Clinical Practice Guidelines

Dr Claire McLintock
Clinical Director Obstetric Medicine
National Women's Health
Auckland City Hospital

Clinical Practice Guidelines

statements that include **recommendations** intended to **optimize patient care** that are informed by a **systematic review of evidence** and an **assessment of the benefits and harms** of **alternative care options**…. and provide ratings of both the **quality of evidence** and the **strength of the recommendations**

Institute of Medicine 2011

New Zealand Guidelines Group

Australian Government
National Health and Medical Research Council
NHMRC

SIGN
1993-2013

Clinical Practice Guideline

NIH National Heart, Lung, and Blood Institute

NICE National Institute for Health and Care Excellence

Ärztliches Zentrum für Qualität in der Medizin
Gemeinsame Einrichtung von Bundesärztekammer (BÄK) und Kassenärztlicher Bundesvereinigung (KBV)

1945-49

20

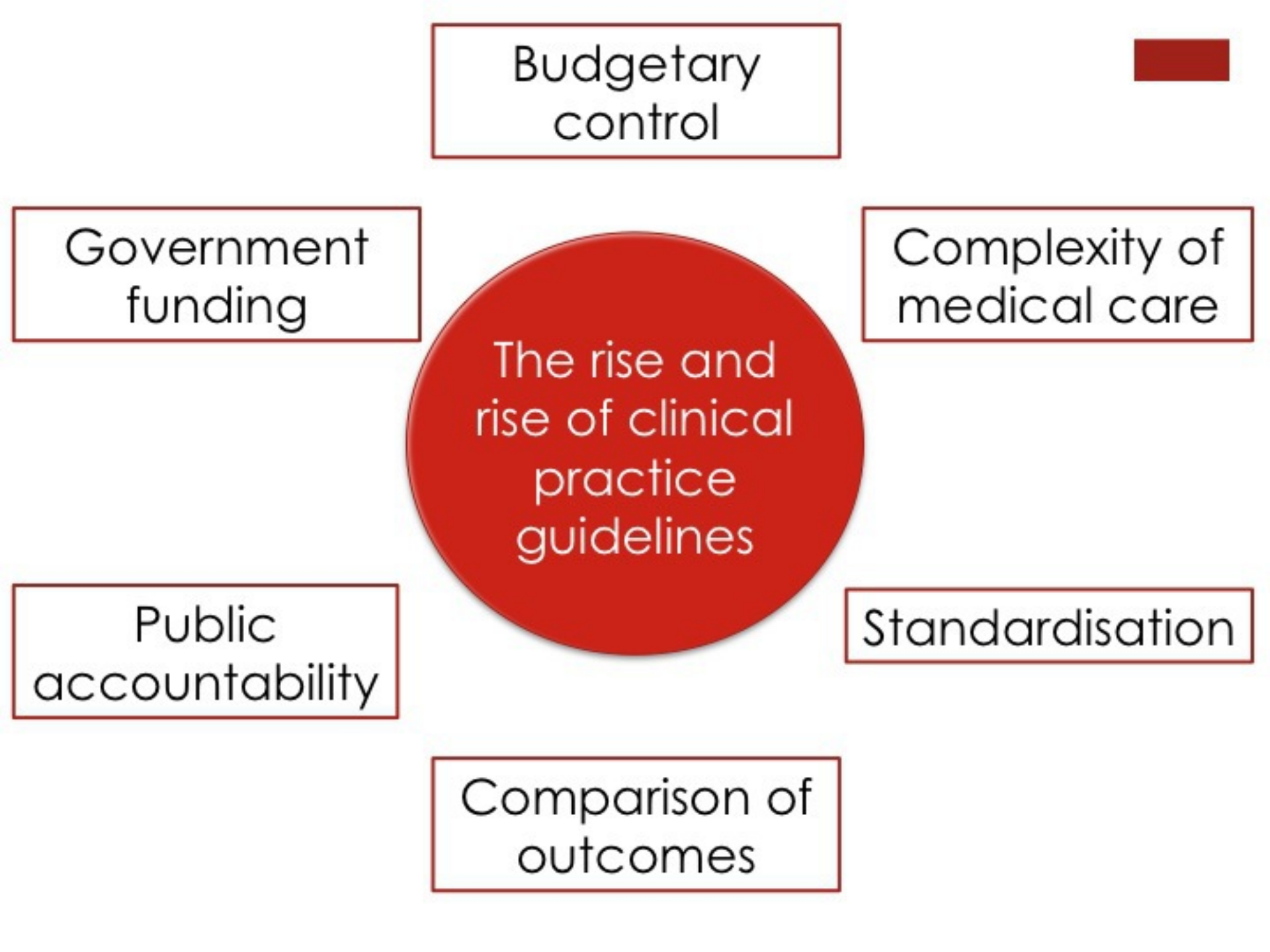
1960-74

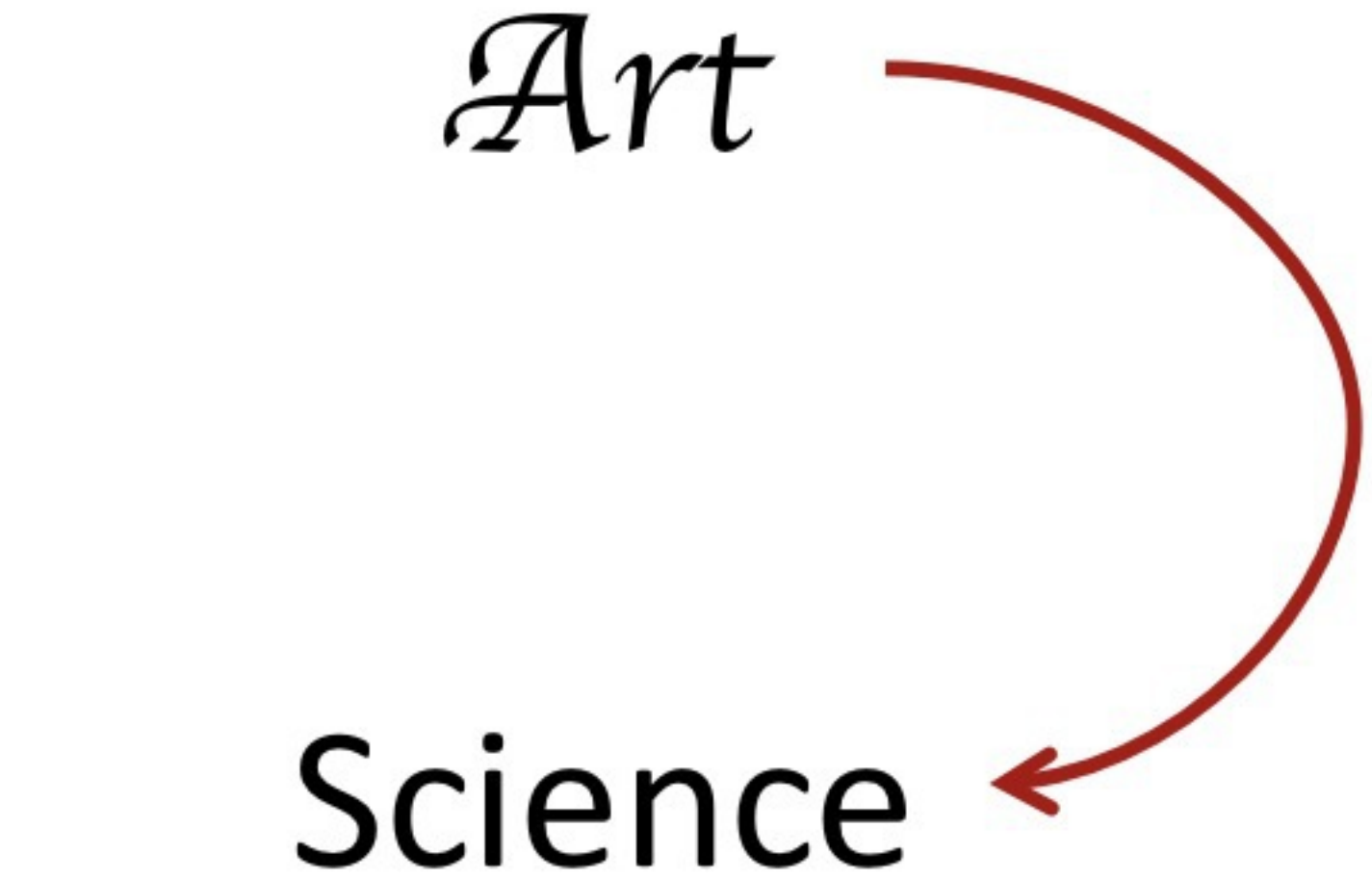
35

The rise and rise of clinical practice guidelines

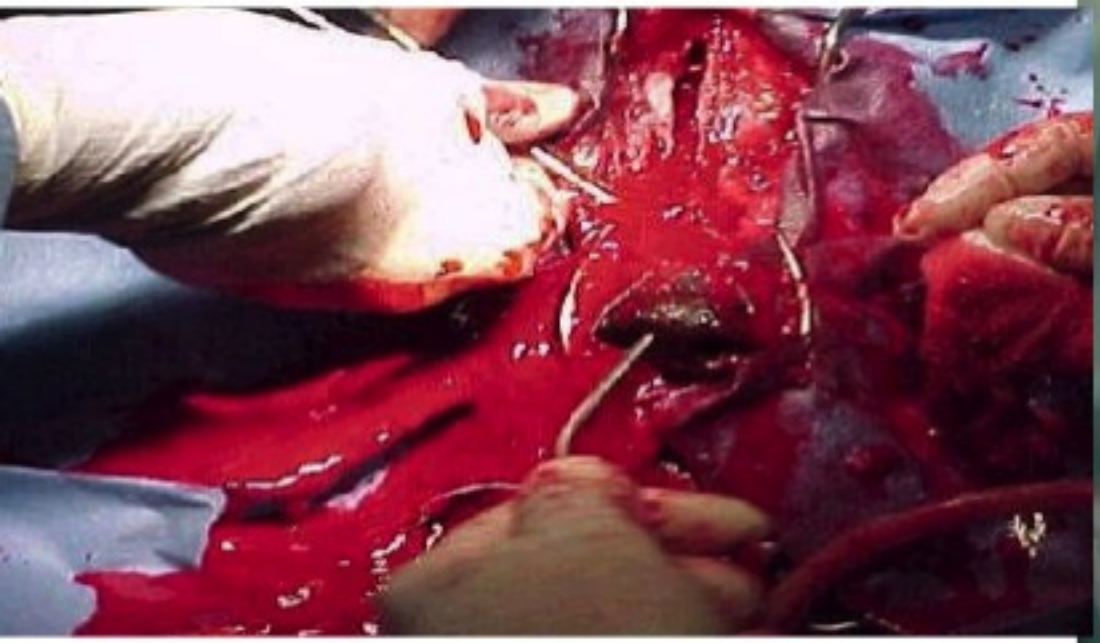
By 2006

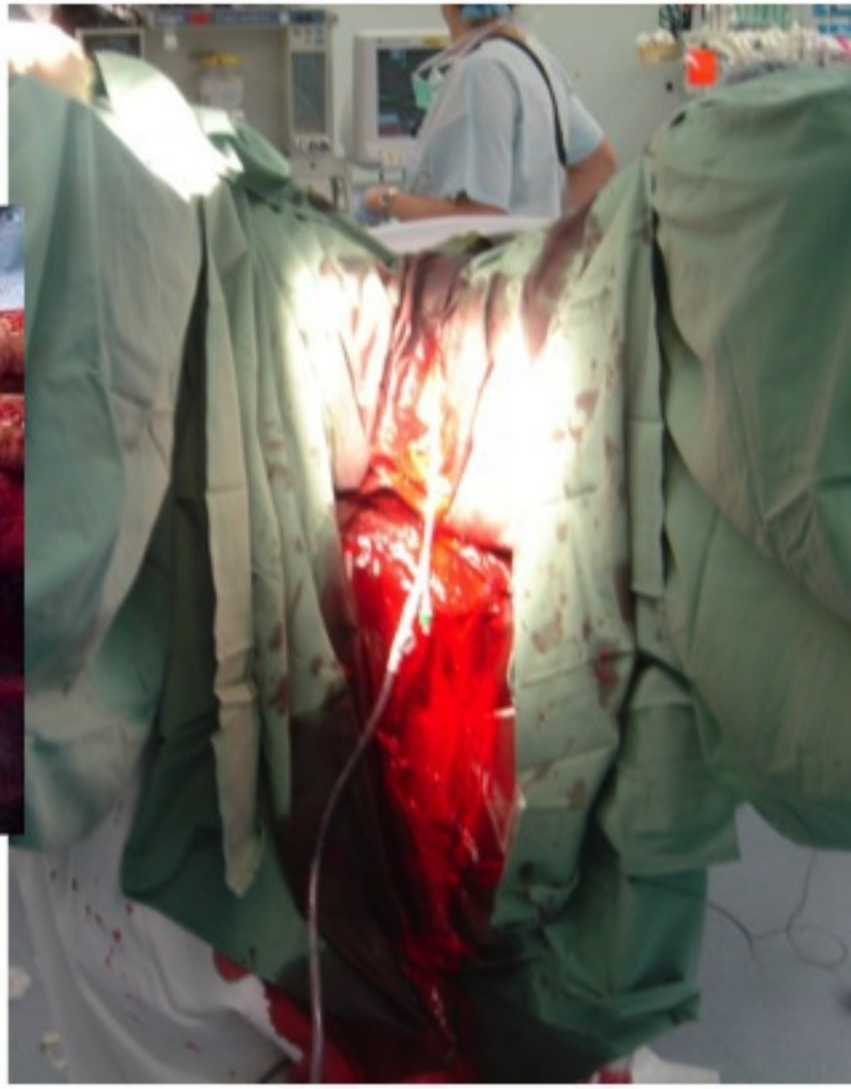
2000 +


Budgetary control
Government funding
Complexity of medical care
The rise and rise of clinical practice guidelines
Public accountability
Standardisation
Comparison of outcomes


Art
Science

Grade of Recommendation	Benefit vs Risk and Burdens	Methodologic Strength of Supporting Evidence	Implications
