

# UNDERSTANDING INFORMED CONSENT: INCONSISTENCY BETWEEN STANDARDS AND THEIR APPLICATION

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# OVERVIEW

- General Medical Council Standards
- Analysis of FTP Decisions
- Focus on 4 Decisions



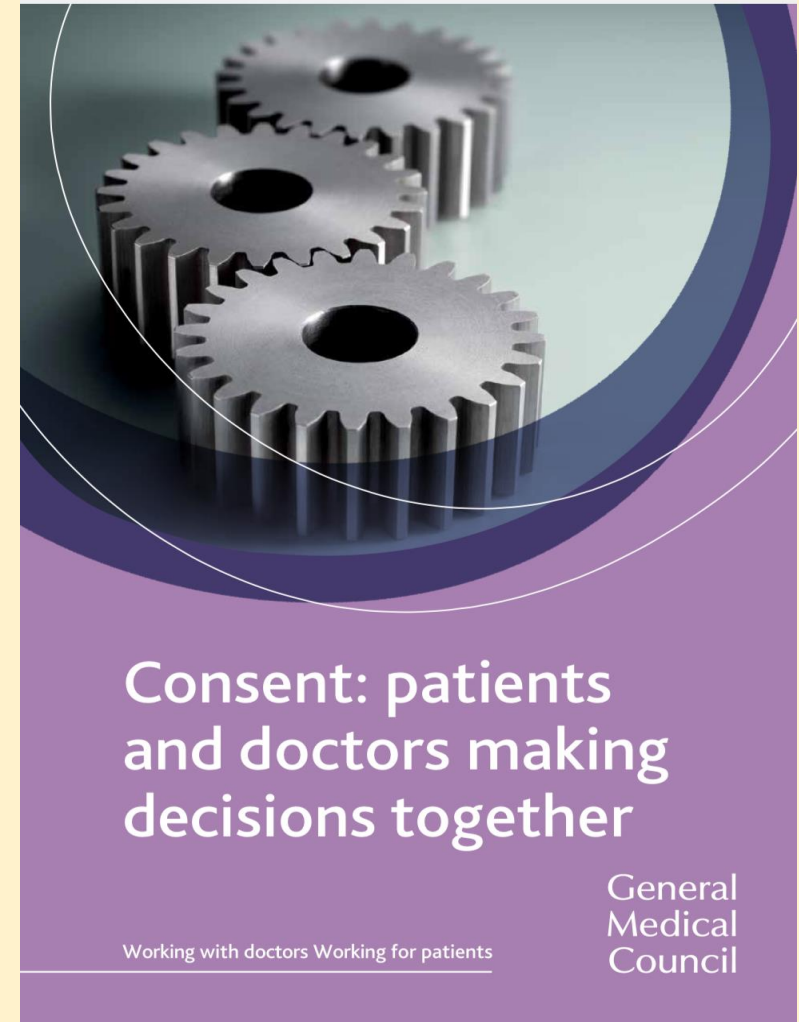
# UNDERSTANDING AND THE GMC STANDARDS OF CONSENT

**‘You should** check whether patients have understood the information they have been given [...]’ [11]

**‘You must** consider [...] how well they understand the details and implications of what is proposed’ [44]

**‘You must** not make assumptions about a patient’s understanding of risk [...]’ [31]

Duty to ‘give patients the information they want or need in a way they can understand.’

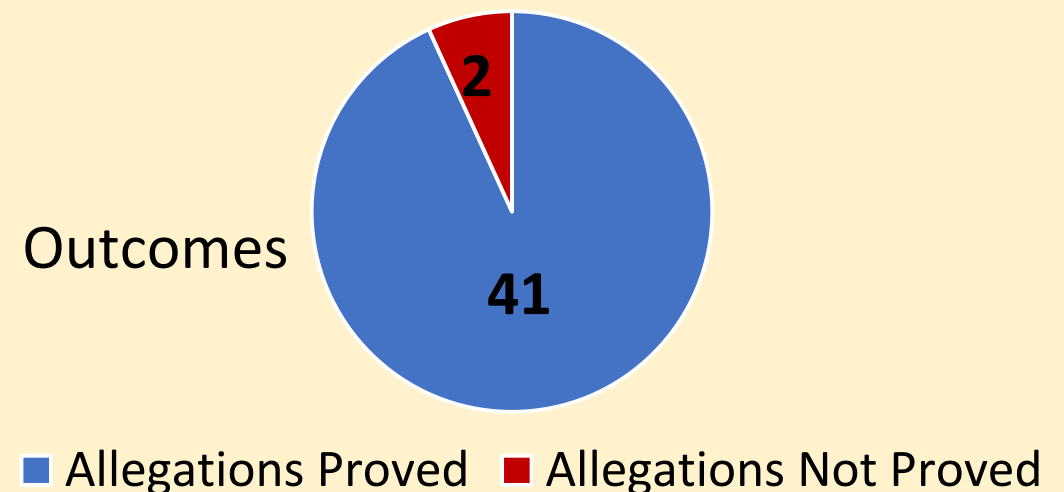
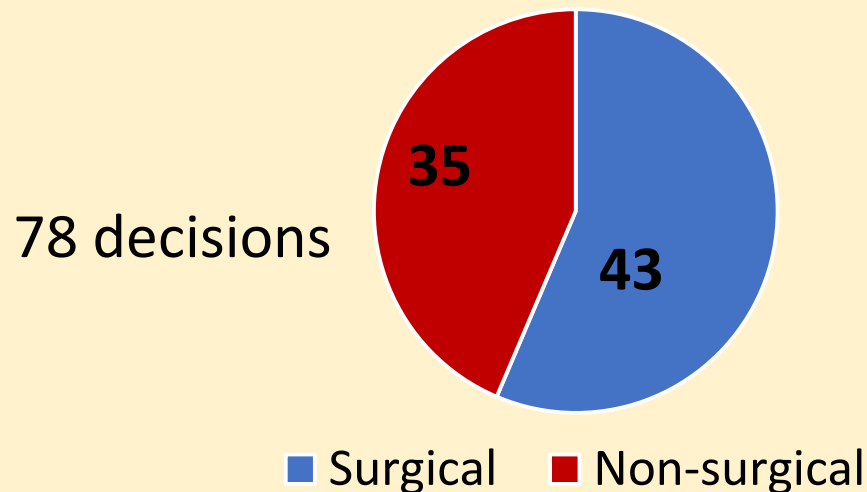


