WORLD THROMBOSIS DAY
OCTOBER 13

Thrombosis UK
Awareness • Research • Care

KING'S HEALTH PARTNERS
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NICE guidance for thromboprophylaxis - One year on!

Prof Beverley Hunt OBE
Guy's & St Thomas' NHS Foundation Trust
Medical Director of Thrombosis UK
Chair of steering committee of World Thrombosis Day
Twitter @bhwords

KING'S College LONDON

Guy's and St Thomas' NHS Foundation Trust

King's College Hospital NHS Foundation Trust

South London and Maudsley NHS Foundation Trust

VTE Exemplar Centres
Providing leadership in thrombosis care

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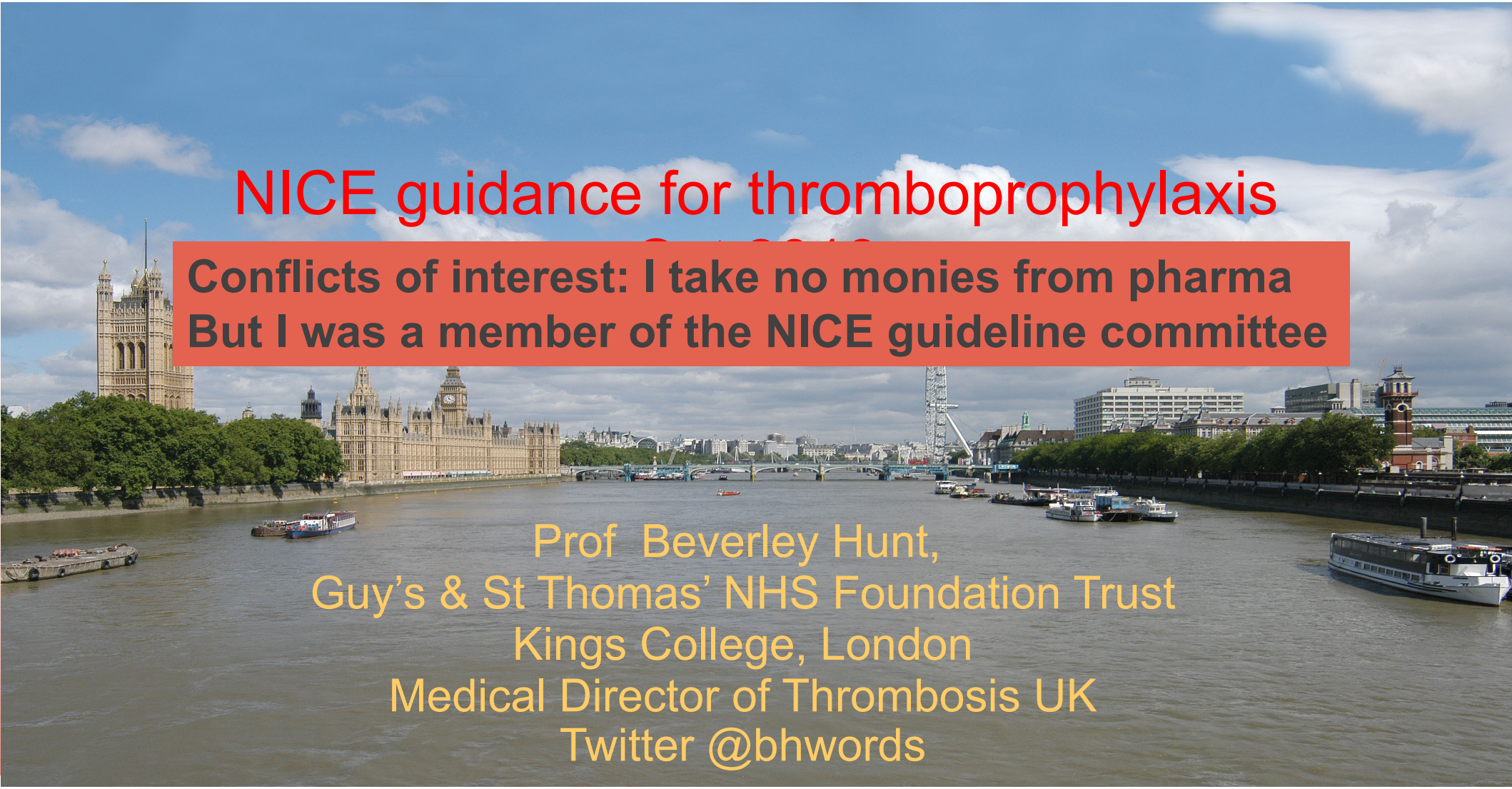
NICE guidance for thromboprophylaxis

Conflicts of interest: I take no monies from pharma
But I was a member of the NICE guideline committee



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I will concentrate on:

1) A global view of current issues-

WHO work

LMWH shortages

Rates in VTE in surgical practice

2) VTE risk assessment

2) Length of thromboprophylaxis

3) Stokings vs IPC

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World Thrombosis Day

A global movement to place a spotlight on thrombosis as an urgent and growing health problem.

World Thrombosis Day

Increasing awareness of thrombosis & VTE

THE FACTS

A blood clot that forms in the leg is called deep vein thrombosis (DVT). If the blood clot breaks loose and travels up to your lungs, it is called a pulmonary embolism (PE).

Together, they are known as venous thromboembolism (VTE).

THE NUMBERS

1 IN 4
people die from causes related to blood clots

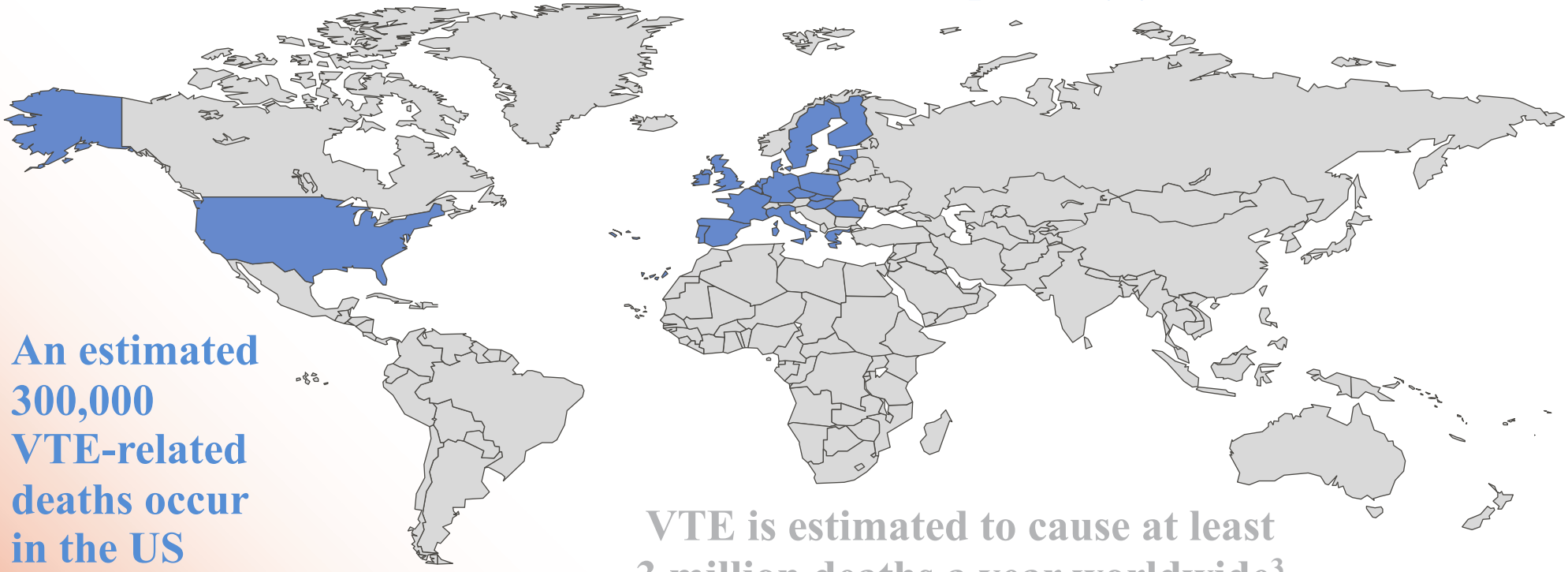
1–3
top cardiovascular killers are linked to blood clots

#1
cause of preventable death in hospitals is VTE

60%
of all VTE cases occur during or following hospitalization

VTE is a leading cause of death worldwide

VTE causes >40,000 deaths in Europe every year[1]

