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ETHICS IN INNOVATIVE PROCEDURES IN BARIATRIC AND METABOLIC SURGERY

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Innovative Bariatric Procedures and Ethics in Bariatric Surgery: the IFSO Position Statement


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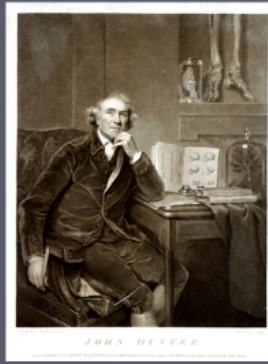
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- I DO NOT HAVE CONFLICTS OF INTEREST

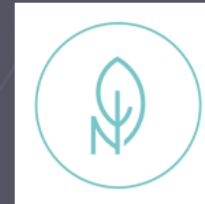


JOHN
HUNTER
1728 - 1793

The imaginative experimental and surgical ventures of **John Hunter** would have been unlikely approved by the arbiters of contemporary ethics.

C M Ward BSc MA FRCS, Ann R Coll Surg Engl 1994;
76: 223-227

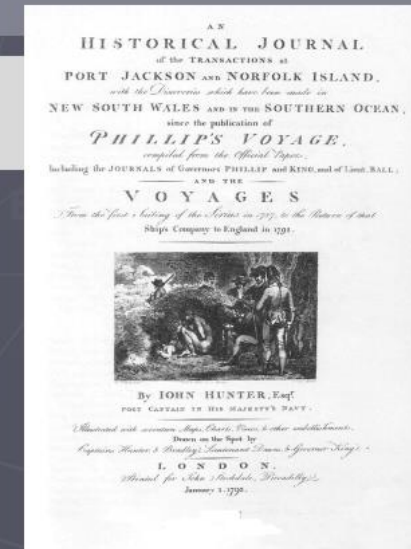
Morris H. John Hunter as a Philosopher. London: John Bale
& Sons & Danielsson Ltd, 1909.



Built on the foundation of **moral philosophy**,
but, by his own admission, John Hunter
regarded himself essentially as an
experimental philosopher rather than a
metaphysician

C M Ward BSc MA FRCS, Ann R Coll Surg Engl 1994;
76: 223-227

Morris H. John Hunter as a Philosopher. London: John
& Sons & Danielsson Ltd, 1909.

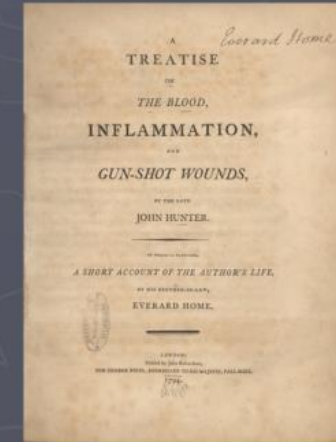


In a Hunterian Oration titled 'John Hunter as a Philosopher' delivered in 1909 the author claimed:

“ It was not as a logician, but as **an observer** and **experimenter** that Hunter excelled”

C M Ward BSc MA FRCS, Ann R Coll Surg Engl 1994; 76: 223-227

Morris H. John Hunter as a Philosopher. London: John Bale & Sons & Danielsson Ltd, 1909.



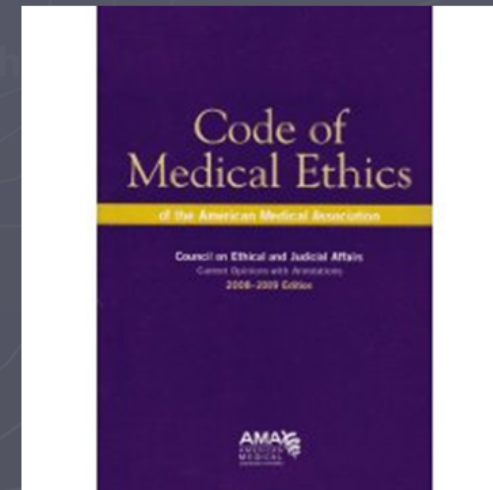
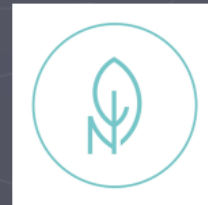
“He naturally expressed a desire for **knowledge, the love of enquiry, an acuteness of observation, ingenuity in devising experiments** and the habit of **taking nothing for granted which he could verify for himself** “

Morris H. John Hunter as a Philosopher. London: John Bale & Sons & Danielsson Ltd, 1909.