Strong recommendation, high-quality evidence (1A)	Benefits clearly outweigh risk and burdens or vice versa.	Consistent evidence from randomized controlled trials without important limitations or exceptionally strong evidence from observational studies.	Recommendation can apply to most patients in most circumstances. Further research is very unlikely to change our confidence in the estimate of effect.
Strong recommendation, moderate-quality evidence (1B)	Benefits clearly outweigh risk and burdens or vice versa.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise) or very strong evidence from observational studies.	Recommendation can apply to most patients in most circumstances. Higher-quality research may well have an important impact on our confidence in the estimate of effect and may change the estimate.
Strong recommendation, low- or very-low-quality evidence (1C)	Benefits clearly outweigh risk and burdens or vice versa.	Evidence for at least one critical outcome from observational studies, case series, or randomized controlled trials, with serious flaws or indirect evidence.	Recommendation can apply to most patients in many circumstances. Higher-quality research is likely to have an important impact on our confidence in the estimate of effect and may well change the estimate.
Weak recommendation, high-quality evidence (2A)	Benefits closely balanced with risks and burden.	Consistent evidence from randomized controlled trials without important limitations or exceptionally strong evidence from observational studies.	The best action may differ depending on circumstances or patient or societal values. Further research is very unlikely to change our confidence in the estimate of effect.
