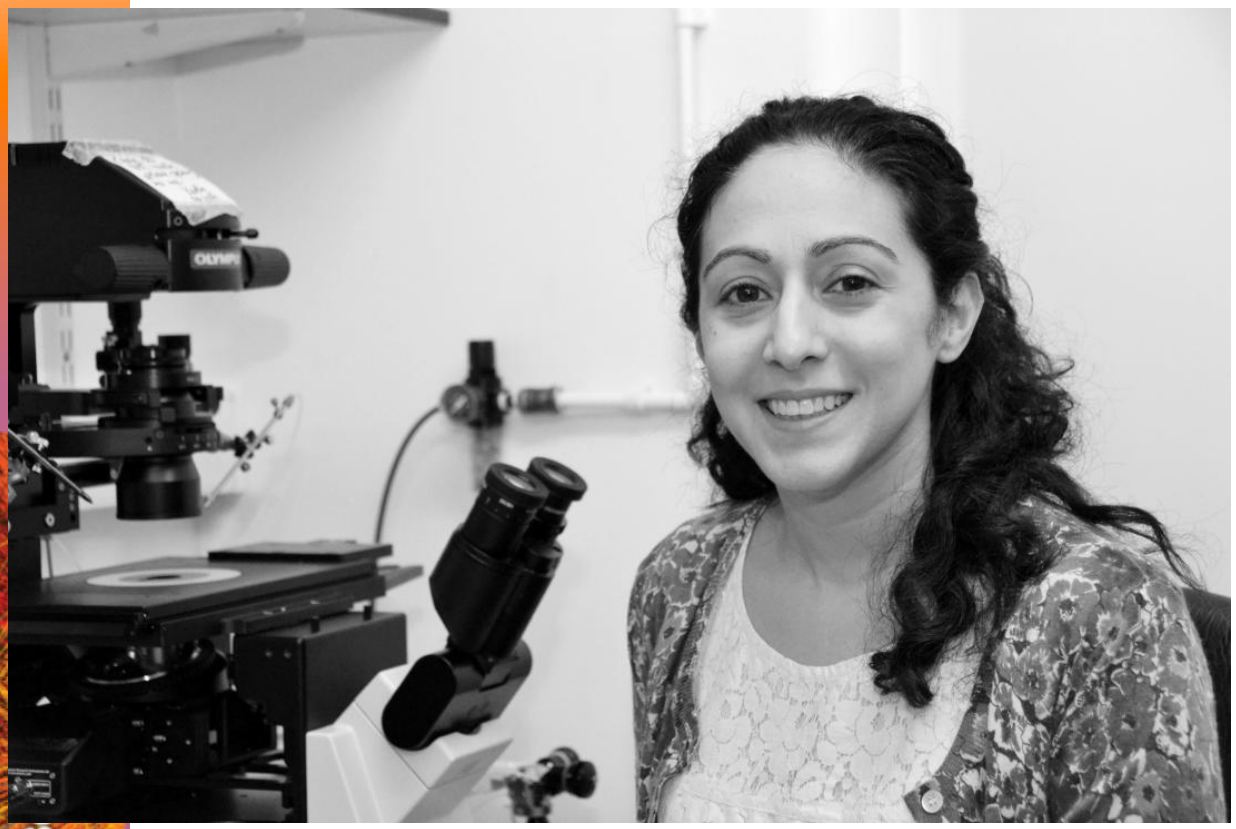
Workshop on human genome editing in the EU

This workshop will consider the landscape for human genome editing in the EU. The objectives of the meeting are to:

- Understand current scientific activities in the EU with respect to genome editing – focussing on human applications.
- Understand the current regulatory landscape for human genome editing research and clinical applications across the EU.
- Understand the ongoing debate on genome editing across the EU.
- Identify any areas where there are significant differences, e.g. between countries, and if possible consider the driving forces for these differences (e.g. ethics, public opinion).
- Discuss the need for a European regulatory framework to govern the safe and acceptable use of human genome editing.

Who is this woman?

Who is this woman?



" Niakan's work will answer previously unanswerable questions about the earliest stages of human reproduction —what makes a healthy embryo, what factors contribute to infertility. Her experiments are settin the stage for a future in which our DNA represents not just our destiny but opportunity as well, a chance to better the human condition—as long as we tread carefully.

TIME 100 PIONEERS

Kathy Niakan

By Jennifer Doudna

April 21, 2016

http://time.com/4301356/kathy-niakan-2016-time-100/

Designer babies?

Home › San Jose Breaking News, Sports, Weather, Traffic › Story

Britain approves controversial gene-editing experiments

By Maria Cheng AP Medical Writer

POSTED: 02/01/2016 02:46:38 AM PST | UPDATED: 3 MONTHS AGO

LONDON (AP) — In a landmark decision that some ethicists warned is a step down the path toward "designer babies," Britain gave scientists approval Monday to conduct gene-editing experiments on human embryos.

The CRISPR revolution seems to be here, is this the coming of eugenics?

by Tyler Cowen on March 25, 2015 at 12:48 am in Current Affairs, Law, Medicine, Science, Uncategorized | Permalink

Regulation of embryo research in the UK

1. CRISPR research on human embryos falls within existing UK regulatory framework
2. In the UK research on human germ-line is allowed *in vitro* within the remit of the law (*Human Embryology Act 1990*) up to 14 days.
3. Embryo transfer to uterus ***NOT permitted.***
4. Each research group working on human embryos needs to apply to the *Human Embryology and Fertilisation Authority* (HFEA) to be granted a specific license
5. Kathy Niakan's application was granted (conditional) approval by the HFEA in February 2016, now awaiting research ethics approval

In the UK: a conditional approval for CRISPR research on human embryos

HFEA approval for new "gene editing" techniques

01 February 2016

The Human Fertilisation and Embryology Authority (HFEA) has approved a research application from the Francis Crick Institute to use new "gene editing" techniques on human embryos.