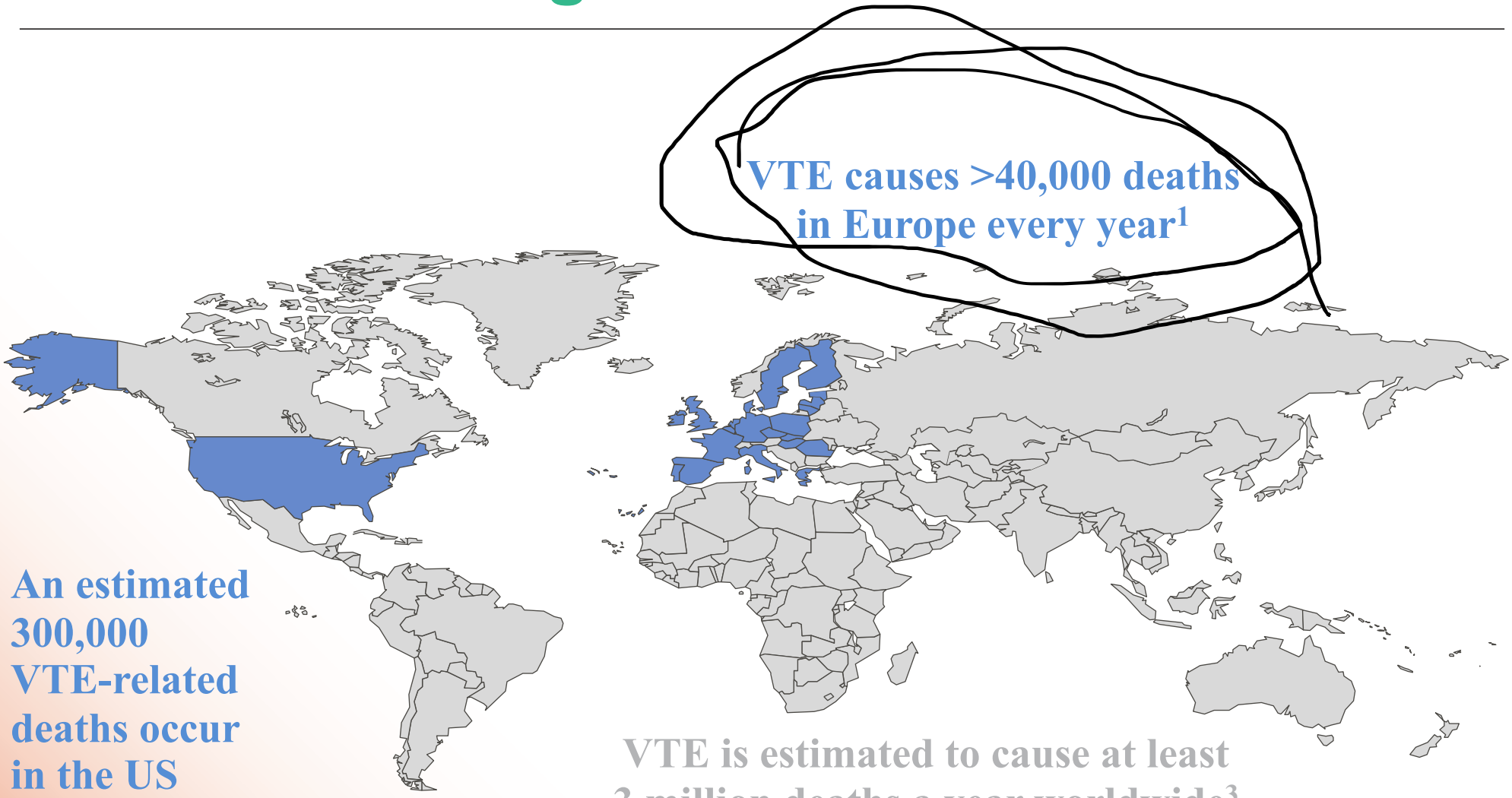


An estimated 300,000 VTE-related deaths occur in the US each year[2]

VTE is estimated to cause at least 3 million deaths a year worldwide[3]

1. Barco et al Lancet Respiratory diseases. 2019 Oct 13 ;
3. ISTH Steering Committee for World Thrombosis Day. *J Thromb Haemost.* 2014;12:1580–1590.

VTE is a leading cause of death worldwide

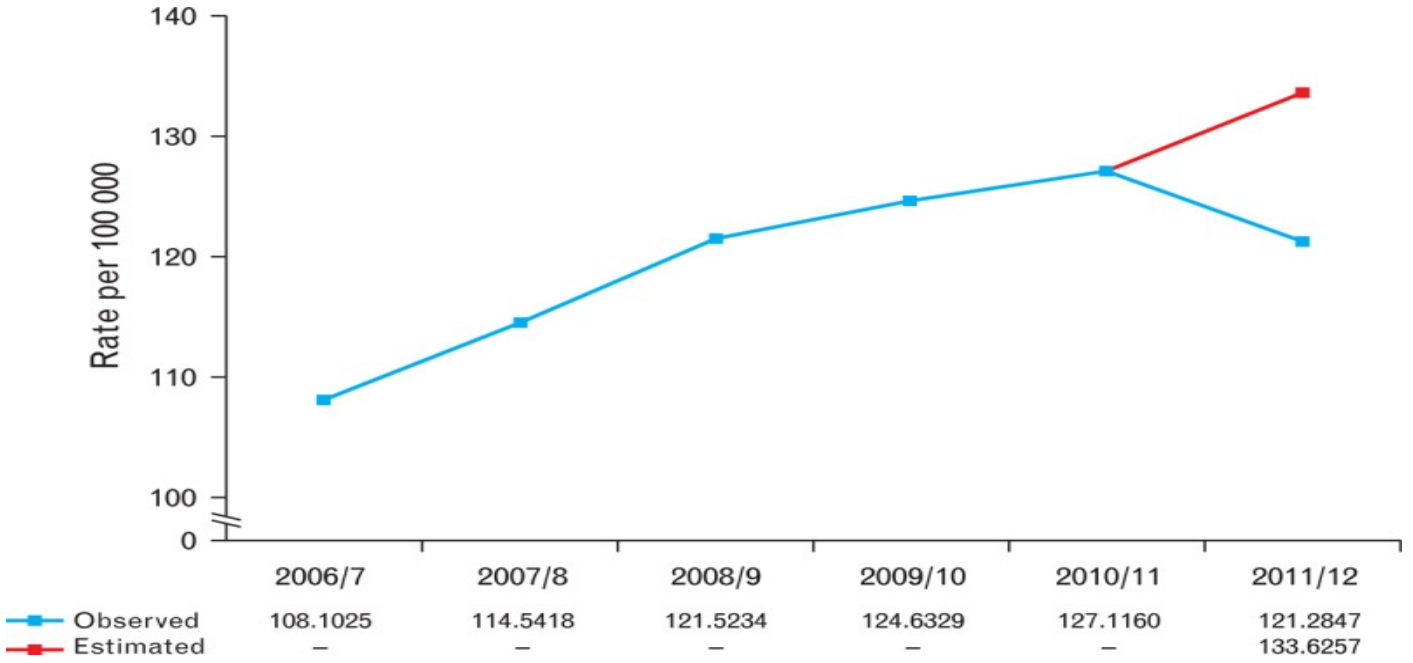


1. Barco et al Lancet Respiratory diseases. 2019 Oct 13 ;
3. ISTH Steering Committee for World Thrombosis Day. *J Thromb Haemost.* 2014;12:1580–1590.

Consequences of a systematic approach to VTE prevention in England

Death rate due to pulmonary embolism has dropped by 9% in England.

Catterick D, Hunt BJ Blood Coag & Fibrinolysis 2014; 25: 571-576

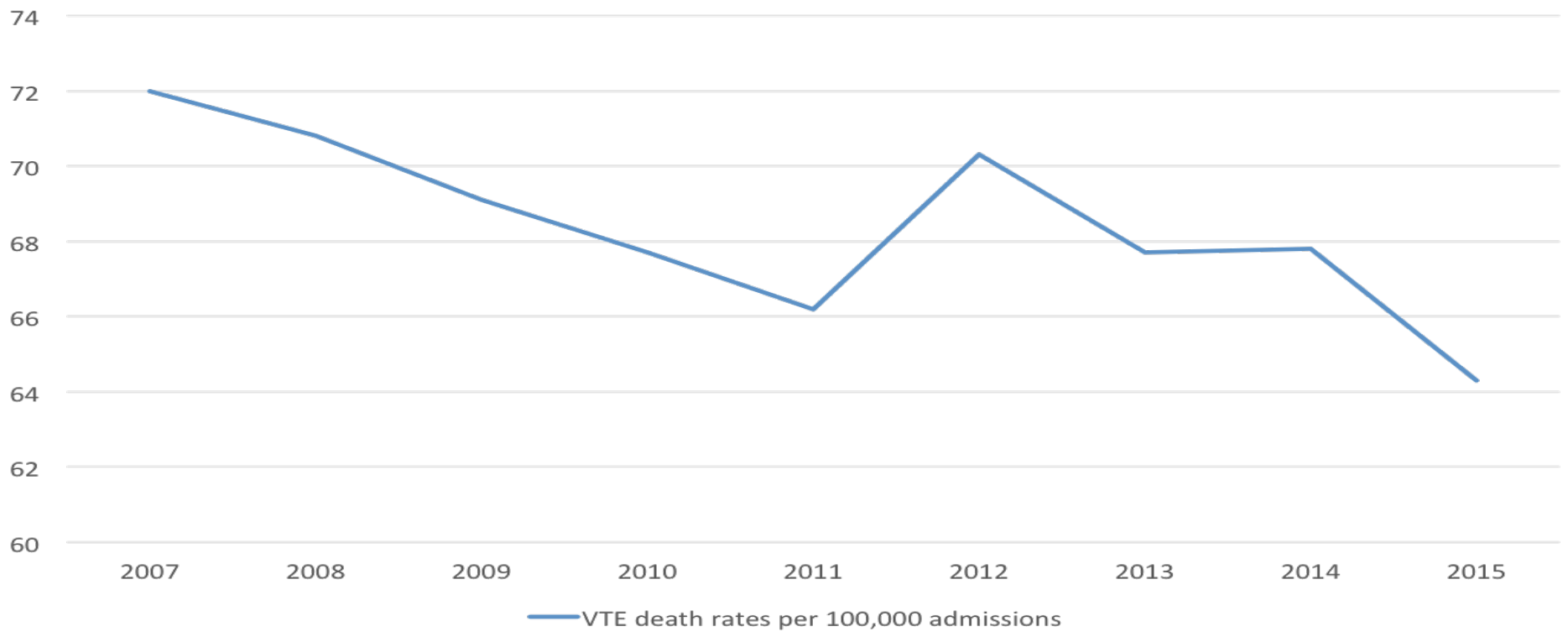


Deaths from VTE related events within 90 days post discharge from hospital (NHS Outcomes Framework Indicator 5.1)

hscic Health & Social Care Information Centre

NHS England

Rate per 100,000 adult admissions, 2007/08 to 2014/15.