Weak recommendation, moderate-quality evidence (2B)	Benefits closely balanced with risks and burden.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise) or very strong evidence from observational studies.	Best action may differ depending on circumstances or patient or societal values. Higher-quality research may well have an important impact on our confidence in the estimate of effect and may change the estimate.
Weak recommendation, low- or very-low-quality evidence (2C)	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced.	Evidence for at least one critical outcome from observational studies, case series, or randomized controlled trials, with serious flaws or indirect evidence.	Other alternatives may be equally reasonable. Higher-quality research is likely to have an important impact on our confidence in the estimate of effect and may well change the estimate.





Australian and New Zealand Journal of Obstetrics and Gynaecology 2011 DOI: 10.1111/j.1479-828X.2011.01361.x

Opinion

Recommendations for the diagnosis and treatment of deep venous thrombosis and pulmonary embolism in pregnancy and the postpartum period

Claire McLINTOCK,[1] Tim BRIGHTON,[2] Sanjeev CHUNILAL,[3] Gus DEKKER,[4,5] Nolan McDONNELL,[6] Simon McRAE,[7] Peter MULLER,[8] Huyen TRAN,[9,10,11] Barry N. J. WALTERS[12] and Laura YOUNG[13,14]

Australian and New Zealand Journal of Obstetrics and Gynaecology 2011 DOI: 10.1111/j.1479-828X.2011.01357.x

Opinion

Recommendations for the prevention of pregnancy-associated venous thromboembolism