The aim of the research, led by Dr Kathy Niakan, a group leader at the Crick, is to understand the genes human embryos need to develop successfully.

The work carried out at the Crick will be for research purposes and will look at the first seven days of a fertilised egg's development (from a single cell to around 250 cells).

Human Fertilisation & Embryology Authority

Donor-conceived
people & their parents

Donors
donating for treatment & research

The **Human Fertilisation and Embryology Authority** is the UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research.

The HFEA licenses fertility clinics and centres carrying out in vitro fertilisation (IVF), other assisted conception procedures and human embryo research.

Department
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2. Decision

2.1. The committee agreed to renew the research licence for project R0162 at centre 0246 for a period of three years.

2.2. The committee agreed that, because part of application has not yet had research ethics approval, the following condition will be placed on the licence:

- None of the additional research activities are to be undertaken until approval for them has been obtained from an appropriately constituted research ethics committee and evidence of this has been provided to and acknowledged by the HFEA Executive.

2.3. The licensed activities are:

- keeping embryos
- use of embryos
- storage of embryos

2.4. The committee approved the amendment of the project title to:

- Derivation of stem cells from human embryos: the development of human embryonic stem cell (hES) cultures, characterisation of factors necessary for maintaining pluripotency and specific differentiation towards transplantable tissues.

http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5966

Brief history on regulation of embryo research in the UK

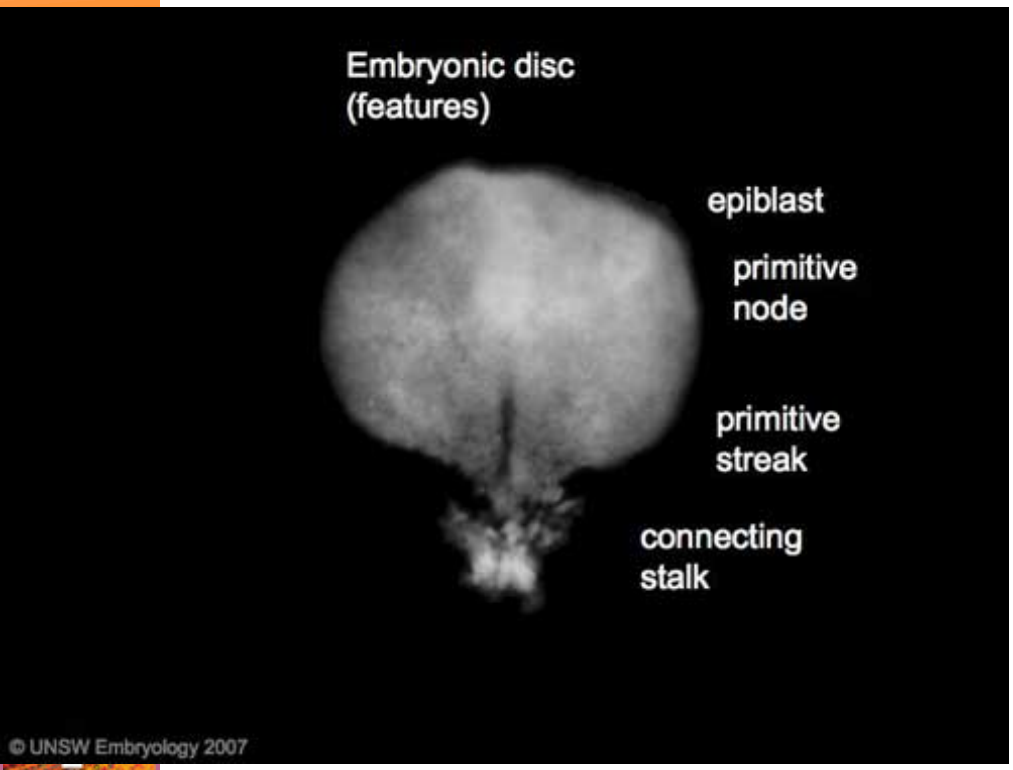
1. The birth of the first test tube baby Louise Brown in the UK in 1978 was the premise for the creation of the Committee for Human Fertilisation and Embryology (also called “IVF Inquiry”) Philosopher Mary Warnock was nominated Chair of IVF Inquiry Committee (1982-1984)
2. The committee responsible for the creation of the 14-days limit cut off for research on human embryos which is still valid day and that led to the establishment of the HFEA

Sunday Telegraph portrait of the British philosopher and bioethicist Mary Warnock, who chaired a government inquiry into human fertilization and embryology between 1982 and 1984.

