Point of Care Testing – current and emerging quality perspectives

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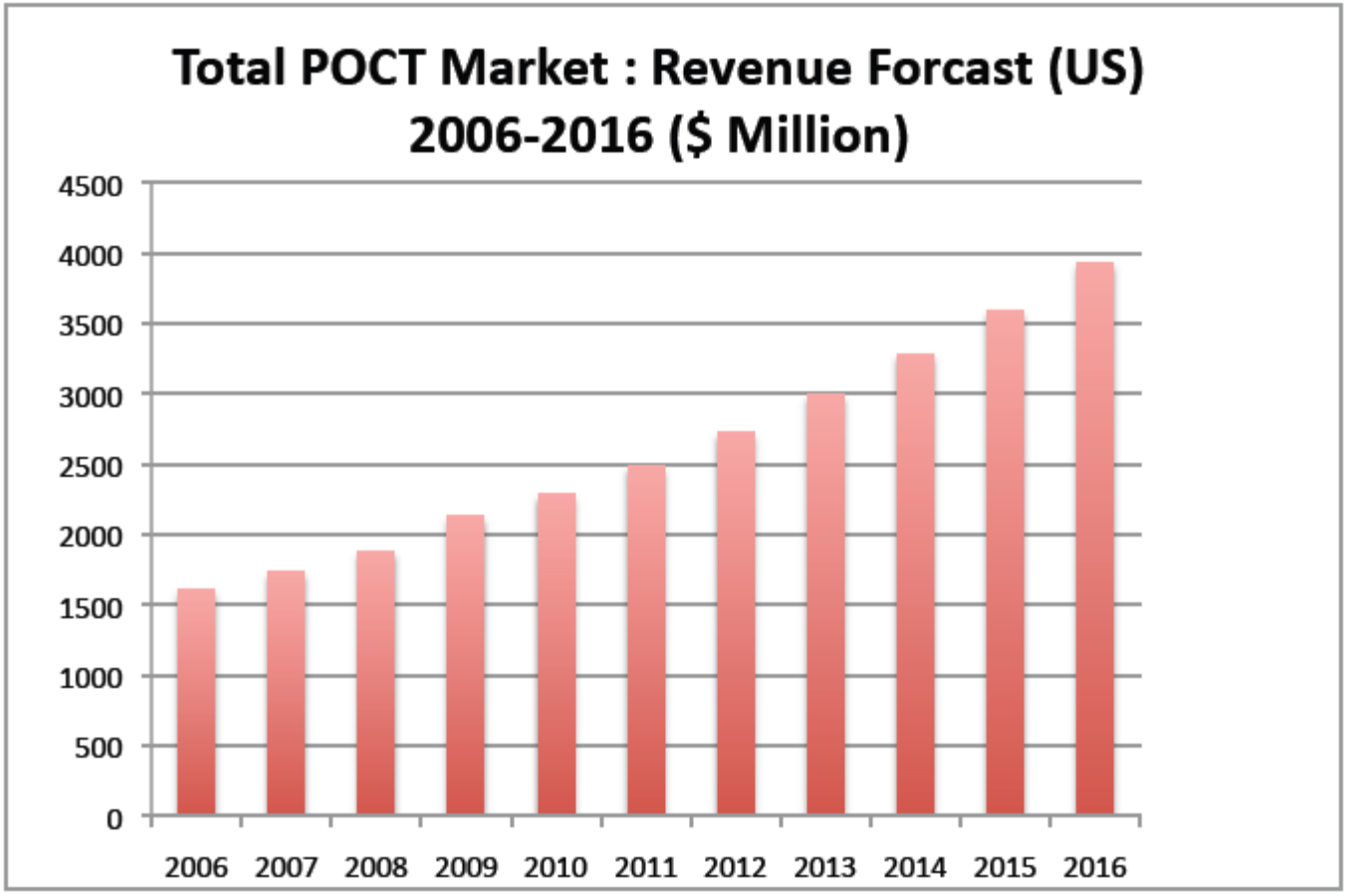