Claire McLINTOCK,[1] Tim BRIGHTON,[2] Sanjeev CHUNILAL,[3] Gus DEKKER,[4,5] Nolan McDONNELL,[6] Simon McRAE,[7] Peter MULLER,[8] Huyen TRAN,[3,9,10] Barry N. J. WALTERS[11] and Laura YOUNG[12,13]

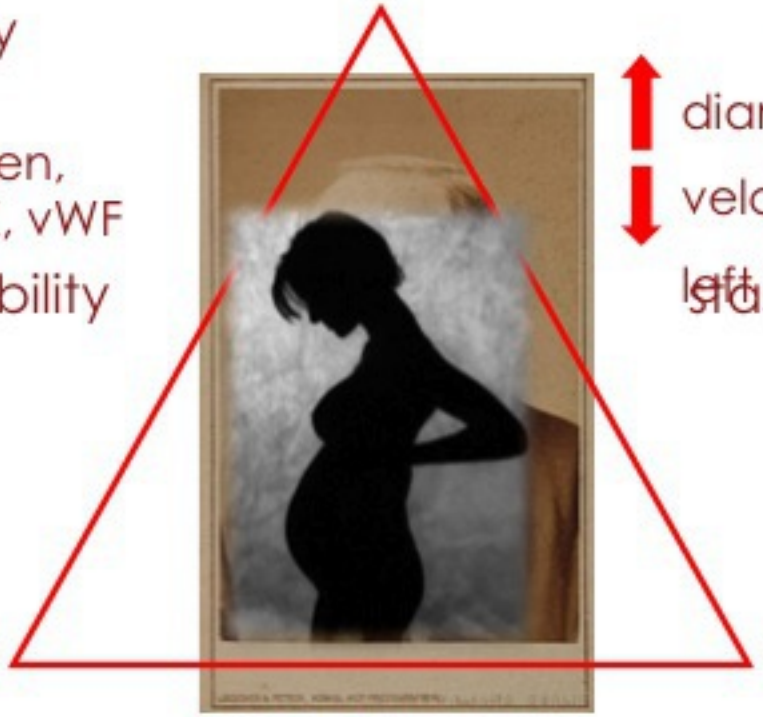
Virchow's Triad

hypercoagulability

↑ thrombin, fibrinogen, factors V, VIII, IX, X, vWF

↓ protein S hypercoagulability

↑ PAI-1, PAI-2



stasis

↑↓ diameter major veins

↓ velocity of blood flow

left > right

stasis

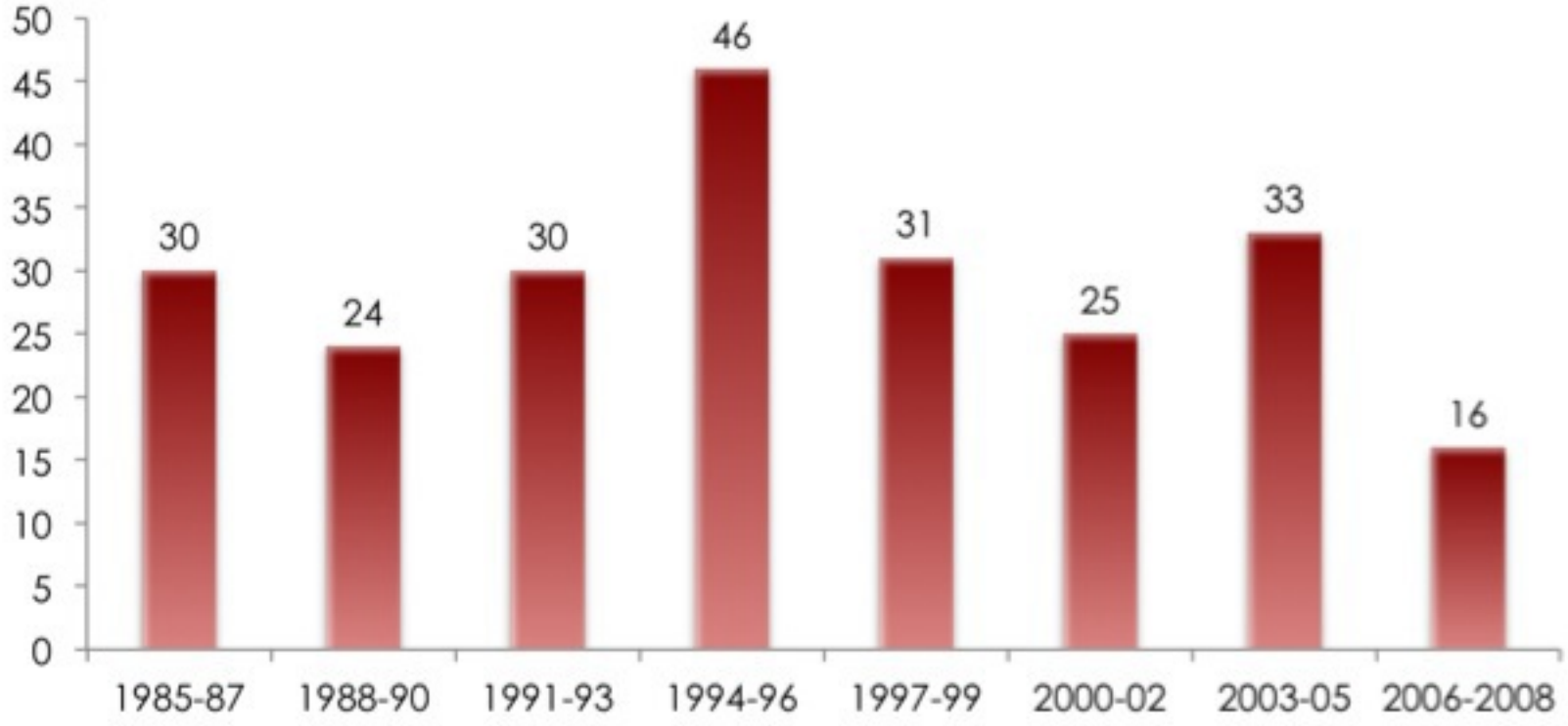
vessel damage

vessel damage

Caesarean section > vaginal delivery

pro-inflammatory effects of pregnancy

Maternal Mortality Pulmonary Embolism



1-2 in 100 000 pregnancies

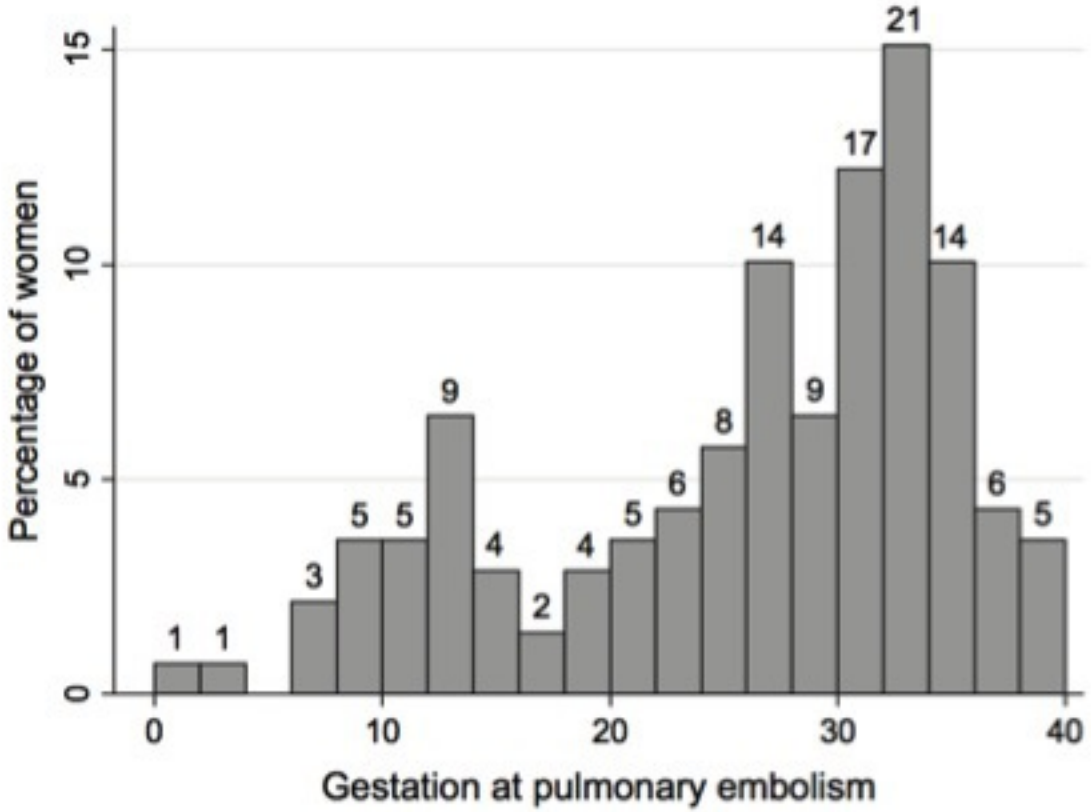
CMACE 2006-2008. BJOG 2011; 118 (Supp 1):1-203

Mortality

- 0.4-1.6/100,000 deliveries – common direct cause of maternal death
