Ethical Challenges of New Treatments in Children:
could we do now what we did then?

M a r t i n E l l i o t t

37th Gresham Professor of Physic

Professor of Cardiothoracic Surgery at UCL

Consultant Paediatric Cardiothoracic Surgeon

&

co-Medical Director

The Great Ormond Street Hospital for Children

core values

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core values

TRUST

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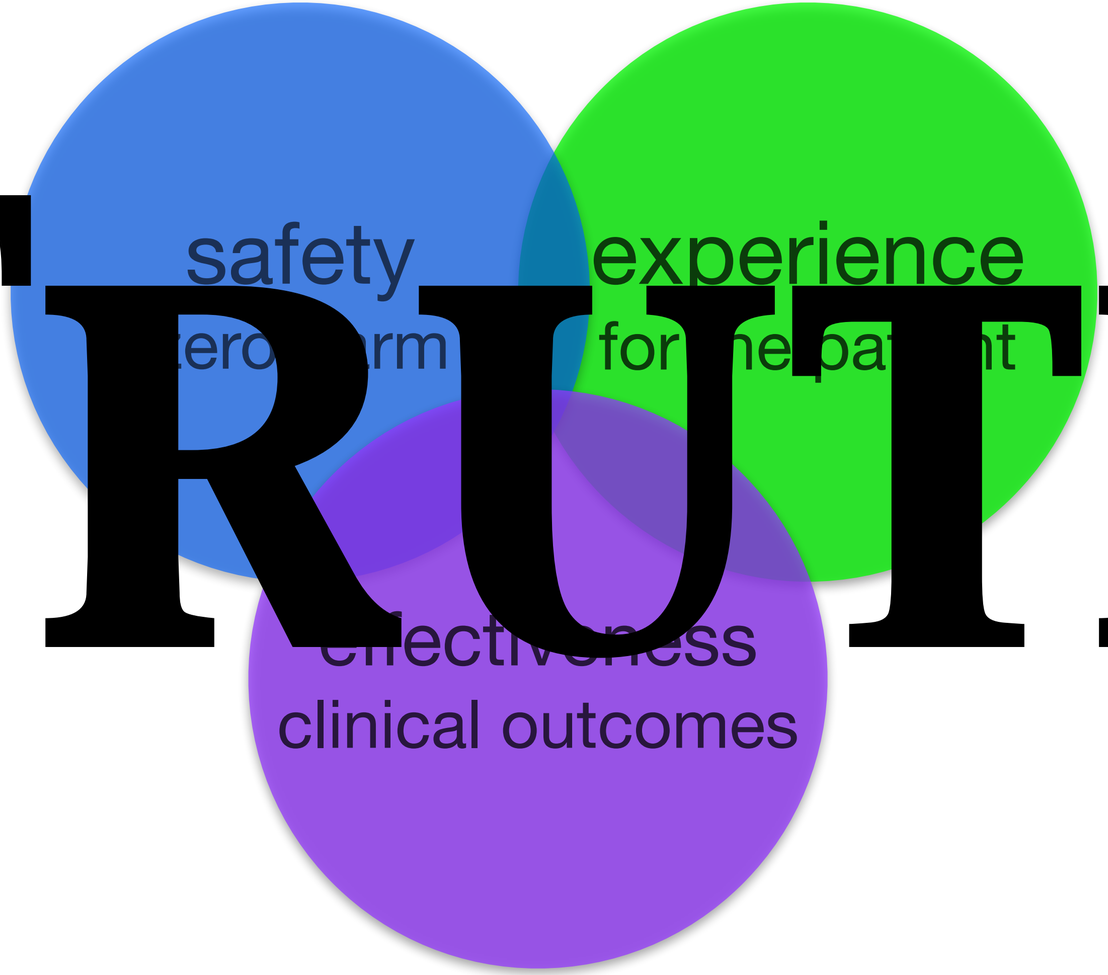
core values



TRUTH

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Trust

years to earn,
seconds to break

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“the medical profession is a conspiracy to exploit popular credulity and human suffering”

George Bernard Shaw, 1909
preface to “The Doctor’s Dilemma”

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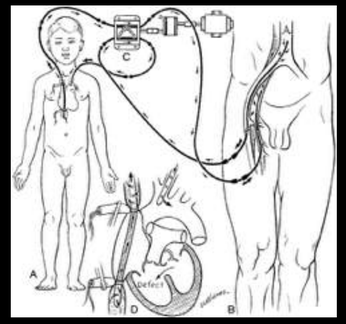
Gross



Maverick

Lillehei

"a person who shows independence of thought or action, especially
by refusing to adhere to the policies of a group to which he or she belongs"

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RISK

something **undesirable**

something with an **unknown outcome**

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could we do now what we did then?

should we have done what we did then?

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The New

Invention; the *creation* of an idea or method

Innovation; the *use* of something new to alter the course of events

Research; creative work undertaken on a *systematic* basis to acquire relevant data

Innovation to improve the lot of patients should be in the interests of **everyone**

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doctors and nurses innovate in small ways every day

- the public ***expects*** them to do so
- the public ***wants*** them to do so
- the staff may ***have a duty*** to do so

Sir Robert Francis QC, 2014

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rewards to medical staff for significant innovation

- seeing the patient get better
- publication, presentation
- kudos, media, career progression
- potential financial benefit

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“doctors are like any other Englishmen: most of them have no honour and no conscience”

George Bernard Shaw, 1909
preface to “The Doctor’s Dilemma”

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many doctors

"have been exposed as charlatans peddling unsuitable or unproven treatments to the weak and vulnerable, raising false hopes, causing pain and even death"

Roy Porter 2000 (Tempus)
Quacks; fakers and charlatans in medicine

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‘Pressed by the iron logic of the cash nexus, practitioners themselves will resort to such quackish practices as undercutting, price wars, gimmicks, nostrum-mongering and client-poaching: **overt competition induces quackery**’

Thomas Percival 1803 *Medical Ethics*

quoted by Roy Porter, 2000, Quacks;fakers and charlatans in medicine

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Harlequin, magician and barber
P.Tanje 1758

A Quack

1. A boastful pretender to arts which he does not understand

2. A vain boastful pretender to Physic, one who proclaims his own medical abilities in public places

3. an artful, tricking practitioner in Physic

Samuel Johnson 1755, *Dictionary*

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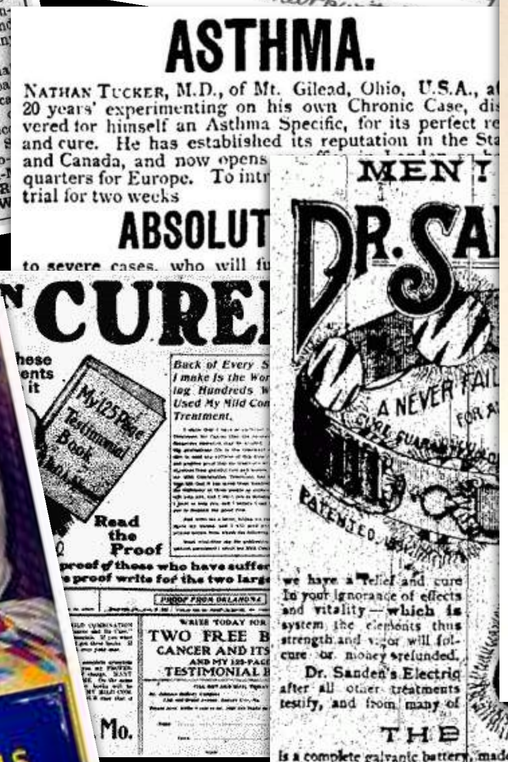

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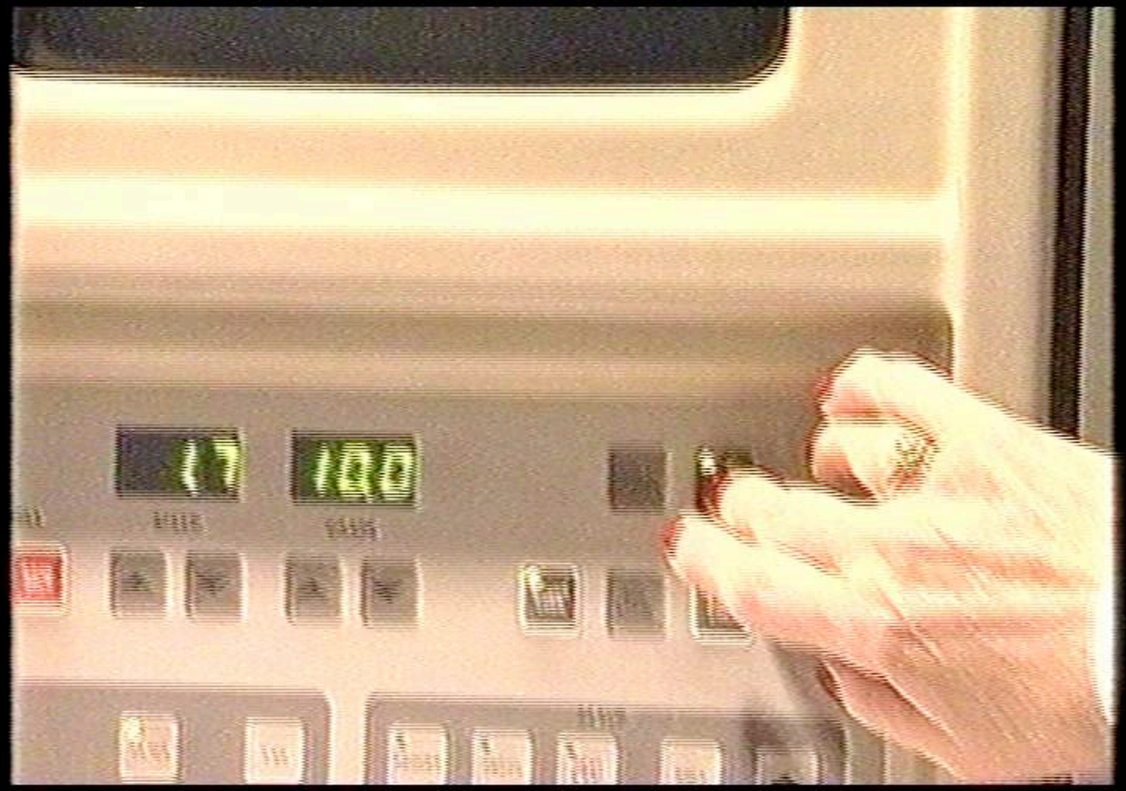
People at their lowest ebb need to be protected from such people



“I’d go anywhere to find the best doctors”

“there is a certain status that comes with treatment by a doctor who is at ‘the cutting edge’, especially when the stakes are high”

Levin, A.V. *Can J Opthalmol* 2005;40:685-688

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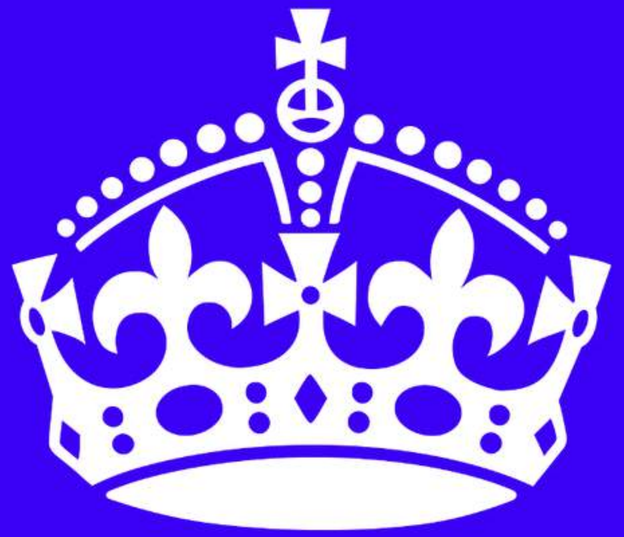

KEEP
CALM
AND
TRUST ME
I'M A DOCTOR

BUT HOW WE HAVE LET DOWN THAT TRUST

Torture

"Torture combined proof of truth and demonstration of power."

Gil Wernovsky, MD

Michel Foucault, 1979
(Discipline and Punish: the birth of the prison
New York; Vintage Books)

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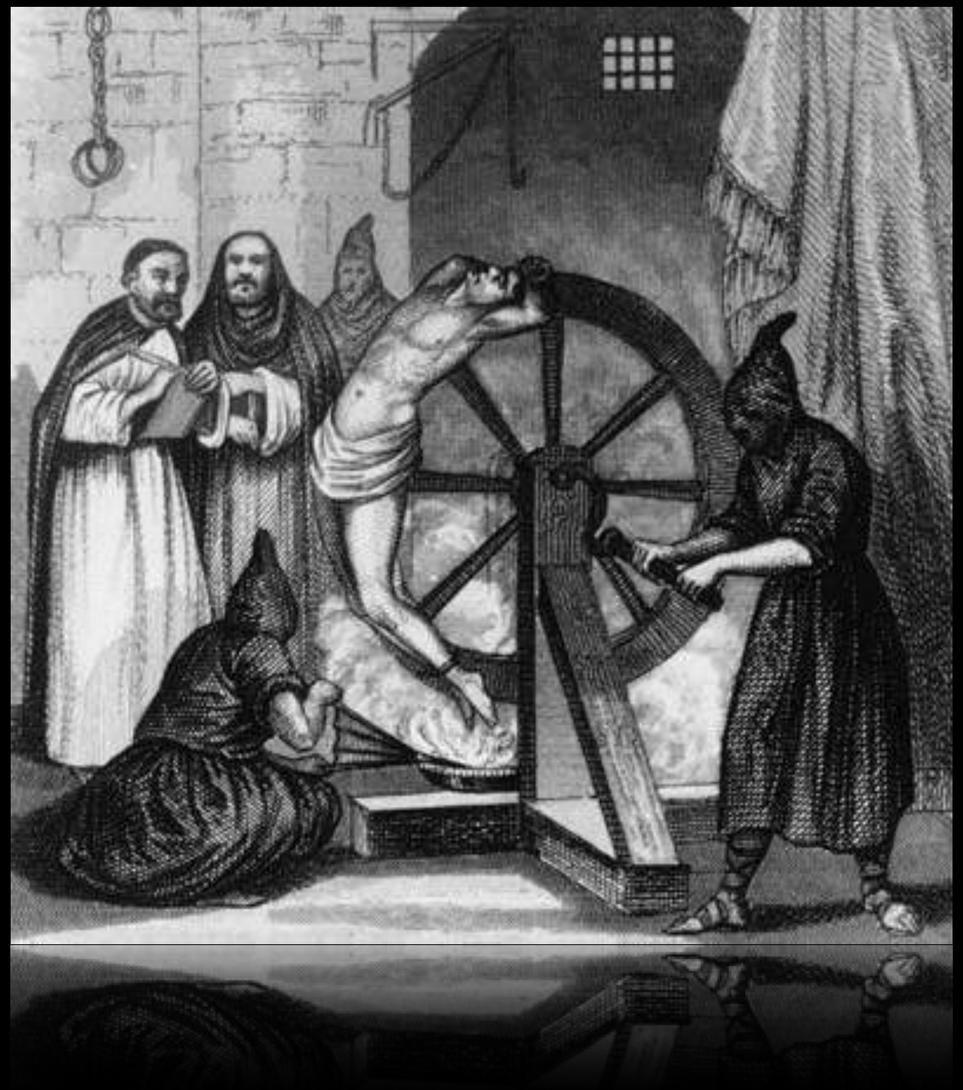

The Spanish Inquisition

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Constitutio Criminalis Carolina 1532

Charles V asked doctors to determine whether defendants could withstand the torture, and codified their presence

Doctors had to certify that the victims were ‘fit for torture’, not blind, mute, handicapped, insane or ill.

they were also asked to ‘recommend the methods of torture the accused could survive’

Maio, G. *Lancet* 2001;357:1609-1611

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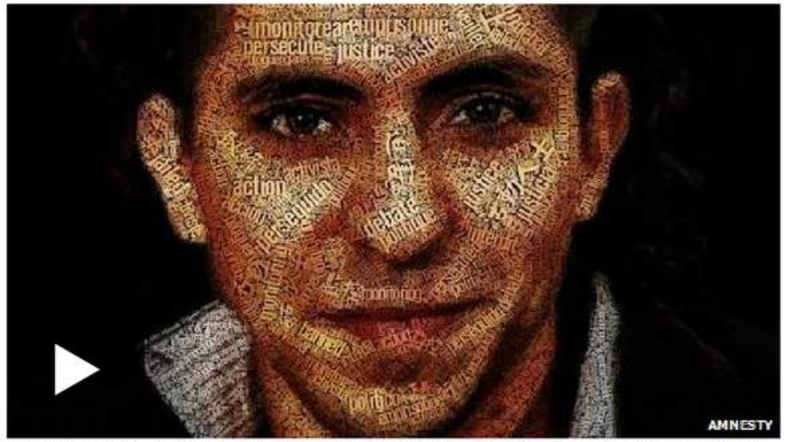
Saudi Arabia postpones public flogging of Raif Badawi



Speaking before the postponement Raif Badawi's wife Ensaf Haidar spoke to the BBC

Saudi Arabia has postponed the flogging of Raif Badawi on medical grounds.