WHO data on hospital-associated VTE

WHO have shown that globally there are almost 10 million hospital-associated VTE every year *Jha et al, BMJ Qual Safety 2013.*

It is the leading cause of adverse events due to hospital admission in low & middle income countries

It is the biggest cause of lost DALY (disability adjusted life years) as a result of hospital admission in low & middle income countries.

VTE causes more hospital-associated adverse events than catheter-related sepsis, hospital-acquired pneumonia & falls

And yet

VTE is not mentioned in the Global Burden of Disease

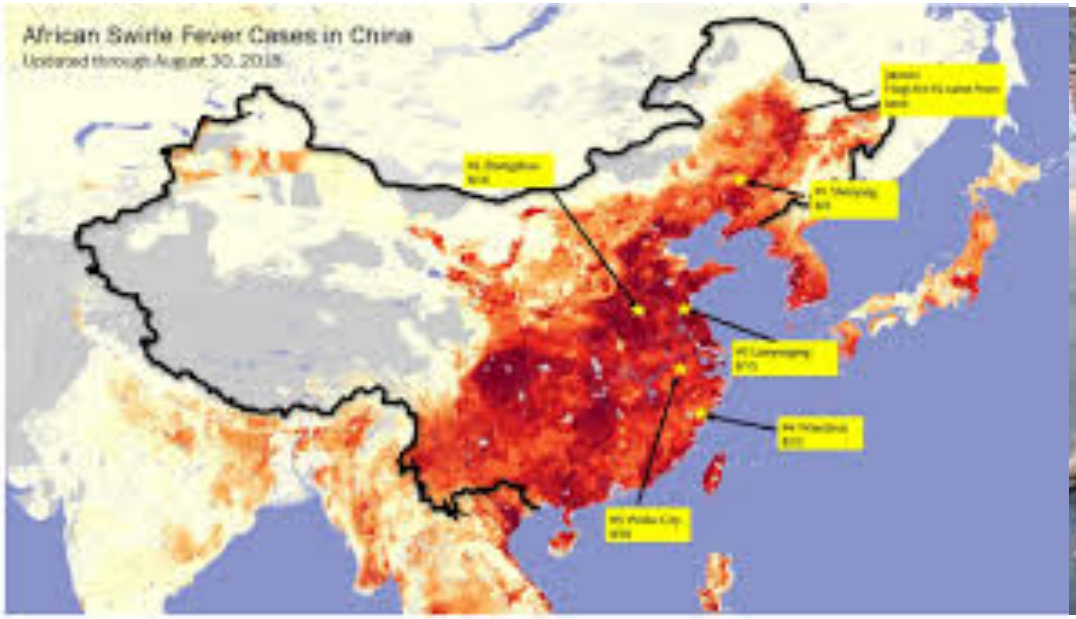
It is not mentioned on the WHO website in either patient safety or non-communicable disease sections… WTD/ISTH is working with them to change this

Current global shortage of LMWH

African swine flu has killed 160 million of 500 million pigs in China

NHS England Dept of Health group monitoring it

Fondaparinux looks v attractive esp as the price has dropped…



Reduction in Mortality following Elective Major Hip and Knee Surgery: A Systematic Review and Meta-Analysis

Ke Xu[1,2,3] Noel C. Chan[4,5] Quazi Ibrahim[1] Paul Kruger[1] Smita Sinha[1] Vinai Bhagirath[1,5]
Jeffrey Ginsberg[5] Shrikant Bangdiwala[1,5,6] Gordon Guyatt[5] John Eikelboom[1,5] Jack Hirsh[5]

Thromb Haemost. 2019 doi: 10.1055/s-0039-1677732

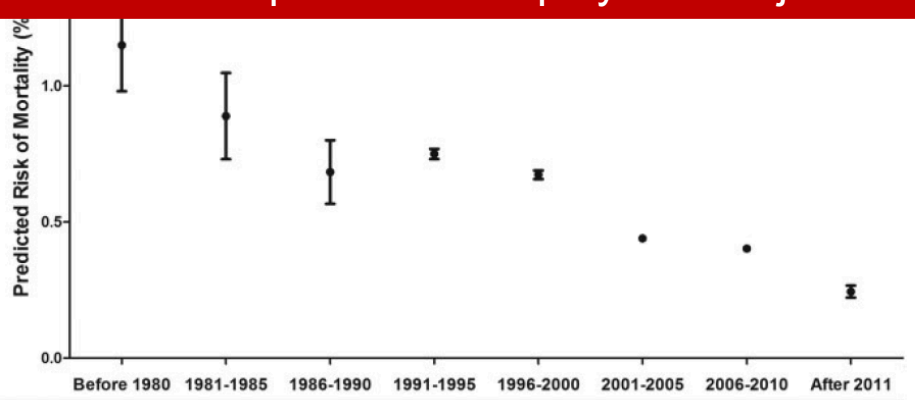
Search PubMed for randomized trials and observational studies, published between 1950 and 2016, reporting on mortality within 3 months of elective total hip and knee replacement (THR/TKR).

255 eligible studies, 31,604 deaths among 6,293,954 patients,

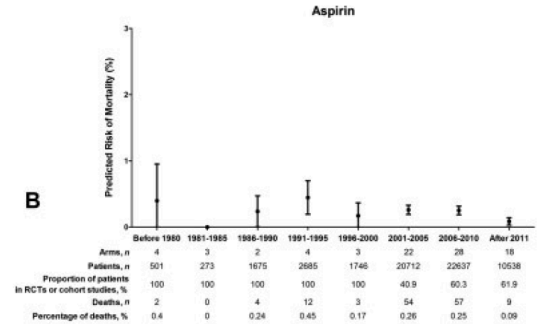
Consistent decline in mortality irrespective of study design and mode of prophylaxis from 1.15% pre-1980 to 0.24% post-2000, a 78.7% relative risk reduction in randomized and cohort studies.

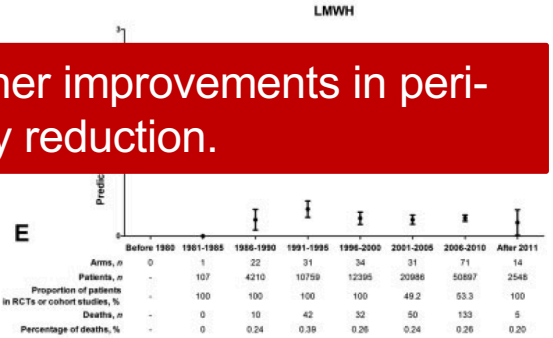
74.4% relative reduction in mortality independent of the methods of prophylaxis

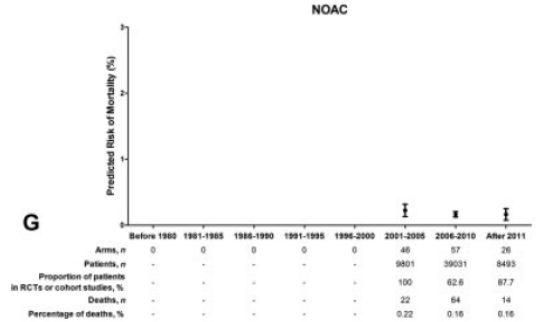
Although anti-thrombotic prophylaxis may have contributed, other improvements in peri-operative care played a major role in the mortality reduction.



	Before 1980	1981-1985	1986-1990	1991-1995	1996-2000	2001-2005	2006-2010	After 2011
Arms, *n*	36	18	58	73	84	146	225	77
Patients, *n*	15305	13608	19306	805188	1025107	2072977	2155289	187174
Deaths, *n*	176	121	132	6039	6905	9110	8664	457
Percentage of deaths, %	1.15	0.89	0.68	0.75	0.67	0.44	0.40	0.24







The NICE PROCESS -2 years to rewrite a guideline
Statisticians review the evidence and present to the committee

Esp on:

VTE risk associated with hospitalisation

Evidence to support thromboprophylaxis

Gaps in the evidence

Venous thromboembolism in **over 16s**: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism

NICE guideline [NG89] Published date: March 2018 , updating 2012

This guideline covers assessing and reducing the risk of venous thromboembolism (VTE or blood clots) and deep vein thrombosis (DVT) in people aged 16 and over in hospital. It aims to help healthcare professionals identify people most at risk and describes interventions that can be used to reduce the risk of VTE.