- Case fatality rate (PE) **2.4-3.5%**

- **NZ – 0.5/100,000** deliveries last 3 years
  - (2.85% of all deaths)
- Australia – 0.65/100,000 deliveries (2003-5)
  - (7.7% of all deaths)

UK Obstetric Surveillance System: antenatal pulmonary embolism



143 antenatal PE

1/ 7700 maternities

5 deaths

Case fatality 3.5%

Knight. BJOG 2008;115:453

Composition

- Haematologist (3* NZ 3 Australia)
- Obstetric Physician (2*)
- Neonatologist (1)
- Anaesthetist (1)
- Obstetrician (2)

Consensus process

1st meeting

- Presentation of background data
- 1st draft

2nd meeting

- Review of sections
- 2nd draft

Recommendations compiled

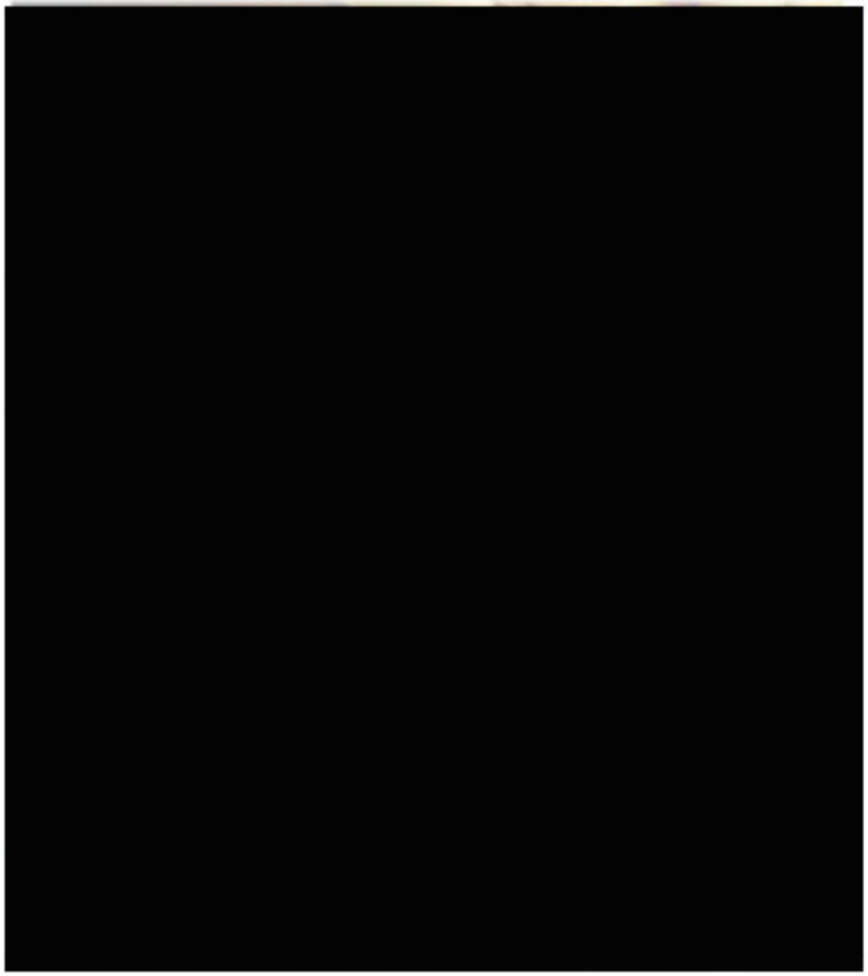
- Voting 1) agree 2) disagree
- Consensus levels: L1 – 10/10 agree; L2 - ≥8/10 agree; L3 – no consensus
- Further drafts…..