Related Stories

2015

Human rights organisation Amnesty International said in a statement that Mr Badawi was examined by a doctor who felt his wounds had not yet healed and that he would not be able to stand another beating.

The doctor recommended that the flogging be postponed until next week, Amnesty added.

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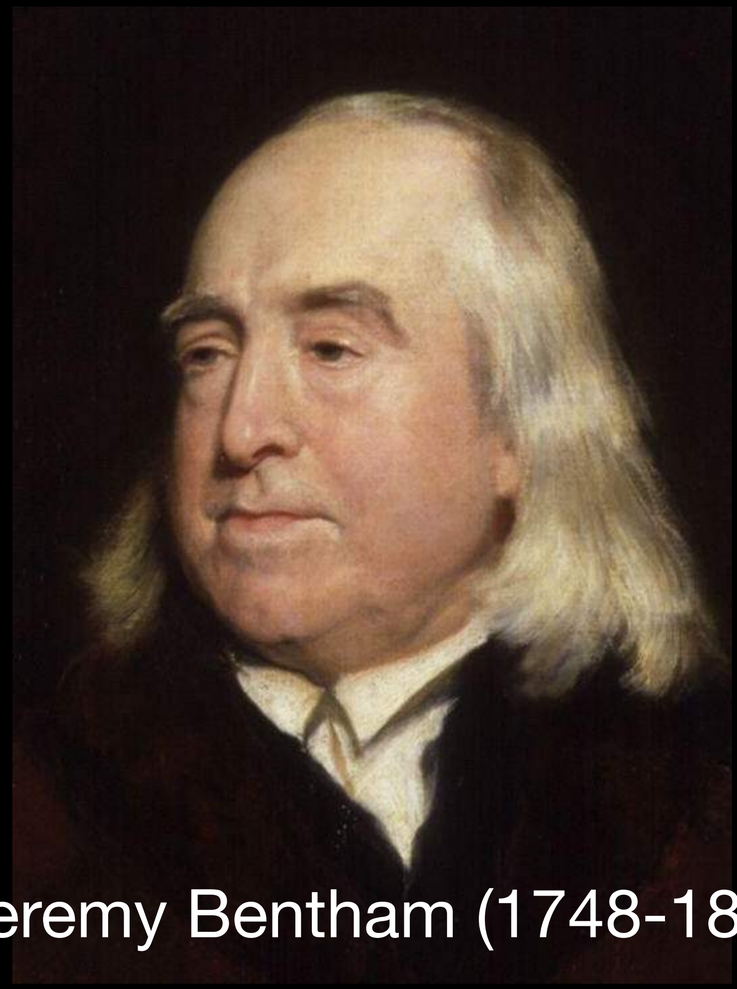
questioned the use of torture

but recommended its use,

especially “*where the safety of the whole state may be endangered* ”

He described torture as a weapon of “*inestimable power* ”



Jeremy Bentham (1748-1832)

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1900

2000

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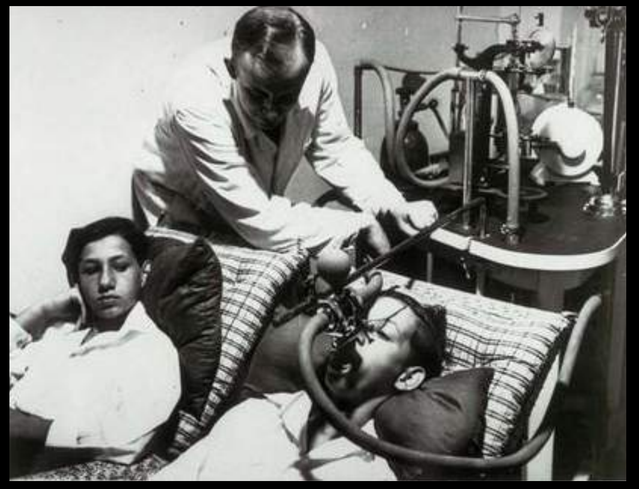
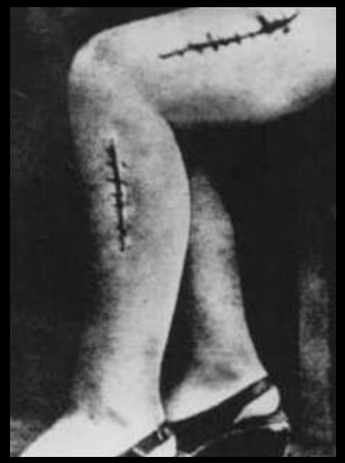
altitude

limb & bone transplantation

hypothermia



twins



http://www.jewishvirtuallibrary.org/jsource/Holocaust/medtoc.html

child victims of
medical experiments in Auschwitz

http://www.jewishvirtuallibrary.org/jsource/Holocaust/medtoc.html

23 doctors in court at Nuremberg: The Doctors' Trial

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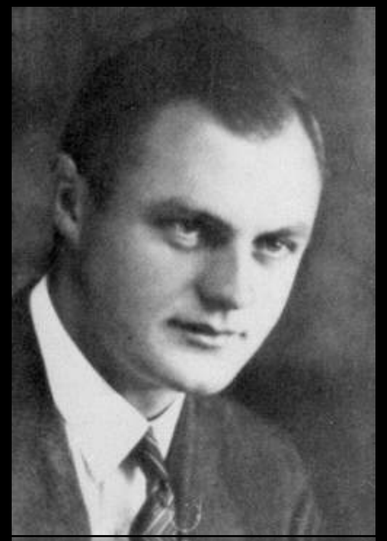
Auschwitz



SS-Standortartz Eduard Wirths (1909 - 1945)

sterilisation of women

Mauthausen

SS-Standortartz Aribert Heim (1914 - 1992))

directly injected toxic agents into the heart
removed organs without anaesthesia

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Auschwitz

SS-Haupsturmfuhrer Josef Mengele (1911 - 1979)

twin research. nature more important than nurture

Dachau

SS-Haupsturmfuhrer Sigmund Rascher (1909 - 1945

high altitude, hypothermia, blood clotting

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Auschwitz

SS-Haupsturmfuhrer Herta Oberheuser(1911 - 1978)

deliberate wounding and infection,
killing of healthy children,
amputation, bone transplantation

Ravensbruck

SS-Brigadfuhrer Karl Gerbhart (1897 - 1948)

fractures, antibiotics, limb transplantation

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people like me?

assistant and tenured professors, clinic directors, personal physician to the Chancellor, Head of the German Red Cross, high ranking military physicians, biomedical researchers in industry and universities

is what is ethical a product of the time in which we live, or the company we keep?

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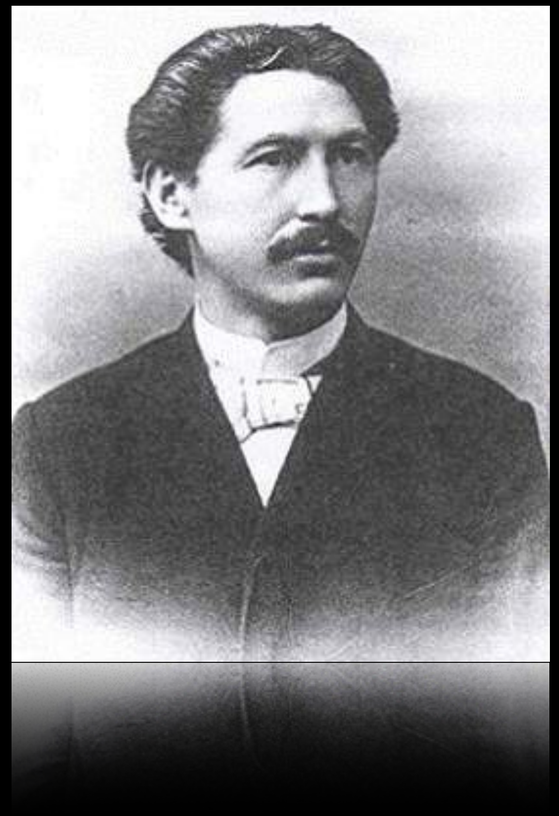
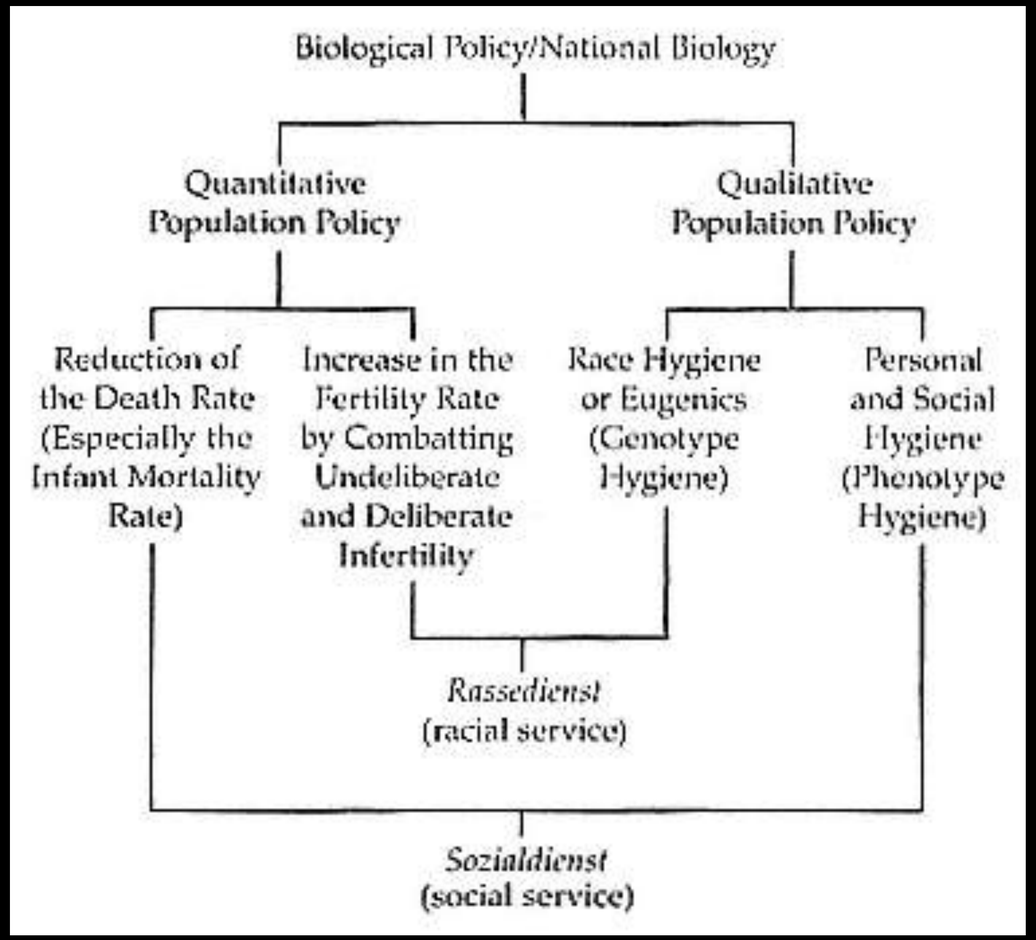


Wilhelm Schallmeyer 1857-1919



Shiela Faith Weiss, 1987
Race Hygeine and National Efficiency: The eugenics of Wilhelm Schallmeyer
University of California Press

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Alfred Ploetz, eugenicist
Wrote “*Rassenhygiene*” in 1895

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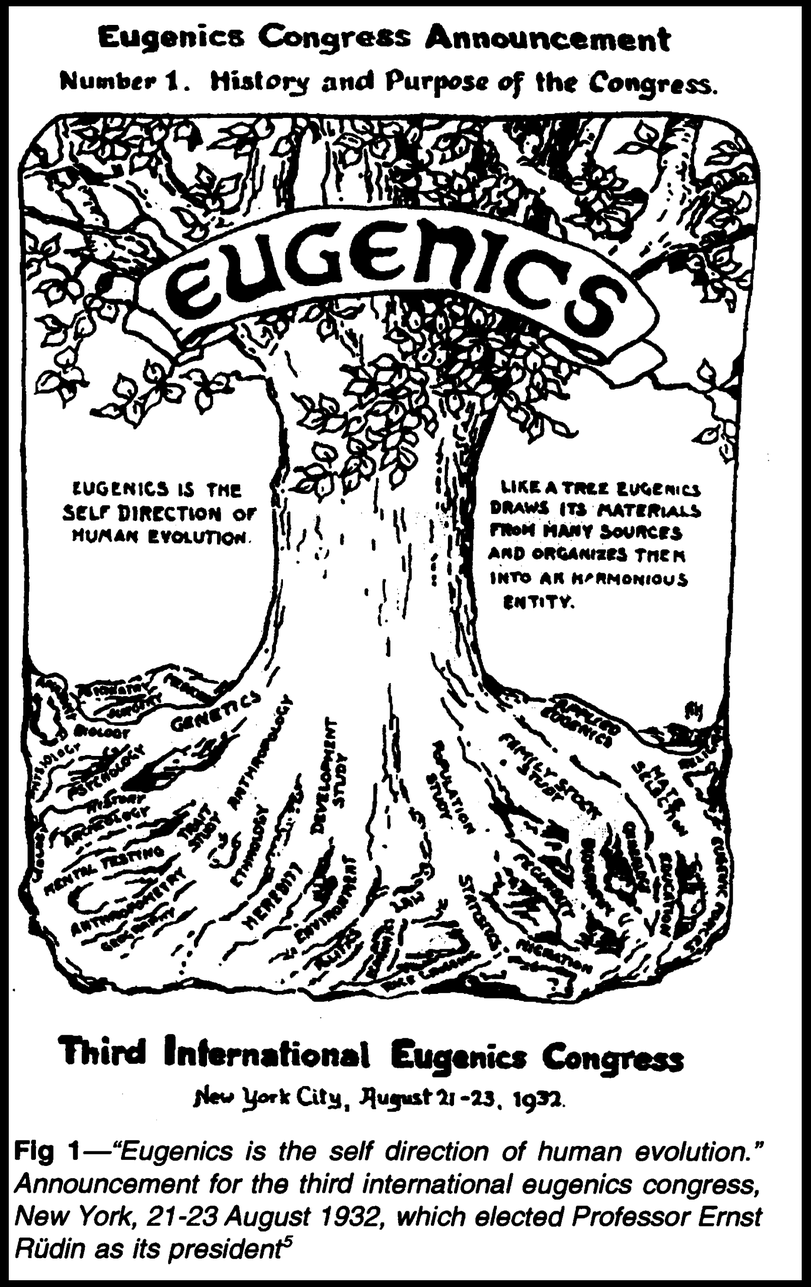

Fig 1—*"Eugenics is the self direction of human evolution." Announcement for the third international eugenics congress, New York, 21-23 August 1932, which elected Professor Ernst Rüdin as its president*[5]

The economic rationale for eugenic sterilisations: "The Sate of Prussia invests annually 125 Reichsmarks for a normal pupil, 573 Reichsmarks for a slow learner, 950 Reichsmarks for an educable but mentally ill child, and 1500 Reichsmarks for a child born blind and deaf"

petition *re* sterilisation

Hartmut M Hanauske-Abel

BMJ 1996;**313**:1453–63

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Professor Dr Alfons Stauder (1878 - 1937)

