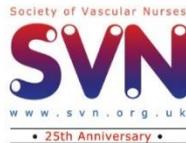


NICE Guidelines on EVAR and F-EVAR – is better case selection the key?

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University of Birmingham, UK**

Friday 30 November 2018 – 11.50-12.00 – Lomond



THE SOCIETY FOR
VASCULAR TECHNOLOGY OF
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EVAR-1: OSR “dominates” EVAR (cheaper and more QALYs)



Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

NICE HE analysis - OSR “dominates” EVAR

ICER is **infinity**

Robust to the most **extreme** sensitivity testing

What should we do?

EVAR-2: > £300-400K per QALY

Every EVAR-2 intervention denies at least 15-20 other people clinically and cost-effective NHS treatment

One EVAR-2 =

c. 50+ venous leg ulcer patients endovenous ablation, EVRA trial

c. 200+ IC patients having a supervised exercise programme

What should we do?

THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Endovascular Repair of Aortic Aneurysm in Patients Physically Ineligible for Open Repair

The United Kingdom EVAR Trial Investigators*

ABSTRACT

BACKGROUND

Endovascular repair of abdominal aortic aneurysm was originally developed for patients who were considered to be physically ineligible for open surgical repair. Data are lacking on the question of whether endovascular repair reduces the rate of death among these patients.

METHODS

From 1999 through 2004 at 33 hospitals in the United Kingdom, we randomly assigned 404 patients with large abdominal aortic aneurysms (≥ 5.5 cm in diameter) who were considered to be physically ineligible for open repair to undergo either endovascular repair or no repair; 197 patients were assigned to undergo endovascular repair, and 207 were assigned to have no intervention. Patients were followed for rates of death, graft-related complications and reinterventions, and costs until the end of 2009. Cox regression was used to compare outcomes in the two groups.

RESULTS

The 30-day operative mortality was 7.3% in the endovascular-repair group. The overall rate of aneurysm rupture in the no-intervention group was 12.4 (95% confidence interval [CI], 9.6 to 16.2) per 100 person-years. Aneurysm-related mortality was lower in the endovascular-repair group (adjusted hazard ratio, 0.53; 95% CI, 0.32 to 0.89; $P=0.02$). This advantage did not result in any benefit in terms of total mortality (adjusted hazard ratio, 0.99; 95% CI, 0.78 to 1.27; $P=0.97$). A total of 48% of patients who survived endovascular repair had graft-related complications, and 27% required reintervention within the first 6 years. During 8 years of follow-up, endovascular repair was considerably more expensive than no repair (cost difference, £9,826 [U.S. \$14,867]; 95% CI, 7,638 to 12,013 [11,556 to 18,176]).

CONCLUSIONS

In this randomized trial involving patients who were physically ineligible for open repair, endovascular repair of abdominal aortic aneurysm was associated with a significantly lower rate of aneurysm-related mortality than no repair. However, endovascular repair was not associated with a reduction in the rate of death from any cause. The rates of graft-related complications and reinterventions were higher with endovascular repair, and it was more costly. (Current Controlled Trials number, ISRCTN55703451.)

Post-NICE EVAR Options

Ignore EVAR 1/2 trials – “business as usual”?

- Patient outcomes poorer overall?
- Mis-use of NHS resources?
- Commissioning? (NHS England, specialised)
- NICE? NIHR? RCTs? Evidence-based surgery?

Disinvest in EVAR - draft NICE guidelines?

- Utilitarian distributive justice

Perform more RCT's?

- Ethical ? Funding? Time?

Post-NICE EVAR Options

Select people “more carefully” for EVAR? How?