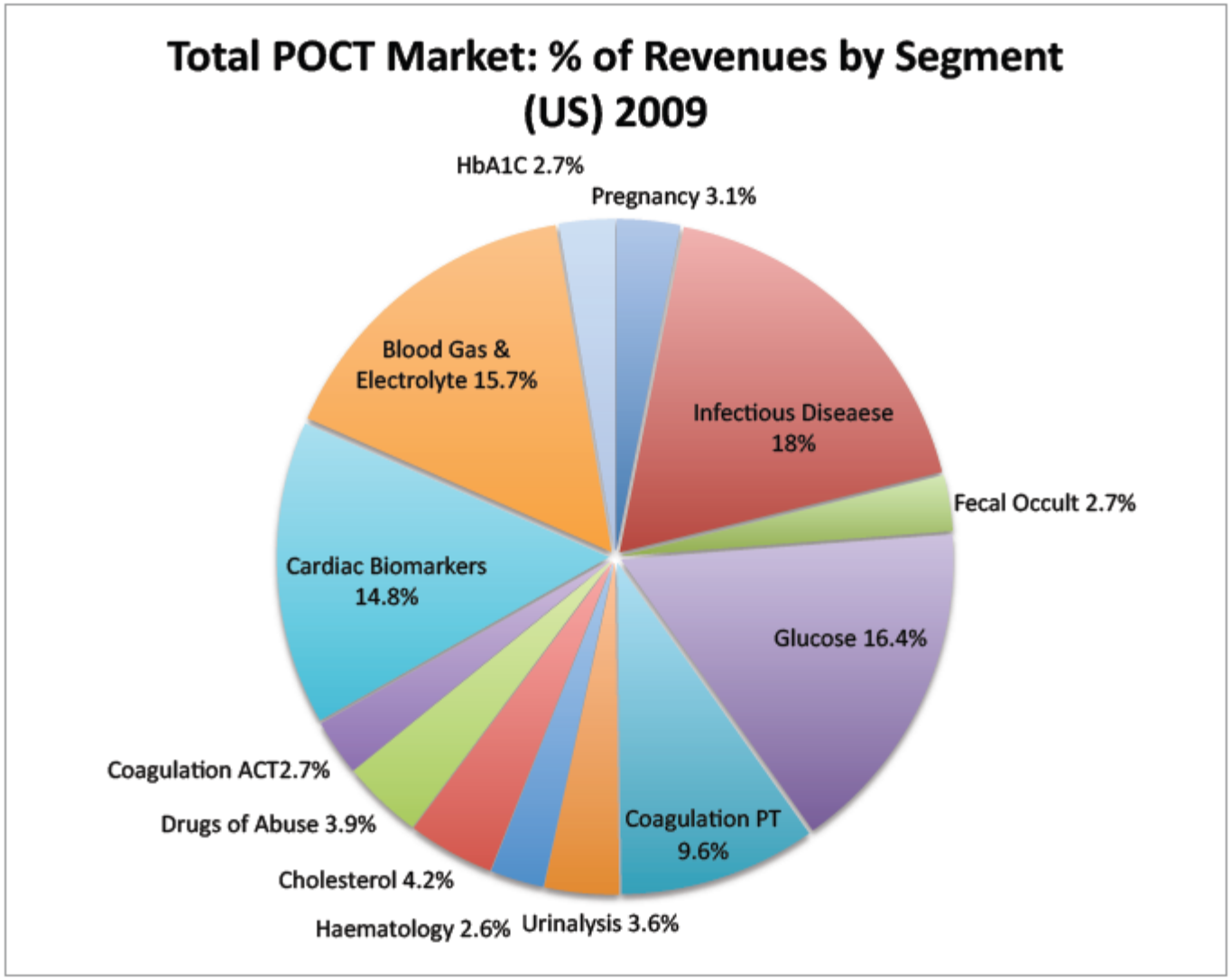
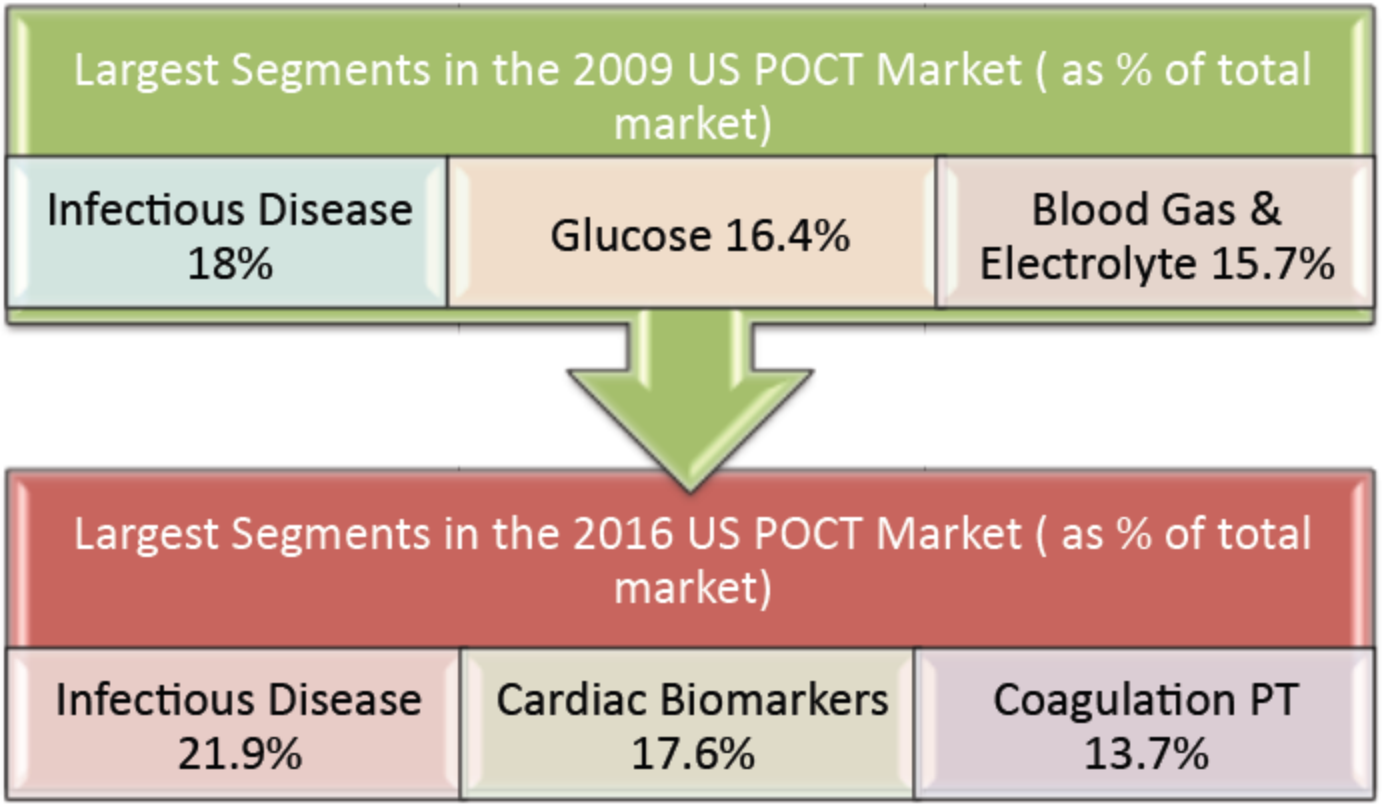