"the principal professional organisations in Germany gladly welcome the firm determination of the Government of National Renewal to build a true community of all ranks, professions and classes, and they gladly place themselves at the service of this great patriotic task."

telegram to Hitler in March 1933

Hartmannbund
Verband der Ärzte Deutschlands

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BMJ 1996;313:1453–63

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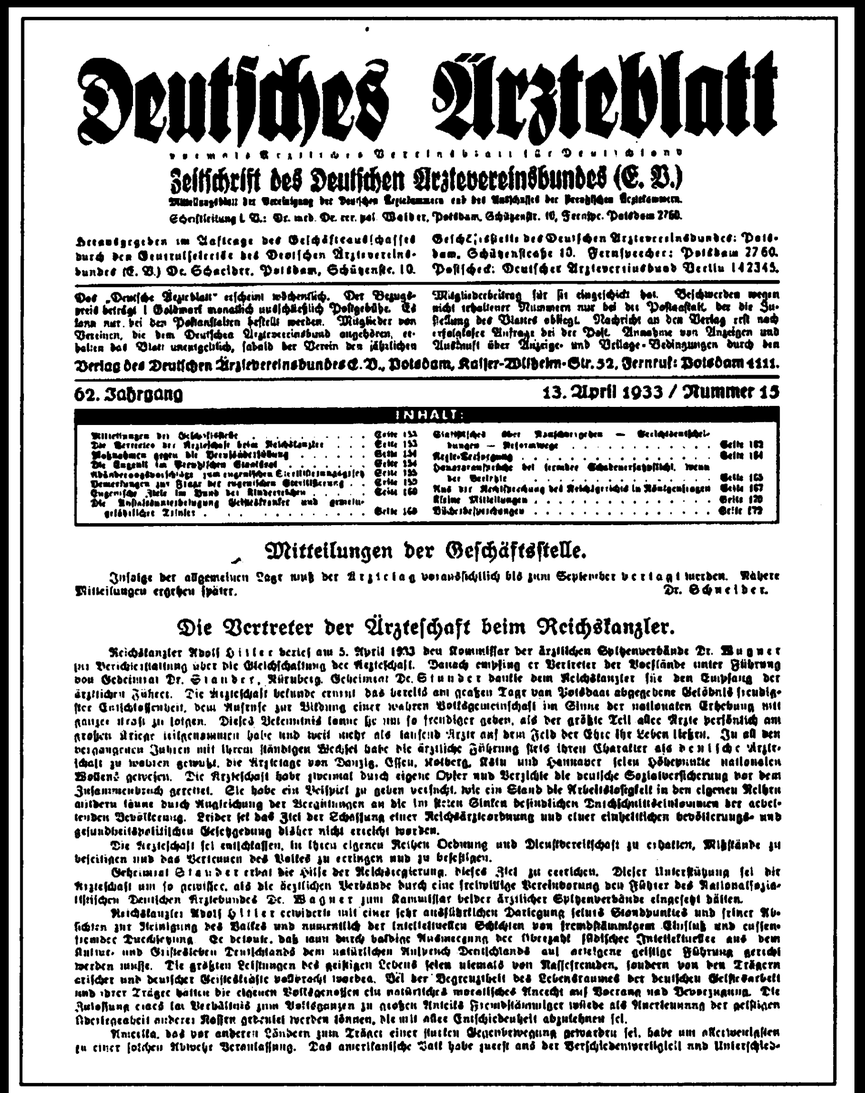
April 1933; Stauder visits Hitler

Hitler's "intentions for cleansing of the nation and particularly the intellectual elite from foreign influence and contamination by alien races." He emphasised Jewish intellectuals must soon be eliminated from the cultural and spiritual life of Germany

call to physicians

"to build a firm foundation for the genetic development of the nation"



Deutsches Ärzteblatt

Zeitschrift des Deutschen Ärztevereinsbundes (E. V.)

62. Jahrgang — 13. April 1933 / Nummer 15

INHALT:

Mitteilungen der Geschäftsstelle.

Infolge der allgemeinen Lage muß der Ärztetag voraussichtlich bis zum September vertagt werden. Nähere Mitteilungen ergehen später.

Dr. Schneider.

Die Vertreter der Ärzteschaft beim Reichskanzler.

Reichskanzler Adolf Hitler berief am 5. April 1933 den Kommissar der ärztlichen Spitzenverbände Dr. Wagner zu Berichterstattung über die Gleichschaltung der Ärzteschaft. Danach empfing er Vertreter der Vorstände unter Führung von Geheimrat Dr. Stauder, Nürnberg. Geheimrat Dr. Stauder dankte dem Reichskanzler für den Empfang der ärztlichen Führer. Die Ärzteschaft bekunde erneut das bereits am großen Tage von Potsdam abgegebene Gelöbnis freudigster Entschlossenheit, dem Aufrufe zur Bildung einer wahren Volksgemeinschaft im Sinne der nationalen Erhebung mit ganzer Kraft zu folgen. Dieses Bekenntnis komme ihr um so freudiger, als der größte Teil aller Ärzte persönlich am großen Kriege teilgenommen habe und weit mehr als tausend Ärzte auf dem Feld der Ehre ihr Leben ließen. In all den vergangenen Jahren mit ihrem ständigen Wechsel habe die ärztliche Führung stets ihren Charakter als deutsche Ärzteschaft zu wahren gewußt, die Ärztetage von Danzig, Essen, Kolberg, Kassel und Hannover seien Höhepunkte nationalen Wollens gewesen. Die Ärzteschaft habe zweimal durch eigene Opfer und Verzichte die deutsche Sozialversicherung vor dem Zusammenbruch gerettet. Sie habe ein Beispiel zu geben versucht, wie ein Stand die Arbeitslosigkeit in den eigenen Reihen ändern könne durch Angleichung der Bezahlungen an die im letzten Sinken befindlichen Durchschnittseinkommen der arbeitenden Bevölkerung. Leider sei das Ziel der Schaffung einer Reichsärzteordnung und einer einheitlichen bevölkerungs- und gesundheitspolitischen Gesetzgebung bisher nicht erreicht worden.

Die Ärzteschaft sei entschlossen, in ihren eigenen Reihen Ordnung und Dienstbereitschaft zu erhalten, Mißstände zu beseitigen und das Vertrauen des Volkes zu erringen und zu besitzen.

Geheimrat Stauder erbat die Hilfe der Reichsregierung, dieses Ziel zu erreichen. Dieser Unterstützung sei die Ärzteschaft um so gewisser, als die ärztlichen Verbände durch eine freiwillige Vereinbarung den Führer des Nationalsozialistischen Deutschen Ärztebundes Dr. Wagner zum Kommissar beider ärztlicher Spitzenverbände eingesetzt hätten.

Reichskanzler Adolf Hitler erwiderte mit einer sehr ausführlichen Darlegung seines Standpunktes und seiner Absichten zur Reinigung des Volkes und namentlich der intellektuellen Schichten von fremdstämmigem Einfluß und zusammenfassender Durchdringung. Er betonte, daß kaum durch wichtige Anregung der überwiegend jüdischen Intellektuellen aus dem Kultur- und Geistesleben Deutschlands dem natürlichen Anspruch Deutschlands auf artgelegene geistige Führung gerecht werden müsse. Die größten Leistungen des geistigen Lebens seien niemals von Rassefremden, sondern von den Trägern echter und deutscher Geisteskräfte vollbracht worden. Bei der Begrenztheit des Lebensraumes der deutschen Geistesarbeit und ihrer Träger hätten die eigenen Volksgenossen ein natürliches moralisches Anrecht auf Vorrang und Bevorzugung. Die Zulassung eines im Verhältnis zum Volksganzen zu großen Anteils Fremdstämmiger wirke als Anerkennung der geistigen Überlegenheit anderer Rassen gedeutet werden können, die mit aller Entschiedenheit abzulehnen sei.

Amerika, das vor anderen Ländern zum Träger einer starken Gegnerbewegung geworden sei, habe um allerwenigsten zu einer solchen Abwehr Veranlassung. Das amerikanische Volk habe zuerst aus der Verschiedenartigkeit und Unterschied-

Title page of Deutsches Ärzteblatt, 13 April 1933, detailing Dr Stauder's visit with Chancellor Hitler. The text proclaims Hitler's plan to eliminate Jews

Hitler's plan to eliminate Jews
Dr Stauder's visit with Chancellor Hitler. The text proclaims
Title page of Deutsches Ärzteblatt, 13 April 1933, detailing

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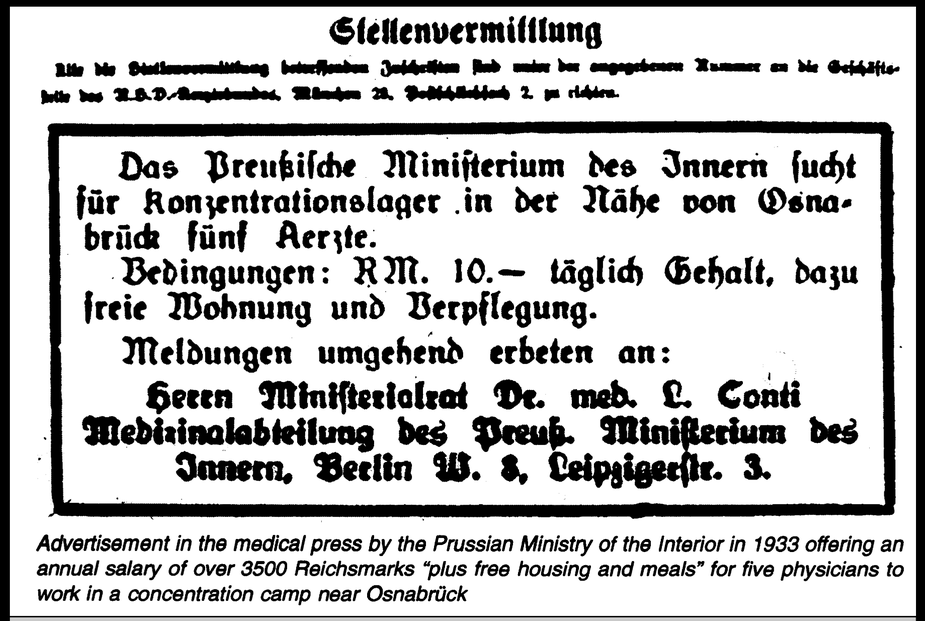
Title page of 1 July 1933 issue of Deutsches Ärzteblatt (editor: Dr K Haedenkamp)



Stellenvermittlung

Das Preußische Ministerium des Innern sucht für Konzentrationslager in der Nähe von Osnabrück fünf Aerzte.

Bedingungen: RM. 10.— täglich Gehalt, dazu freie Wohnung und Verpflegung.

Meldungen umgehend erbeten an:

Herrn Ministerialrat Dr. med. L. Conti Medizinalabteilung des Preuß. Ministerium des Innern, Berlin W. 8, Leipzigerstr. 3.

Advertisement in the medical press by the Prussian Ministry of the Interior in 1933 offering an annual salary of over 3500 Reichsmarks "plus free housing and meals" for five physicians to work in a concentration camp near Osnabrück

July 1933

Doctors Wanted
for Concentration Camps

good pay and conditions

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August 1933, Deutches Artzeblatt

- legally enforced sterilisation
- creating a new, biologically based nobility
- extermination of life not worth living

Lommel F *Volkische Aufartung und Arzt. Dtsch Arztebl* 1933;63:221-4.

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Zealous doctors exceed government sterilisation quotas

In the first year of the Sterilisation Act Germany's genetic health courts received 84 525 physician initiated applications and reached 64 499 decisions, 56 244 in favour. "Doctors competed to fulfill sterilisation quotas; sterilisation research and engineering rapidly became one of the largest medical industries. Medical supply companies made a substantial amount of money designing sterilisation equipment. Medical students wrote at least 183 doctoral theses exploring the criteria, methods, and consequences of sterilisation.[29] Within two years up to 1% of 17-24 year olds had been sterilised (for example, in Thuringia).[50] Within four years almost 300 000 patients had been sterilised,[29] at least half for "feeble mindedness" as evidenced by failing scientifically designed intelligence tests.[29 50]

The doctors beat the Nazi targets, and were reined back

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BMJ 1996;313:1453–63

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T4 Euthanasia programme: the economics of "disinfecting" hospital patients classified as futile or terminal

The 70 273 futile or terminal patients "disinfected" (murdered) in German killing hospitals up to 1 September 1941 are calculated to free up "4 781 339.72 kg of bread, 19 754 325.27 kg of potatoes . . .," a total of "33 733 003.40 kg" of 17 categories of food, plus "2 124 568 eggs."[63] Projected over 10 years, these savings are predicted to amount to "400 244 520 kg" of 20 categories of food worth "141 775 573.80 Reichsmarks."[64] Removal of these patients from the wards saves estimated hospital expenses of "245 955.50 Reichsmarks per day," or "88 543 980.00 Reichsmarks per year."[63]

T4

Physicians selected and killed these patients

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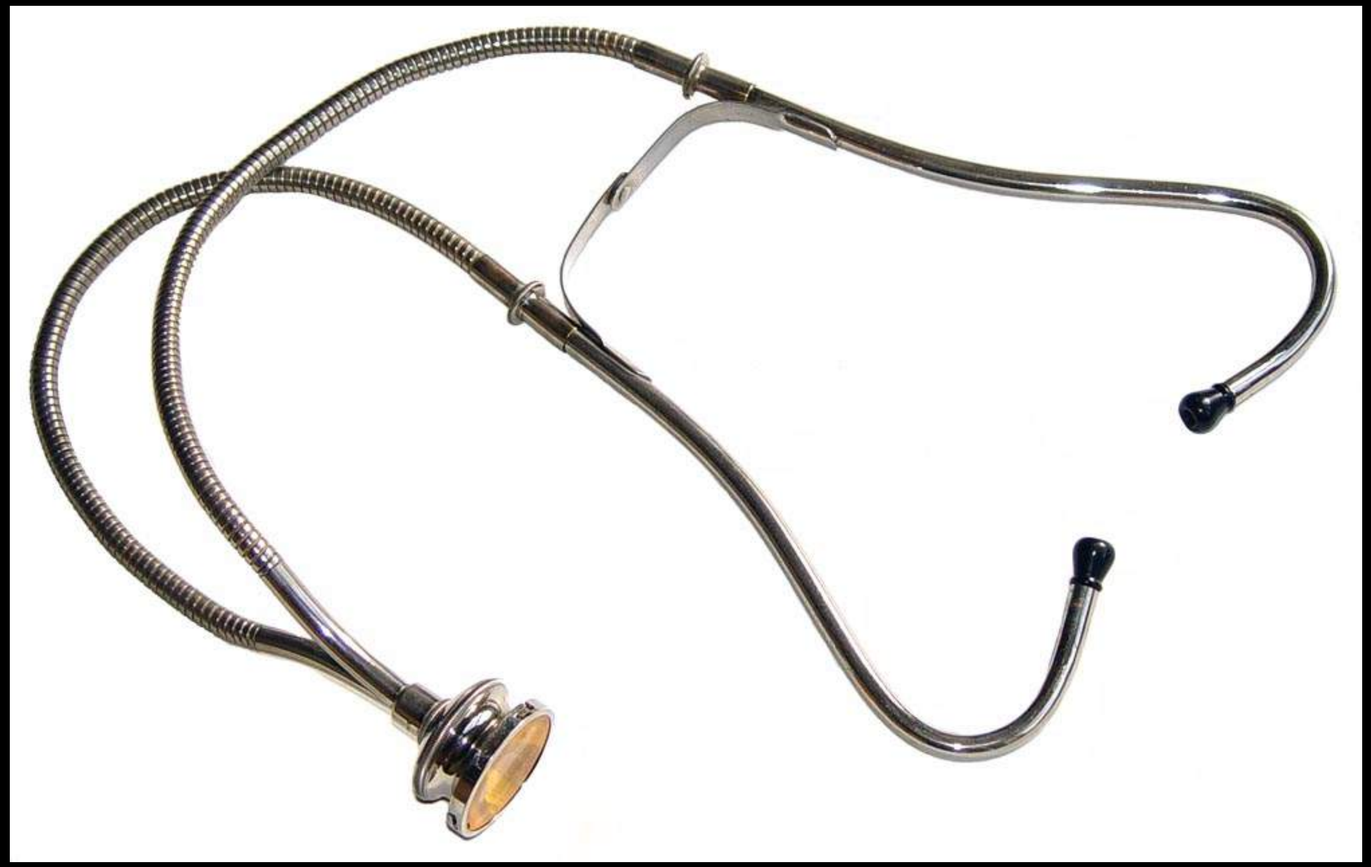

