Monitoring chronic conditions in primary care

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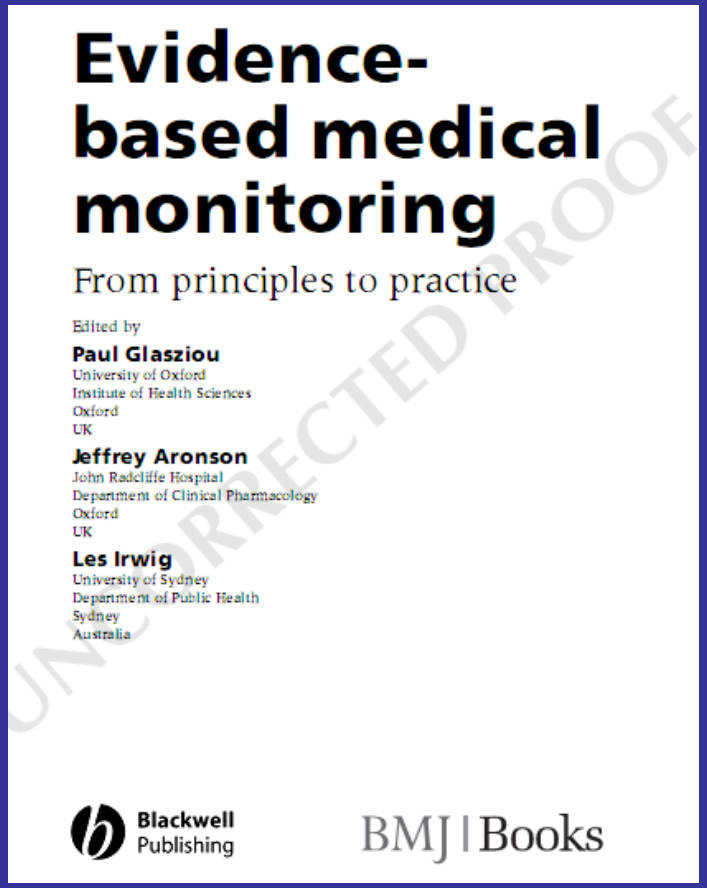


Monitoring: Overview

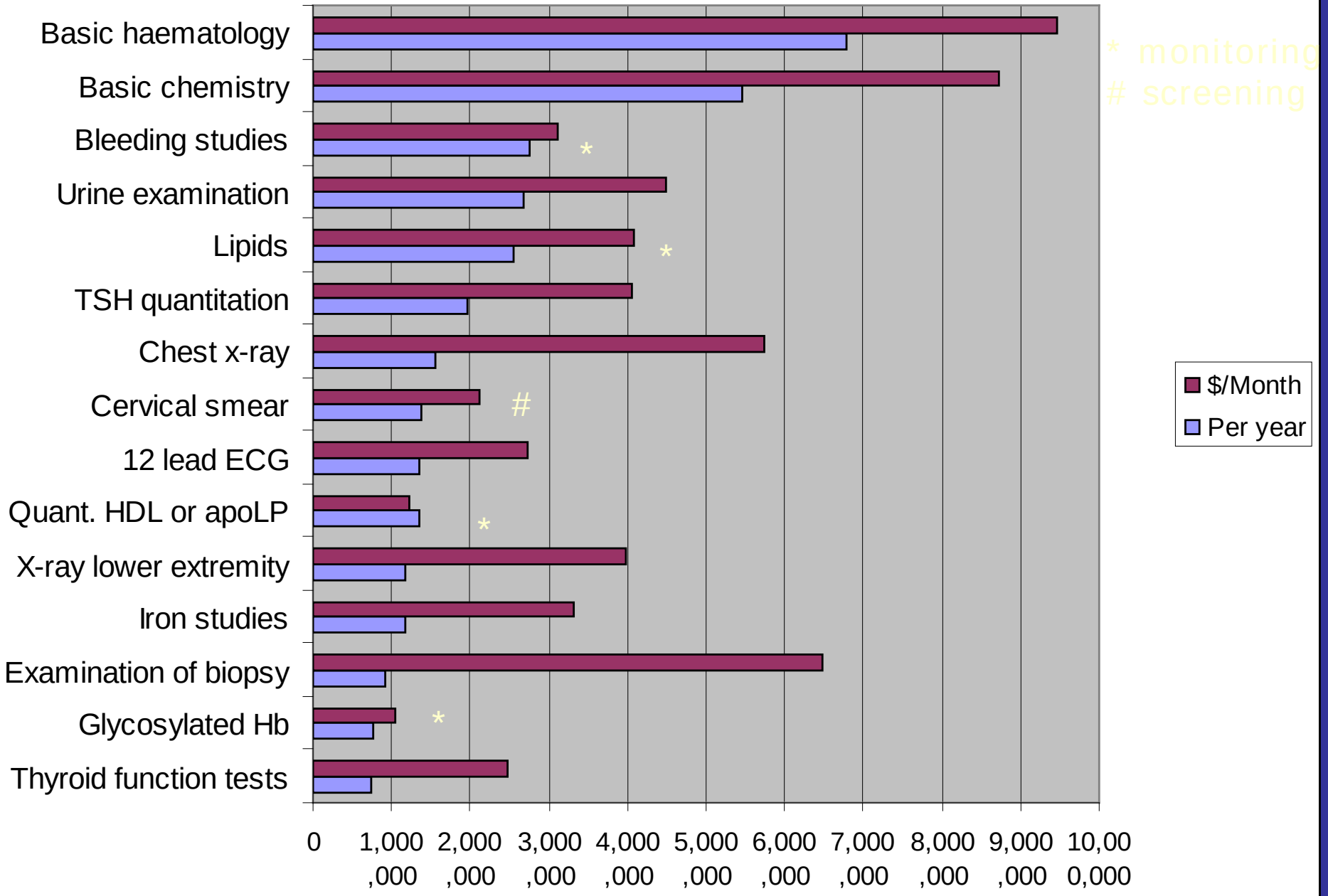
- "Know which abnormality you are going to follow during treatment. Pick something you can measure."
  - Clifton Meador - *A Little Book of Doctors' Rules*