Total POCT Market : Revenue Forcast (US)
2006-2016 ($ Million)
4500
4000
3500
3000
2500
2000
1500
1000
500
0
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016


Total POCT Market: % of Revenues by Segment (US) 2009
HbA1C 2.7%
Pregnancy 3.1%
Blood Gas & Electrolyte 15.7%
Infectious Diseaese 18%
Fecal Occult 2.7%
Cardiac Biomarkers 14.8%
Glucose 16.4%
Coagulation ACT2.7%
Drugs of Abuse 3.9%
Coagulation PT 9.6%
Cholesterol 4.2%
Haematology 2.6%
Urinalysis 3.6%


Largest Segments in the 2009 US POCT Market (as % of total market)
Infectious Disease 18%
Glucose 16.4%
Blood Gas & Electrolyte 15.7%
Largest Segments in the 2016 US POCT Market (as % of total market)
Infectious Disease 21.9%
Cardiac Biomarkers 17.6%
Coagulation PT 13.7%

Diverse role of POCT

- Use by health care professionals
- Use by patients [glucose, PT/INR,pregnancy]
- Use in different settings e.g. ICU, home

Themes

- Quality of the POCT process

- Quality of the care pathway which incorporates POCT i.e. are patient outcomes improved?

Patient safety

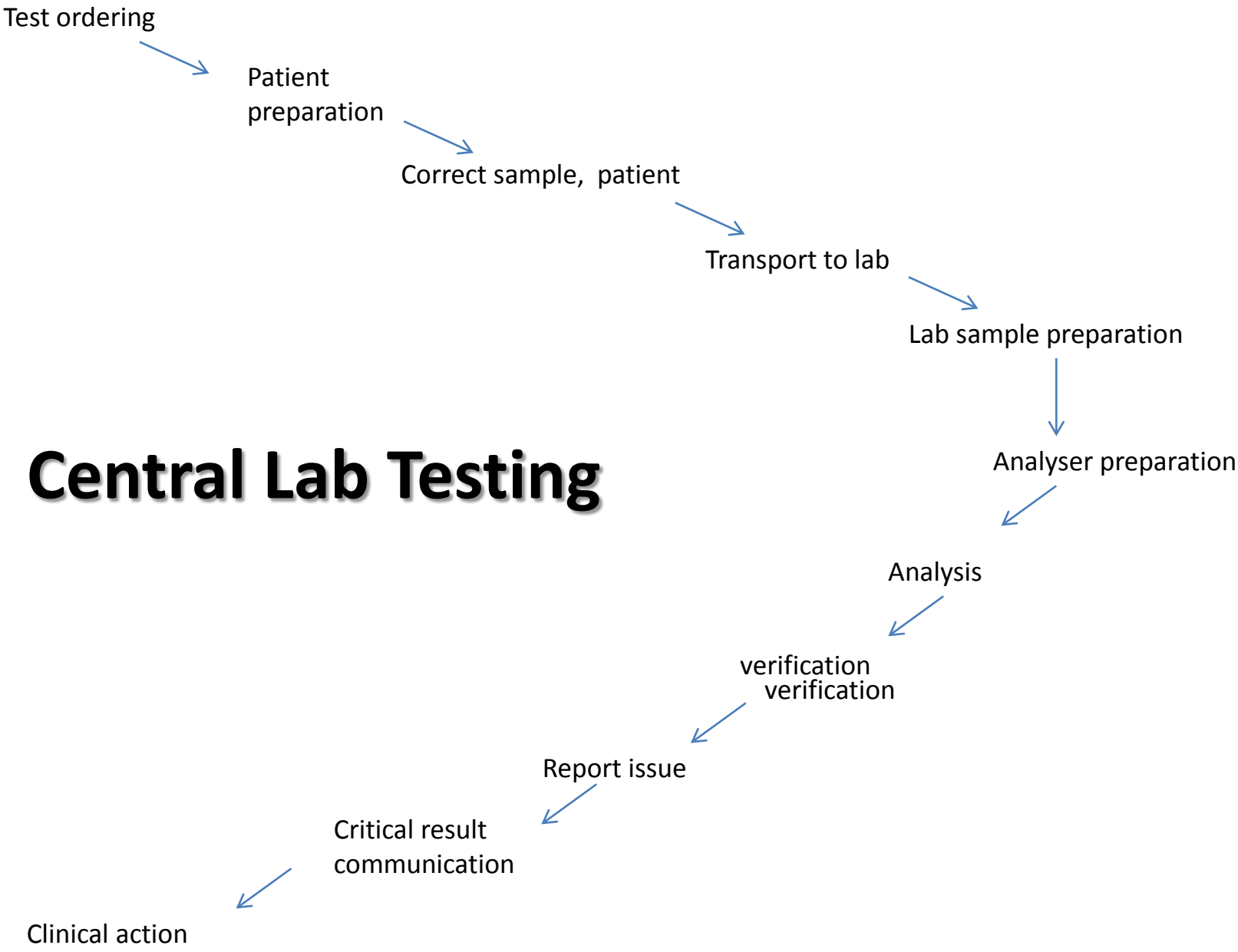
‘To err is human: Building a Safer Health System’