However, **was it coincidence or consequence** that **10 years** after the death of John Hunter the most influential treatise in medical ethics in the last two centuries was published?

Morris H. John Hunter as a Philosopher. London: John & Sons & Danielsson Ltd, 1909.



Code of Institutes and Precepts adapted to the **Professional Conduct of Physicians and Surgeons** was a major influence on Anglo-American medical and surgical practice into the early twentieth century.

Percival T. Medical Ethics: Or a Code of Institutes and Precepts Adapted to the Professional Conduct of Physicians and Surgeons. Manchester: J Johnson, 1803.



It contains **no criticism**
of contemporaries indulging in a **style of surgical
innovation or experimentation** which would be seen
by medical ethicists of today as a gross breach of
the dominant framework of medical ethics.

Beauchamp TL, Childress TF. The Principles of Biomedical Ethics. 3rd Edition. Oxford: Oxford University Press, 1989.



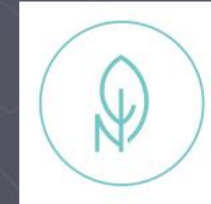
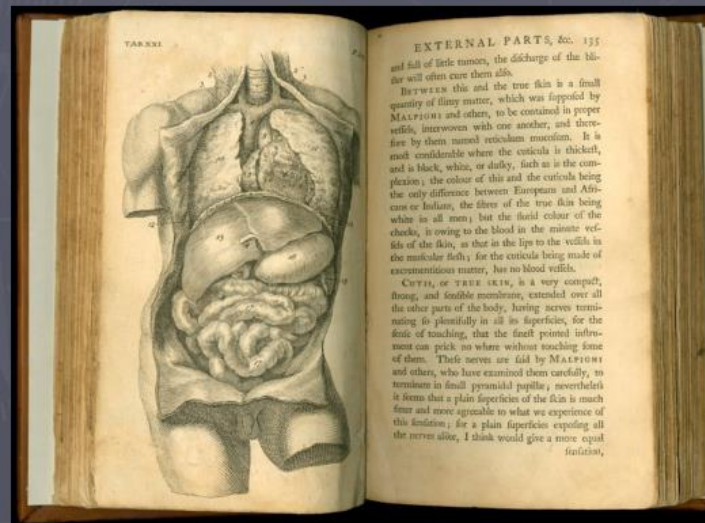
Percival held great store in virtue ethics whereby
**The welfare of the patient was governed by the
good and virtuous behaviour of the doctor**
*making scant allowance for patients to
determine their own therapeutic destiny.*

Percival T. *Medical Ethics: Or a Code of Institutes and
Precepts Adapted to the Professional Conduct of Physicians and
Surgeons.* Manchester: J Johnson, 1803.



The late **Richard Porter** reminds us, “For thousands of years surgery had been a business of boils and broken bones, hernias, venesection and the occasional amputation”.

Stirrat GM, Farndon J, Farrow SC, et al. The challenge of evaluating surgical procedures. *Ann R Coll Surg Engl* 1992;74:80–4.



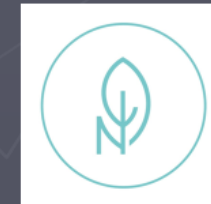
The factors that placed **severe limitations** on what could be successfully achieved were **lack of understanding of the nature and causes of disease, pain, and infection.**

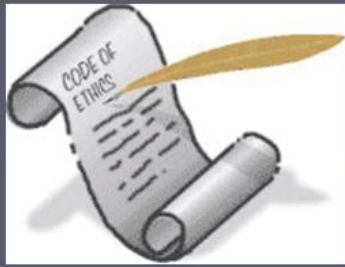
Stirrat GM, Farndon J, Farrow SC, et al. The challenge of evaluating surgical procedures. *Ann R Coll Surg Engl* 1992;74:80–4.