Mary Warnock and emergence of Bioethics in the UK

1. Warnock's motivation to engage with IVF Inquiry Committee was the belief that refusal to discuss practical issues in philosophy had rendered the discipline trivial: necessary to engage in applied ethics
2. Premise of the work of the IVF Inquiry committee: in a pluralist society there are *incompatible moral premises*. The goal was to reach an acceptable compromise on the basis of *a shared decision making process:*
    1. No "moral experts"
    2. Bioethicist as "midwife" able to reach a middle way between competing interests: the essence is the process

How the 14-days limit came about (1)



Gastrulation is the process when the embryonic inner cell mass divides into three layers one of which (endoderm) differentiates into spinal cord antecedent nervous system

Developmental biologist Anne McLaren was called in and advised on 14-days limit for embryo research:

1. The primitive streak marks the beginning of gastrulation: this can be seen as the beginning of individual development, since it marks the last point in embryonic development in which the embryo can cleave to form twins
2. there is no possibility for the embryo of experiencing pain before the emergence of the nervous system

How the 14-days limit came about (2)

Anne McLaren coined the term "pre-embryo" should be used before the primitive streak form: ethical and political significance

Dame Anne McLaren by Emma Wesley, one of the portraits of female scientists commissioned for Scientists. Photograph: Emma Wesley/Royal Society The Royal Society

" We can for the first time recognise and delineate the boundaries of a discrete human entity, an individual, that can become transformed through growth and differentiation into an adult human being. If I had to point to a stage and say "This is when I began being me", I would think it would have to be here".

The Human Fertilisation & Embryology Act

- Warnock's 14 days recommendation was passed into law in 1990 with the *Human Fertilisation and Embryology Act*
- The HFEA was created to regulate research on human embryos/human embryonic stem cells and assisted reproduction in the UK
- In 2008 the Act was amended to include provisions for human admixed embryos (after the cybrids case)

Human Fertilisation and Embryology Act 1990

http://www.legislation.gov.uk/ukpga/1990/37/pdfs/ukpga_19900037_en.pdf

Human Fertilisation & Embryology Authority

Licence Committee - minutes

Thursday 14 January 2016

HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Centre 0246 (The Francis Crick Institute at Mill Hill) – application for research licence renewal for research project R0162

1.18. The committee was satisfied that the activities to be licensed are necessary or desirable for the following purposes, specified in paragraphs 3A(1) and 3A(2) of Schedule 2 to the Act, for the following reasons:

- developing treatments for serious diseases or other serious medical conditions:

  This study may facilitate, in the long term, the development of treatments for serious diseases or other serious medical conditions. The human embryonic stem cells (hESC) derived may also be used as a drug discovery platform for the testing of drugs and for the future development of GMP hESC which might be used directly in cell replacement therapies.

- increasing knowledge about the development of embryos:

  The genes and proteins the team studies, eg pluripotency genes, and their role in human preimplantation development, may provide insight into the mechanisms of human embryo development.

- promoting advances in the treatment of infertility:

  The committee noted that this was an additional purpose to be added to the research licence. It was satisfied that the genes or proteins the team will be studying may, in the long term, be important in understanding human embryo development and in developing biomarkers of embryonic health which might be used in clinical IVF treatment.

http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5966

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Department of Social Science, Health & Medicine
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Aim 1: Determine the relationship between the cellular and molecular properties of preimplantation human embryos and hESC lines and seek to *functionally test the requirement of human-specific genes during embryonic development, using CRISPR/Cas9 gene-editing techniques CRISPR-Cas9 […]which means that ultimately, we need to test the function of genes directly in the human embryo to determine if they are necessary for development.*

Aim 2: Develop an efficient method to derive and maintain hESCs under defined and animal product-free culture conditions

Aim 3: Develop an efficient method to derive human extraembryonic cell lines as a resource for modelling early development and therapeutic applications (collaboration with University of Cambridge Stem Cell Institute)

http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5966

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http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5966

1.19. The committee was satisfied that the proposed research project does not involve any prohibited activities and specifically would never involve:

- placing in a woman any non-permitted embryos (including embryos which may have been subject to gene editing techniques) or non-permitted eggs or sperm; or,
- keeping or using an embryo after 14 days from creation or the appearance of the primitive streak if earlier than the 14 day period.

1.20. The committee noted that the proposed research does involve the derivation of human embryonic stem cells but that these are not intended for human application.