1. Monitoring is a common activity
2. Sometimes it saves lives; sometimes a waste of effort
3. Better monitoring requires
   - Good signal-noise ratio
   - Good feedback

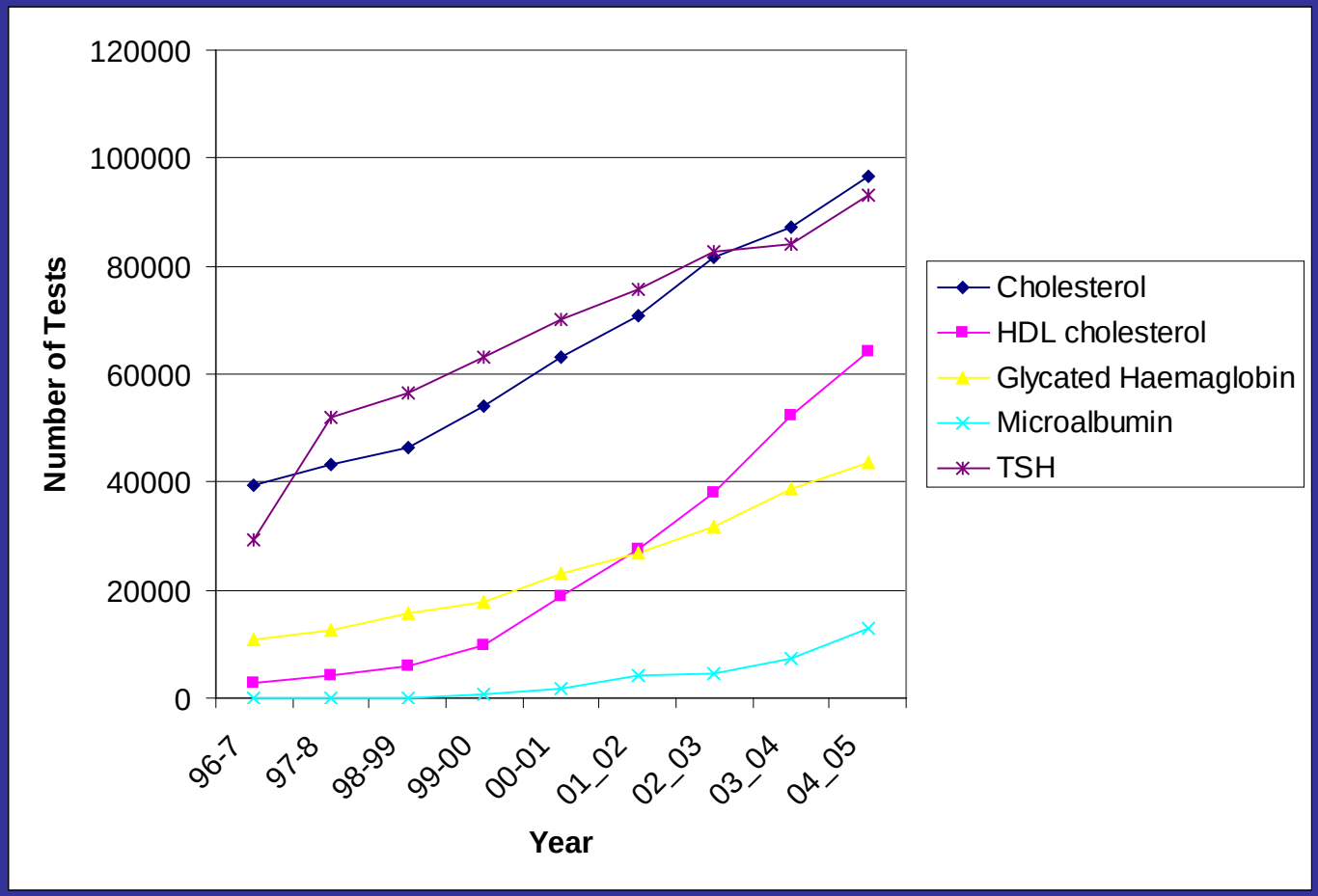
What are “tests” used for?

- Log of reasons for tests by several docs:
  - Diagnosis
  - **Monitoring** – has it changed?
  - Prognosis – risk/stage within Dx
  - Treatment planning,
    e.g., imaging for FB location
  - Stalling for time!

HIC frequency & cost data, 2001 – 15 most common tests



Monitoring tests over a decade



James T, Kay J. John Radcliffe Labs, Oxford

What is monitoring?
Objectives differ by phase

Monitoring = Periodic measurement to assess and adjust therapy

EARLY PHASES

- Does treatment works as expected?
- Titration to response or target
- Are there adverse effects?

LATER PHASES

- Is patient in target range? e.g, BP, INR
- Can we stop (yet)?