And, even now, one continues to witness
tragic consequences to the patient for
failing to observe ethical principles in the
pursuit of 'progress' **through surgical
research and innovation**. But what are
these principles?

Anonymous editorial. Surgical innovation under
scrutiny. Lancet 1993;343:187–8.





Four fundamental principles to tag along
in order to make a procedure choice and
respect ethical guidelines

**Botros S. Three Approaches to the Analysis of Ethical Problems
in Medical Practice: Manual for Research Ethical Problems
Compiled by Claire Foster. London: The Centre for Medical
Law and Ethics, King's College, 1992.**



The first principle is that all medical practitioners must **make the interests of their patients paramount.**

Botros S. Three Approaches to the Analysis of Ethical Problems in Medical Practice: Manual for Research Ethical Problems Compiled by Claire Foster. London: The Centre for Medical Law and Ethics, King's College, 1992.

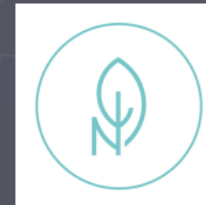




The second principle :

“Any recommendation to a patient, a colleague, or those third parties to the doctor-patient relationship such as economists, lawyers, insurers, or hospital managers **must be supportable on (best available) evidence**”

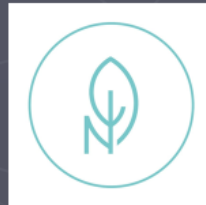
Botros S. Three Approaches to the Analysis of Ethical Problems in Medical Practice: Manual for Research Ethical Problems Compiled by Claire Foster. London: The Centre for Medical Law and Ethics, King's College, 1992.



The third principle:

It is imperative is that all new interventions and procedures must be **properly compared with correspondence to: the currently accepted method**

Botros S. Three Approaches to the Analysis of Ethical Problems in Medical Practice: Manual for Research Ethical Problems Compiled by Claire Foster. London: The Centre for Medical Law and Ethics, King's College, 1992.



Accountability:

Actions toward or involving others that reflect the integrity of the person you want to be.



The fourth principle :

Those who do not fulfill the first three must be held to account.

Botros S. Three Approaches to the Analysis of Ethical Problems in Medical Practice: Manual for Research Ethical Problems Compiled by Claire Foster. London: The Centre for Medical Law and Ethics, King's College, 1992.

The **major oaths**, codes, and guidelines regarding medical ethics **have not come from surgical organizations**. In fact, the **Hippocratic oath forbade surgery !!!**



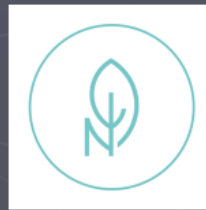
Gillon R. Medical oaths, declarations and codes. *Br Med J (Clin Res Ed)*. 1985;290:1194-1195.



Innovation should not be discouraged. There is, after all, a **public interest in encouraging new and more widely available surgical treatments** providing that, in the process, the **law is not trespassed**, **scientific principles are not abused** and **ethical guidelines ignored.**



But for now, **the chaotic way by which new surgical techniques are allowed to be introduced**, and the impotence of the consumer and peers to prevent a surgeon from continuing to use a demonstrably useless or harmful procedure, does not pass muster when compared with **the rigorous control and monitoring demanded in the introduction of a new drug.**



This is not easy to understand if one acknowledges that **the act of surgery has a greater potential for irreversible harm** than the act of physic, **particularly when introducing new operations.**

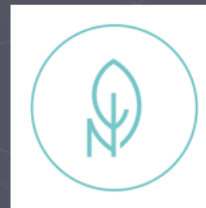
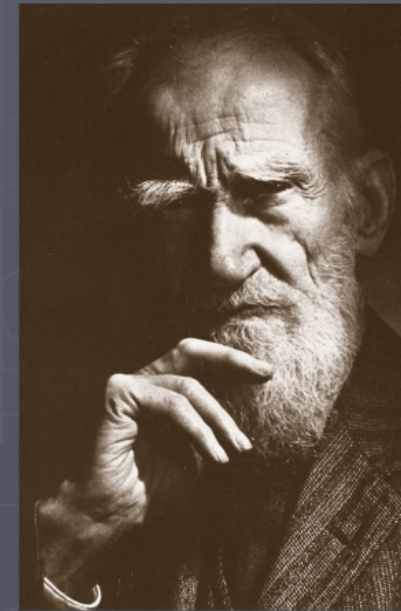
FIRST DO NOT HARM
primum non nocere



While one could argue that.....