Anatomy

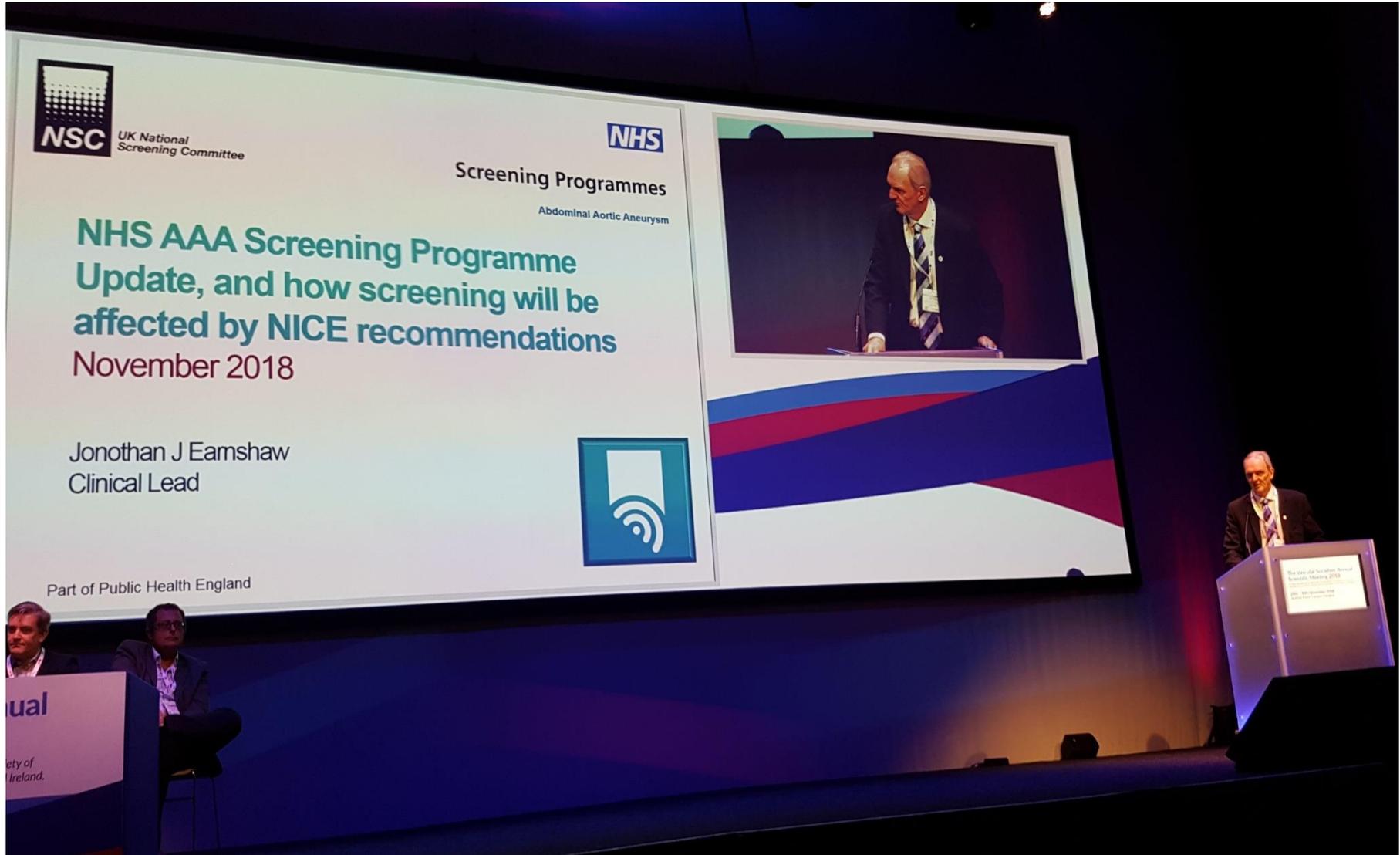
- Size
- IFU

Patients

- Age
- Gender
- Morbidity
- **Choice**

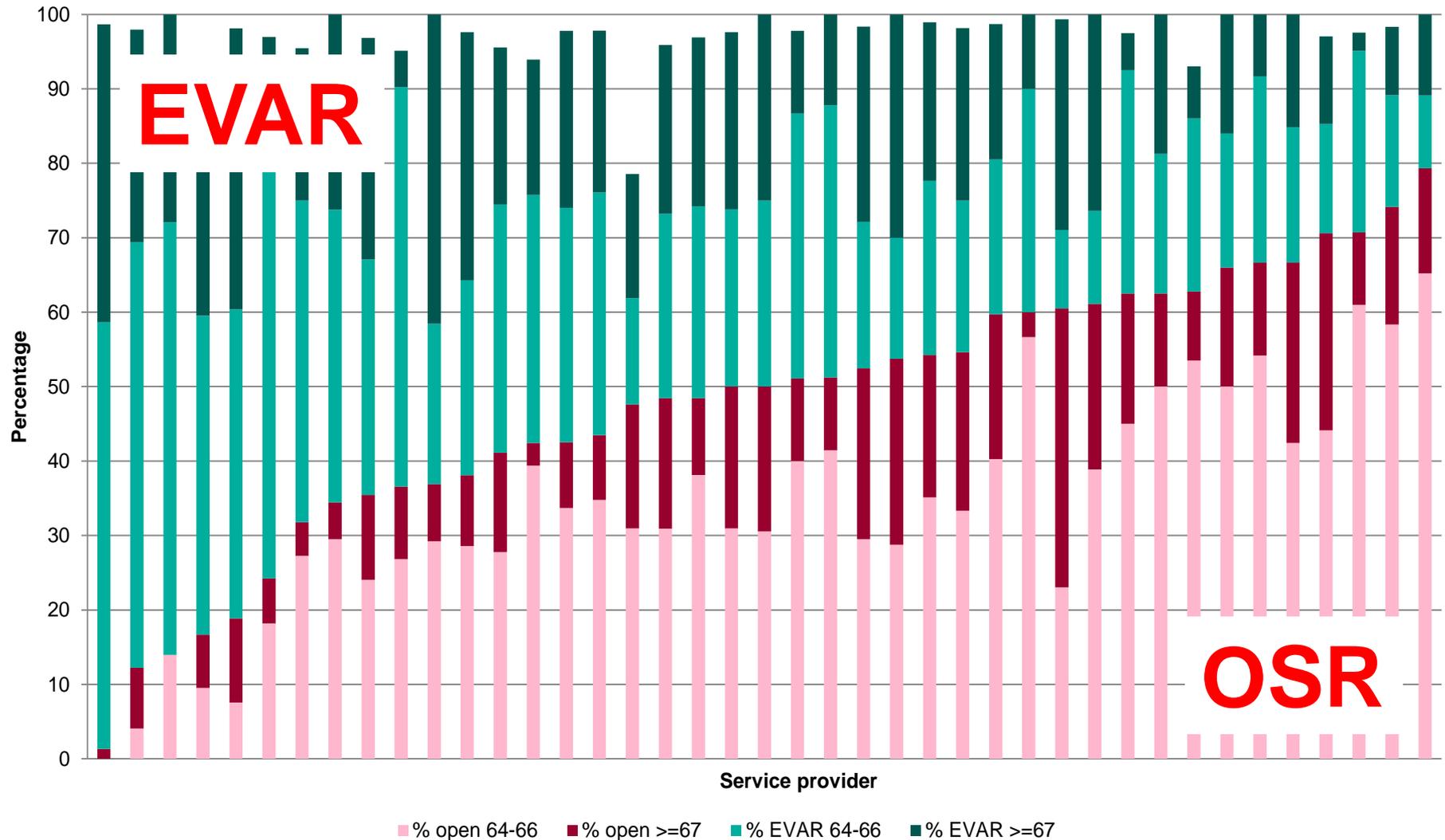


National AAA Screening Programme



NAAASP – patient selection

AAA repair method by age 2009 to 2016 for each screening centre



Patient selection

Does this variation in practice represent appropriate personalized shared decision making based upon sound clinical judgement?