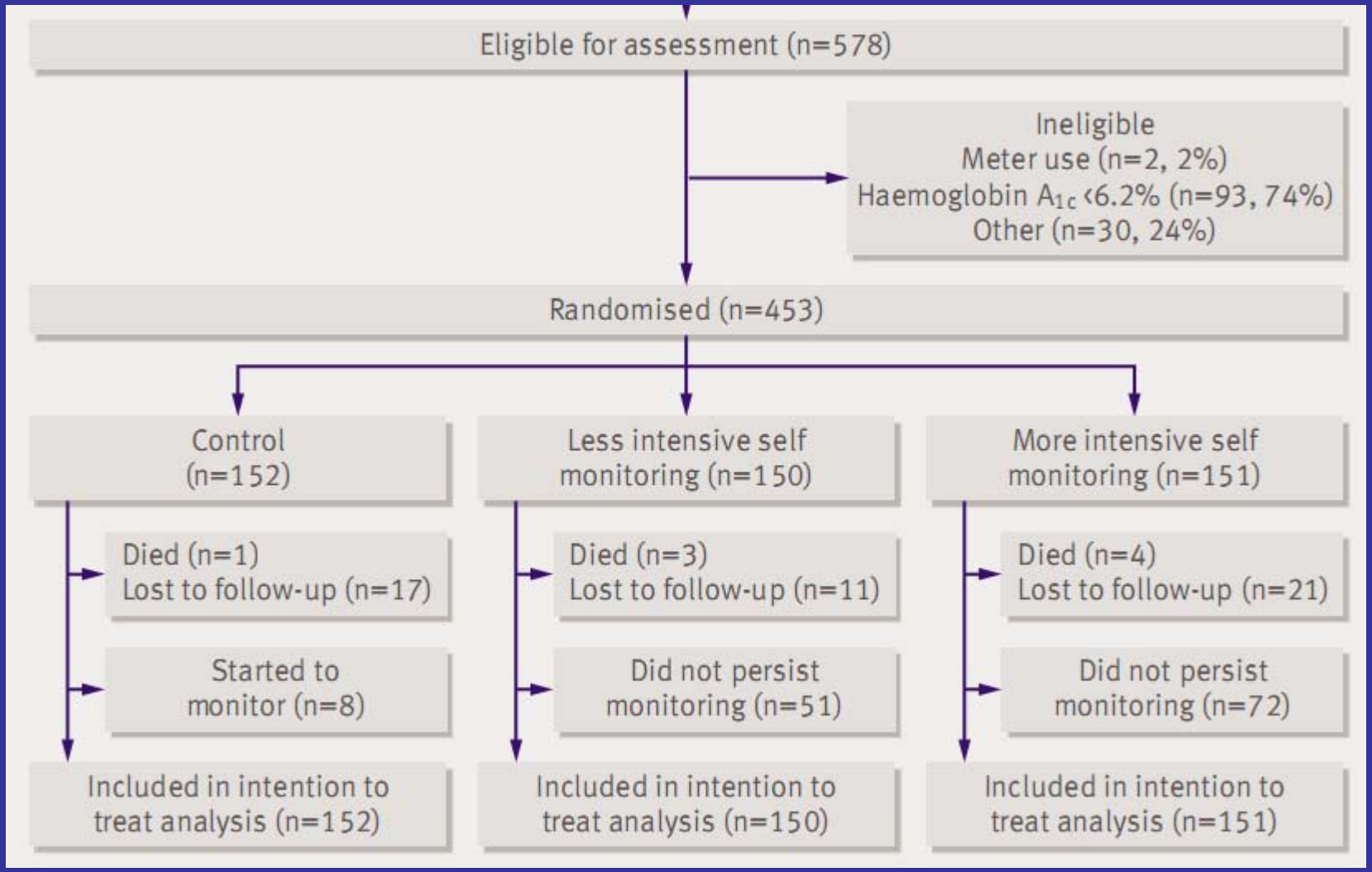
From: Glasziou P, Irwig L, Mant D. Monitoring in chronic disease. BMJ, 2005

But does monitoring help?

= Is Adjusted Treatment better than Fixed Dose?

- Not used or not helpful
  - Aspirin for CHD
- Used but does not work
  - Glucose monitoring in NIDDM
  - Swan-Ganz catheters in ICU
- (under) Used and evidence it is helpful
  - INR self-monitoring for warfarinisation
  - BNP monitoring in heart failure

Trial of blood glucose self monitoring (DiGEM)



Blood Glucose Monitoring does not improve overall control

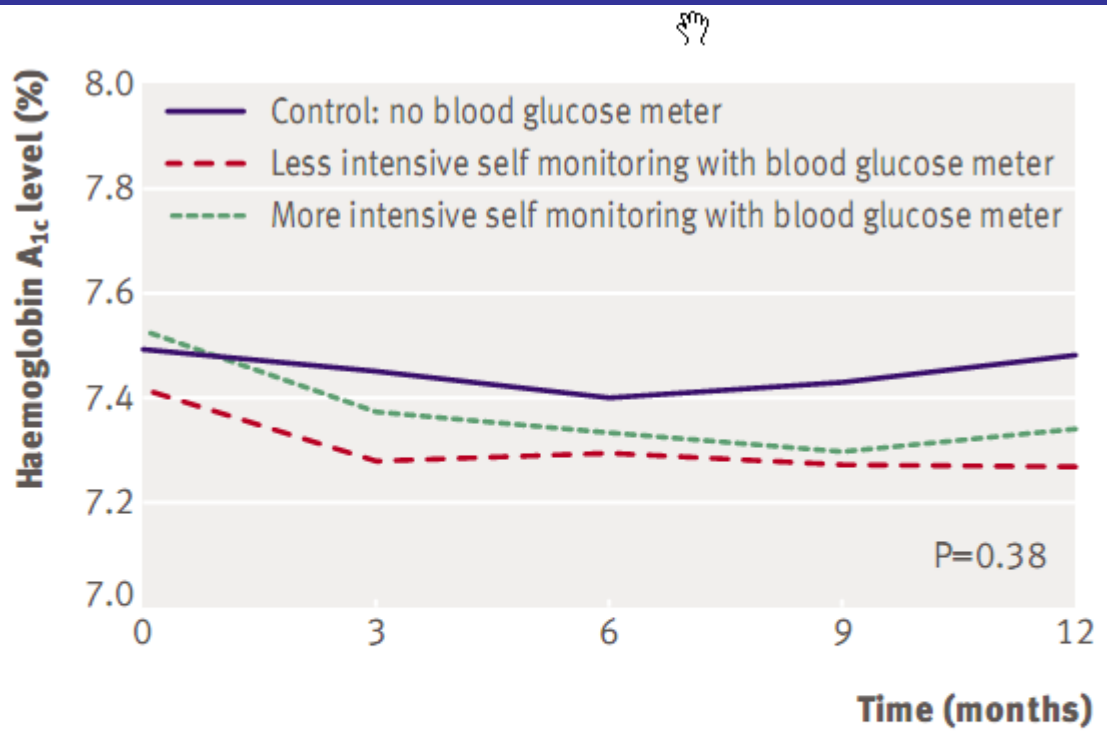


Fig 2 | Change in HbA_{1c} levels over 12 months' follow-up of patients with non-insulin treated type 2 diabetes according to randomisation group