They Were Doctors

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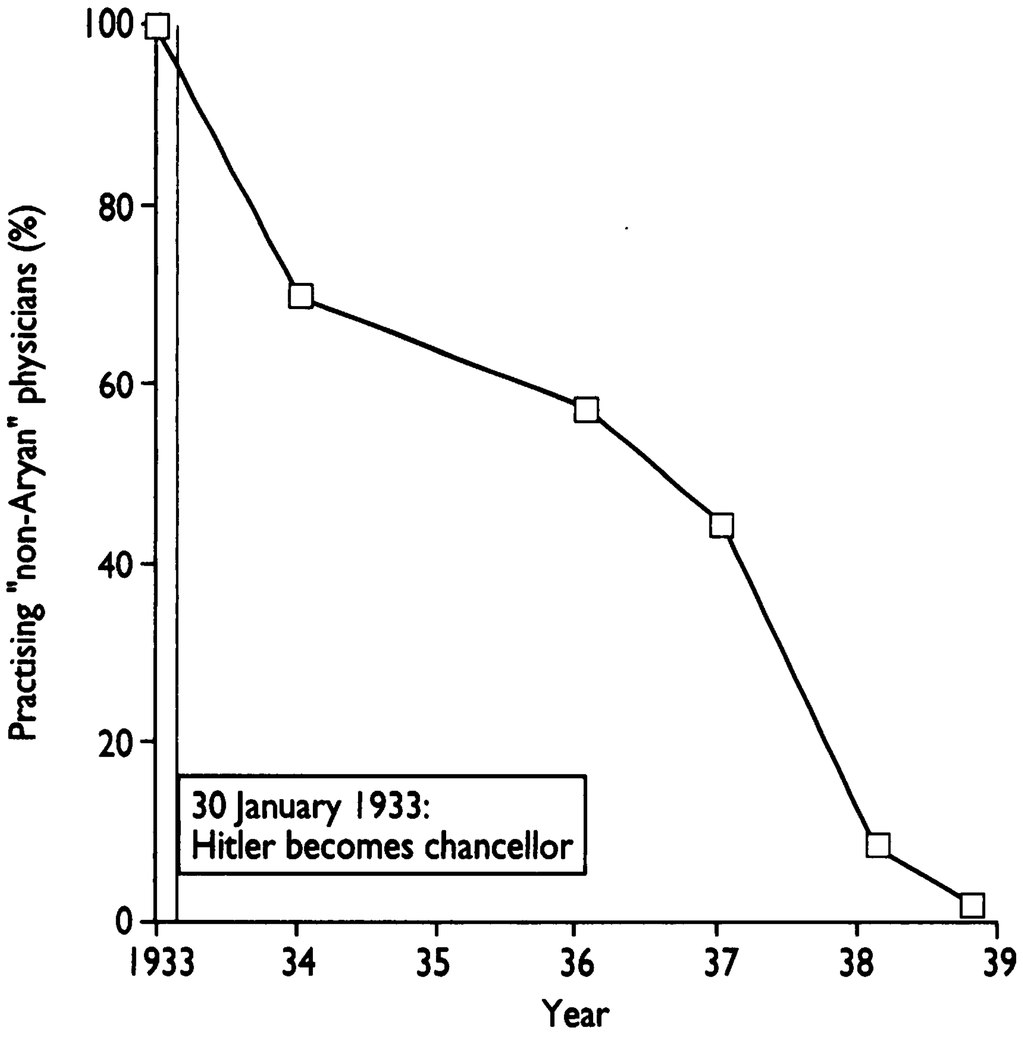
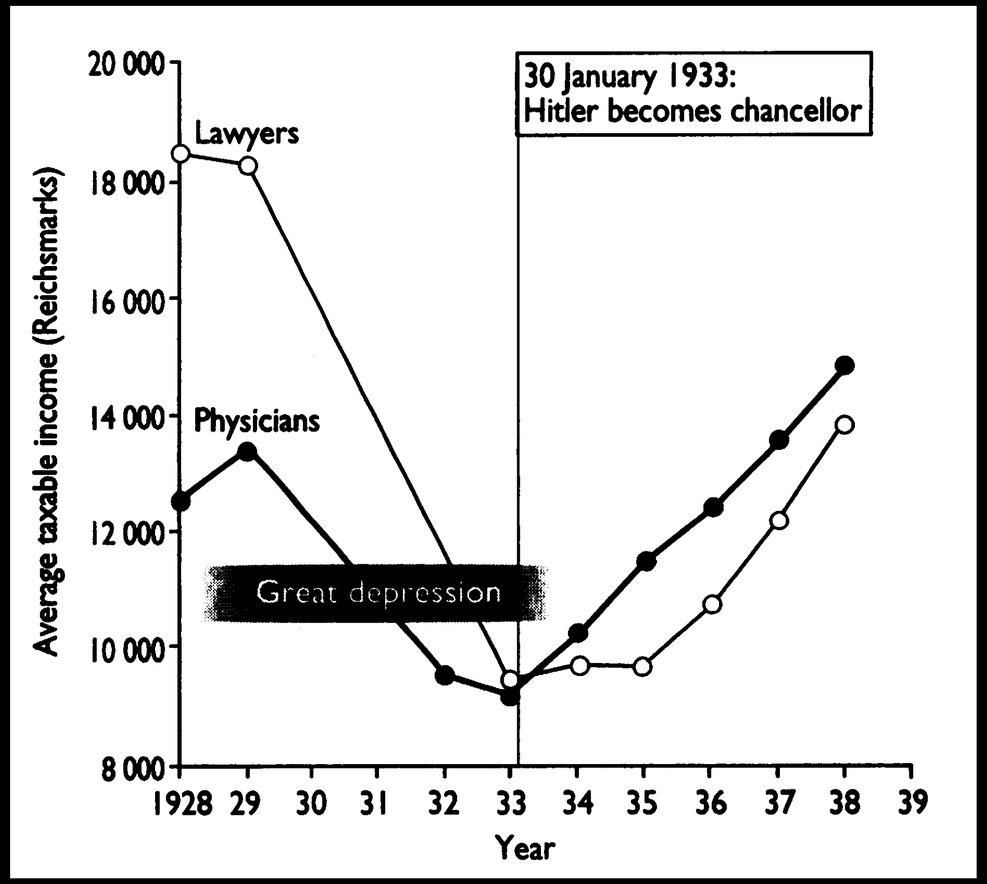


Fig 3—*Percentage decline in practising non-Aryan physicians during 1933-9 as a result of decertification and delicensing by the German government*[26 28]



financially good for remaining doctors

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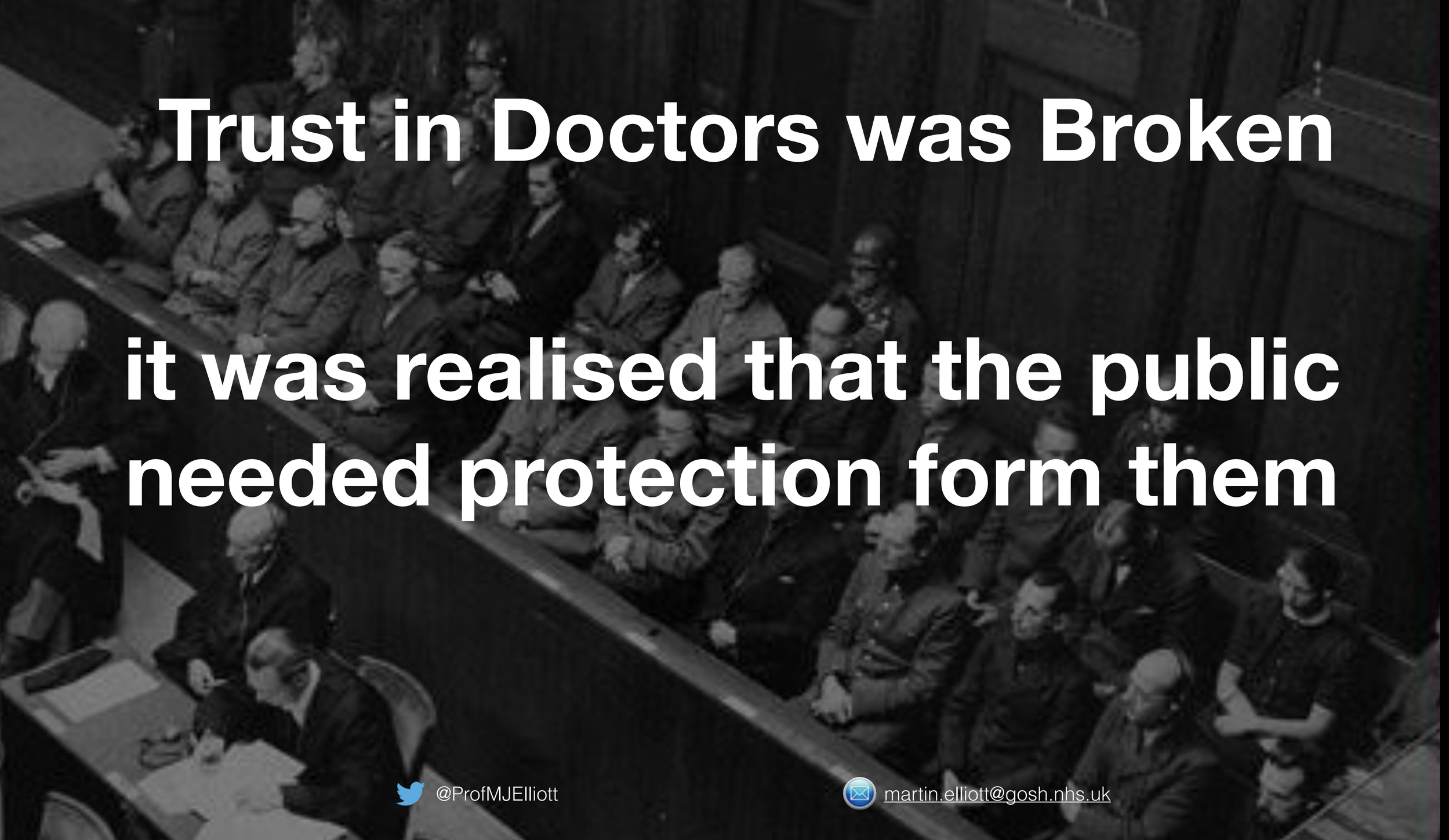

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THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. 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.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted, where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith,

10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

["Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10", Vol. 2, pp. 181-182. Washington, D.C.: U.S. Government Printing Office, 1949.]

superseded by the Helsinki Declarations and Good Clinical Practice Regulations

prior to this there was
no ***generally*** accepted code of conduct
governing medical research

US Army clinicians designed, collaborated in and did not report torture

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UNCLASSIFIED

~~TOP SECRET~~ [redacted] ~~NOFORN~~

Senate Select Committee on Intelligence

Committee Study of the Central Intelligence Agency's Detention and Interrogation Program

Foreword by Senate Select Committee on Intelligence Chairman Dianne Feinstein

Findings and Conclusions

Executive Summary

Approved December 13, 2012

Updated for Release April 3, 2014

Declassification Revisions December 3, 2014

~~TOP SECRET~~ [redacted] ~~NOFORN~~

UNCLASSIFIED

US Army clinicians c d not report torture

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Basic Principles of Medical Ethics

- **BENEFICENCE** act in the best interests of the patient;remove and prevent harm
- **NON-MALEFICENCE** “First Do No Harm”
- **AUTONOMY** people have the right to control their own bodies, consent
- **JUSTICE** be as fair as possible in offering treatment, including resource allocation

dignity, veracity

Beauchamp & Childress 2009
Principles of Medical Ethics, 6th Ed
New York, OUP (1st ed 1979)

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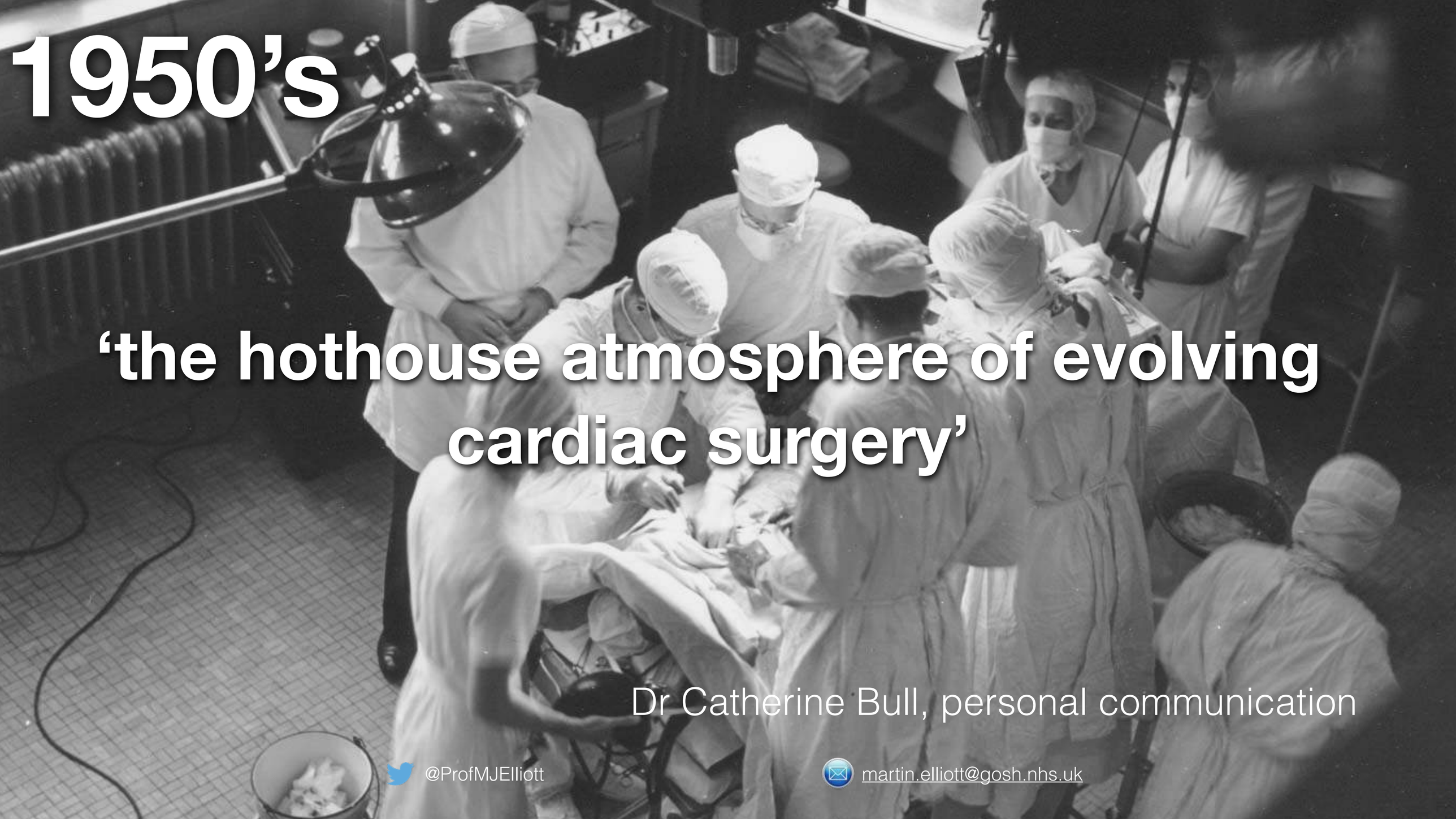

1950’s

‘the hothouse atmosphere of evolving cardiac surgery’

Dr Catherine Bull, personal communication

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the ethics of innovation in children are even more complex

child not *competent*

parent has to act as their agent

pressure from others

long, unknown future ahead

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1950's

without surgery,
children with CHD
would die, perhaps
unpleasantly,
but the treatments
were radical,
pioneering and
barely tested

were the new ethical
rules followed?
did the families feel
pressure?
was there real
informed consent?