“Progress depends on the
unreasonable man”

George Bernard Shaw



Others would say that.....

Man has such a predilection for systems and abstract deductions that he is ready to distort the truth intentionally, he is ready to deny the evidence of his senses only to justify his logic



Fyodor Dostoyevsky



Let's consider and think

- ▶ Do you let to perform a new procedure, that is not widely accepted, in my wife? In one of my sons? In my mother or father?
- ▶ Or in me?
- ▶ Please answer this question to you.



ETHICS AND LEGAL ASPECTS

- ▶ This kind of talk is not easy to design.
- ▶ Much less to give it to you.
- ▶ But it is an honor for me to do it.
- ▶ Ethics and legal aspects are our everyday concern.
- ▶ Each one of us has passed through a medical – legal problem.
- ▶ It is exhausting and very expensive



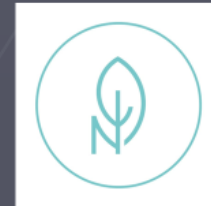
ETHICS AND LEGAL ASPECTS

- ▶ Please do not forget the 3 Ethical principles.
- ▶ To avoid that someone wants to take you out your right of PRACTICE YOUR ART – THE SURGERY.
- ▶ IT IS OUR ART AND WAY OF LIFE
- ▶ Always remember:

primum non nocere

Primero no hagamos daño

First do not harm



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IFSO POSITION STATEMENT

In this position statement IFSO highlights the importance of **SURGICAL ETHICS** in innovation and when offering new procedures. Most of the procedures are performed surgically, while endoluminal approaches constituted less than 5% of cases.

IFSO POSITION STATEMENT

* Throughout history, the defining parameter of surgical progress has been the reduction of morbidity and mortality.

* In recent years: cosmesis, improved technical feasibility, and economic efficacy, including the development of surgical tools, have emerged in the new procedures' evaluation process.

IFSO POSITION STATEMENT

* A systematic review revealed that surgical innovation overall revolves around 4 major themes: ***oversight, informed consent, learning curve and vulnerable patient groups.***

<https://www.surgeons.org/en/become-a-surgeon/about-specialist-surgeons>

THE DUTY OF THE SURGEON TO THE PATIENT

* Surgeons should demonstrate objectivity and compassion, placing patient's interests first and always respecting patient's dignity, individuality, and autonomy as stated in Hippocrates' oath.

<https://www.surgeons.org/en/become-a-surgeon/about-specialist-surgeons>

ETHICS IN INNOVATIVE PROCEDURES OVERSIGHT

* Implementation of Ethics in Innovative procedures: Role of the Institutional Review Board (IRB) & Research Ethics Committees (REC)

ETHICS IN INNOVATIVE PROCEDURES

INFORMED CONSENT

- * Before undergoing (innovative) bariatric/metabolic surgery, patients should be fully informed of the surgical risks, the surgeon's acquaintance with the innovative procedure as well as the short and long-term outcomes.
- * Ensure that the patient understands the information.

ETHICS IN INNOVATIVE PROCEDURES

LEARNING CURVE

- * Always train yourself adequately, search for the masters in a specific training, ask for help in the first cases until you feel yourself comfortable with the procedure.
- * Continue Medical Education.
- * Evidence based surgery.

ETHICS IN INNOVATIVE PROCEDURES

VULNERABLE POPULATION

- * Bariatric Surgery patients should be regarded as a vulnerable population as a whole.
- * Children and adolescents.
- * Parental permission.
- * Understand Information.

**THANK YOU VERY
MUCH FOR YOUR
KIND ATTENTION**

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