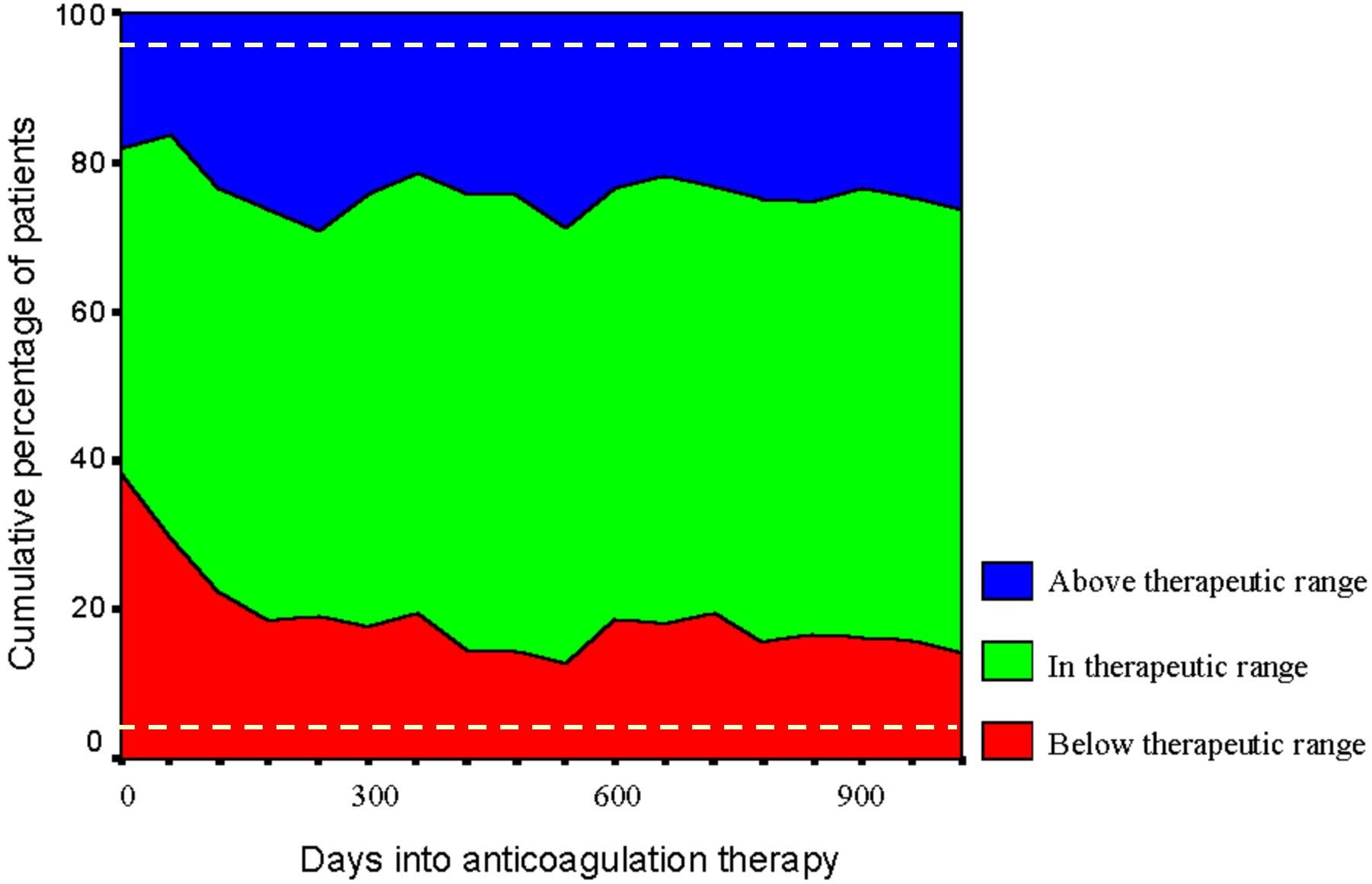
Farmer et al, BMJ 2007

3. Self-monitoring of INR for warfarin

Home Self Monitoring versus Usual Care

Control is often poor

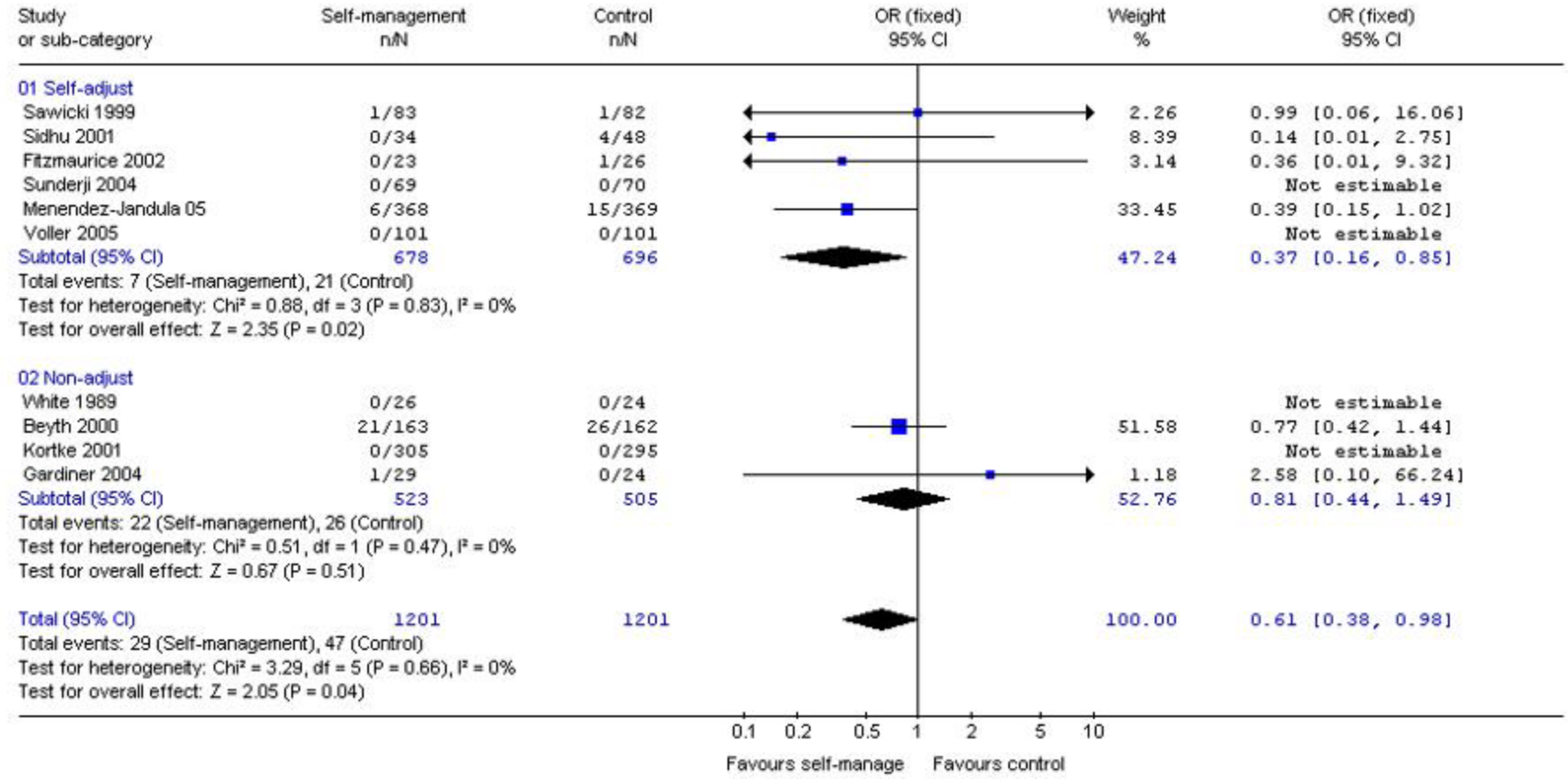
INR: In range (2.0-3.0) 50-60% of time (ideal = 95%)