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1950's

A Contract with Uncertainty

without surgery, children with CHD would die, perhaps unpleasantly, but the treatments were radical, pioneering and barely tested

were the new ethical rules followed?
did the families feel pressure?
was there real informed consent?

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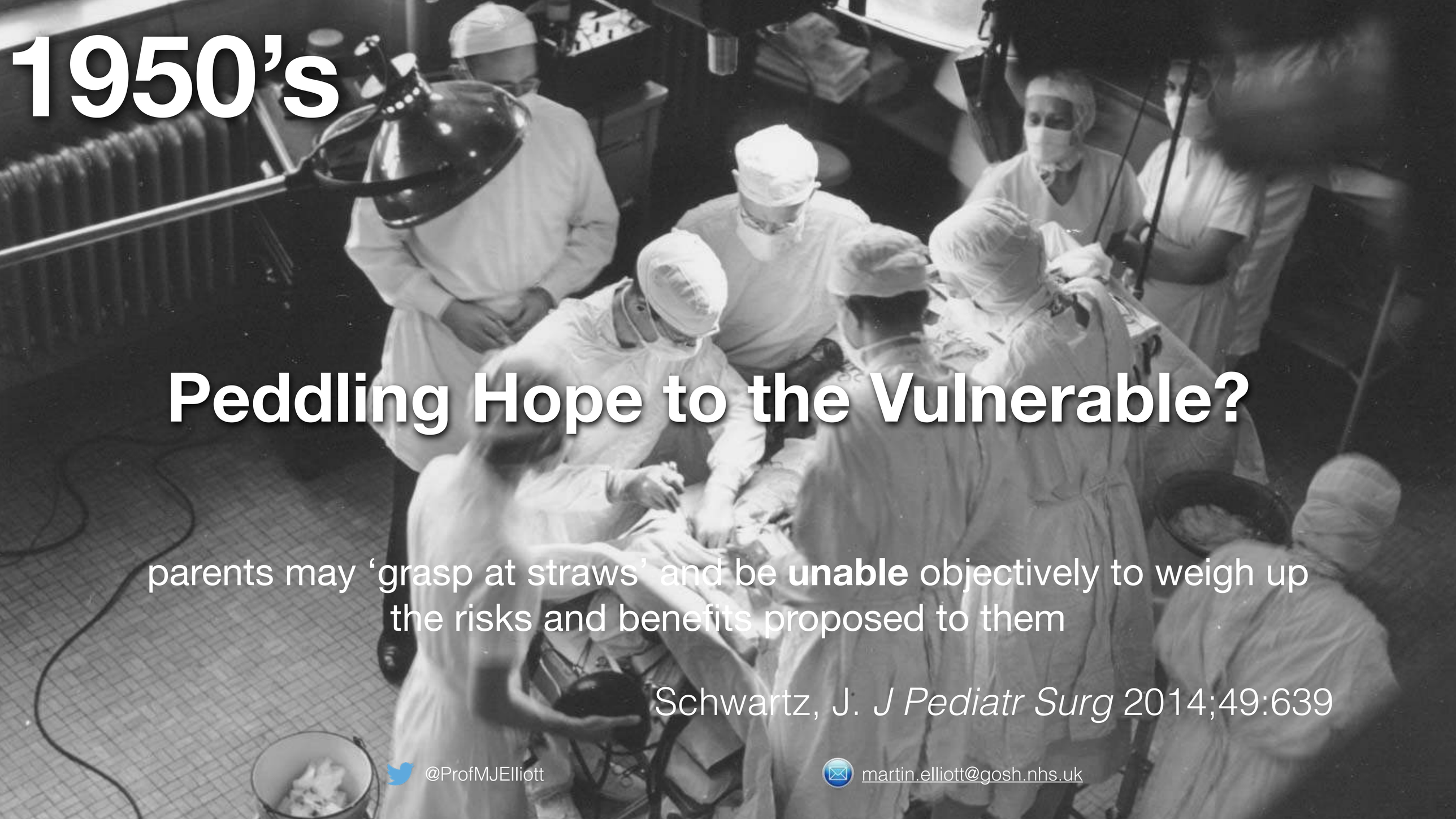

Peddling Hope to the Vulnerable?

parents may ‘grasp at straws’ and be **unable** objectively to weigh up the risks and benefits proposed to them

Schwartz, J. *J Pediatr Surg* 2014;49:639

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A Child's Life

- Is life itself to be valued above all else, even if that life involves permanent suffering?
- For the parent, does the hope of life overpower the possibility of suffering?
- Might the weight of risk be better managed by trying to have another child? Allowing grief, but creating life.
- Should others (siblings, parents) be considered?

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Just because we **CAN**, **SHOULD** we?

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The Ethics of Using **Innovative** Therapies in Children

Al Eyadhy A, Razack S. *Paediatr Child Health* 2008; **13**(3): 181-4.

- **Patient's Autonomy**
  - the parents have the right to refuse treatment
  - the paediatrician should help them decide
  - they should tell the truth, simply
- **Professional Consensus**
  - little evidence? seek consensus
- **The Role of the Institution**
  - QA, risk management & resource allocation
- **Evaluation**
  - there must be evaluation and reporting

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	Stages 0–1 (Innovation)	Stage 2a (Development)	Stage 2b (Exploration)	Stage 3 (Assessment)	Stage 4 (Long term)
Number and types of patients	Single digit, highly selected (or pre-human)	Few, selected	Many, mixed but not all	Many, variable	Almost all
Number of surgeons	Very few	Few, innovators	Many	Many, early majority	Most, late majority
Ethics	Sometimes	Yes	Yes	Yes	No
Learning curve in human beings	No	Yes	Yes	Maybe	No

Table 2: **Stages of surgical innovation (IDEAL paradigm)**

Barkun, J et al *Lancet* 2009;374:1089-96

the IDEAL group

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ETHICAL

Expertise
Technical
Hazards
Informed consent
Conflict of interest
Analysis
Literature

Schwartz, JAT 2014 *J Pediatr Surg;*49:639-645

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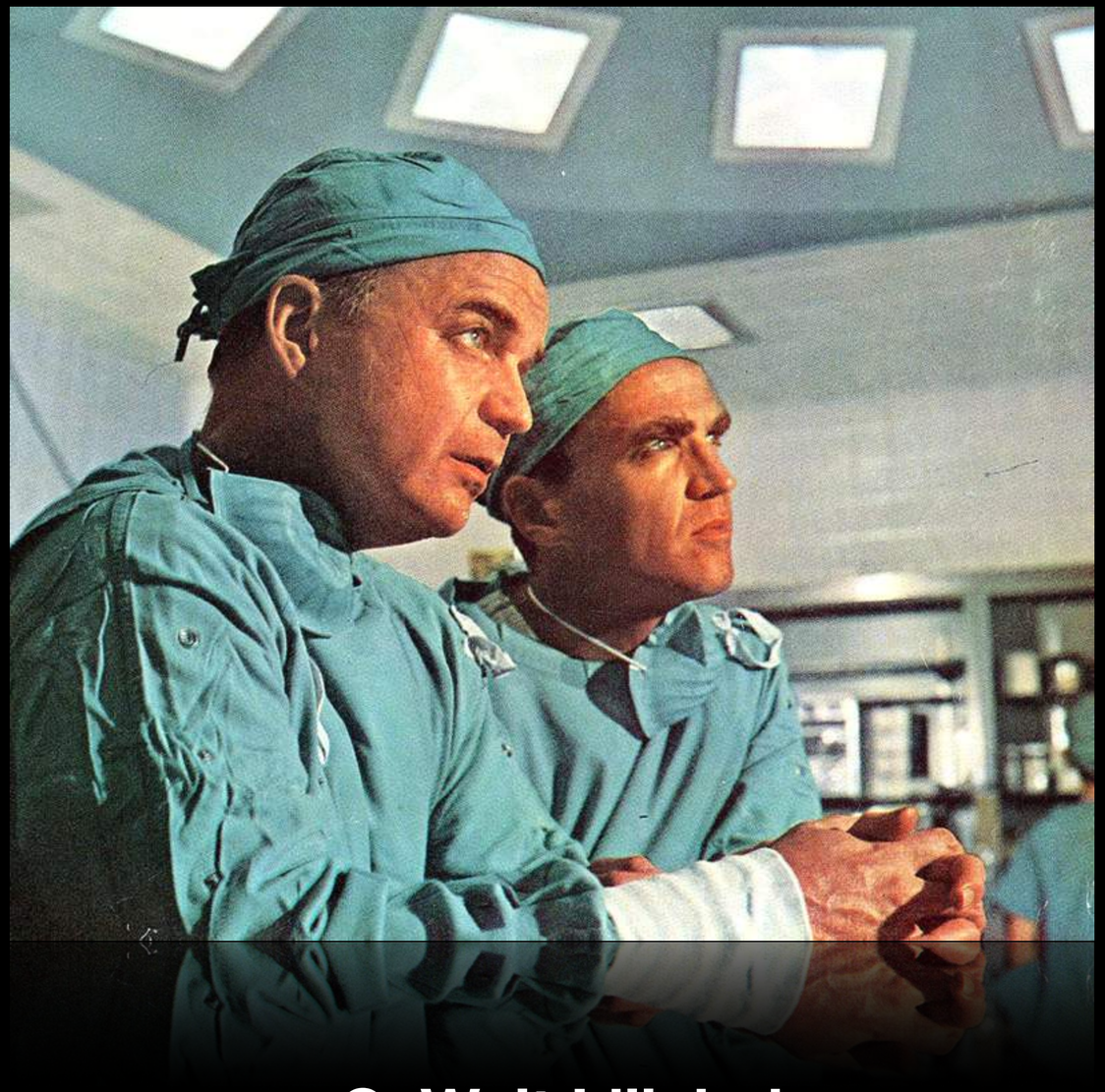
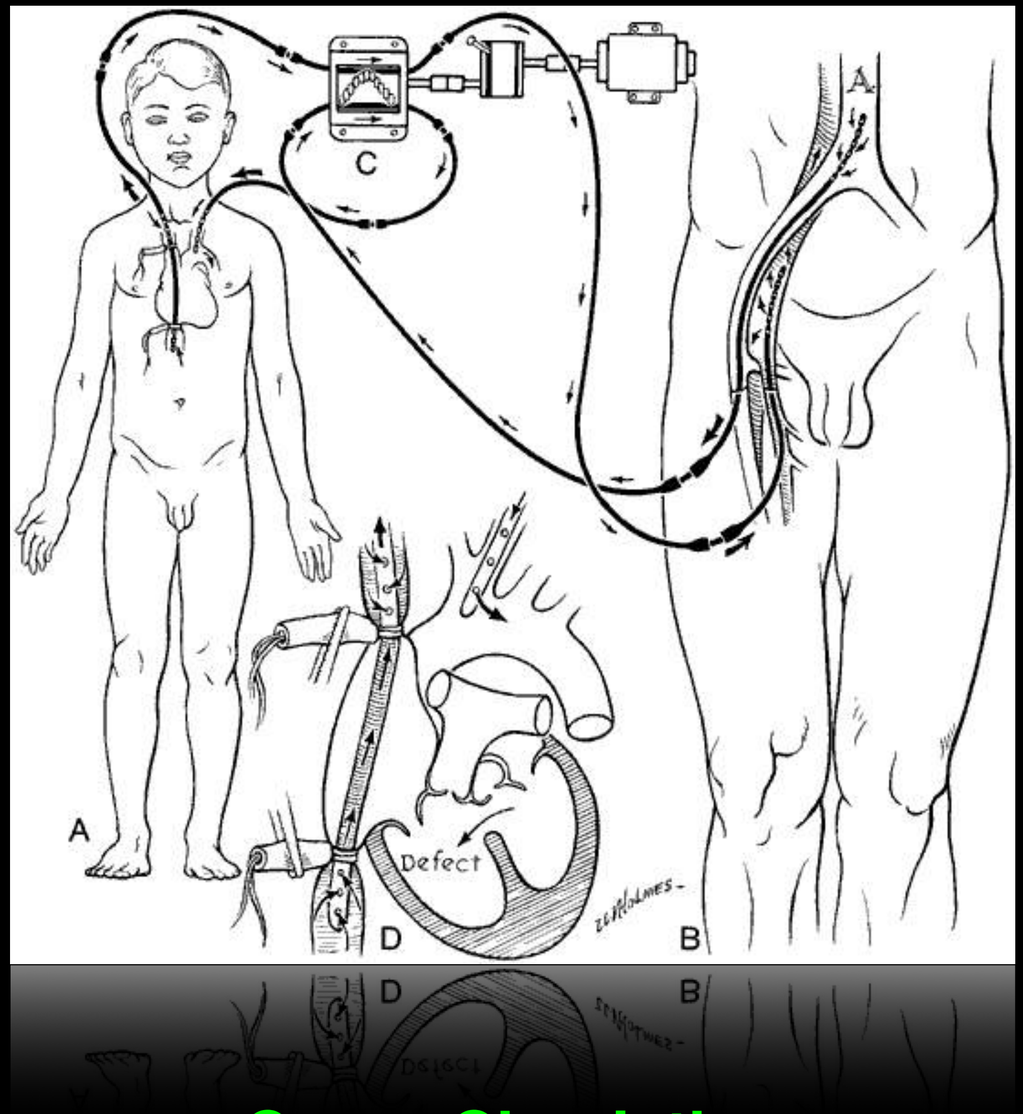


C. Walt Lillehei



Cross-Circulation

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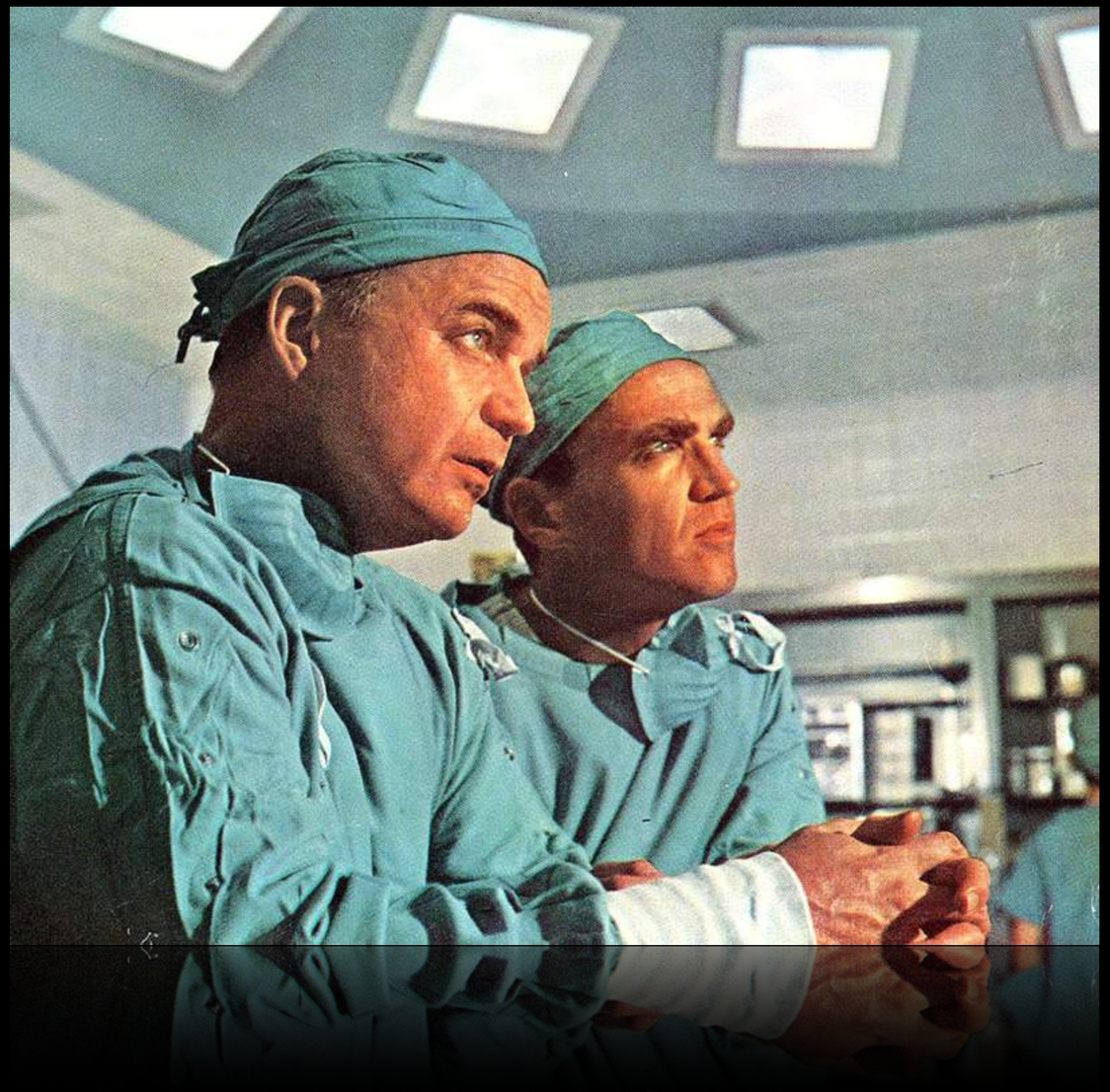