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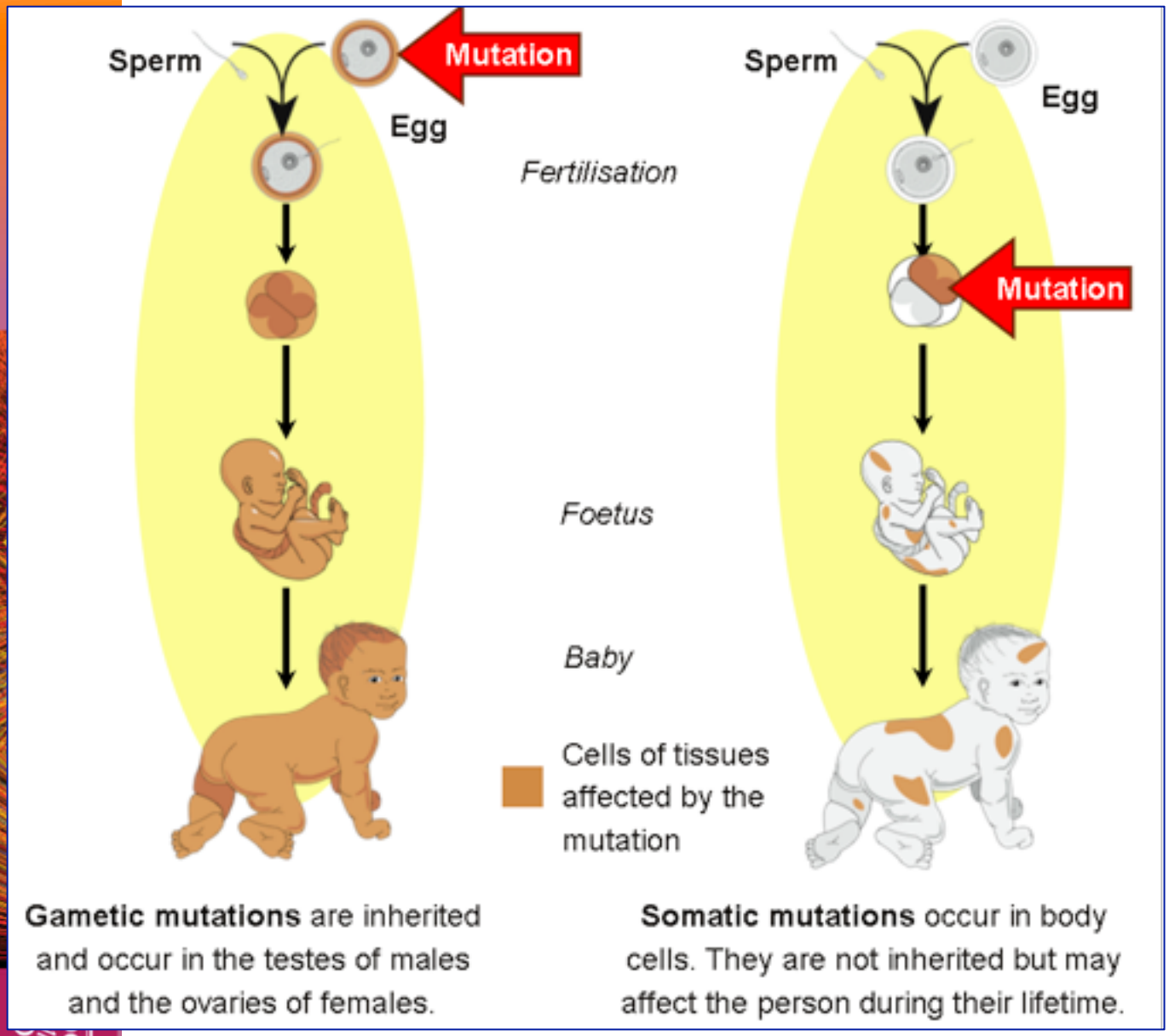
http://guide.hfea.gov.uk/guide/ShowPDF.aspx?ID=5966

Somatic/germline distinction



In **somatic editing**, altered DNA sequence would only affect the treated individual.

In **germ-line editing**, the individual's gametes (reproductive cells, sperm cells and oocytes) would carry the modified sequence as well, which would therefore be transmitted to offspring/ future generations

Significance of somatic/germline distinction

1. The distinction has played a very important ethical and political role from 1982 up to now in US and UK to demarcate permissible from impermissible applications of gene therapy
2. Went hand in hand with therapy/enhancement distinction

United States. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. ***Splicing Life: A Report on the Social and Ethical Issues of Genetic Engineering with Human Beings***. Washington, DC: President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982. 126 p.

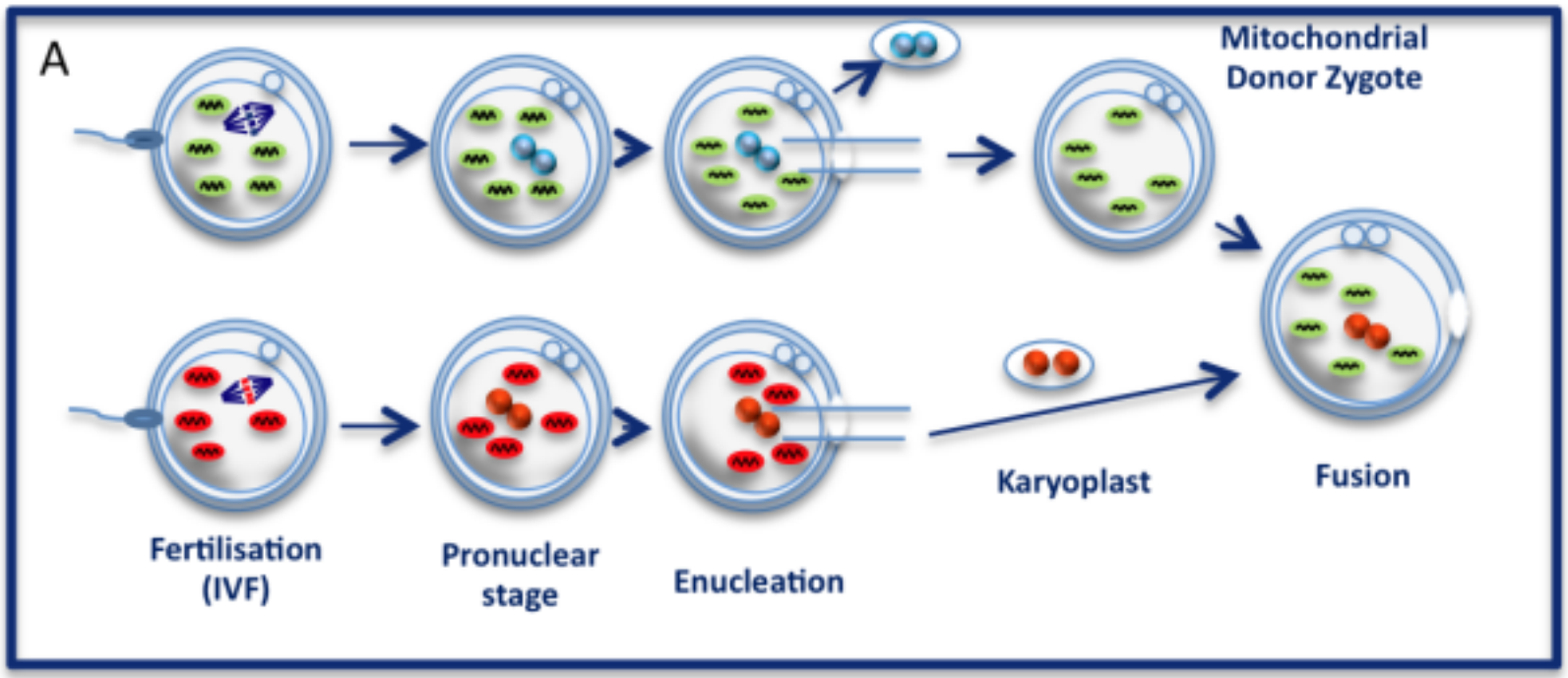
https://bioethics.georgetown.edu/documents/pcemr/splicinglife.pdf