Utley M, BMJ, letter, 2002

Self-monitoring of INR for warfarin decreases all cause mortality

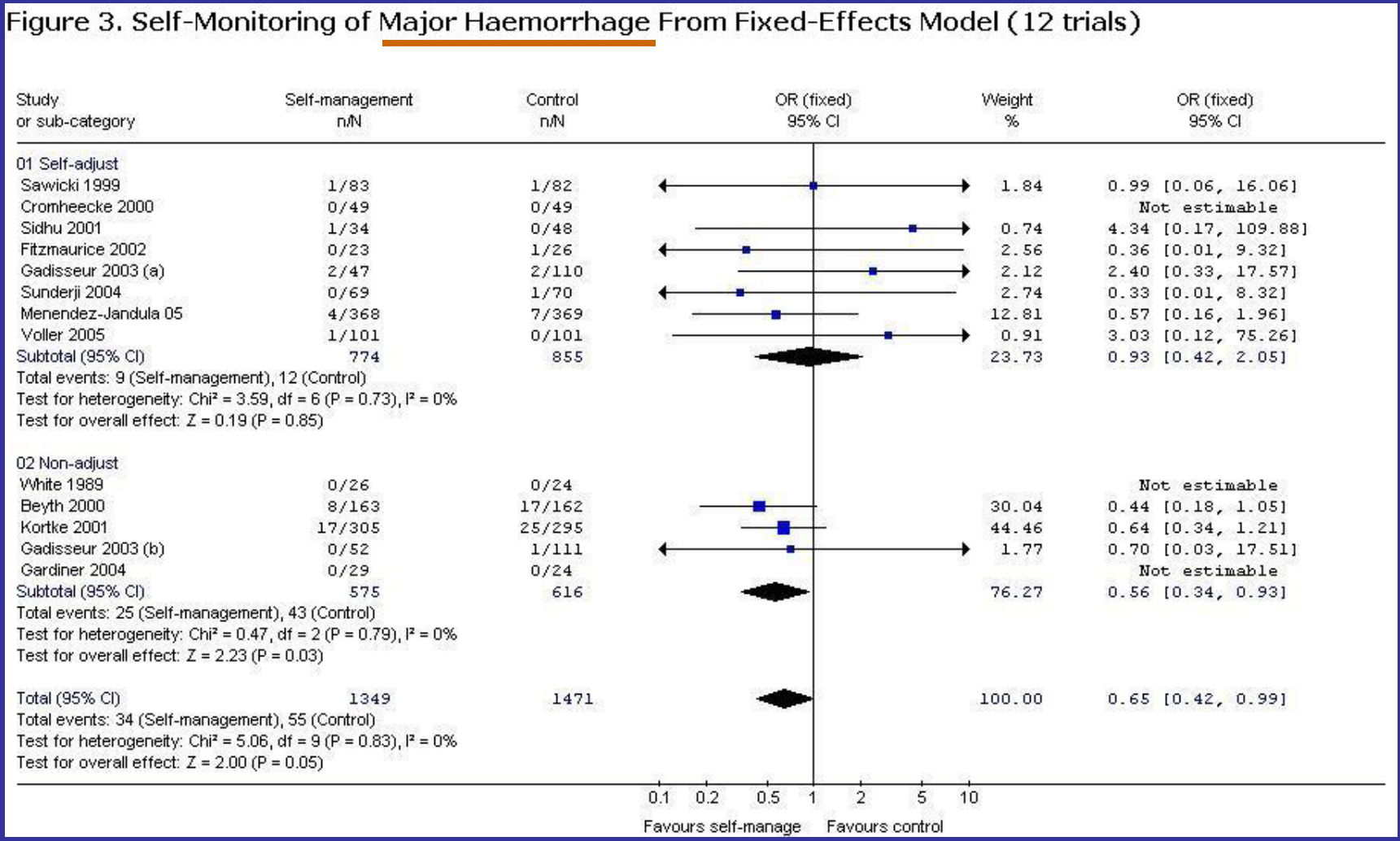
Figure 4. Self-monitoring and Death From Fixed-Effects Model (10 trials)



Heneghan C, Alonso-Coello P ,Garcia JM, Perera R, Meats E, Glasziou P. The Lancet, 2006.