C. Walt Lillehei

- ✔ **E**xpertise
- ✔ **T**echnical
- ? **H**azards
- ? **I**nformed consent
- ✖ **C**onflict of interest
- ✔ **A**nalysis
- ✔ **L**iterature

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Gross

- ✔ **E**xpertise
- ✔ **T**echnical
- × **H**azards
- ? **I**nformed consent
- × **C**onflict of interest
- ✔ **A**nalysis
- ✔ **L**iterature

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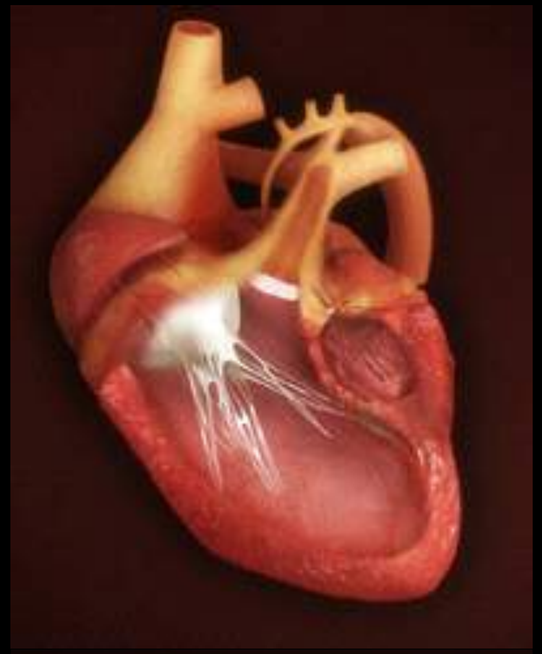
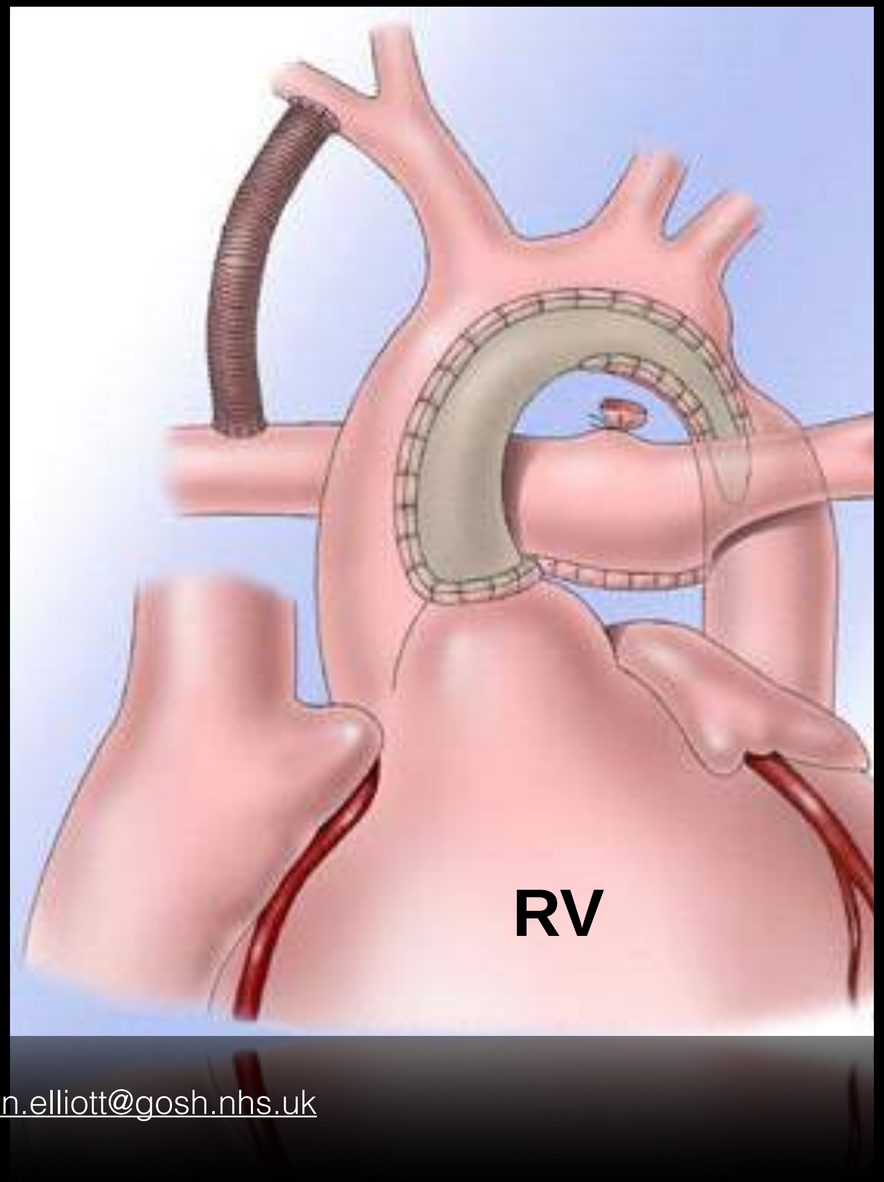
Bill Norwood
(Boston & Philadelphia)



hypoplastic left heart syndrome

untreated, all neonates
with HLHS will die in < 4 weeks



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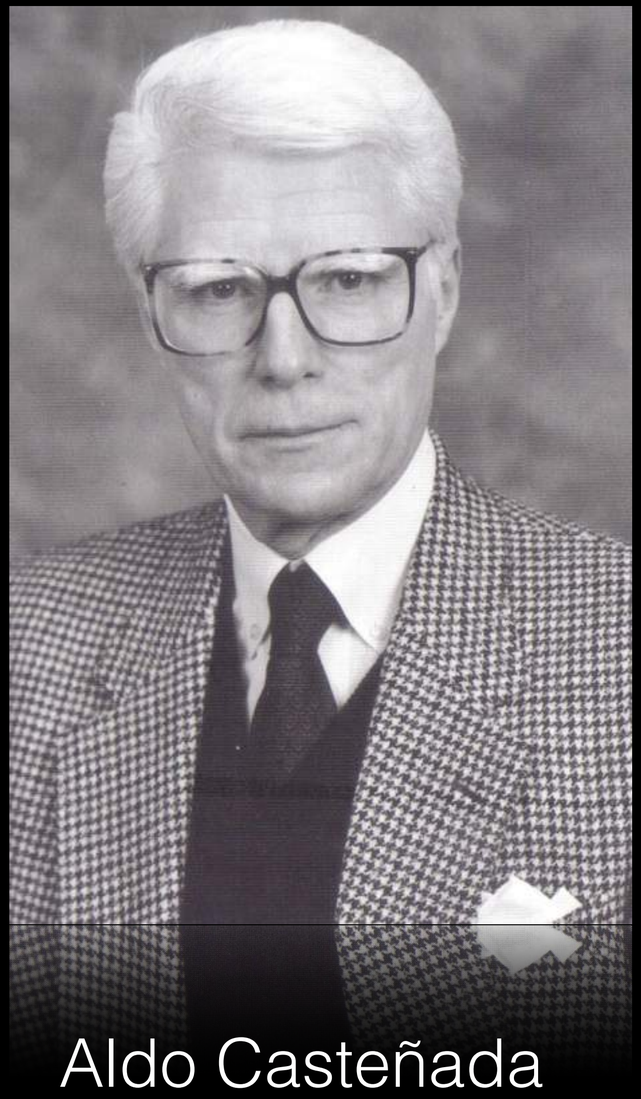

Aldo Casteñada

Chief in Boston in 1970's

- all cardiologists preferred to refer to him
- Norwood had 'time on his hands' and started thinking about HLHS
- Norwood worked out a hypothetical operation and tried to convince Casteñeda (1979)
- reputedly said '*over my dead body*'
- eventually gave in, but 'left Norwood to it'

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2/3 survived

Hypoplastic Left Heart Syndrome: Experience With Palliative Surgery

WILLIAM I. NORWOOD, MD, FACC*
JAMES K. KIRKLIN, MD*
STEPHEN P. SANDERS, MD†

Boston, Massachusetts

January 1980 The American Journal of CARDIOLOGY Volume 45 87

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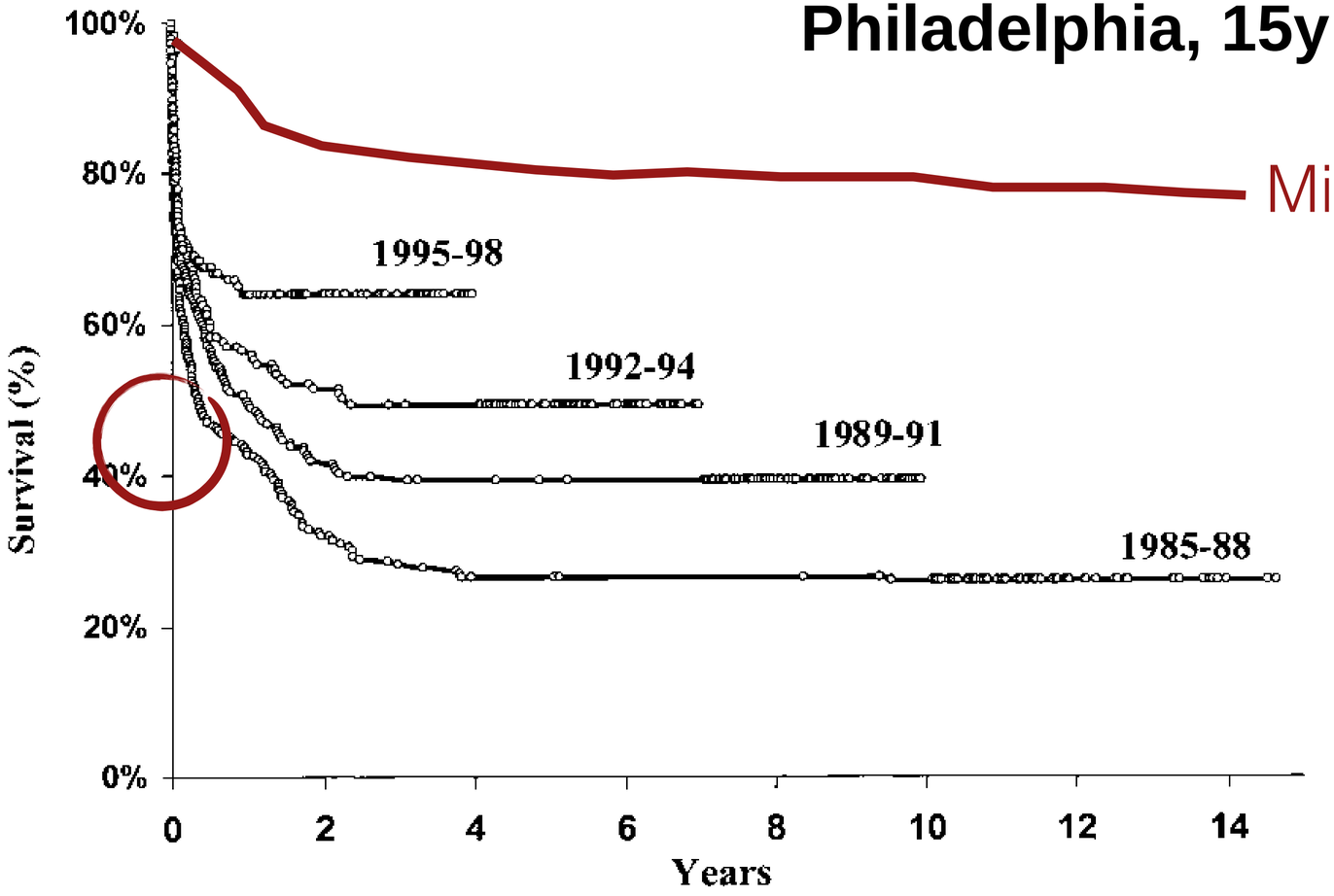
Philadelphia, 15y of the Norwood operation

Milwaukee Group (Prof K Mussatto)



3 operations
RV dependant circulation
? quality of life

Figure 3. Comparison of overall survival for patients adjusted for era of stage I surgery.

Mahle,WT et al *Circulation*. 2000;102[suppl III]:III-136-III-141.

I'll advise you to have a Norwood for your child

but I wouldn't have it done for mine

Renella P, Chang R-KR, Ferry DA, Bart RD, Sklansky MS. Hypolastic left heart syndrome: attitudes among pediatric residents and nurses toward fetal and neonatal management. *Prenat Diagn* 2007; **27**: 1045-55.

Murtuza B, Elliott MJ. Changing attitudes to the management of hypoplastic left heart syndrome: a European perspective. *Cardiol Young* 2011; **21**(Suppl 2): 148-58.

Elliott MJ. A European perspective on the management of hypoplastic left heart syndrome. *Cardiol Young* 2004; **14**(Suppl 1): 41-6.

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in 2006, Norwood was fired from the hospital in Delaware to which he had moved for;
failing to comply with hospital policies regarding informed consent and the use of medical device”

✔ **E**xpertise
✔ **T**echnical
✖ **H**azards
✖ **I**nformed consent
✖ **C**onflict of interest
✔ **A**nalysis
✔ **L**iterature

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Bill Norwood
(Boston & Philadelphia)

- ✔ **E**xpertise
- ✔ **T**echnical
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- ✖ **C**onflict of interest
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- ✔ **L**iterature

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“had Norwood finally lost the ethical battle he had been fighting for 30 years - caught in the gap between the human desire for progress and the equally human unwillingness to bear it?”

Did Dr Norwood go too far? (Parts 1&2). The Philadelphia Magazine. 2006.

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Medical Micawberism?

"By not intervening for HLHS, we deprive today's patient of today's results, but more tragically, we deprive them of what is to come in the future."