Recommendations

This guideline includes recommendations on:

- risk assessment
- giving information and planning for discharge
- all patients
- interventions for people with acute coronary syndromes or acute stroke or for acutely ill patients
- interventions for people with renal impairment
- interventions for people with cancer
- interventions for people having palliative care
- interventions for people admitted to critical care
- interventions for people with psychiatric illness
- interventions when using anaesthesia
- interventions for people having orthopaedic surgery
- interventions for people having CNS surgery
- interventions for people with major trauma
- interventions for people having abdominal, thoracic or head and neck surgery
- interventions for people having cardiac or vascular surgery
- interventions for pregnant women and women who gave birth or had a miscarriage or termination of pregnancy in the past 6 weeks

Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism

NICE guideline [NG89] Published date: March 2018

Medical patients

1.1.2Assess all medical patients to identify the risk of VTE and bleeding:

- As soon as possible after admission to hospital or by the time of the first consultant review
- Using a tool published by a national UK body, professional network or peer-reviewed journal. The most commonly used risk assessment tool for medical patients is the Department of Health VTE risk assessment tool[1]. **[2018]**

1.1.3 Balance the person's individual risk of VTE against their risk of bleeding when deciding whether to offer pharmacological thromboprophylaxis to medical patients. **[2018]**

1.1.4 If using pharmacological VTE prophylaxis for medical patients, start it as soon as possible and within 14 hours of admission, unless otherwise stated in the population-specific recommendations (see sections 1.4 to 1.9). **[2018]**

The NHS England VTE prevention tool

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RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

All patients should be risk assessed on admission to hospital. Patients should be reassessed within 24 hours of admission and whenever the clinical situation changes.

STEP ONE

Assess all patients admitted to hospital for level of mobility (tick one box). All surgical patients, and all medical patients with significantly reduced mobility, should be considered for further risk assessment.

STEP TWO

Review the patient-related factors shown on the assessment sheet against **thrombosis** risk, ticking each box that applies (more than one box can be ticked).

Any tick for thrombosis risk should prompt thromboprophylaxis according to NICE guidance.

The risk factors identified are not exhaustive. Clinicians may consider additional risks in individual patients and offer thromboprophylaxis as appropriate.

STEP THREE

Review the patient-related factors shown against **bleeding risk** and tick each box that applies (more than one box can be ticked).

Any tick should prompt clinical staff to consider if bleeding risk is sufficient to preclude pharmacological intervention.

Guidance on thromboprophylaxis is available at:

National Institute for Health and Clinical Excellence (2010) Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital. NICE clinical guideline 92. London: National Institute for Health and Clinical Excellence.

http://www.nice.org.uk/guidance/CG92

This document has been authorised by the Department of Health
Gateway reference no: 10278

DH Department of Health

DH Department of Health

RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

Mobility – all patients (tick one box)	Tick		Tick		Tick
Surgical patient		Medical patient expected to have ongoing reduced mobility relative to normal state		Medical patient NOT expected to have significantly reduced mobility relative to normal state	
Assess for thrombosis and bleeding risk below				**Risk assessment now complete**	

Thrombosis risk			
Patient related	**Tick**	**Admission related**	**Tick**
Active cancer or cancer treatment		Significantly reduced mobility for 3 days or more	
Age > 60		Hip or knee replacement	
Dehydration		Hip fracture	
Known thrombophilias		Total anaesthetic + surgical time > 90 minutes	
Obesity (BMI >30 kg/m^2)		Surgery involving pelvis or lower limb with a total anaesthetic + surgical time > 60 minutes	
One or more significant medical comorbidities (eg heart disease;metabolic,endocrine or respiratory pathologies;acute infectious diseases; inflammatory conditions)		Acute surgical admission with inflammatory or intra-abdominal condition	
Personal history or first-degree relative with a history of VTE		Critical care admission	
Use of hormone replacement therapy		Surgery with significant reduction in mobility	
Use of oestrogen-containing contraceptive therapy			
Varicose veins with phlebitis			
Pregnancy or < 6 weeks post partum (see NICE guidance for specific risk factors)			

Bleeding risk			
Patient related	**Tick**	**Admission related**	**Tick**
Active bleeding		Neurosurgery, spinal surgery or eye surgery	
Acquired bleeding disorders (such as acute liver failure)		Other procedure with high bleeding risk	
Concurrent use of anticoagulants known to increase the risk of bleeding (such as warfarin with INR >2)		Lumbar puncture/epidural/spinal anaesthesia expected within the next 12 hours	
Acute stroke		Lumbar puncture/epidural/spinal anaesthesia within the previous 4 hours	
Thrombocytopaenia (platelets< 75x10^9/l)			
Uncontrolled systolic hypertension (230/120 mmHg or higher)			

The NHS England VTE prevention tool

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RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

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DH Department of Health

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Bleeding risk

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Acute stroke		Lumbar puncture/epidural/spinal anaesthesia within the previous 4 hours	
Thrombocytopaenia (platelets< $75x10^9$/l)			
Uncontrolled systolic hypertension (230/120 mmHg or higher)			

But despite sustained falls in VTE rates and reduced death rate due to PE
According to NICE criteria it is not "validated" because it has not been assessed in a formal randomised controlled trial.

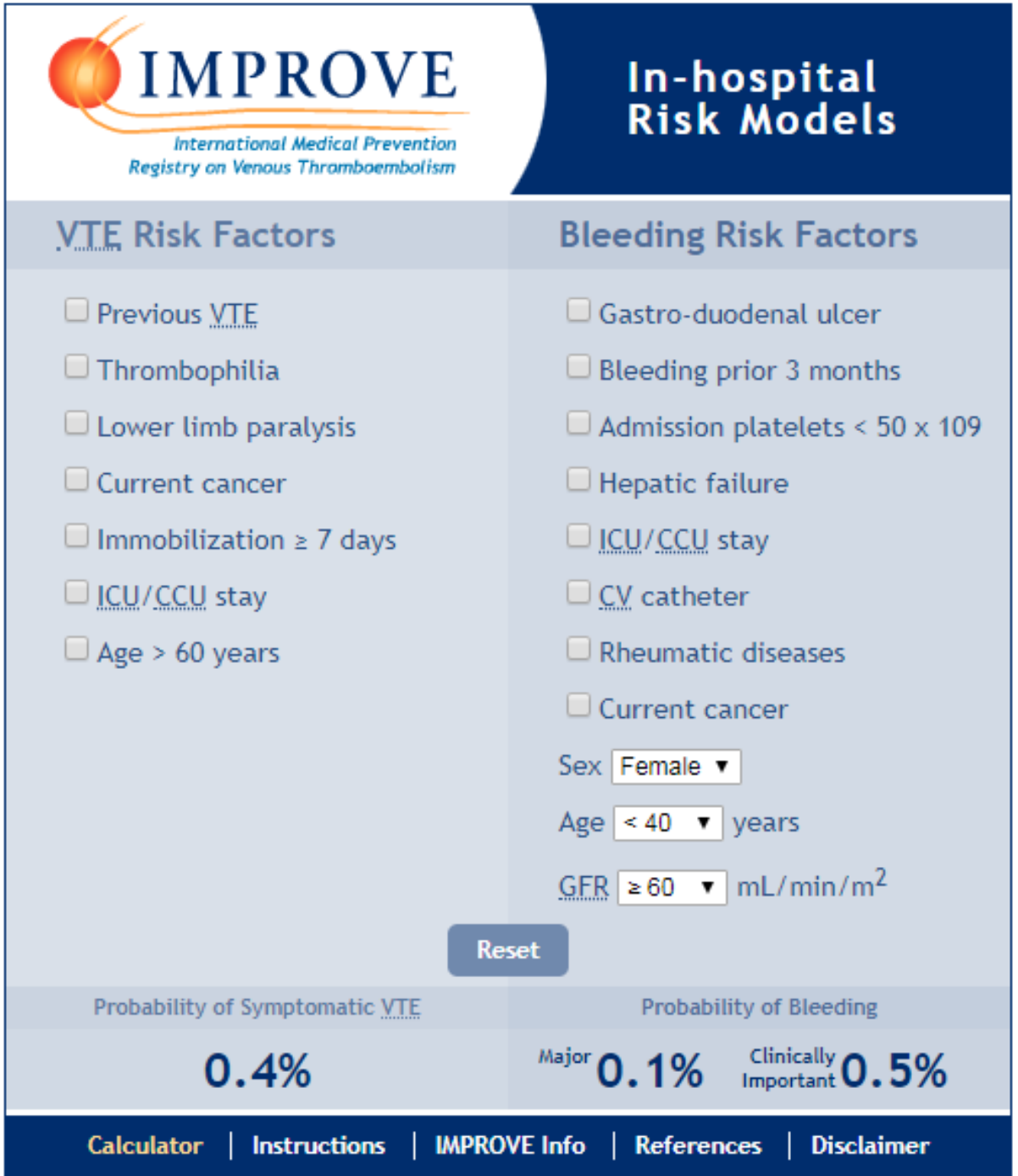
There are other risk assessment tools…..
But none validated in the British system

Padua Prediction Score, medical inpatients, high risk 4 or more

Baseline features	**Score**
Active cancer*	3
Previous VTE (with the exclusion of superficial vein thrombosis)	3
Reduced mobility†	3
Already known thrombophilic condition‡	3
Recent (≤1 month) trauma and/or surgery	2
Elderly age (≥70 years)	1
Heart and/or respiratory failure	1
Acute myocardial infarction or ischemic stroke	1
Acute infection and/or rheumatologic disorder	1
Obesity (BMI ≥30)	1
Ongoing hormonal treatment	1

•*Patients with local or distant metastases and/or in whom chemotherapy or radiotherapy had been performed in the previous 6 months. †Bedrest with bathroom privileges (either due to patient's limitations or on physicians order) for at least 3 days. ‡Carriage of defects of antithrombin, protein C or S, factor V Leiden, G20210A prothrombin mutation, antiphospholipid syndrome.