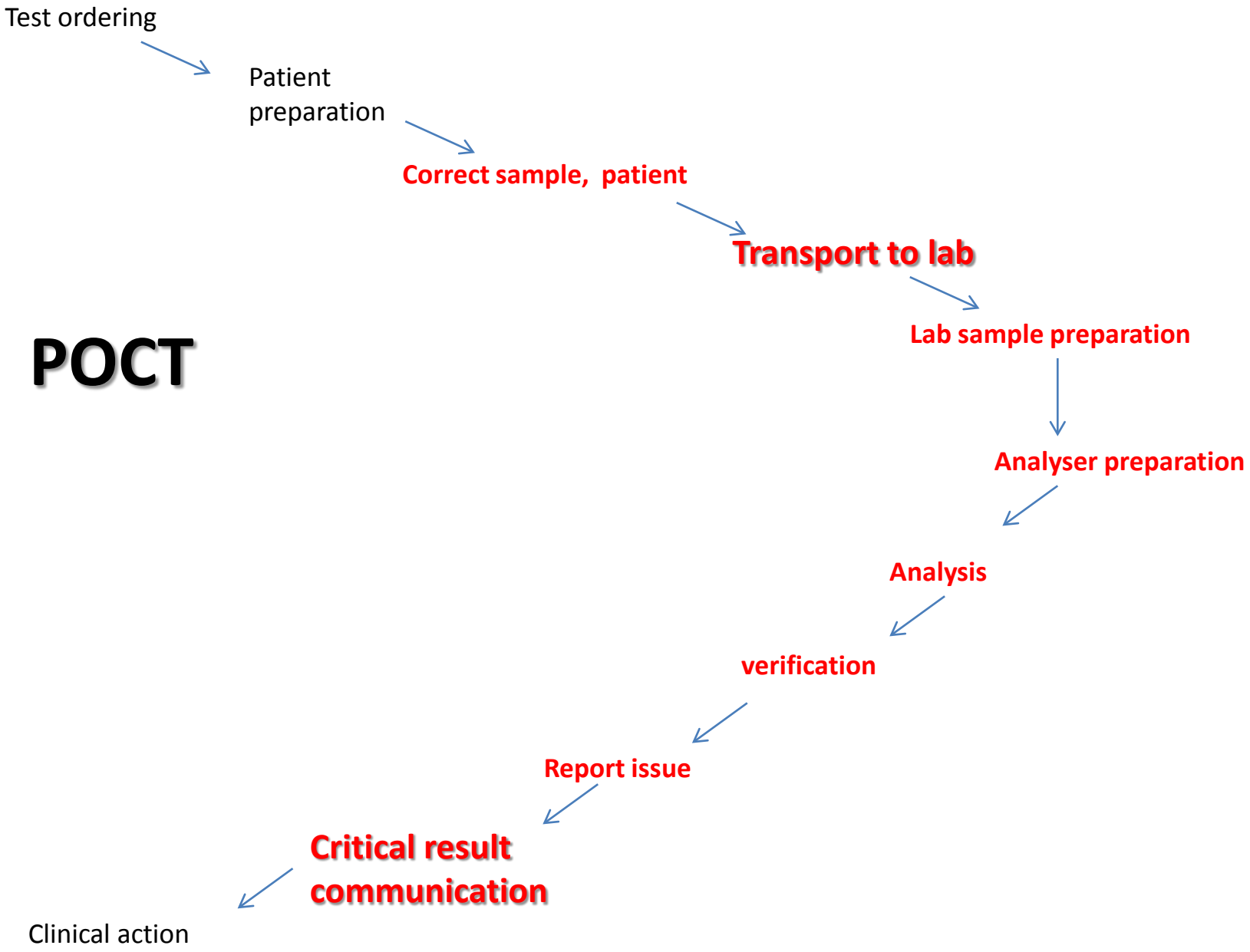
Institute of Medicine 1999

Medical error – 98 000 deaths per year in US

- Laboratory tests?
- POCT??

Central Lab Testing




Test ordering
Patient preparation
Correct sample, patient
Transport to lab
Lab sample preparation
Analyser preparation
Analysis
verification
Report issue
Critical result communication
Clinical action

POCT

Errors - sources and amplifiers

Meier FA, Jones BA. Arch Pathol Lab Med 2005;129:1262

Latent conditions:

- Operator competence
- Non adherence to procedures
- Uncontrolled instruments

Amplifiers:

- Rapid result availability
- Immediate therapeutic implication
- Incoherent regulation

Governance failure

CMS survey [2001]:

- 19% operators untrained
- 32% no SOP available
- 25% did not follow SOP

Frequency of POCT error

- Little information available – difficult to investigate
- Central lab error rate 0.085 - 0.6%
- POCT error rate: 0 – 0.65%

Error rates in POCT

Clinical Chemistry 57:9
1267–1271 (2011)

Point-of-Care Testing

Quality Error Rates in Point-of-Care Testing

Maurice J. O'Kane,* Paul McManus, Noel McGowan, and P.L. Mark Lynch

- ~ 400 000 POC tests [glucose, BG/electrolytes, pregnancy , ketones, DoA, urinalysis]
- 2 acute / 1 non acute hospital sites
- Accredited service

Table 1. Breakdown of POCT quality errors by test type.

Test type	Number of tests	Number of defects	Defect, % of total tests
Blood gas/electrolytes[a]	22 687	119	0.52
Blood gas/electrolytes/ troponin I[b]	5809	10	0.17
Pregnancy[c]	8879	14	0.158
Glucose[d]	303 389	71	0.02
Drugs of abuse[e]	247	1	0.4
Hb A_{1c}[f]	1236	8	0.65
Urinalysis[g]	64 370	2	0.003
Blood ketones[h]	1087	0	0

Sources of Error

	POCT [1]	Central Lab [2]
Pre-analytical	32 %	87.6%
Analytical	65.3%	11.1%
Post - analytical	2.7%	1.3%

[1] Clin Chem 2011; 57:1267-71

[2] Ann Clin Biochem 2008;45:129-134

Impact of POCT errors

Severity	Actual Impact [1] %	Potential Impact [1] %	Stat testing [2] Actual impact %
1 [least]	51.2	2.7	74
2	48.4	77.8	
3	0	1.3	19.6
4	0	14.7	6.4
5 [worst]	0	3.6	

[1] Clin Chem 2011; 57:1267-71
[2] Clin Chem 1997;43: 1345-51

How to minimise POCT defects?