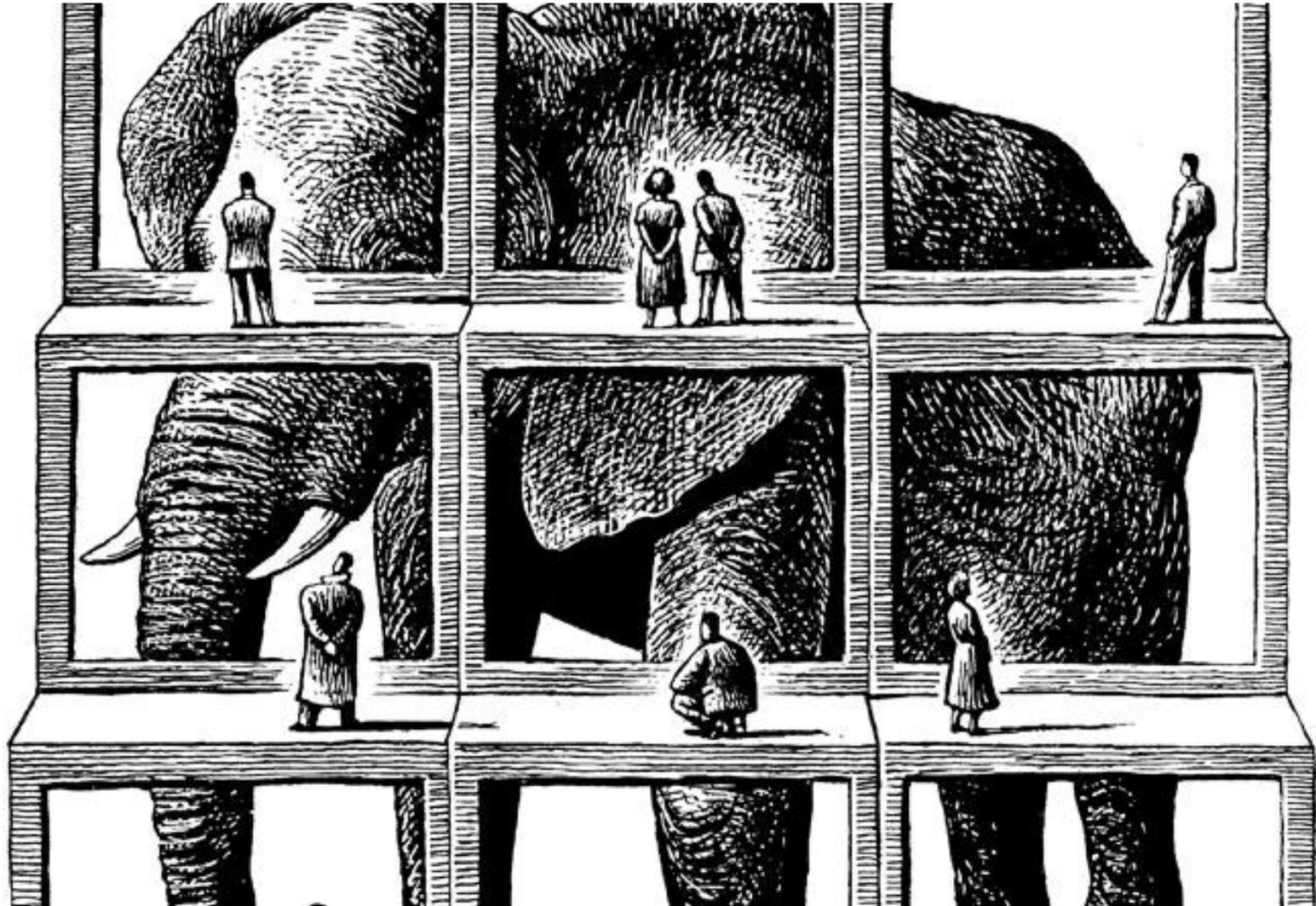


Patient selection

Or is it, in reality, the product of fairly arbitrary decision making based upon local preferences in the absence of a strong evidence base as to who should have intervention and, if so, what



NICE Guidelines in Context



National AAA Screening Programme



NHS
Screening Programmes

Draft NICE guidelines (2)

Endorse ITI method of ultrasound assessment

Offer surveillance with aortic ultrasound to people with an asymptomatic AAA:

- every 3 months if the AAA is 4.5–5.4 cm
- every 2 years if the AAA is 3.0–4.4 cm.

AAA grow much less quickly than we thought
Agreed 'doubling' of screening intervals

National AAA Screening Programme

NHS
Screening Programmes

AAA rupture in surveillance

	Number of men	Ruptures (N)	Follow-up (person-years)	Incidence rate per 100 person-years (95% CI)
Overall	18,652	31	50,095	0.06 (0.04, 0.09)
Routinely invited	15,527	25	42,220	0.06 (0.04, 0.09)
Self-referred	3,125	6	7,876	0.08 (0.03, 0.17)
Initial aortic measurement				
Grouping 1				
3.0-4.4cm	16,430	20	46,576	0.04 (0.03, 0.07)
4.5-5.4cm	2,222	11	3,519	0.31 (0.17, 0.56)
Grouping 2				
3.0-4.9cm	17,883	28	49,349	0.06 (0.04, 0.08)
5.0-5.4cm	769	3	746	0.40 (0.13, 1.25)
Last known aortic measurement				
Grouping 1				
<3.0cm	-	0	1,713	0 -
3.0-4.4cm	-	13	41,788	0.03 (0.02, 0.05)
4.5-5.4cm	-	18	6,532	0.28 (0.17, 0.44)
5.5cm+	-	0	32	0 -
Grouping 2				
<3.0cm	-	0	1,713	0 -
3.0-4.9cm	-	20	45,594	0.04 (0.03, 0.07)
5.0-5.4cm	-	11	2,726	0.40 (0.22, 0.73)
5.5cm+	-	0	32	0

Men safe in surveillance in NAAASP
No need to change referral threshold

AAA rupture much less often than we thought

AAA 50-54mm I-to-I (55-60mm on CT?)