IMPROVE risk assessment tool for medical inpatients



Validated in USA population
But US healthcare is v different..

www.outcomes-umassmed.org/IMPROVE/

VTE RISK ASSESSMENT IN ENGLAND & WALES

World-leading national VTE Prevention Programme

Our risk assessment model (RAM) is much admired

BUT

NICE are saying from an academic perspective :

1) there is no clear “best” RAM?

2) This need more research- asked National Instutute for Health Research to put out a research call to compare risk assessment in the British population- now in progress….

What should the Trusts do now?

My view

1) Changing is v expensive!

2) No evidence that any other RAM is better, so stick with English

NICE guidance on length of thromboprophylaxis has changed

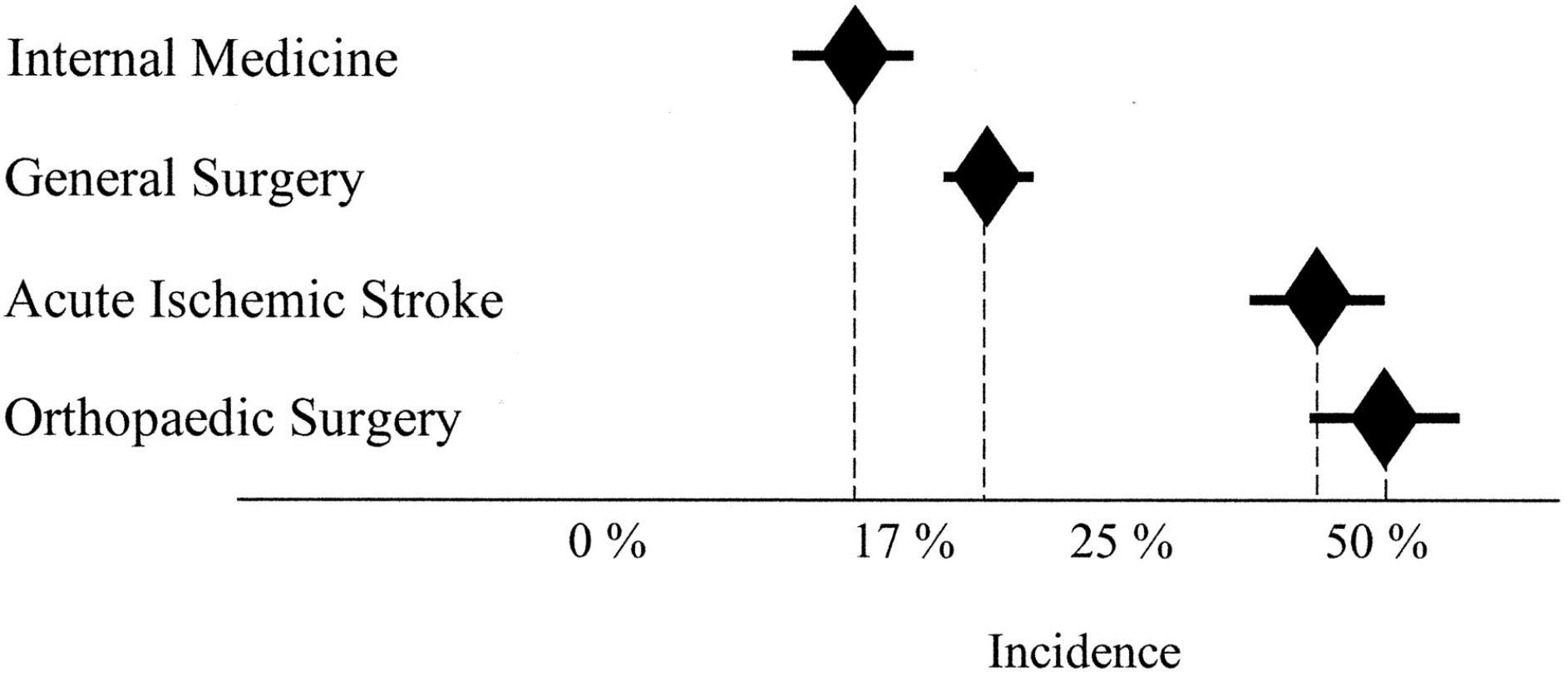
Acutely ill medical patients

1.4.6 Offer pharmacological VTE prophylaxis for a minimum of 7 days to acutely ill medical patients whose risk of VTE outweighs their risk of bleeding:

Use LMWH[4] as first-line treatment.

If LMWH[4] is contraindicated, use fondaparinux sodium[5]. [2018]

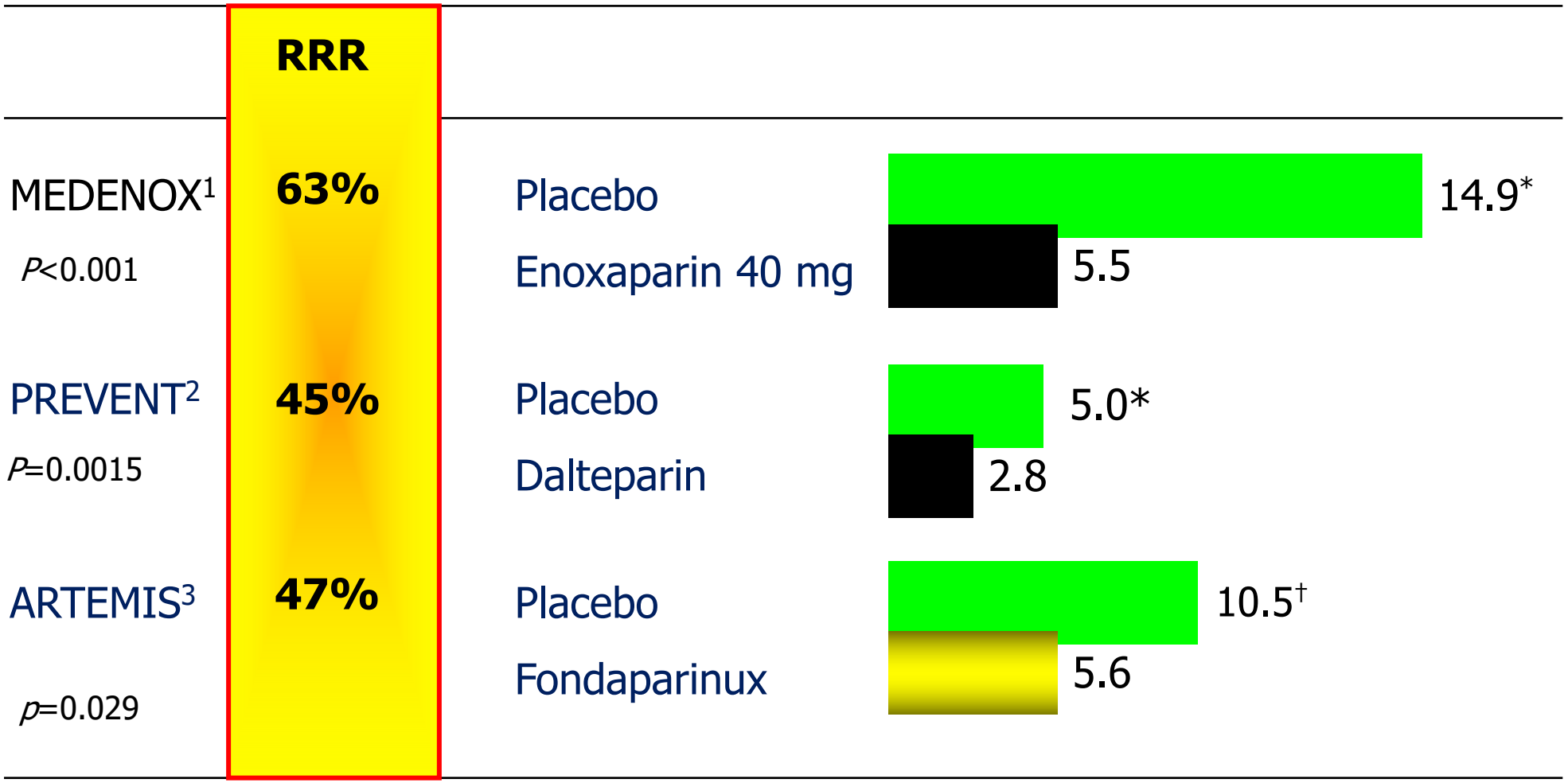
Risk of DVT as inpatient without prophylaxis



American Heart Association.