# FITNESS TO PRACTICE DECISIONS ANALYSED

Time Period: 1<sup>st</sup> January 2006 – 31<sup>st</sup> July 2018

Surgery: 'An operation, invasive procedure, or use of a medical device'

[McCulloch et al, 'IDEAL Framework for Surgical Innovation 1: The Idea and Development Stages' (2013) *BMJ* 346]



## TYPES OF SURGERY: COSMETIC

15 cases featured cosmetic surgery

➤ PIP Implant Scandal

➤ Inadequate Regulation

Department of Health, *Review of the Regulation of Cosmetic Interventions: Final Report* (2013)

Nuffield Council on Bioethics, *Cosmetic Procedures: Ethical Issues* (2017)

➤ More people having cosmetic procedures:

British Association of Aesthetic Plastic Surgeons, *Annual Audit* (2009-2018)

## TYPES OF SURGERY: OTHER

- Orthopaedic (5)
- Gynaecology (4)
- G.P. (3)
- Colorectal (3)
- A&E (2)
- Renal surgery (2)
- Ophthalmic (2)
- General Surgery (2)
- Urology (1)
- Stem Cell Therapy (1)
- Vascular Radiology (1)
- Pain Management (1)
- Anaesthesia (1)
- Ear, Nose & Throat (10)

# UNDERSTANDING

Thematic analysis

14 decisions referenced understanding

6 of those referred to the need to check a patient's understanding

- 2 decisions: Sufficient to check on the day of surgery  
Cason (2009); Bowen (2017)
- 4 decisions: Patient had not understood information and/or the doctor had failed to check understanding

## BORA (2017)

- Provided '*comprehensive*' leaflet
- Assumed '*she must have read and understood the leaflet because she did not ask [...] any questions*' (p.17)
- Had fulfilled his duty, '*albeit a more careful practitioner would have checked her understanding*' (p.17)
- Contrary to 2008 guidance and expert opinion
- BUT medical expert '*on occasion [...] applying her own standards rather than those applicable to a competent GP*' (p.9)





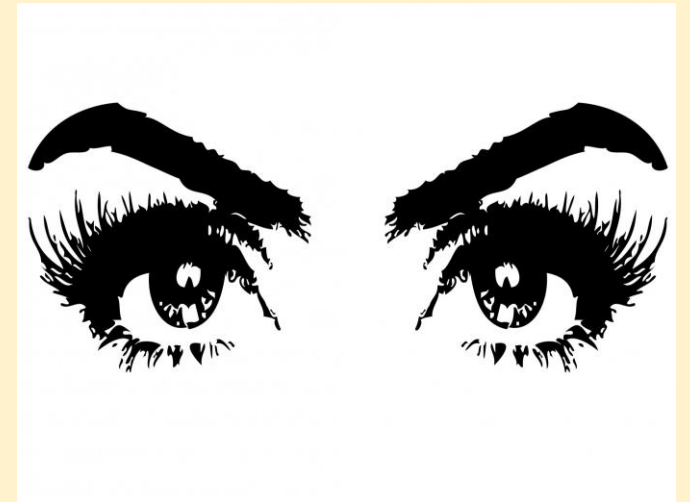
## JEYAPRAGASH (2017)

- Used sedation and local anaesthetic instead of general anaesthetic
- Patient had misunderstood but she had:  
*‘an evident disinclination to listen to explanations and an aversion to reading documents.’* (p.53)
- No evidence of steps taken to check understanding
- No reference to 2008 guidance



## PATERSON (2015)

- Eyebrow lift and browpexy
- *'May not have fully comprehended'* information (p.37)
- Had *'demonstrated an inability to understand the implications of some questions [...]'* (p.37)
- *'It was likely to have been discussed but possibly not fully understood'* (p.37)



## DARTEY (2011)

- Labiaplasty
- Patient signed risks and complications form
- Concluded had understood and accepted risks of procedure
- Excluded reference to overreduction



# SUMMARY

Data limited but:

- In 2 cases, sufficient to check understanding on the day of surgery
- In 3 cases, patients lack of understanding not a basis for finding inadequate consent
- In 1 case, a specific allegation about understanding was ignored

Apparent conflict between 2008 guidance and Tribunal's approach