Risk factor	Adjusted OR
Prior VTE	**24.8**
Immobility	7.7-10.1
BMI>30	1.7-5.3
Active medical illness	2.1-8.7
Preeclampsia	3.0-5.8
Family history VTE	**2.9-4.1**
Assisted reproductive technology	2.6-4.3
Hyperemesis	2.5
Varicose veins	2.4
Multiple pregnancy	1.6-4.2
Smoking	1.7-3.4
Multiparity >2	1.6-2.9
Age >35	1.4-1.7

McLintock et al ANZJOG 2012

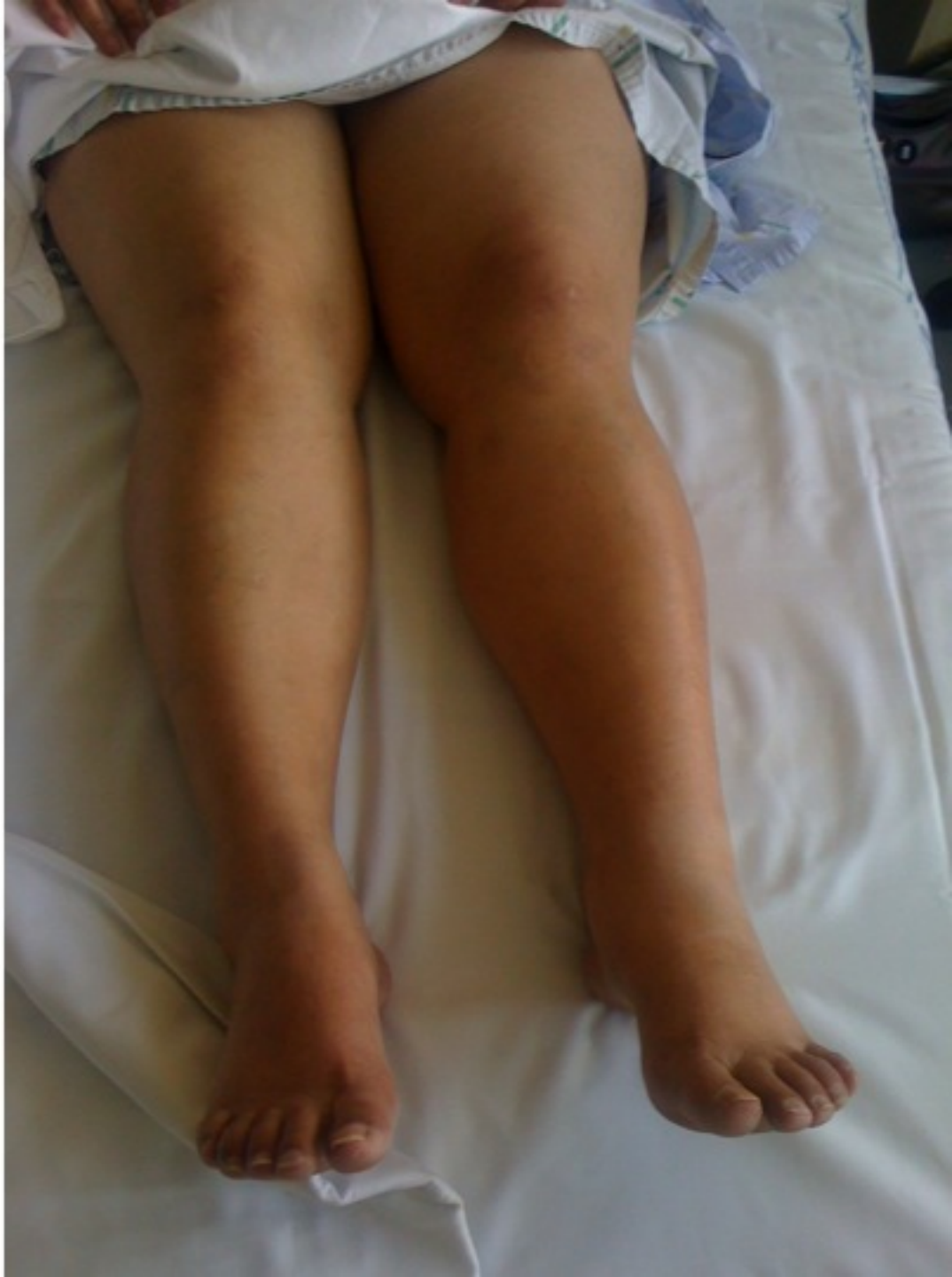
Postpartum Risk Factors

Risk factor	OR
Elective CS	1.3-2.7
Emergency CS	2.7-4.0
Placental abruption	2.5-16.6
Postpartum infection	4.1-20.2
Postpartum haemorrhage > 1000 mL	1.3-12.0
Red cell transfusion[2]	3.9
Plasma product transfusion[2]	8.2