Alain Leizorovicz, and Patrick Mismetti Circulation. 2004;110:IV-13-IV-19

Clear Benefits of thromboprophylaxis over placebo in medical patients



NB PREVENT risk of major bleeding 0.49% dalteparin, 0.16% placebo (p=0.15)

RRR = relative risk reduction

[1]Samama MM *et al. N Engl J Med* 1999;341:793–800

[2]Leizorovicz A *et al. J Circulation* 2004;110:874–9

[3]Cohen AT *et al. J Thromb Haemost* 2003;1 (Suppl 1):P2046

Medical population in clinical trials of prophylaxis

- Trials run in a time when median length of stay 7 days

- > 40 years
- Congestive heart failure, acute respiratory failure
- *Or* other medical conditions (eg acute infection without septic shock; acute rheumatic disorders, inflammatory bowel disease) PLUS
  - age > 75 yrs
  - cancer
  - previous VTE
  - obesity

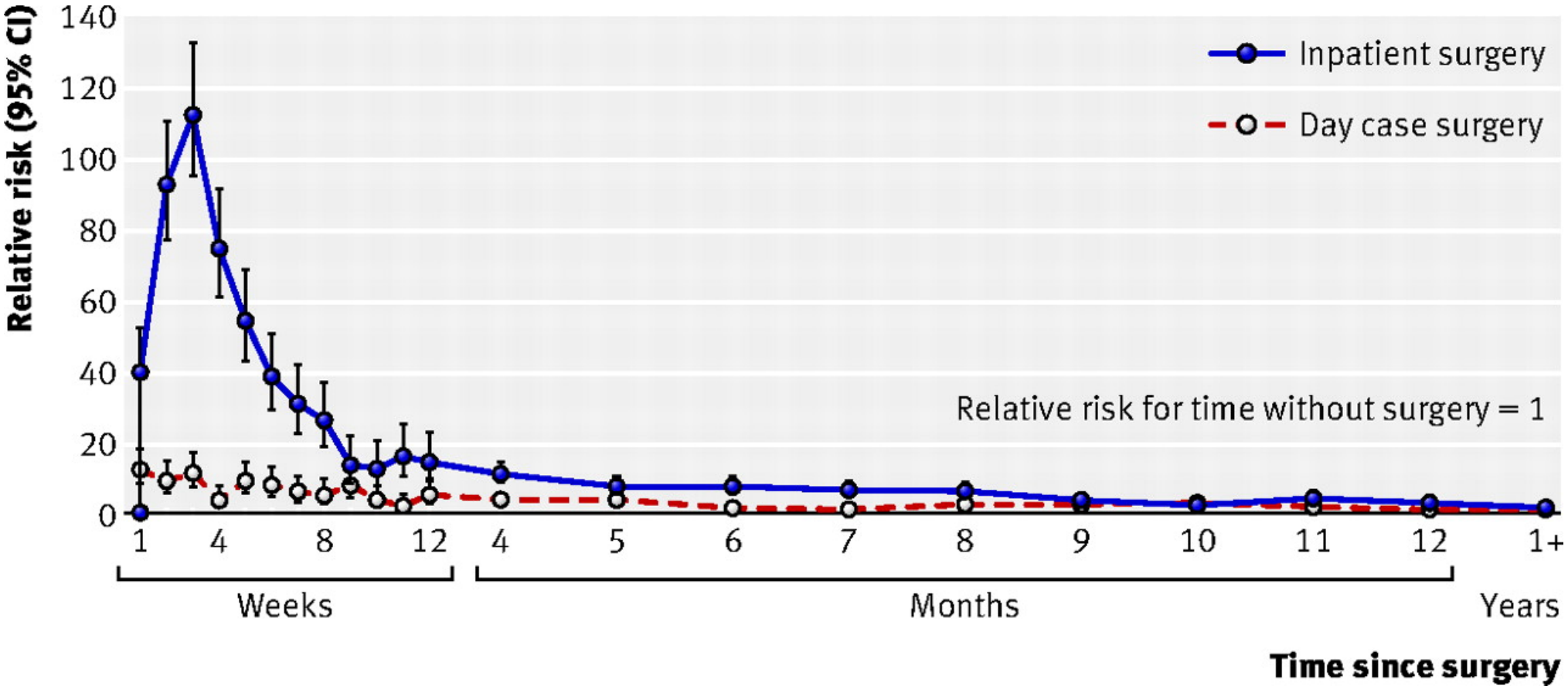
Trials of extended thromboprophylaxis for medical inpatients

Trial	VTE rate on drug	VTE after 10 +/-4 drug	Bleeds on extended	Bleeds on short alone
EXCLAIM extended enoxaparin 6,000+	2.5%	4%	0.8%	0.3%
ADOPT Extended apixaban 6,000+	2.7%	3.6%	0.47	0.19
MAGELLAN Rivaroxaban 8,000+	2.7	2.7	2.8	1.2
APEX Betrixaban ↑D-dimer >75 7,000+	6.9	8.5	0.7	0.6

Question to the audience!!

Who is adhering to giving LMWH for 7 days in medical patients?

Relative risk of VTE by time since surgery

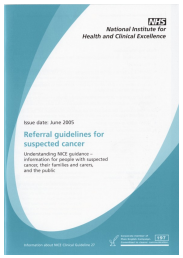


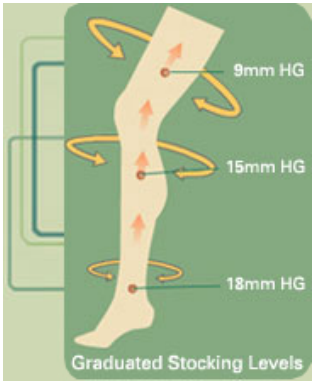
thebmj

Siân Sweetland et al. BMJ 2009;339:bmj.b4583

Mechanical Compression

Graduated compression stockings





NHS
National Institute for Clinical Excellence

Never shown to reduce the risk of death due to PE

<u>Do not offer stockings to patients who have:</u>

Suspected peripheral arterial disease

Peripheral arterial bypass grafting

Peripheral neuropathy or other causes of sensory impairment

Any local condition in which stockings may cause damage

Known allergy to material of manufacture

Cardiac failure/severe leg oedema

Unusual leg size or shape

If arterial disease suspected seek expert opinion

Encourage them to wear them day and night until they no longer have reduced mobility

Remove daily for hygiene purposes and to inspect skin 2-3 times a day for integrity or sensory impairment and discontinue if problems develop.

<u>The CLOT Study</u>

Dennis M et al, Lancet 2009; 373: 1958

2,500 stroke patients

Thigh length anti-embolic stockings vs no stockings

<u>Result</u>

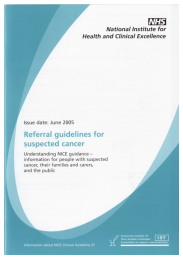
10% vs 9.5% VTE rate

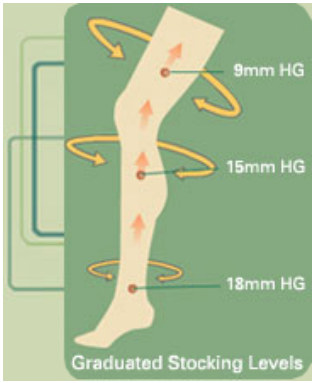
BUT

5% with stockings had skin problems

Mechanical Compression

Graduated compression stockings





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Cost of purchasing and applying GCS to surgical inpatients in England estimated at £63.1 million per annum

9; 373: 1958

2,500 stroke patients
Thigh length anti-embolic stockings vs no stockings

Result
10% vs 9.5% VTE rate
BUT
5% with stockings had skin problems


LACK OF
EVIDENCE

GAPS

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Centre for London

Pioneering better health for all

GAPS: Graduated compression as an Adjunct to Pharmacoprophylaxis in Surgery

3,250 moderate risk surgical patients receive LMWH +/- stockings

Primary outcome: symptomatic & asymptomatic vTE

Imperial College London

Thrombosis UK

Awareness • Research • Care

NHS National Institute for Health Research

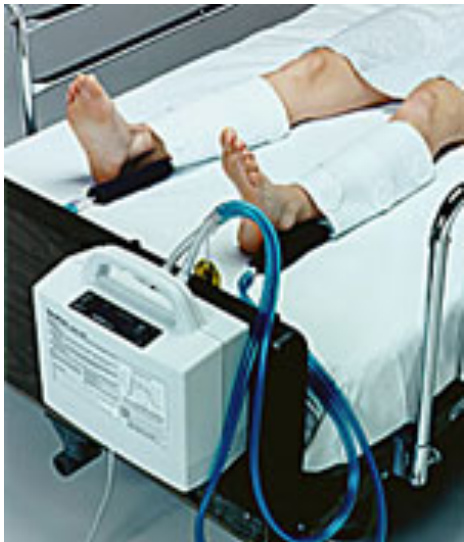
Intermittent Pneumatic Compression (IPC)