- Instrument design / engineering
- Assay design
- Ensure assay performance is appropriate to purpose
- Operator training
- Better governance
- Regulation

POCT – The quality of the care pathway

POCT and care pathways – a paradigm shift

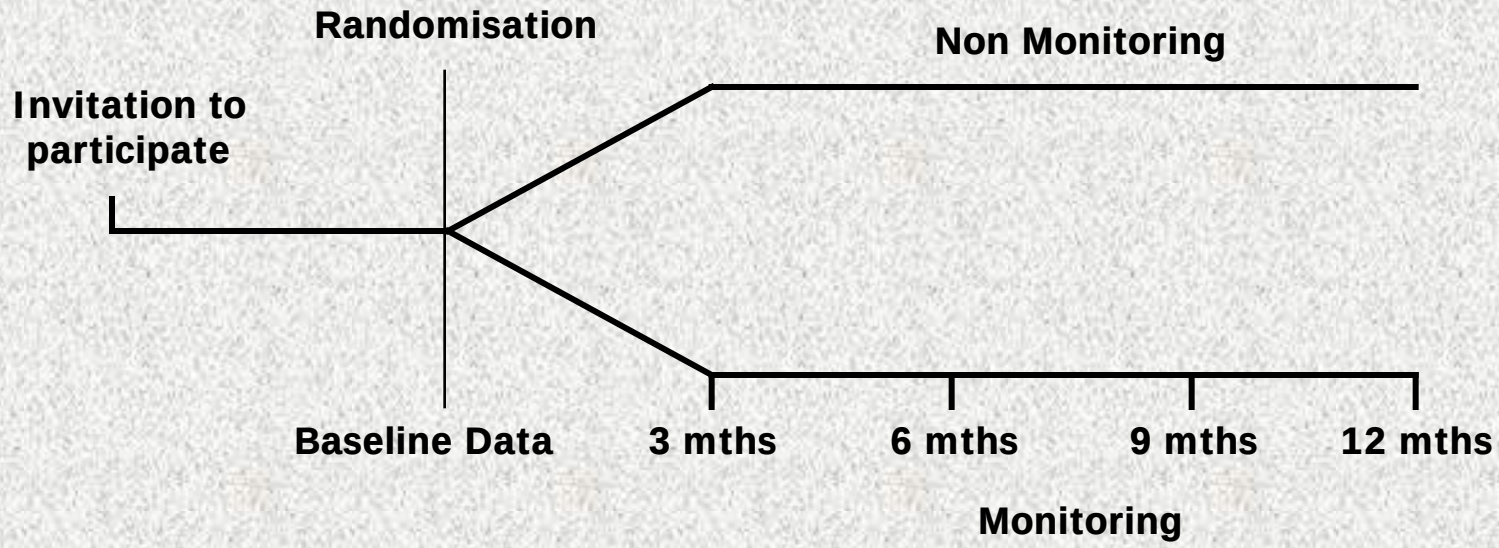
- Need to demonstrate clinical benefit – ultimate quality measure

- May need to restructure care pathway to achieve benefit – ‘disruptive technology’

Self monitoring of blood glucose in Type 2 DM

- Supported by ADA guidelines since 1987
- Clear evidence of benefit lacking
- It depends what you do with the results!

ESMON Study Design



ESMON
EFFICACY OF SELF MONITORING

Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial

Maurice J O'Kane, consultant,[1] Brendan Bunting, professor,[2] Margaret Copeland, trial manager,[3] Vivien E Coates, professor,[3] on behalf of the ESMON study group