Gil Wernovsky, 2008

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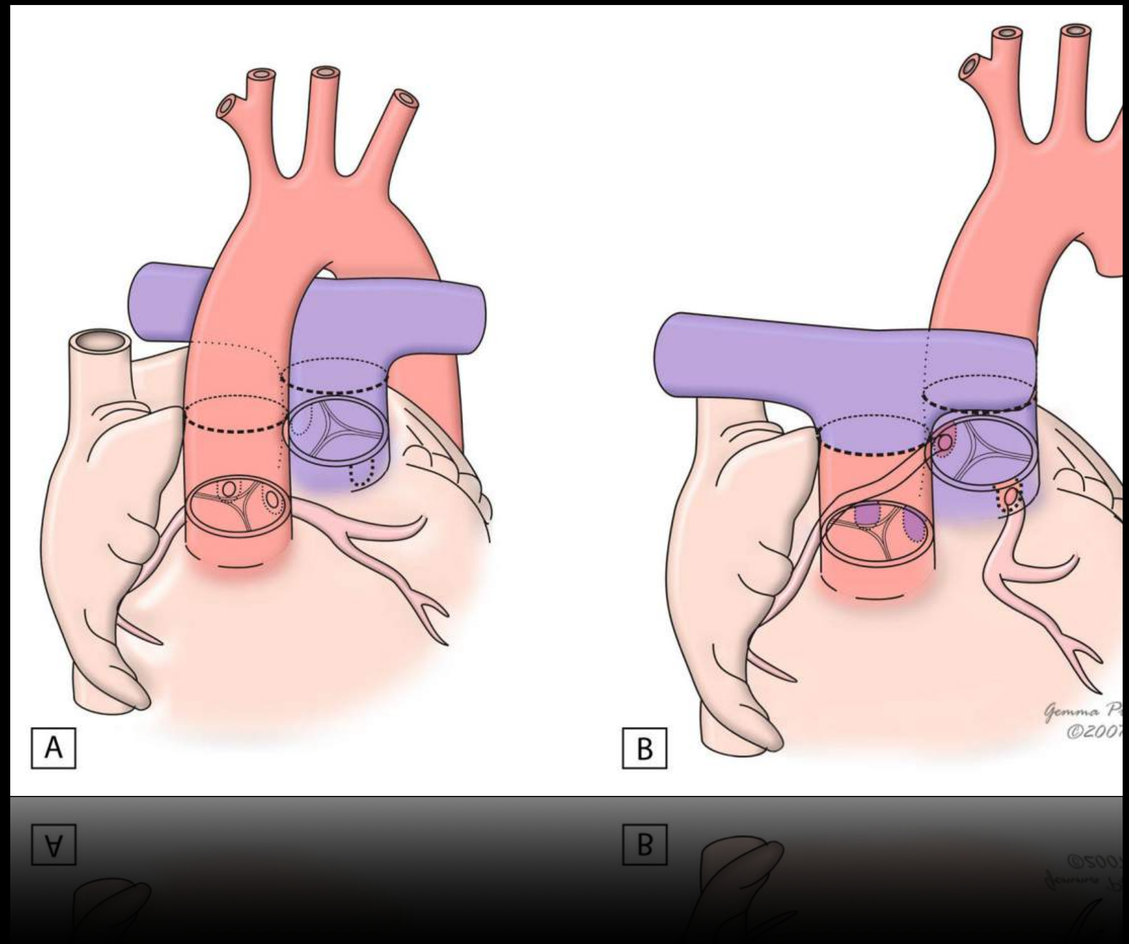
Adib Jatene (Sao Paolo)

the arterial switch operation



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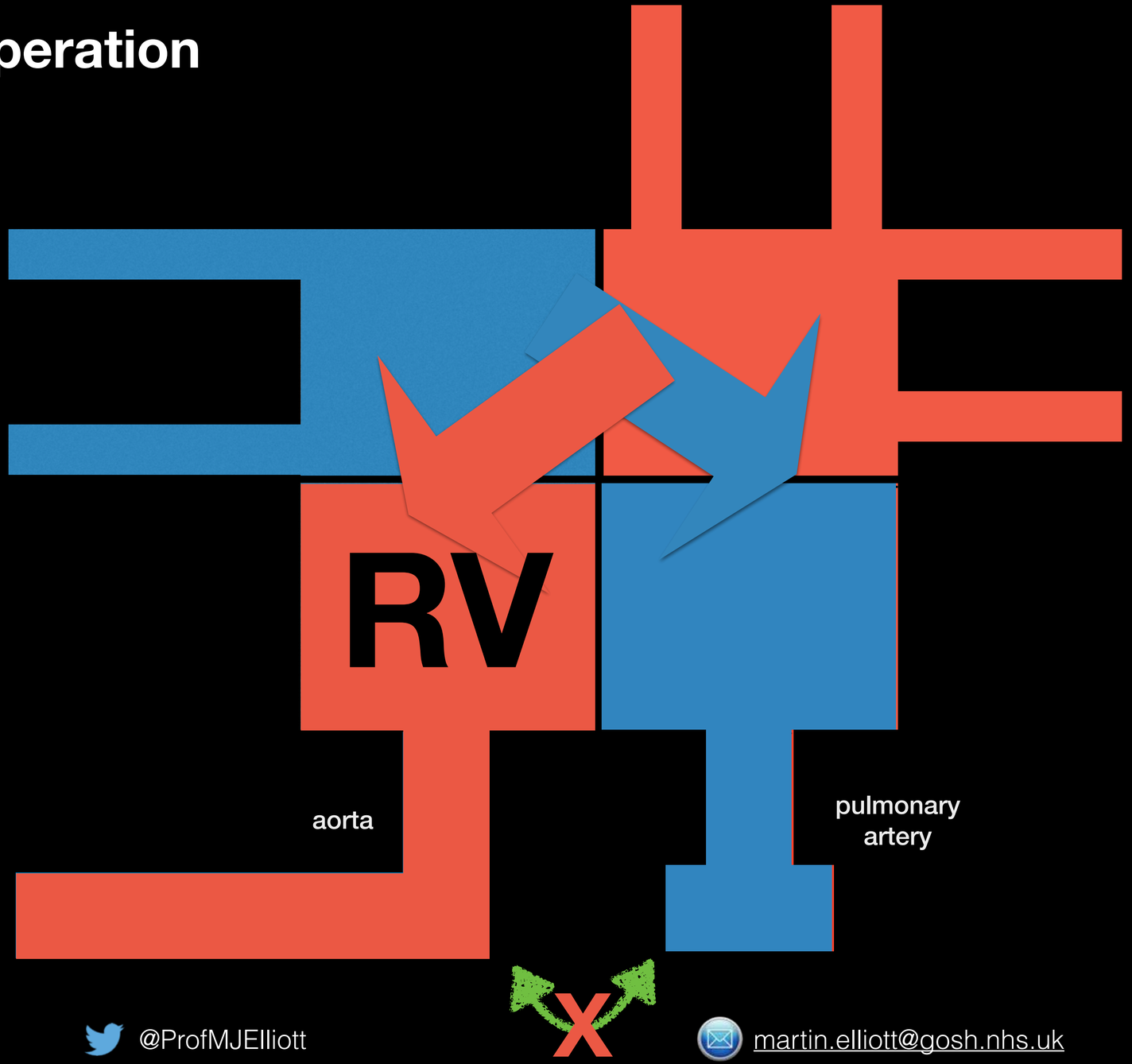
Senning Operation



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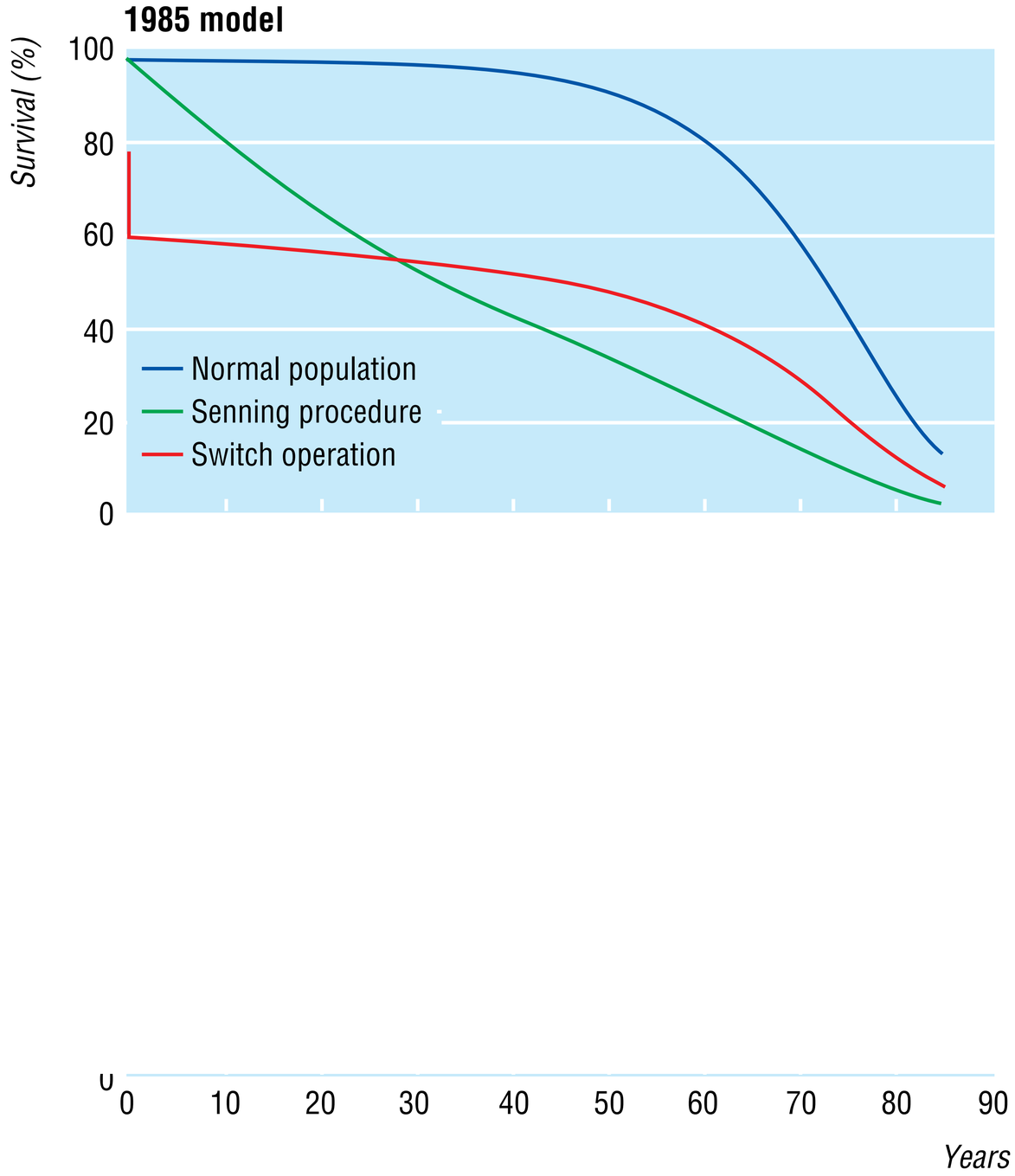
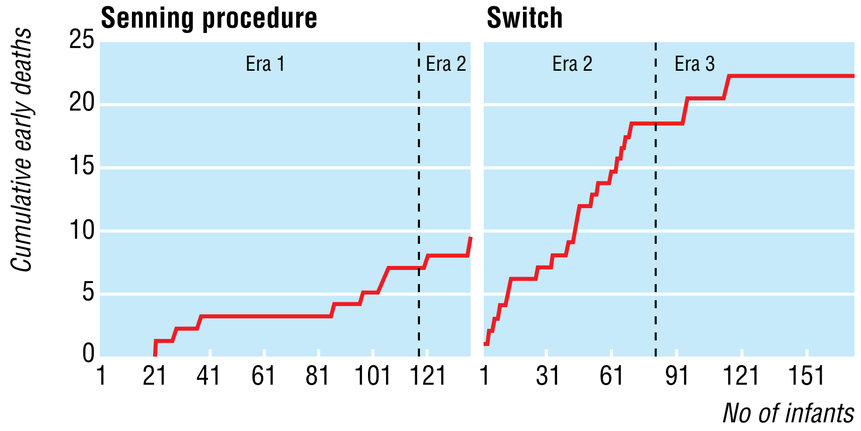
Scientific, ethical, and logistical considerations in introducing a new operation: a retrospective cohort study from paediatric cardiac surgery

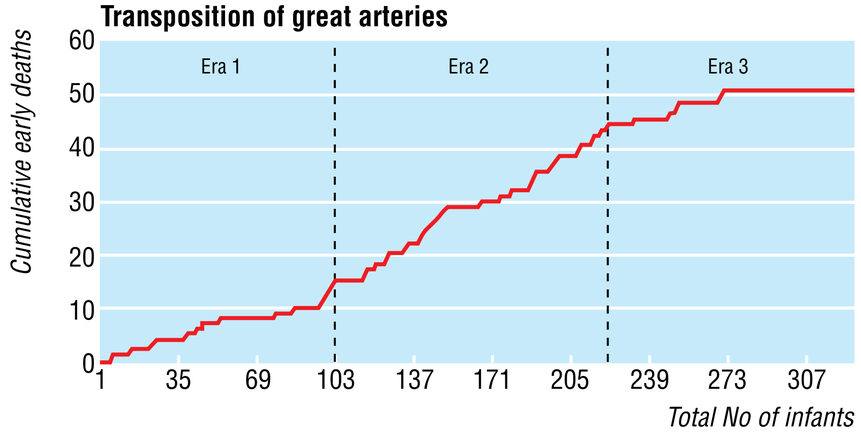
Catherine Bull, R Yates, D Sarkar, J Deanfield, M de Leval

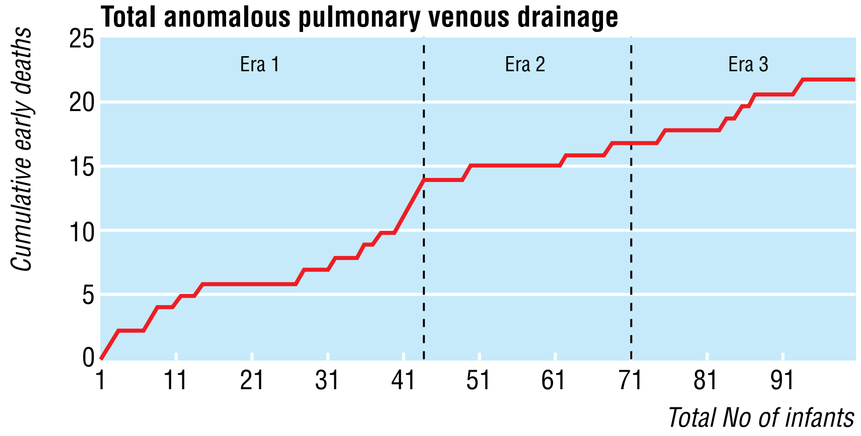
BMJ 2000;320:1168–73

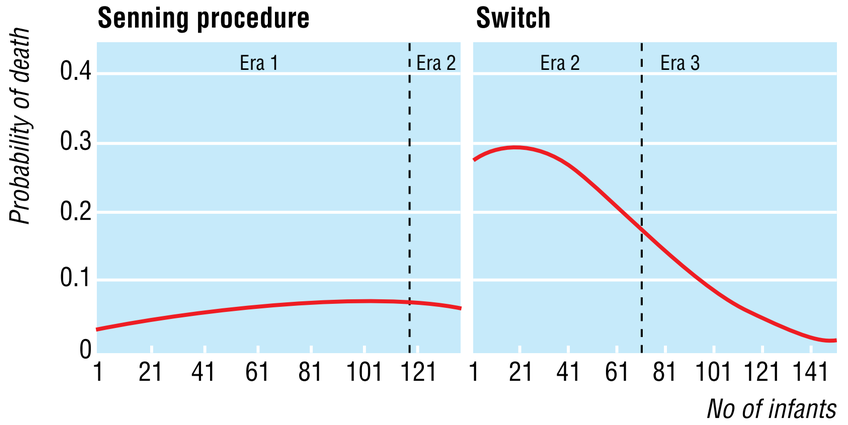


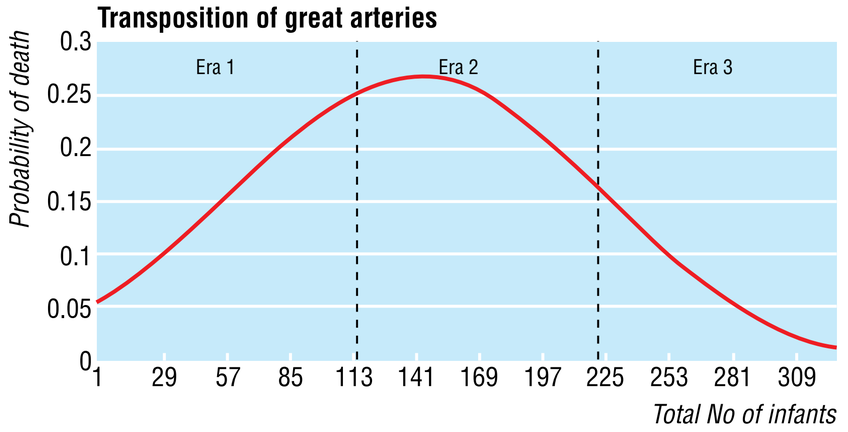
If early risk alone had been considered, the arterial switch operation (which had a higher early mortality when first introduced) might have been abandoned.