CLOTS 3 (Clots in legs after **stroke**)

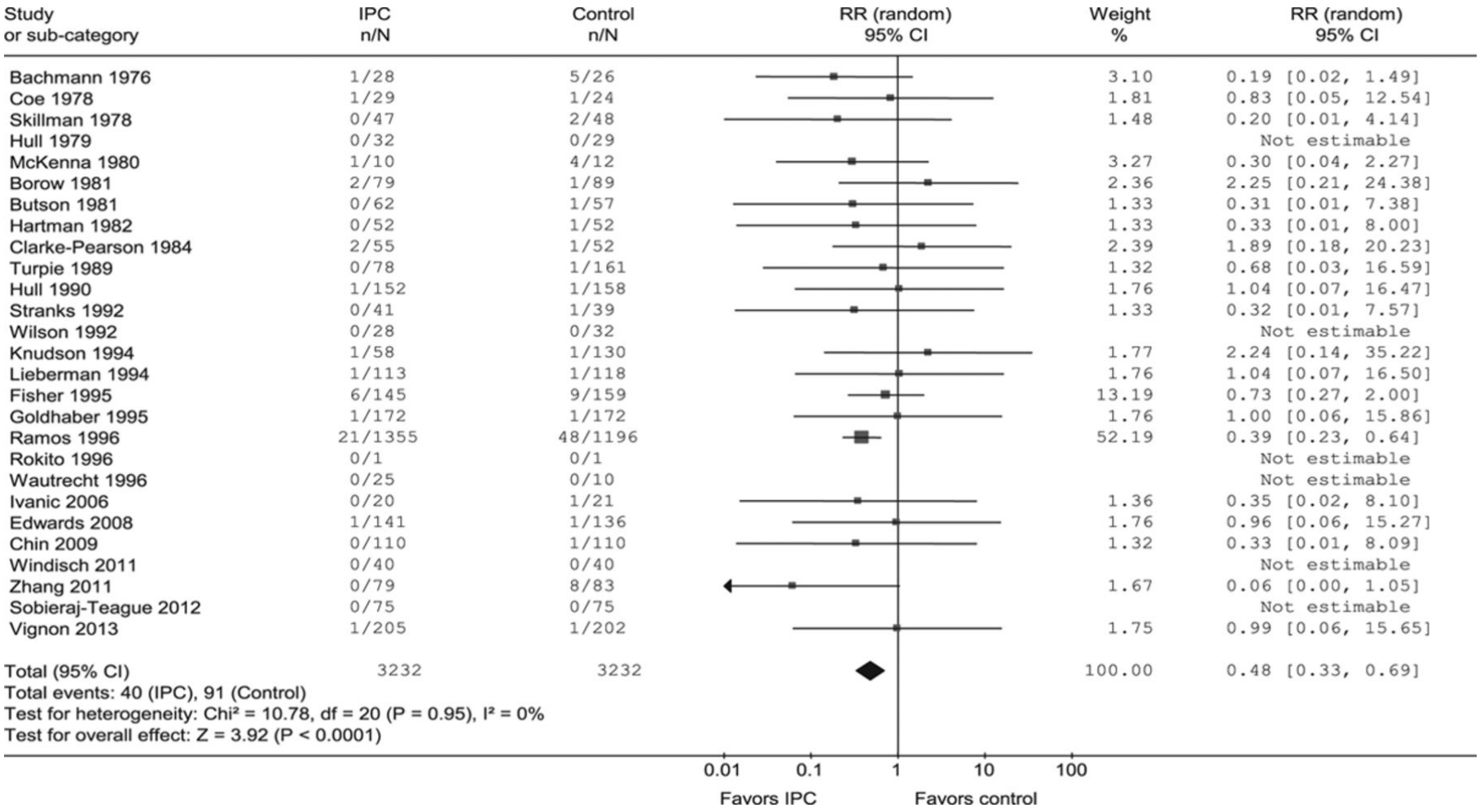
Dennis M et al, Lancet. 2013 Aug 10;382:516-24

2,800+ randomised to IPC post-stroke. Follow up for 6 months

	IPC	**No IPC**	
DVT rate	8.5%	12.1%	
Death rate	11%	13%	(p=0.057)
Skin breaks	3%	1%	(p=0.002)

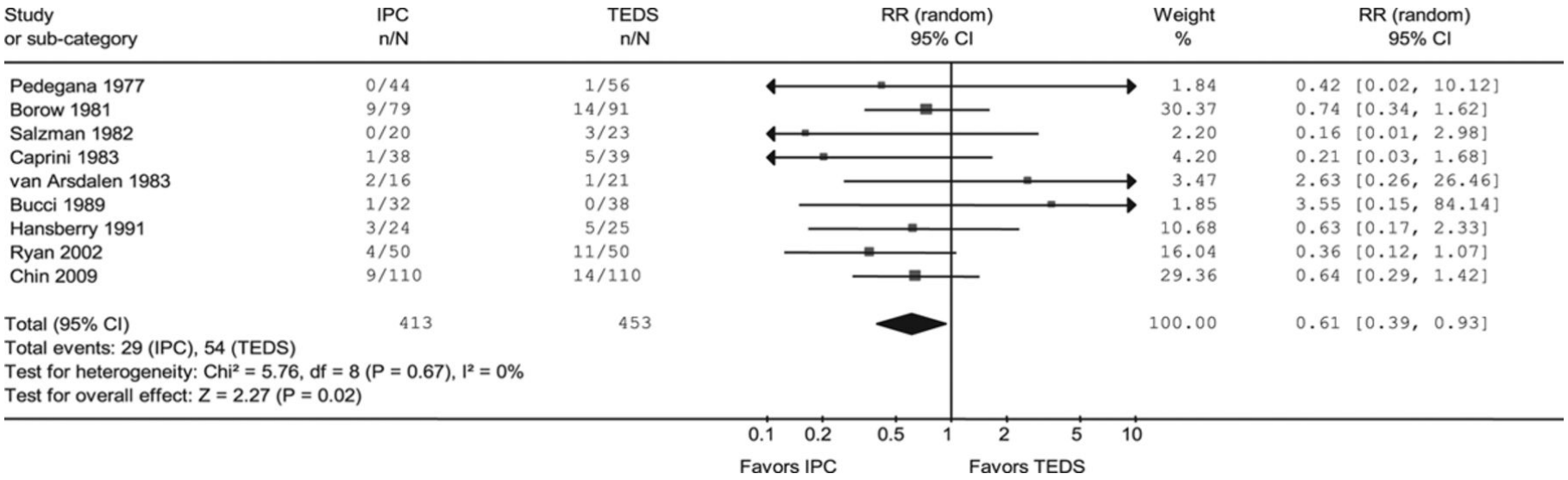


Forest plot showing the effect of intermittent pneumatic compression (IPC) on the risk of pulmonary embolism compared with placebo.



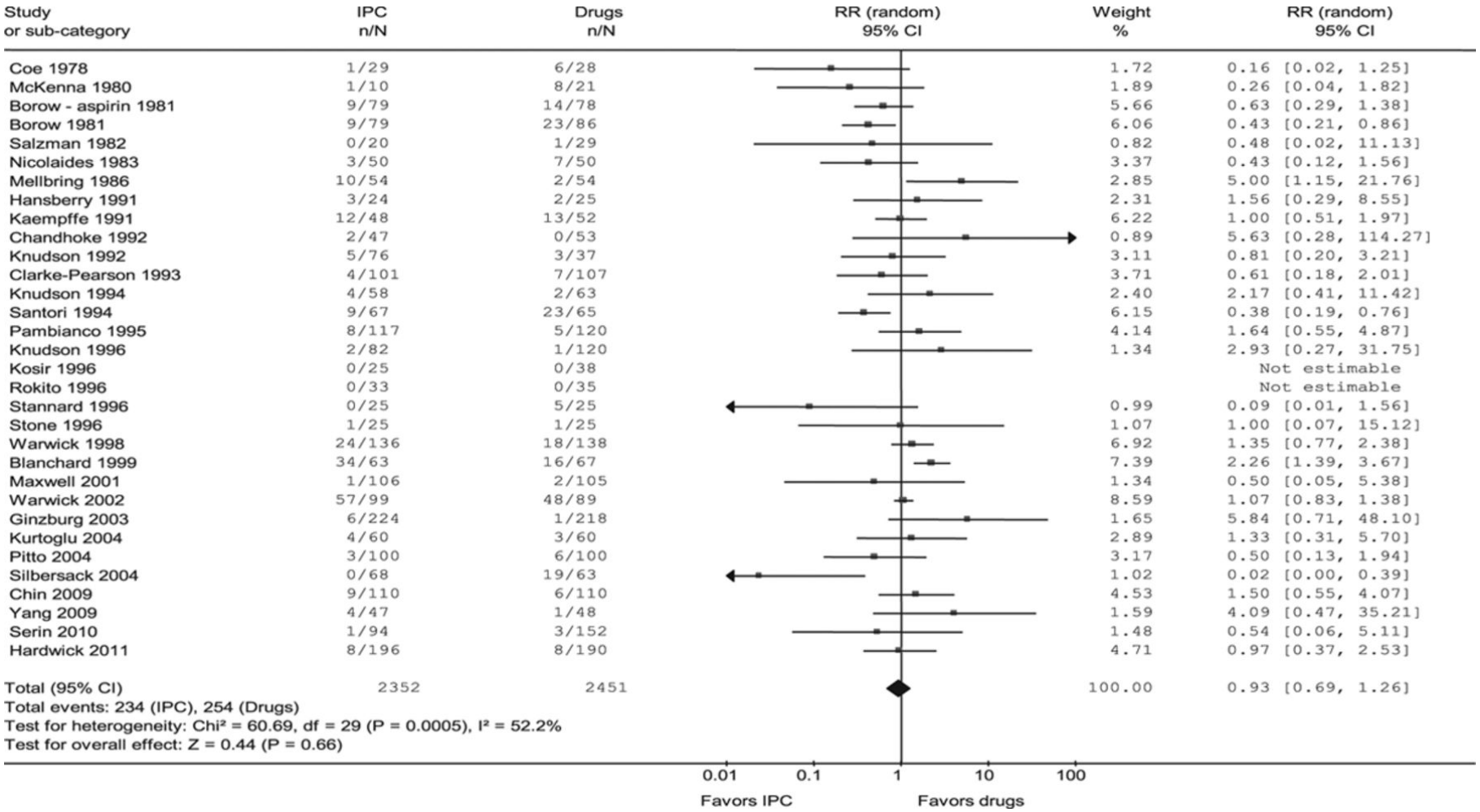
Kwok M. Ho, and Jen Aik Tan Circulation. 2013;128:1003-1020