mtDNA transfer technologies: boundary shift?

U.K. Parliament approves controversial three-parent mitochondrial gene therapy

By Gretchen Vogel, Erik Stokstad | Feb. 3, 2015 , 2:00 PM

In February 2015 the UK is the first country to approve a type of germ-line intervention i.e. mitochondrial DNA transfer technologies to be used with IVF to avoid the transmission of mitochondrial related disorders



Somatic/germline distinction in the US

Expert Committee: FDA Should Allow Mitochondrial Replacement Trials Under Certain Conditions

Posted 03 February 2016

Reiterated in recent report (February 2016) published by National Academies of Sciences, Engineering and Medicine advising FDA to approve mtDNA transfer technologies ***only for male embryos.***

Why?

1. To observe the effects of the procedure without risks of being passed to future generations (since mitochondrial are only inherited maternally)
2. To avoid germline modifications which can be seen as a slippery slope to eugenics.

http://www.nap.edu/catalog/21871/mitochondrial-replacement-techniques-ethical-social-and-policy-considerations

Somatic/germline distinction: still relevant?

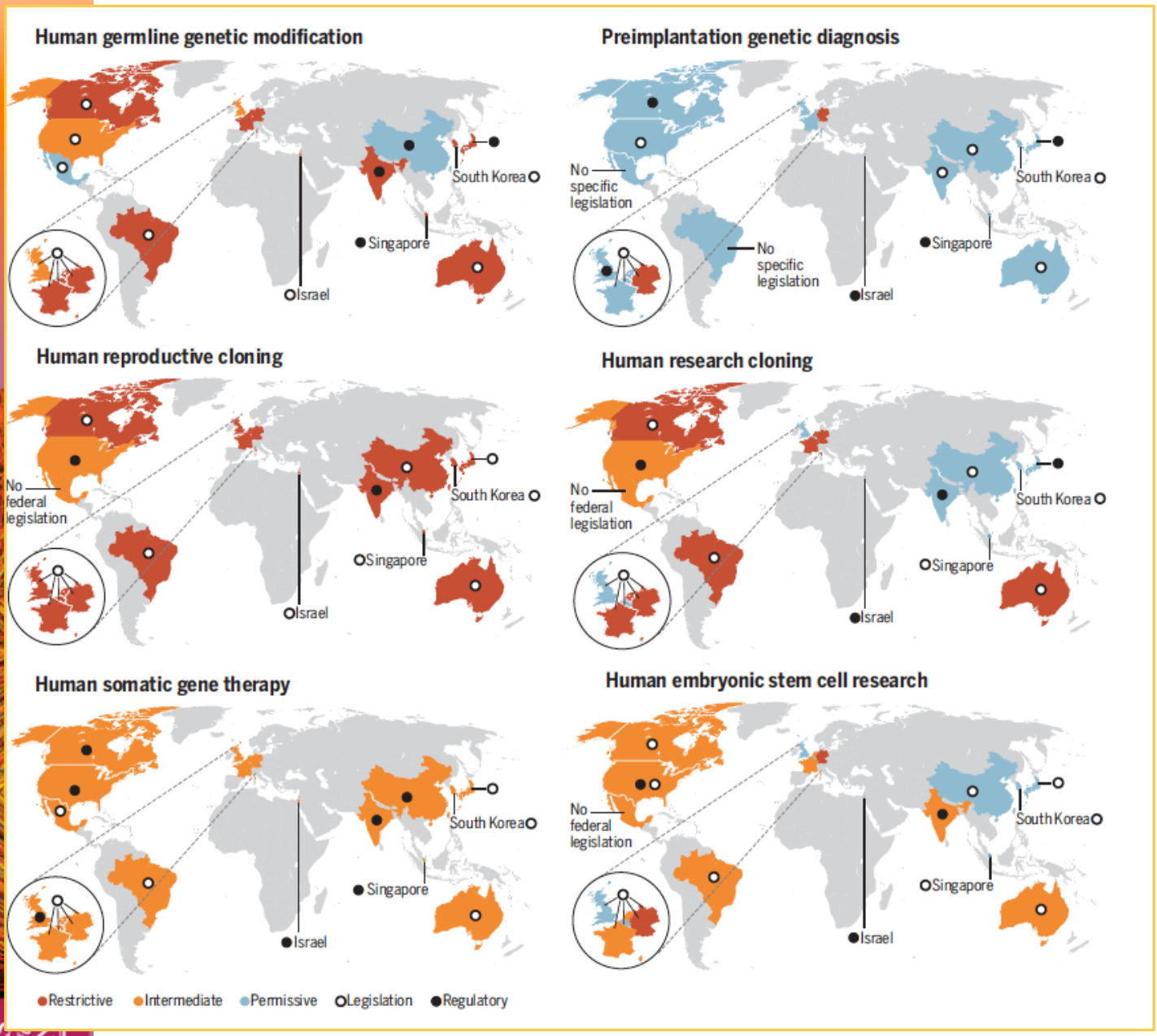
1) This distinction is inscribed also in **UK regulatory documents** (British Medical Association; Committee Ethics Gene Therapy; UK Medicines and Healthcare products Regulatory Agency) and in other regulations worldwide
2) The approval of mitochondrial DNA transfer technologies challenges the continued policy significance of the distinction: Addison (2016) talks about a '***boundary shift'*** in regulation of gene therapy: from somatic/germline distinction to mitochondrial/nuclear distinction
3) Experiments are challenging the significance of the distinction: information does not only flow from germ-line to soma but also from soma to germ-line!