doi:10.1136/bmj.39534.571644.BE

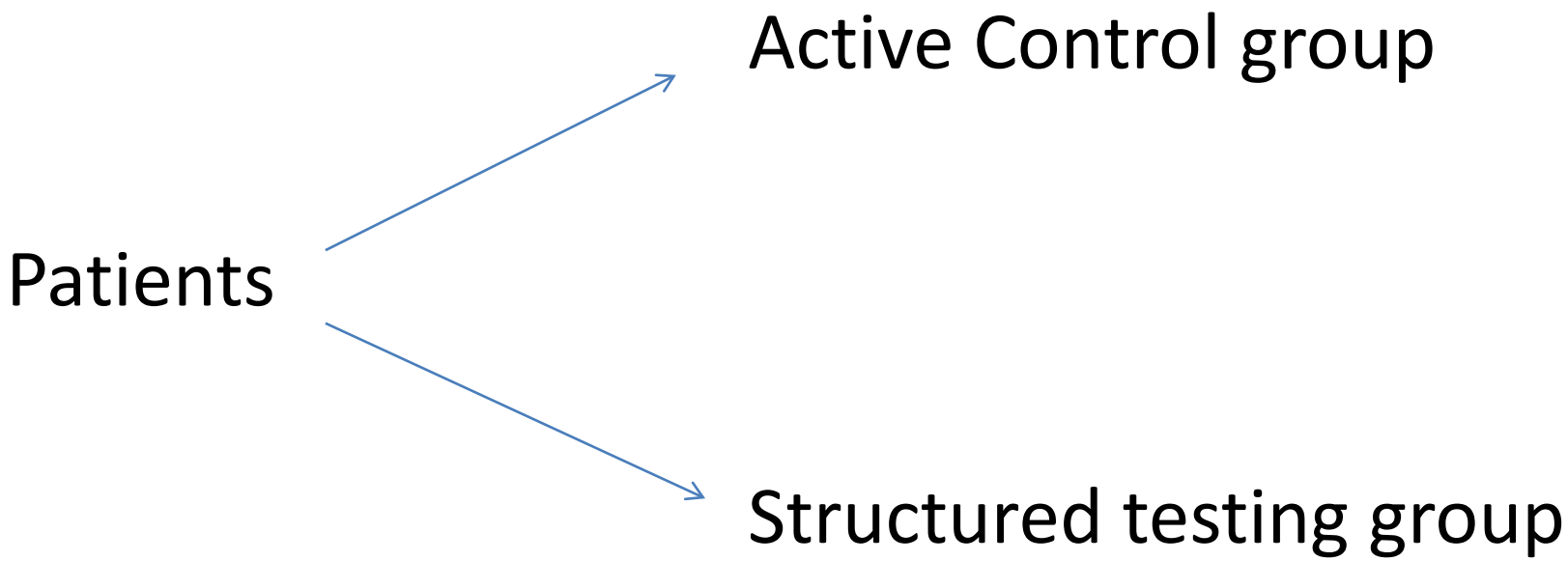
New Type 2 DM patients randomised to SMBG or non SMBG groups

HbA1c

Time (months)	Monitoring	Control	P value	Mean difference (95% CI)
0	8.8 (2.1)	8.6 (2.3)	0.68	−0.33 (−0.77 to 0.51)
3	7.2 (1.1)	7.1 (1.2)	0.50	0.18 (−0.47 to 0.23)
6	7.0 (0.9)	7.0 (1.1)	0.82	0.04 (−0.27 to 0.35)
9	6.9 (0.8)	7.1 (1.4)	0.30	0.19 (−0.16 to 0.54)
12	6.9 (0.8)	6.9 (1.2)	0.69	0.07 (−0.25 to 0.38)

Structured Testing programme study

Polonsky *et al.* Diab Care 2011;34:262-67



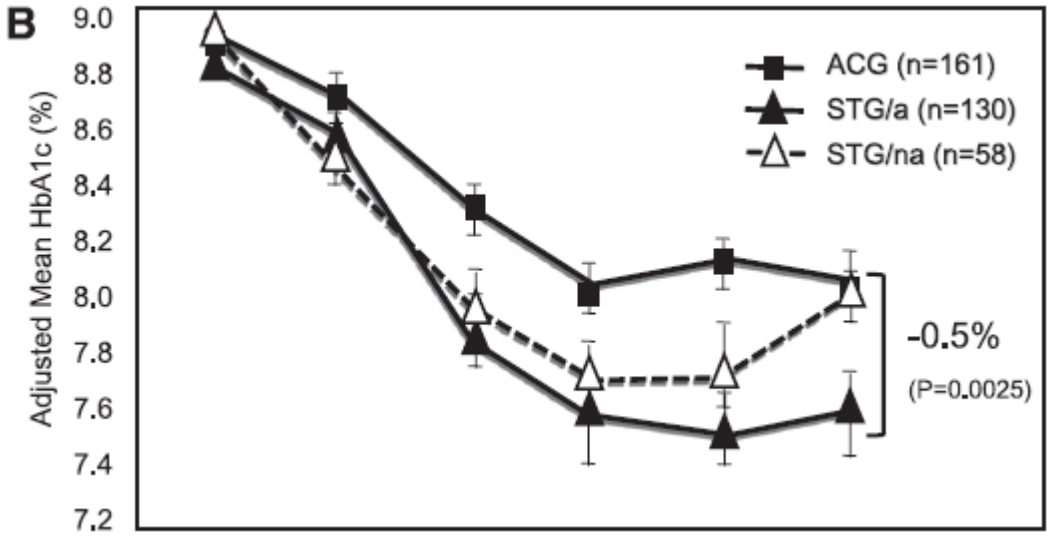
ORIGINAL ARTICLE

Structured Self-Monitoring of Blood Glucose Significantly Reduces A1C Levels in Poorly Controlled, Noninsulin-Treated Type 2 Diabetes

Results from the Structured Testing Program study

Diabetes Care 34:262–267, 2011

WILLIAM H. POLONSKY, PHD[1,2]



Anticoagulant monitoring

- 5%-10% of over 65y on anticoagulant
- Narrow therapeutic range
- Potential for patient self testing and dosing

How does this compare with usual care?