Self-monitoring of INR for warfarin does not change bleeding risk

Figure 3. Self-Monitoring of Major Haemorrhage From Fixed-Effects Model (12 trials)



Heneghan C, Alonso-Coello P ,Garcia JM, Perera R, Meats E, Glasziou P. The Lancet, 2006.

Some conclusions: so far

- Monitoring is common (1/3? of testing) and increasing
- Some may be unnecessary
- Some works and needs wider usage
- Self-monitoring may be even better

Inside the monitoring box

What is “on target”?

- NICE Guideline: “The aim of medication is to reduce blood pressure to 140/90 mmHg or below.”
- What percentage of measures should be below target (140/90)?
  1. 99%
  2. 95%
  3. 67%
  4. 50%
  5. < 50%

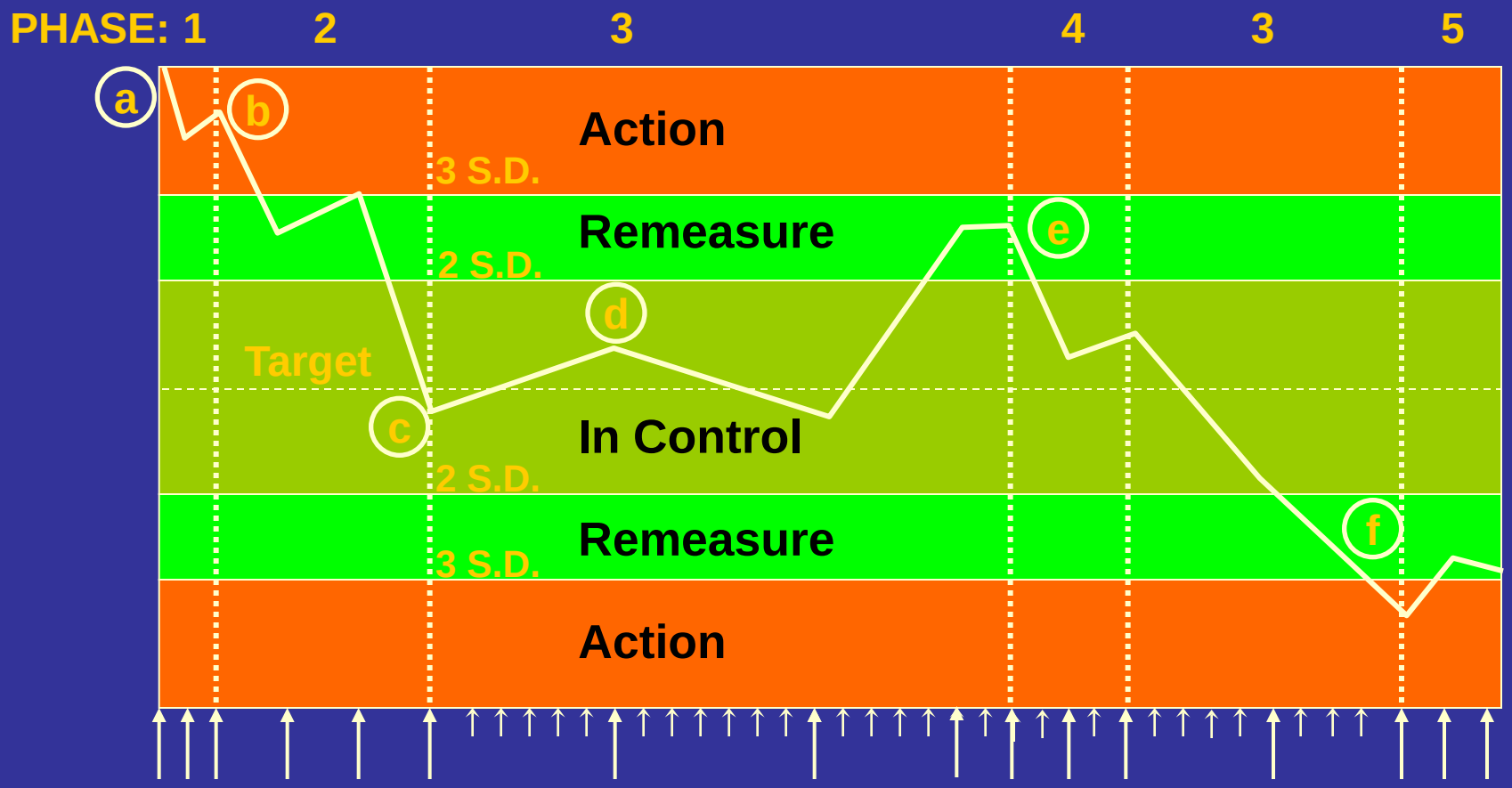
Your implied “target”?

- NICE Guideline: “The aim of medication is to reduce blood pressure to 140/90 mmHg or below.”
- What % of measures below target?
  1. 50% - 0SD = 140
  2. 67% - 1SD = 133
  3. 95% - 2SD = 124
  4. 99% - 3SD = 119 (implied target)