BioSocieties , (18 April 2016) | doi:10.1057/biosoc.2016.9

Spliced: Boundary-work and the establishment of human gene therapy

Courtney Addison

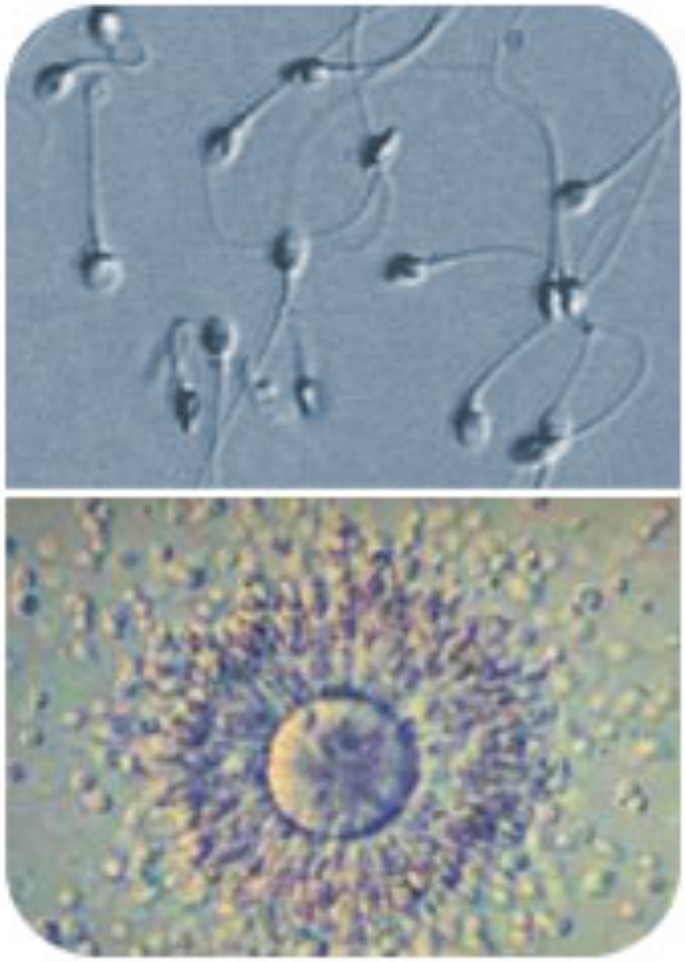
Why this is important



1. Vagueness in basic definitions of embryo and germ-line create **ambiguities and loopholes** that allow for different interpretations
2. Vagueness in distinctions between clinical and research applications

Isasi, R., E. Kleiderman, and B. M. Knoppers. "Editing policy to fit the genome?." *Science* 351, no. 6271 (2016): 337-339.