Senning procedure
Switch
Era 1
Era 2
Era 3
Cumulative early deaths
No of infants


Transposition of great arteries
Era 1
Era 2
Era 3
Cumulative early deaths
Total No of infants


Total anomalous pulmonary venous drainage
Era 1
Era 2
Era 3
Cumulative early deaths
Total No of infants


Senning procedure
Switch
Era 1
Era 2
Era 3
Probability of death
No of infants


Transposition of great arteries
Era 1
Era 2
Era 3
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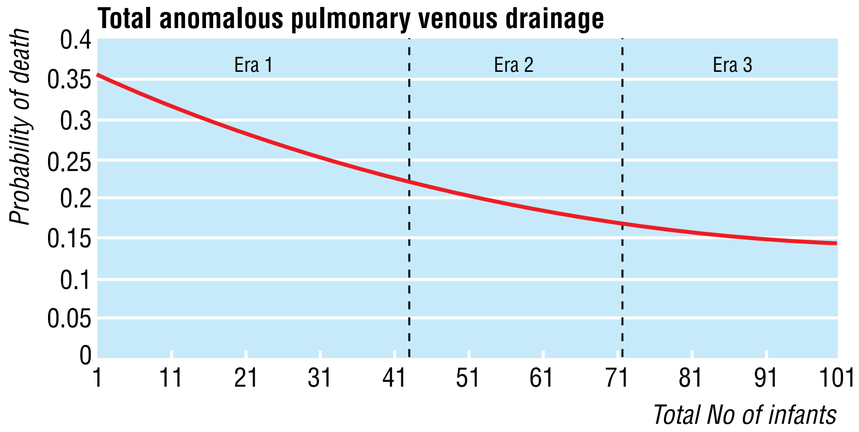
Total No of infants


Total anomalous pulmonary venous drainage
Era 1
Era 2
Era 3
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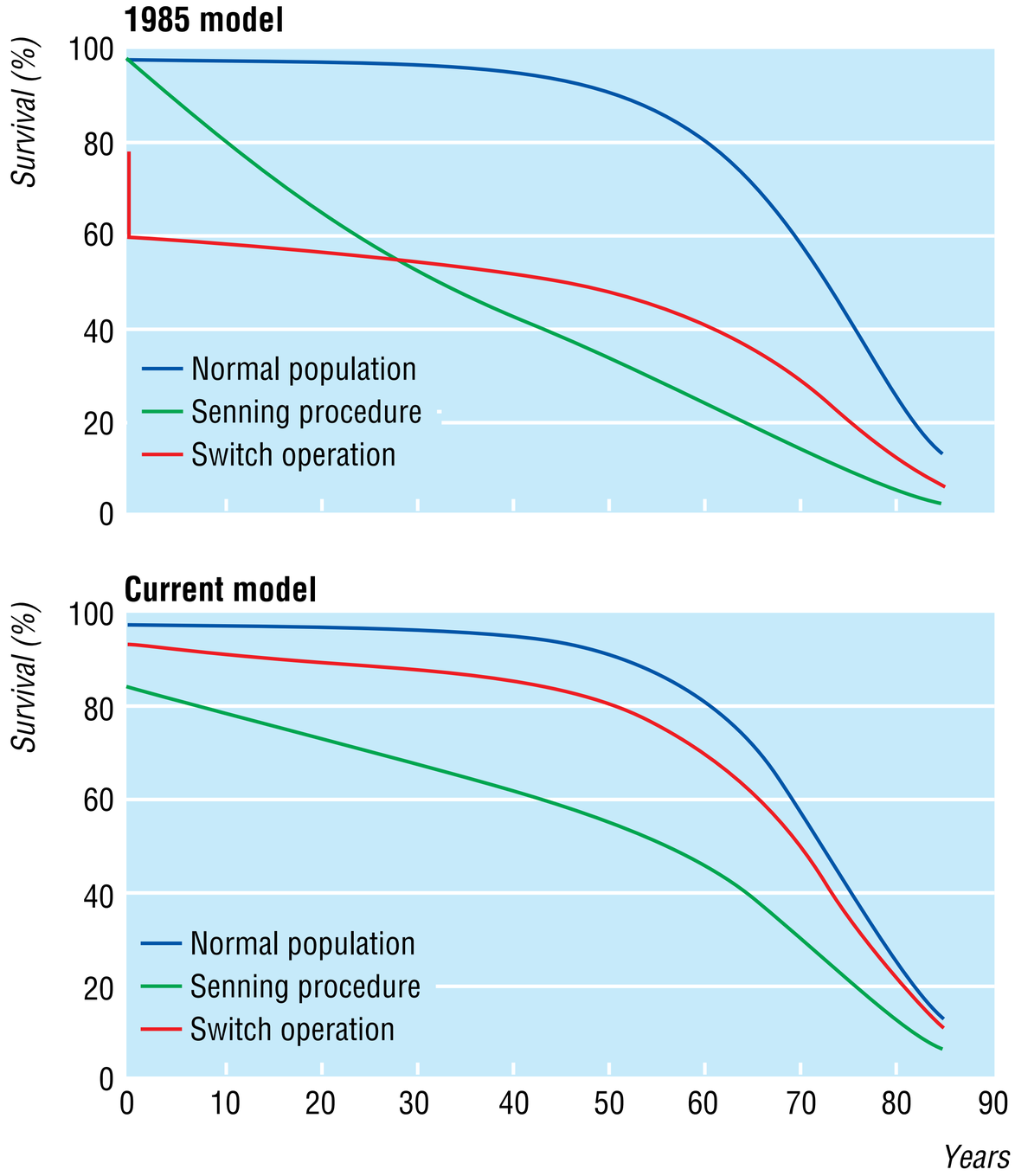
Total No of infants



The ultimate success of the switch had **a significant cost** for those families treated in the transition period.

Was this an acceptable ‘**sacrifice**’?

How can one rationally **consent** during that period?

Buxton's Law

"it is always too early (for rigorous evaluation) until, unfortunately, it's suddenly too late".

Buxton MJ.
Problems in the economic appraisal of new health technology: the evaluation of heart transplants in
Economic appraisal of health technology in the European Community 1987: 103–18.

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Medical Director, Chair of Ethics, Board or CEO

how many deaths would we have allowed?
when/how would we have intervened?
could/should we have afforded it?
would we be confident we were hearing the ‘truth’?

might we have prevented a potentially successful innovation?

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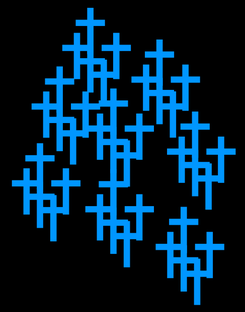
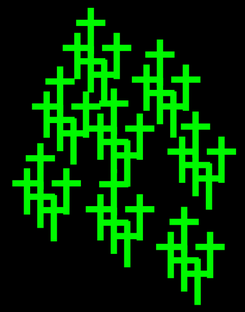
Retrospective Application of Our Culture

Their Culture, Their Time

Our Culture, Their Time

Which group would **you** choose?





Deaths *by* Innovation?

Deaths *Waiting for* Innovation?

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We have an obligation to design our experiments better, and to carry them out in an ethical way, not as mavericks, not as paternalistic decision makers but

respecting our patients,

treating them as if they were our friends and working with them as partners.

It is about our culture, and our humanity.

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core values

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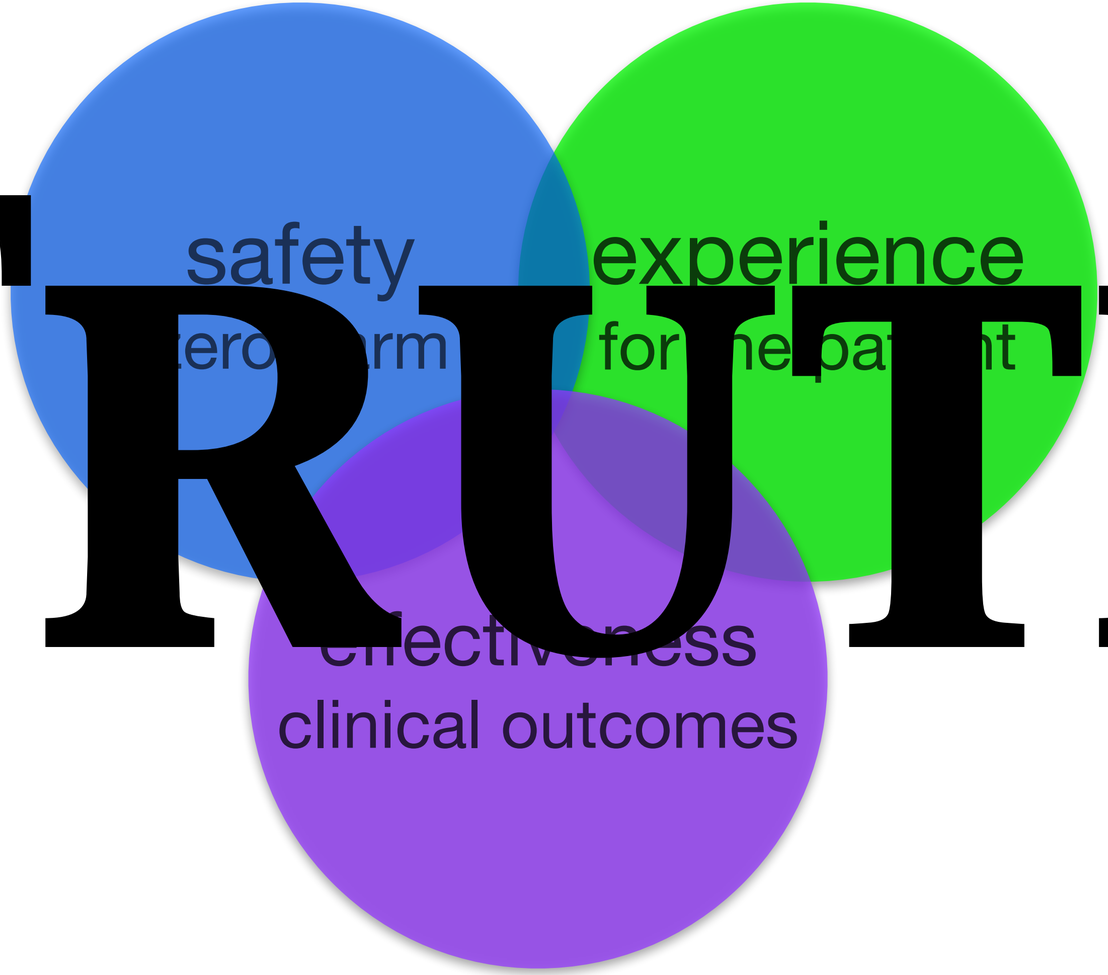
core values



TRUTH

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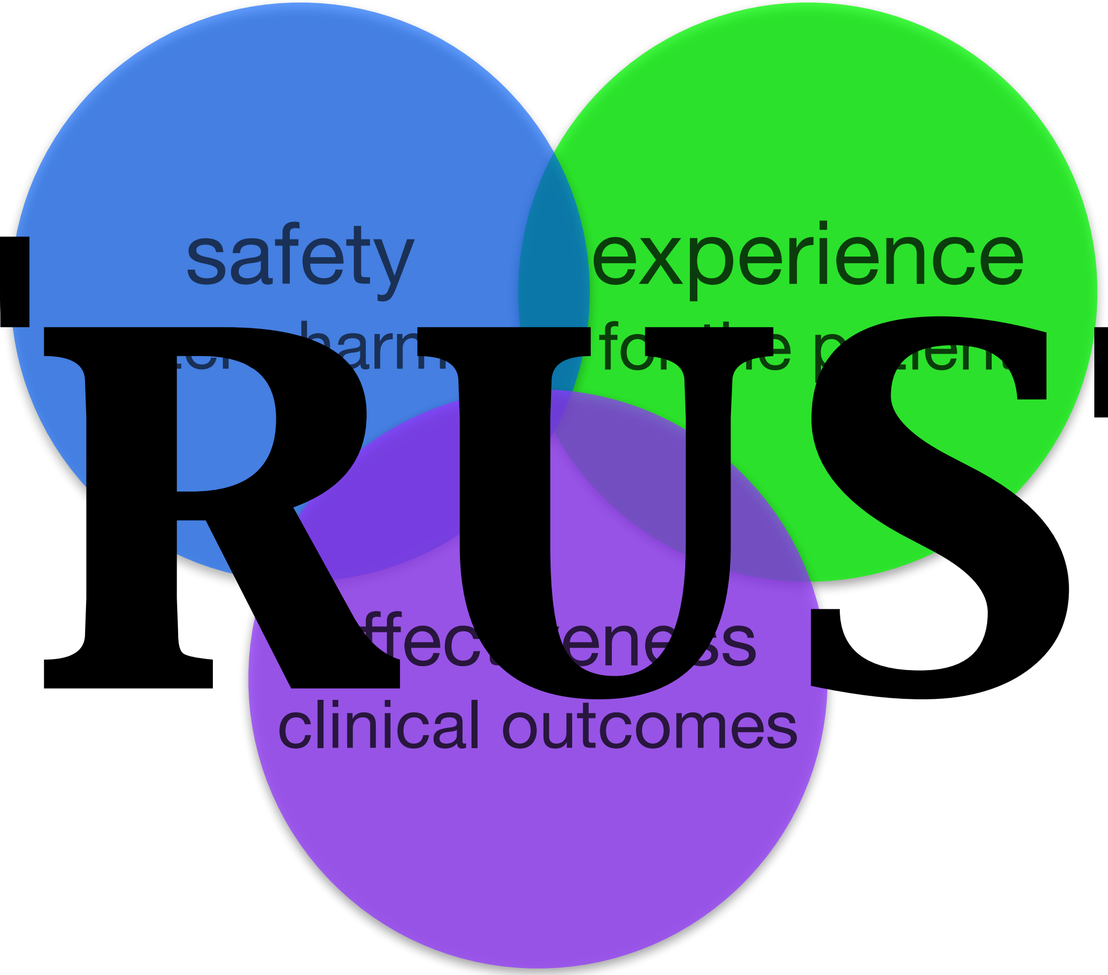
core values



TRUST

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“**Perhaps there is something worse than death**, something like losing humanity, like perpetual suffering without any hope of redemption.”

“Families could use **a more candid explanation** of procedures and their lifelong implications, earlier in the disease course, because in my experience these conversations often occur when the family is already **too committed to contemplate doing less**”

Ashley Treece, Pediatric ICU Resident, Oregon

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Ethical Challenges of New Treatments in Children:
could we do now what we did then?

Martin Elliott

37th Gresham Professor of Physic

Professor of Cardiothoracic Surgery at UCL

Consultant Paediatric Cardiothoracic Surgeon

&

co-Medical Director

The Great Ormond Street Hospital for Children

Ethical Challenges of New Treatments in Children:
could we do now what we did then?

Special Thanks are due to
Piers Dubin (Cambridge)
Professor Robert Sade (Charleston)
Michiel Vriesendorp (Holland)
Dr Catherine Bull (London)
Mary Macleod (London)
Professor Bill Gaynor (Philadelphia)
Professor Gil Wernovsky (Miami)
and all our patients and their families

M a r t i n E l l i o t t
37th Gresham Professor of Physic
Professor of Cardiothoracic Surgery at UCL
Consultant Paediatric Cardiothoracic Surgeon
&
co-Medical Director
The Great Ormond Street Hospital for Children

The Bristol Scandal and Its Consequences

18th February 2015

Next Time

M a r t i n E l l i o t t

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Consultant Paediatric Cardiothoracic Surgeon

&

co-Medical Director

The Great Ormond Street Hospital for Children