Pregnancy-associated VTE

1 in 1000-1500



Interpretation of Risk

Risk factor	Adjusted OR	Estimated absolute risk
		Background risk 1 in 1000
Prior VTE	**24.8**	**1 in 40**
Immobility	7.7-10.1	1 in 125
Preeclampsia	3.0-5.8	1 in 330
Family history VTE	2.9-4.1	1 in 330
Hyperemesis	2.5	1 in 400
Elective CS	**1.3-2.7**	**In 330**
Emergency CS	**2.7-4.0**	**1 in 250**
Age >35	1.4-1.7	1 in 700

McLintock et al ANZJOG 2012

Personal history VTE

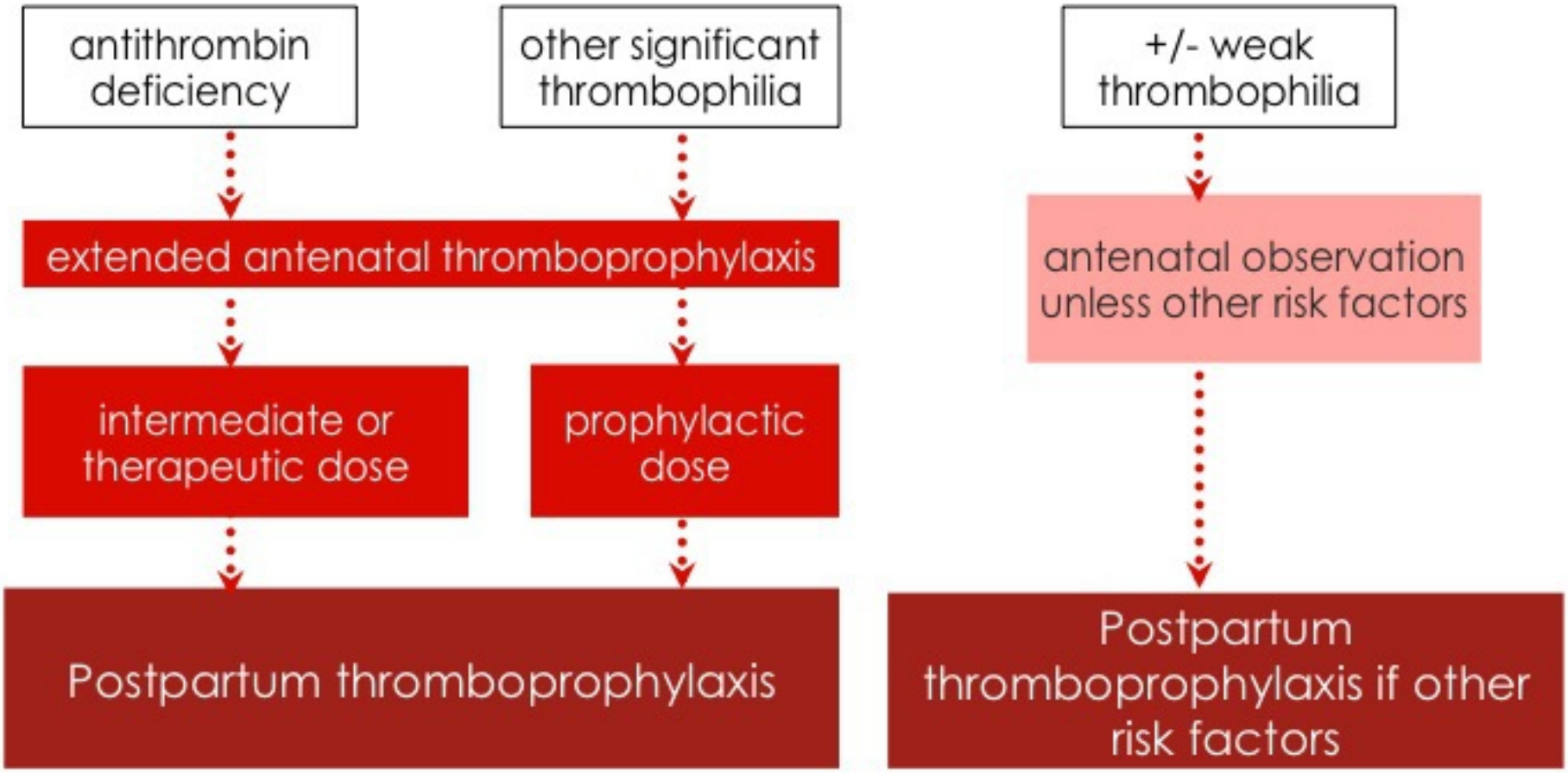
Recurrent VTE on oral anticoagulant (OAC) Any VTE with antithrombin deficiency	Idiopathic Pregnancy related COC related Recurrent VTE not on OAC	single other provoked VTE
↓	↓	↓
extended antenatal thromboprophylaxis therapeutic dose	extended antenatal thromboprophylaxis prophylactic dose	antenatal observation unless other risk factors

Postpartum thromboprophylaxis for all women

Family History of VTE, Thrombophilia & Risk of PA-VTE

Thrombophilia	Risk of PA-VTE weighted mean; *range* (%)
Antithrombin deficiency	29.1% (3-37)
Protein C deficiency	12.5% (1.7-16.1)
Protein S deficiency	9.5% (6.6-13.6)
FVL homozygous	11.1% (4.2-15.8)
PT20210 homozygous	*no family studies*
Compound heterozygote PT20210/FVL	8.8% (7.1-17.8)
PT20210 heterozygote	1-2.8%
FVL heterozygote	1.5-3.9%