Scientific challenges to the distinction



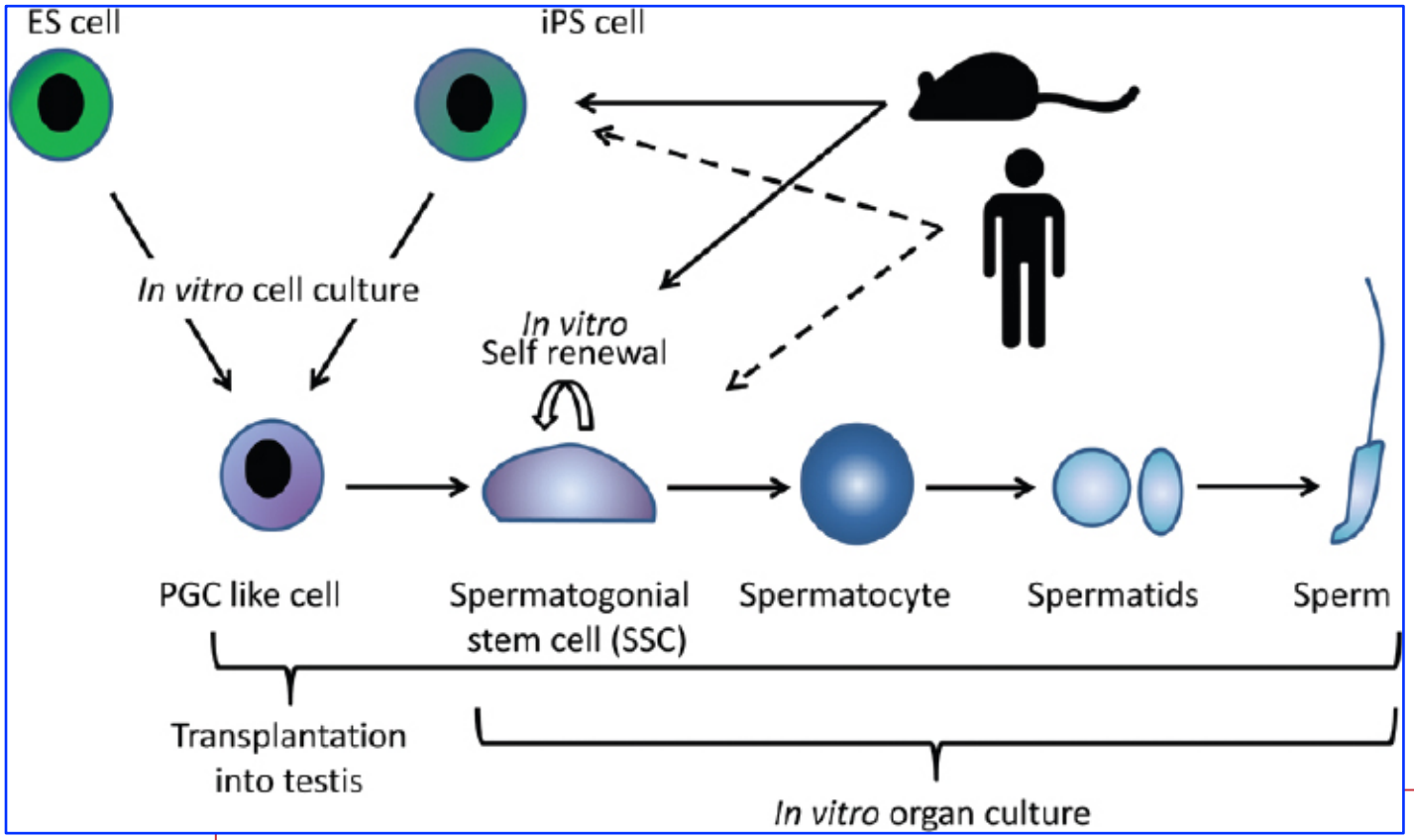
Egg (bottom) and sperm (top) cells are germline cells.

Experiments are challenging the significance of the distinction: *it is no longer universally true that information can only flow from germ-line to soma:*

1. In mice somatic cells can be used for the derivation of iPS cells, which, in turn can be differentiated into germ cells and contribute to development of embryos (this cannot be done in humans)

2. While still under debate there is an increasing body of evidence suggesting the inheritance of epigenetic information thus defying the dogma of classic inheritance

1) Derivation of gametes from somatic cells



Offspring from Oocytes Derived from in Vitro Primordial Germ Cell–like Cells in Mice

Katsuhiko Hayashi[1,2,3,*], Sugako Ogushi[1,4], Kazuki Kurimoto[1,5], So Shimamoto[1], Hiroshi Ohta[1,5], Mitinori Saitou[1,2,5,6,*]

https://hinxtongroup2015.wordpress.com/briefing-materials/pluripotent-stem-cell-derived-gametes/

2) Inheritance of epigenetic information

REPORT

Germline DNA Demethylation Dynamics and Imprint Erasure Through 5-Hydroxymethylcytosine

Jamie A. Hackett[1,2], Roopsha Sengupta[1,2,*], Jan J. Zylicz[1,2,3,*], Kazuhiro Murakami[1,2,*], Caroline Lee[1,2], Thomas A. Down[1], M. Azim Surani[1,2,3,†]

Scientists have amassing an increasing body of evidence that demonstrate **transgenerational epigenetic inheritance** in humans, i.e. offspring may inherit altered traits due to their parents' past experiences (e.g., historical incidences of famine)

http://www.cam.ac.uk/research/news/scientists-discover-how-epigenetic-information-could-be-inherited

> *"Our research demonstrates how genes could retain some memory of their past experiences, revealing that one of the big barriers to the theory of epigenetic inheritance - that epigenetic information is erased between generations - should be reassessed."*
>
> — *Jamie Hackett*

The way forward in ethics and policy making

1. Necessary to re-discuss the regulatory significance of the somatic/germ line distinction in light of the above
2. Affecting future generations through the germ-line should *not* be an argument to prohibit research on human embryos: this should be assessed on a *case by case analysis (*as it was for mtDNA transfer technologies)
3. The rethinking of the somatic/germline distinction should prompt a discussion of other ways we are impacting possibly irreversibly on future generations and on our planet
4. The current focus of the CRISPR debate on human embryos risks crowding out other areas of ethical concerns e.g. applications of CRISPR to non-human animals and environment

http://www.publicpolicy.cam.ac.uk/research-impact/stem-cells-report

Which possible CRISPR futures (beyond human embryo applications?