When is a change “significant” The WECO rules

- 1x 3SD or
- 2x SD or
- 7x 1 SD

Five Phases of Monitoring



When is phase 3 monitoring worthwhile: preconditions

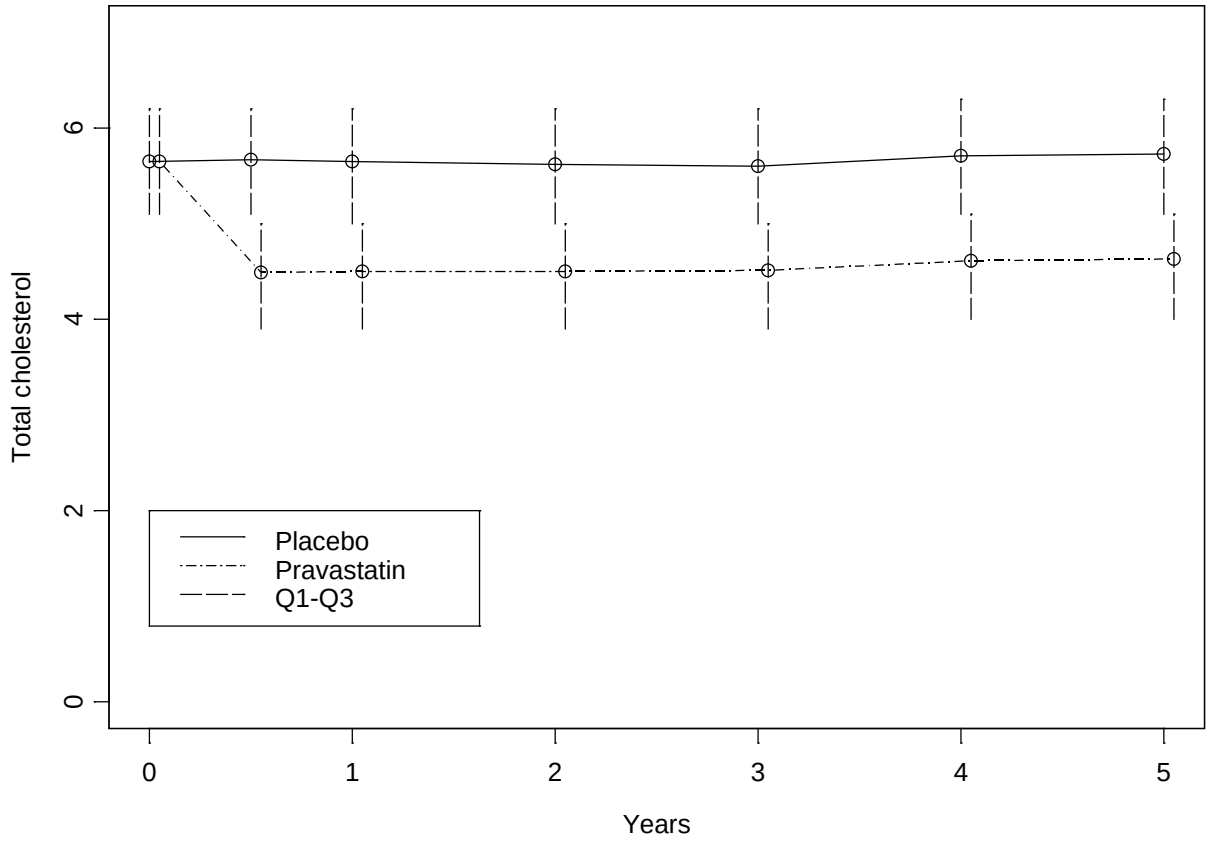
1. The test valid measures disease state and/or future risk
2. The signal >> noise
3. Some action can be taken to correct the problem

If all 3 hold then RCT worthwhile

Is cholesterol monitoring worthwhile?

The LIPID trial

- 9000 patients
- Fixed dose
  - Statin
  - placebo
- 5 year FU
- 21%↓ mortality



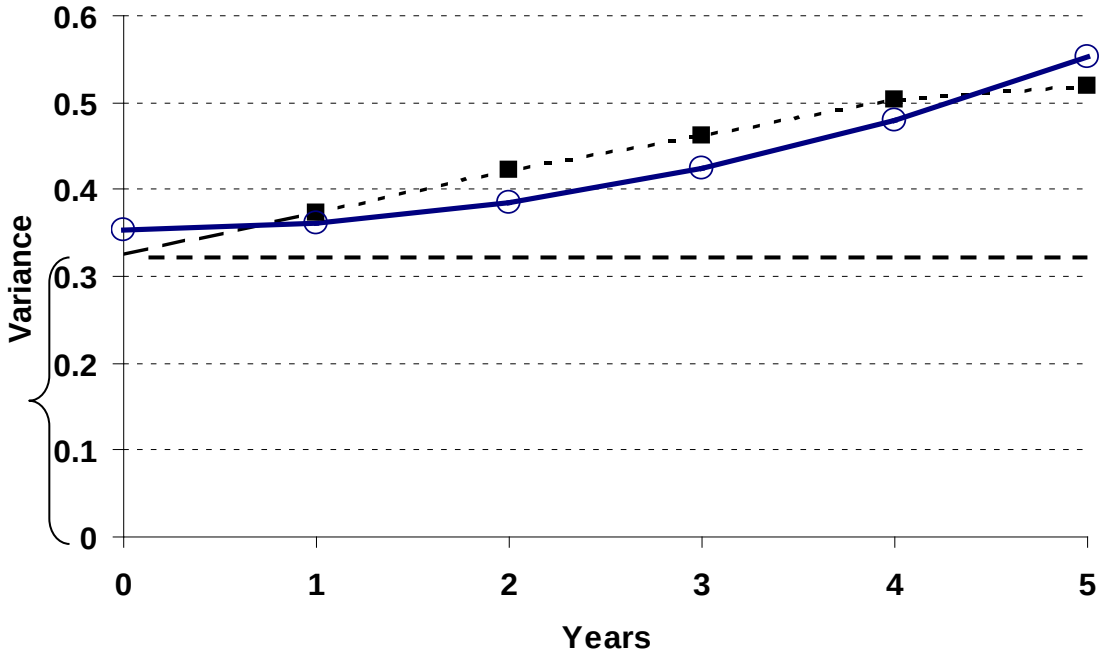
Re-measuring when stable

- How long does a clinically important change take?