REVIEW | Annals of Internal Medicine

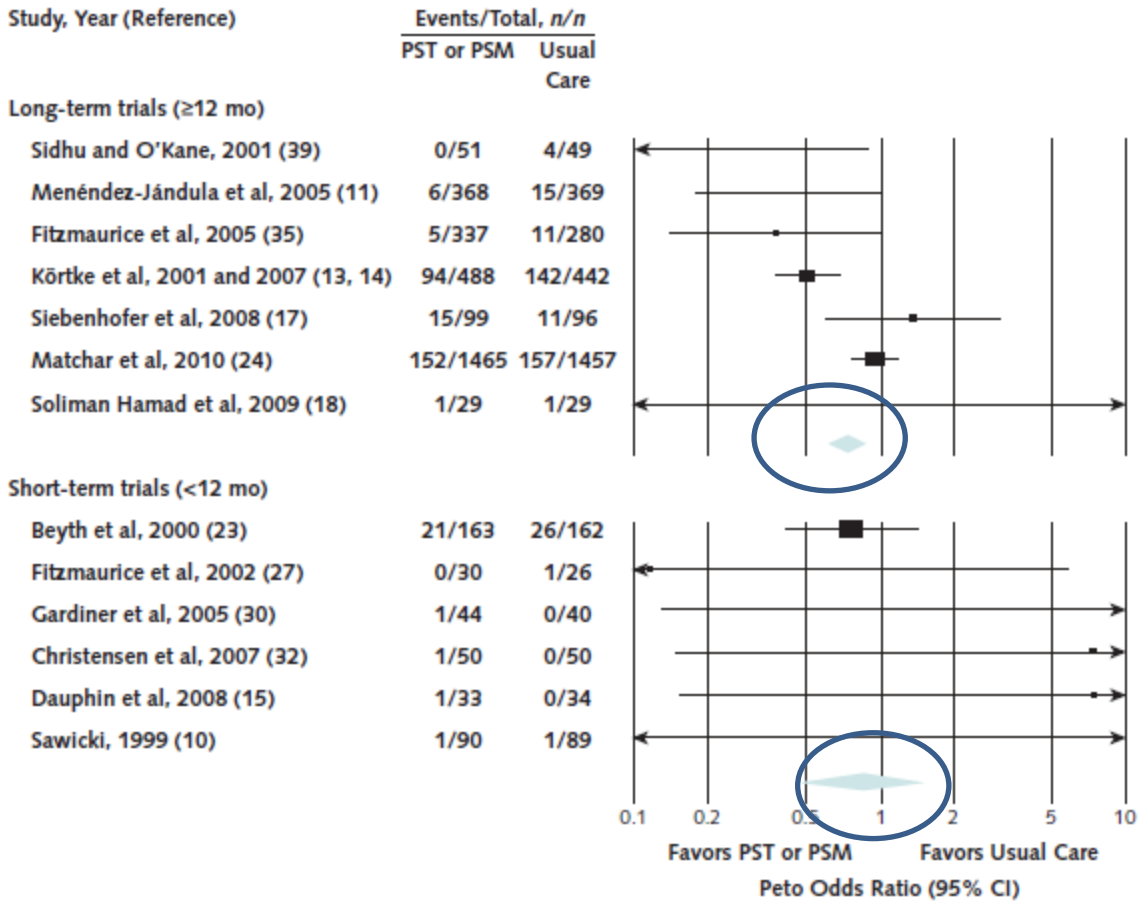
Meta-analysis: Effect of Patient Self-testing and Self-management of Long-Term Anticoagulation on Major Clinical Outcomes

Hanna E. Bloomfield, MD, MPH; Ange Krause, MD; Nancy Greer, PhD; Brent C. Taylor, PhD, MPH; Roderick MacDonald, MS; Indulis Rutks, BS; Preetham Reddy, MD; and Timothy J. Wilt, MD, MPH

Ann Intern Med. 2011;154:472-482.

22 trials, 8413 patients of patient self testing [PST] alone or in conjunction with self–dose adjustment.

Figure 4. **All-cause mortality in PST or PSM versus usual care studies.**



- ‘Compared with usual care, PST with or without PSM is associated with significantly fewer deaths and thromboembolic events ….. without increased risk for a serious bleeding event, for a highly selected group of motivated adult patients …’

Conclusions

- Defect rate may be higher than central lab testing
- Operator factors important
- Robust governance and regulation essential
- Clinical impact of POCT must be established