Rupture risk 0.4% / year (1 / 250)

55mm threshold? NNT?

Patient choice?

Utilitarianism “It is the greatest happiness of the greatest number that is the measure of right and wrong”

HE Consideration Does this treatment / intervention produce more health than its cost will take away (or vice versa)?

Exercise for IC **£771-1608**

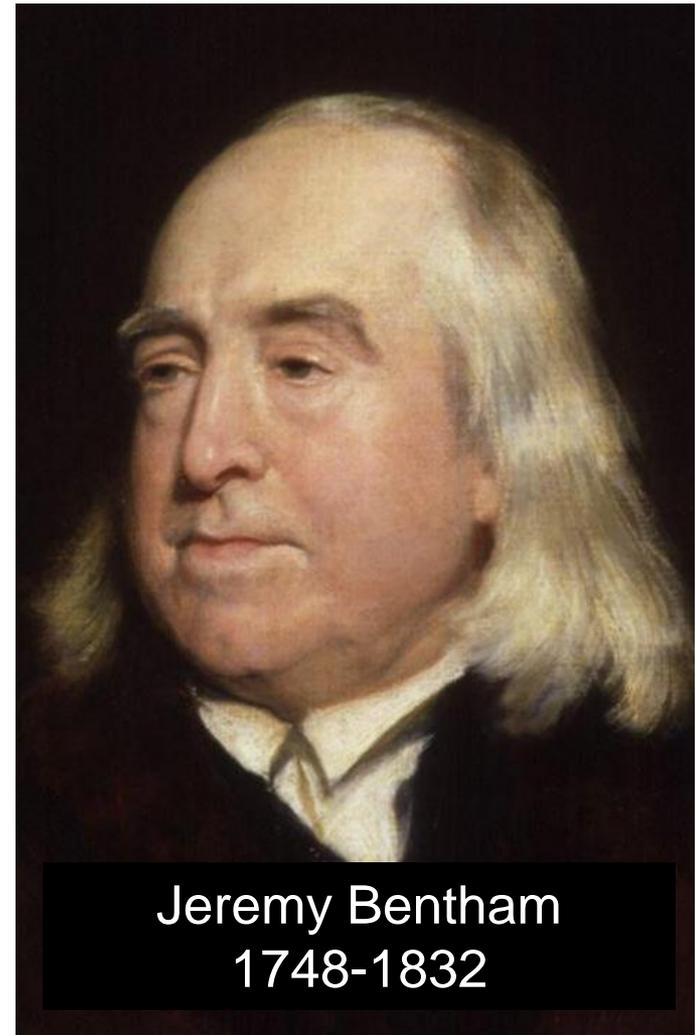
EVAR-1 (**infinity**) / EVAR-2 (**>£300K**)

NICE social value judgments

Distributive justice

People can only make rational choices based on accurate advice which is based on sound evidence, which is lacking

People cannot always have what they want



Jeremy Bentham
1748-1832

NICE guideline committees

NICE guideline advisory committees do the “science” and **not** the “politics”

Committees can only work in accordance with the policies and procedures (social value judgements) agreed by NICE and DoH Colleagues, and the patients with ‘lived experience’, who sit on these multi-disciplinary committees have no Col, and give a very considerable amount of their valuable time, completely unpaid, over a 2-3 year period

NICE AAA guideline committee

So I would politely ask that you please treat them with the respect they deserve for their service



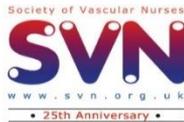
All of the recommendations were **unanimously** agreed
(without and without the vascular and endovascular
surgeons in the room)

EVAR and F-EVAR – is better case selection the key?

Yes, probably, in an ideal world

But, at present, we do not have the tools / data

So, until such time as we do, we have to use the best evidence we have to make the best use of the limited resources we have for the most people



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