- “Signal” has two elements
  - Progression of whole population
  - Random drift by individuals
- “Noise” is stable within-person variation

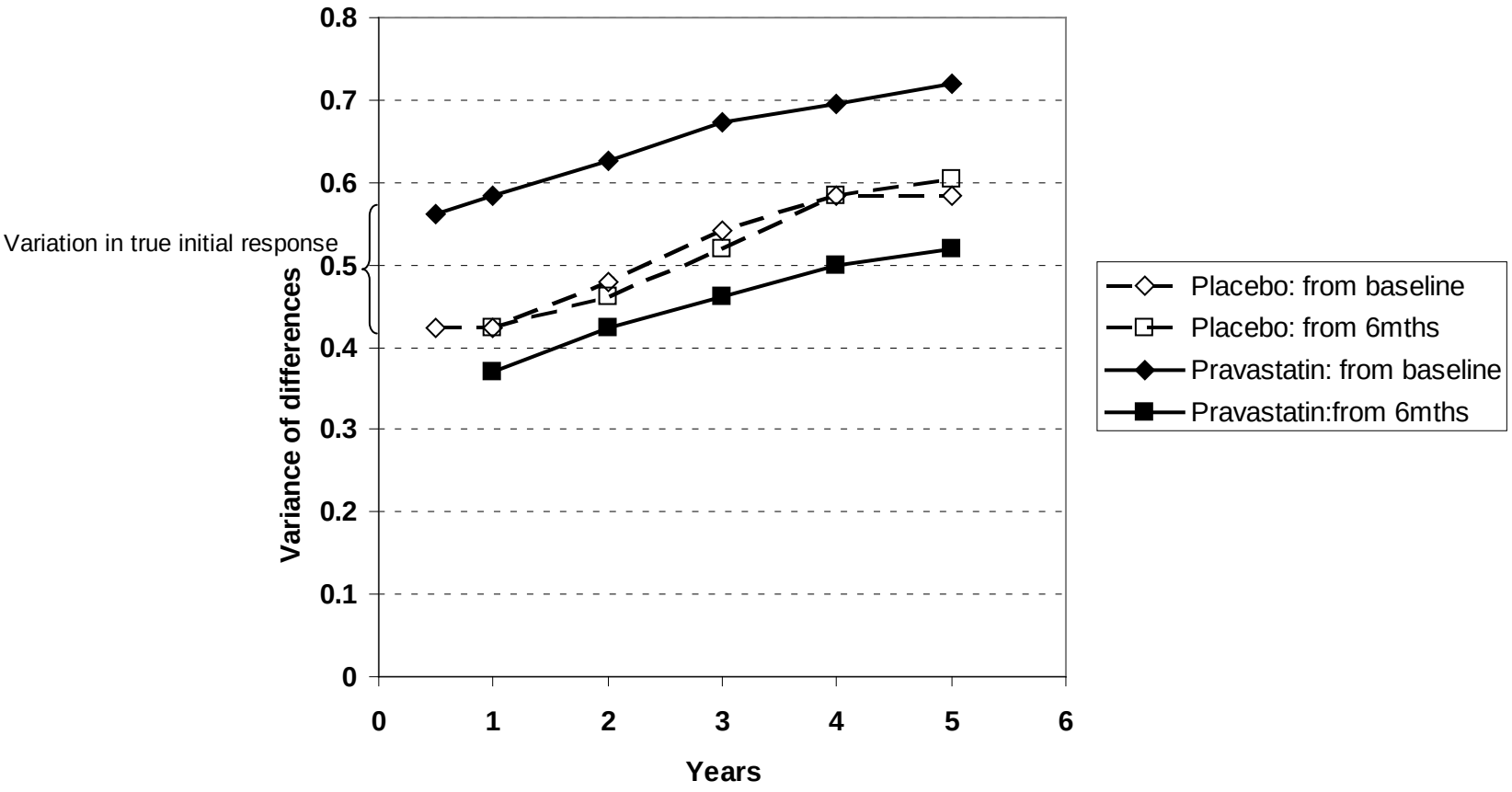
Within person variability over time

2 x short term (within-person) variation



long-term variation

Cholesterol over 5 yrs in LIPID



Estimated true and false positive measurements over a threshold of **5mmol/l** of cholesterol

Initial true level	True positive rate %	False positive rate %	Ratio FP/TP
True Initial = 4.5 mmol/l (so 0.5mmol increase needed)			
Year 1	0.87%	14%	16
Year 3	8.9%	14%	1.6
Year 5	15%	13%	1
4.0 mmol/l			
Year 1	0.0006%	1.7%	> 1,000
Year 3	0.43%	4.3%	10
Year 5	1.7%	6.0%	3

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Year 1	0.0006%	1.7%	> 1,000
Year 3	0.43%	4.3%	10
Year 5	1.7%	6.0%	3

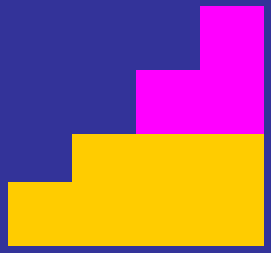
Some unanswered questions

- How do we choose the best measurement?
- How do we design studies to determine the interval between tests (random & systematic drift)
- When to 2-stage measurement appropriate?
  - E.g. BP and ABPM
- Is stepped or low-dose sequential treatment better?
- When is self-monitoring effective? Cost-effective?

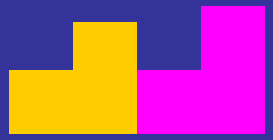
Phase 4: adjusting treatment

- How much to adjust?
  - Make small adjustments
    - Common error is overadjustment
      -> worse control
- How to adjust
  - General strategies:
    - titrate, stepped care, switch, PolyPill
- Timing of re-measurement

Strategies with multiple agents



- Stepped Care
  - Titrate then add new agents



- Switch
  - Titrate and switch if insufficient

- PolyPill
  - Add new low-dose agent

Future research agenda

- Methods
  - Criteria for evaluation of monitoring;
  - Simulations of control “rules” & strategies
- Primary Studies, e.g., trials of tools
  - BNP in heart failure
  - Cholesterol variation
  - NIDDM monitoring RCT (Farmer)
- Systematic Reviews
  - Heart failure monitoring (not BNP)
  - Anticoagulation self-monitoring attrition

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Future research into monitoring

- Aim: to develop and test appropriate monitoring for common chronic conditions
  - Control chart + adjustment algorithm
  - Understand optimal processes (technical & human)
  - Test optimal methods in controlled trials

- Involves multiple disciplines
  - Clinical pharmacology
  - Clinical biochemistry
  - Statistical quality control
  - Clinical Epidemiology
  - Behavioural psychology

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- Is it important?
- Example Research
- Monitoring stages
- Further research