Forest plot showing the effect of intermittent pneumatic compression (IPC) on the risk of deep vein thrombosis compared with thromboembolic deterrent stockings (TEDS).



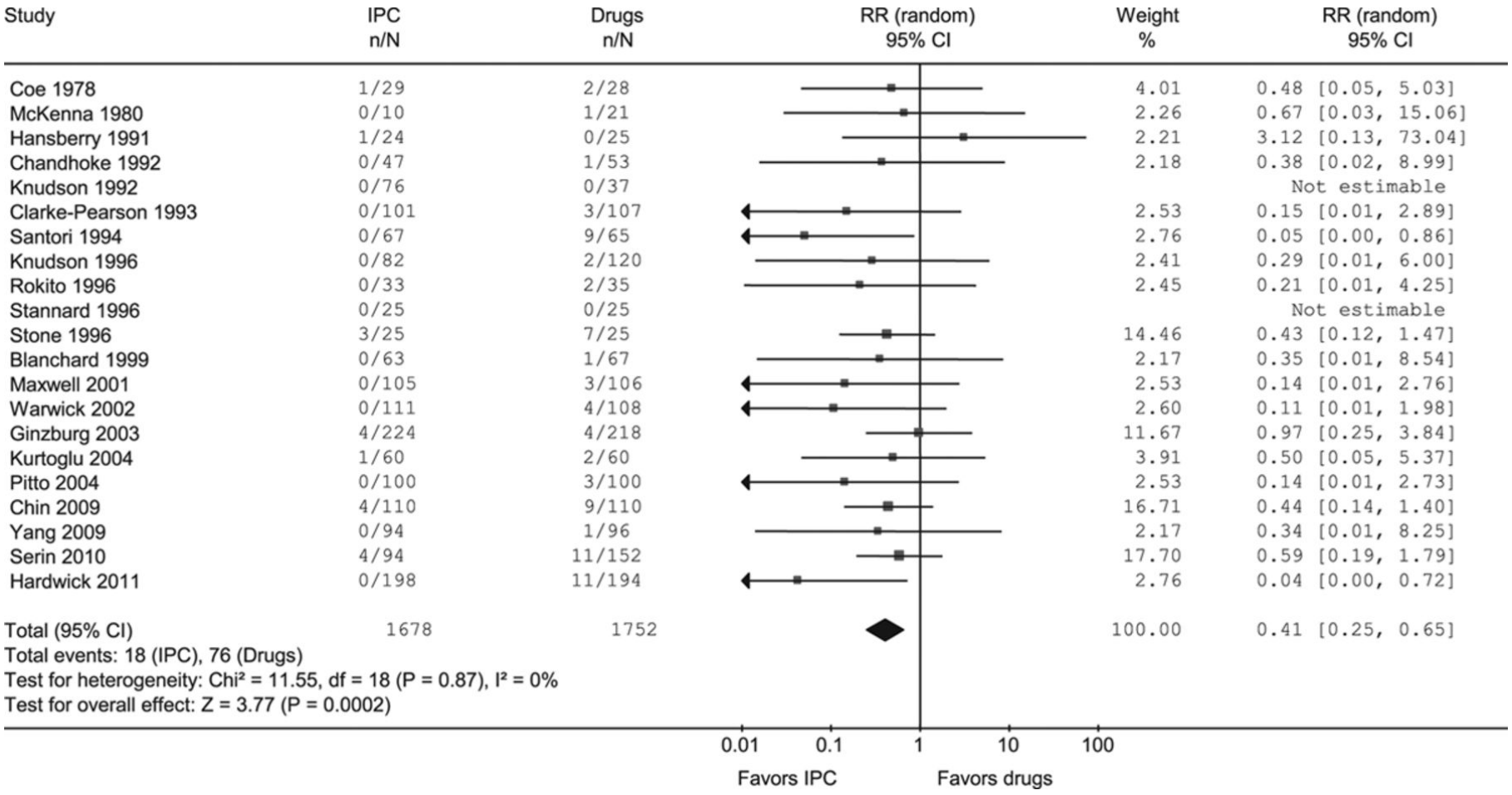
Kwok M. Ho, and Jen Aik Tan Circulation. 2013;128:1003-1020

Forest plot showing the effect of intermittent pneumatic compression (IPC) on risk of deep vein thrombosis compared with pharmacological thromboprophylaxis.



Kwok M. Ho, and Jen Aik Tan Circulation. 2013;128:1003-1020

Forest plot showing the effect of intermittent pneumatic compression (IPC) on risk of systemic bleeding or bleeding complications from the wound compared with a pharmacological thromboprophylaxis.



Kwok M. Ho, and Jen Aik Tan Circulation. 2013;128:1003-1020

Cochrane Review
IPC vs IPC + pharm in the prevention of DVT & PE
Kakkos et al, 2016

	IPC	IPC + pharm
Symptomatic PE	2.9%	1.2% OR 0.39 (95% CI 0.23-.64
All DVT	6.2%	2.9% OR 0.42 (95% CI 0.18-1.03
Bleeding	0.7%	4.1%

Problems

Although trials included >9,000 patients,

Trials overall of moderate quality

IPC used widely intraoperatively & immediately post op pre
Pharmacological thromboprophylaxis – no data on benefit

Evidence of pregnancy on the effect of graduated compression stockings:
on blood velocity in the deep venous system of the lower limb in the postnatal period.

Jamieson R1, Calderwood CJ, Greer IA. BJOG. 2007 Oct;114(10):1292-4.

This study of 17 women examined the effects of GCS on the deep venous system in the immediate postpartum period and found a statistically significant reduction in the diameter of the common femoral vein (CFV) (pre- versus post stocking diameter: mean 10.39 mm [SD 2.09] versus mean 9.69 mm [SD 1.99]) and an increase in the rate of blood velocity in the CFV (pre- versus post stocking velocity: mean 10.0 cm/s [SD 2.7] versus 13.9 cm/s [SD 4.2]) 30 minutes after application of thigh length GCS in women 1 or 2 days following a singleton vaginal delivery at term.
This confirms reduction in venous stasis in the deep venous system in the immediate postpartum woman by the use of GCS, supporting their use in improving venous function in this context.

RCOG PREVENTION OF VTE 37b 2015

Anti-embolism stockings

The use of properly applied anti-embolism stockings (AES) of appropriate size and providing graduated compression with a calf pressure of 14–15 mmHg is recommended in pregnancy and the puerperium for women who are hospitalised and have a contraindication to LMWH. These include women who are hospitalised post-caesarean section (combined with LMWH) and considered to be at particularly high risk of VTE (e.g. previous VTE, more than four risk factors antenatally or more than two risk factors postnatally) and women travelling long distance for more than 4 hours. [*New 2015*]

There are few data regarding the most efficacious length of AES to use in pregnancy and advice in the non pregnant population is contradictory. More DVTs in pregnant women are iliofemoral compared to the non pregnant population where calf vein DVTs are more common. Studies of AES in pregnancy have only concerned full-length stockings.162 However, in the obstetric population, there is the added problem of full-length stockings becoming bloodstained. Therefore, on balance, properly applied full-length AES are advocated for pregnant women but knee-length AES should be considered if (as is often the case) full-length AES are ill-fitting or compliance is poor.

Conclusions

Which risk assessment model should we use?

New NICE guidelines on length of thromboprophylaxis are controversial & not being adhered to. RCT needed

Shortages of LMWH are causing problems & will continue to do so

Awaiting the GAPS trial

Mechanical methods summary

Poor evidence base for using stockings

Much better evidence base for intermittent pneumatic compression but

-how useful is it perioperatively

-for short periods?

MORE RESEARCH REQUIRED!

WORLD THROMBOSIS DAY
OCTOBER 13

Thrombosis UK
Awareness • Research • Care