Family history VTE, no personal history




VTE post trauma
1 in 2 ➔ 1 in 200

CHEST Supplement
ANTITHROMBOTIC THERAPY AND PREVENTION OF THROMBOSIS, 9TH ED: ACCP GUIDELINES

Prevention of VTE in Nonorthopedic Surgical Patients

Major trauma

Low dose unfractionated heparin

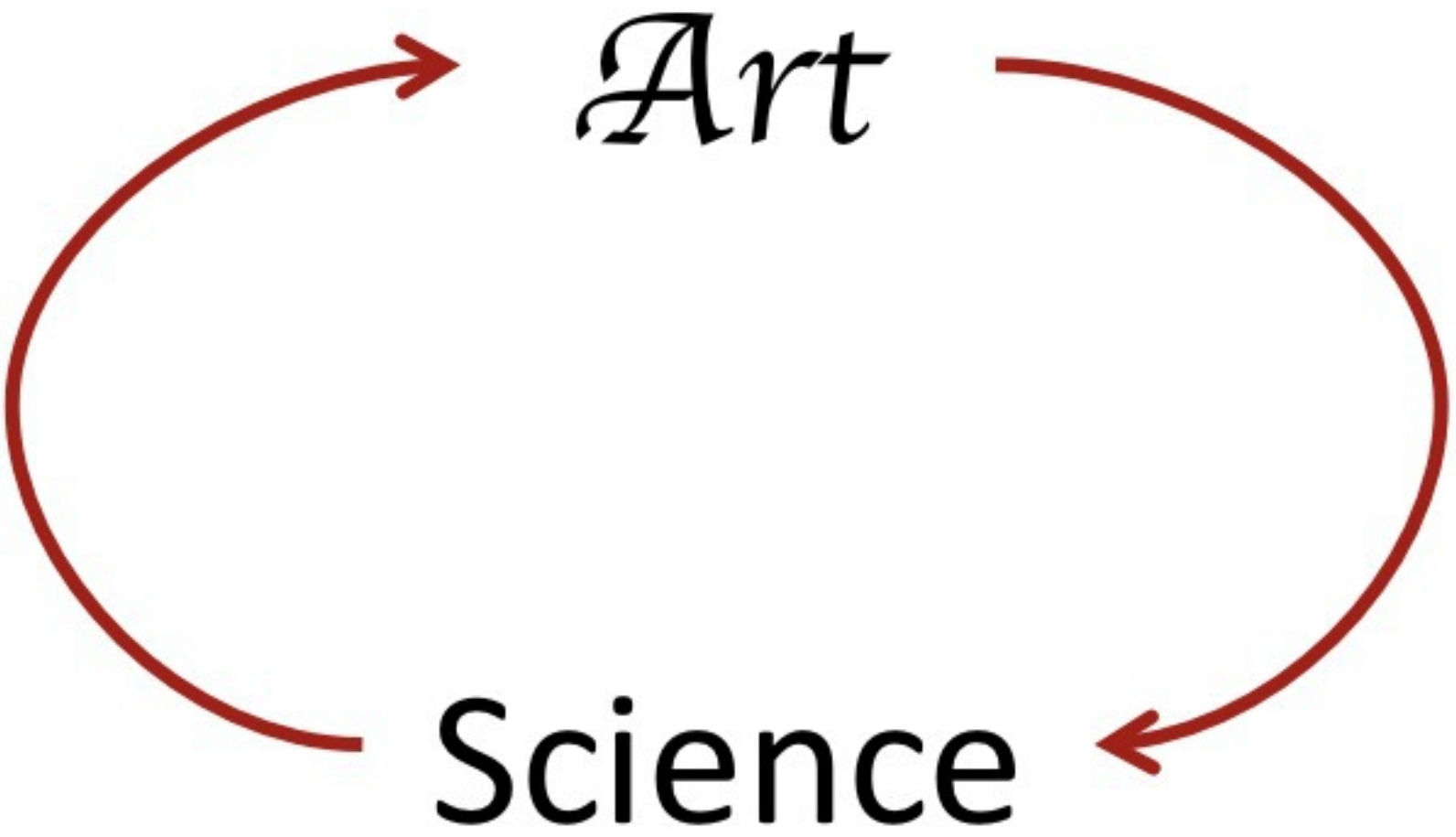
Low molecular weight heparin

Mechanical prophylaxis

Grade 2C – weak recommendation: low or very low quality evidence

Barriers to Adoption of Guidelines

Cabana et al JAMA 1999


Art
Science

"The trouble with the world is that the stupid are  *sure… and the intelligent are full of doubt."*

Bertrand Russell

Worst injury	Score
Head & neck	Minor **+1**
Face	Moderate **+2**
Chest	Serious **+3**
Abdomen	Severe **+4**
Extremity (incl pelvis)	Critical **+5**
External	Unsurvivable **+6**

Take 3 worst areas

ISS = $(score)^2 + (score)^2 + (score)^2$

Range 1-75 (75 automatically if any score is 6)

Polytrauma = ISS >15

Randomised studies trauma patients

Study (patients N)	ISS	Comparison (VTE rate)		Significant
Fisher (n=304)	? (mainly hip fractures)	SCD (4%)	No prophylaxis (11%)	Yes (p=0.02)
Knudson (n=181)	15	SCD (1.6%)	LMWH (0.8%)	No
Ginzburg (n=442)	2/3: 9-19	SCD (2.7%)	LMWH (0.5%)	No
Geerts (n=435)	23	LDUH (44%)	LMWH (31%)	Yes; p=0.014
Stannard (n=200)	14	LMWH (13.4%)	Footpump + LMWH (8.7%)	

The trouble with the world is that the stupid are cocksure and the intelligent are full of doubt.

Bertrand Russell