1) CRISPR applied to eradicate disease vectors

Genetic engineering could thwart the Zika virus, among other mosquito-borne diseases

By Aaron Krumins on January 25, 2016 at 12:01 pm | 19 Comments

http://www.technologyreview.com/news/545596/zika-virus-could-stir-demand-for-gm-mosquitoes/

The Brazilian city of Piracicaba announced on **January 18th 2016** would expand the use of genetically modified mosquitoes to fight *Aedes aegypti*, the species that spreads dengue fever as well as the Zika virus.
The genetically engineered mosquitoes were created by **Oxitec**, a British company recently purchased by Intrexon, a synthetic-biology company based in Maryland.
The company has already released the engineered mosquitos in parts of Brazil and the Cayman Islands to battle dengue fever

2) CRISPR applied to animals: Humanised animal models for organ donation

Safety and ethical issues remain in respect to developing human/pig chimeras. Human iPSC-derived chimeras would possibly carry human neural and germ cells

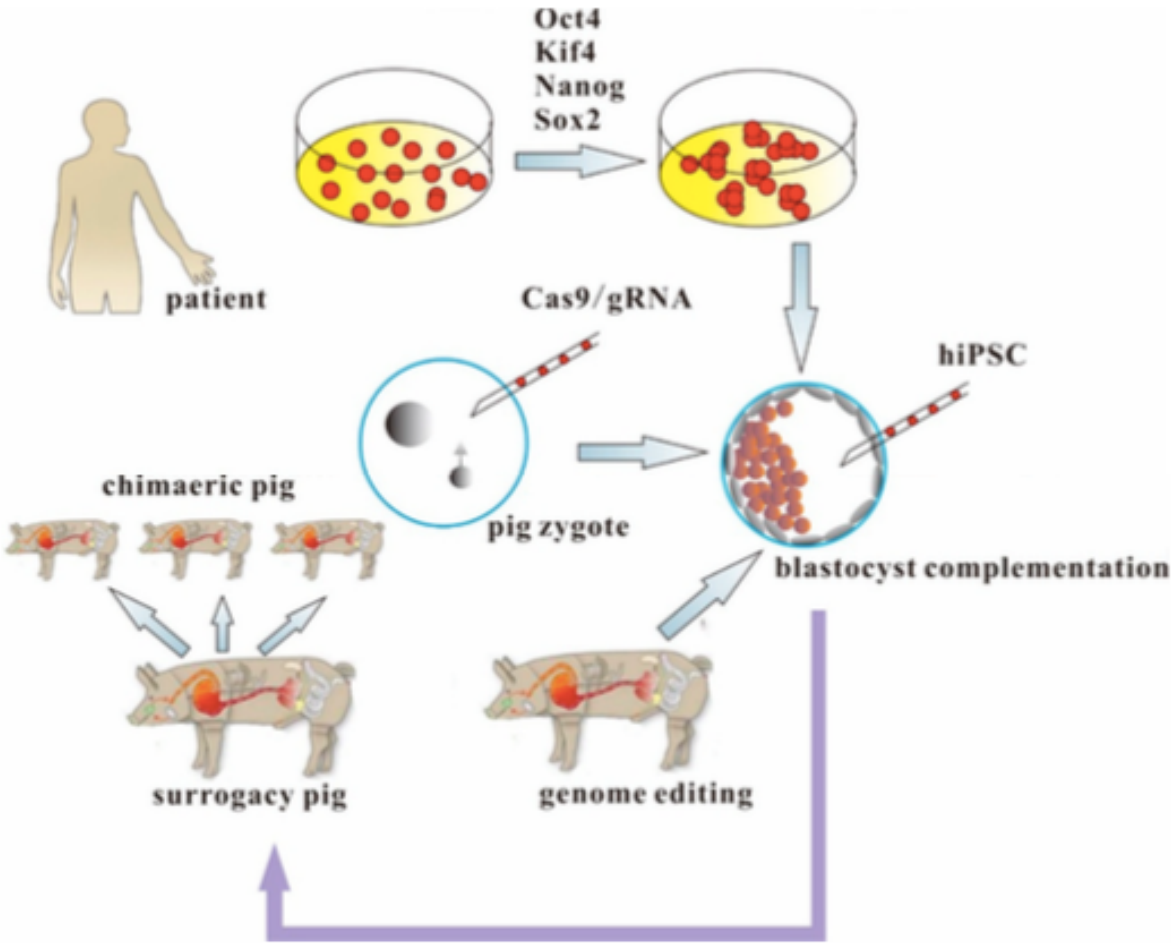


Figure 3. Combination of CRISPR/Cas9 and pluripotent stem cells to provide human organs from chimaeric pigs. Generation of human organs by producing multigene mutations of essential regulators of vascular and lymphatic tissues in the desired organ via rapid and efficient CRISPR/Cas9-mediated genome editing in concert with blastocyst complementation.

3) CRISPR applications to agriculture: does it count as GMO?

In Sweden, authorities recently said that CRISPR-edited plants (as long as they don't contain foreign DNA) shouldn't be defined as GMOs under EU legislation

http://linkis.com/businessinsider.com/vUd2s

CRISPR differs from previous methods of agricultural genetic engineering: it no longer requires the insertion of foreign DNA using a virus, bacterial plasmid, or other vector system i.e. *does not longer as transgenic organisms in sensu strictu.* The US Department of Agriculture said that it does not consider the CRISPR corn as regulated by USDA Biotechnology Regulatory Services (April 2016)

The way forward in ethics and policy making

Stem Cells and Society Workshop: Planning for the Future of Gene Editing

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We aim to support public policy research across Cambridge University, working with colleagues in science, social science, the arts and humanities, to apply new thinking to public policy problems and promote research and analysis into the public policy process. We hope to connect and raise the profile of existing public policy related work across the University and support collaborative research that includes policy development in a range of subject areas.

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http://www.publicpolicy.cam.ac.uk/research-impact/stem-cells-report

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Thank you!

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