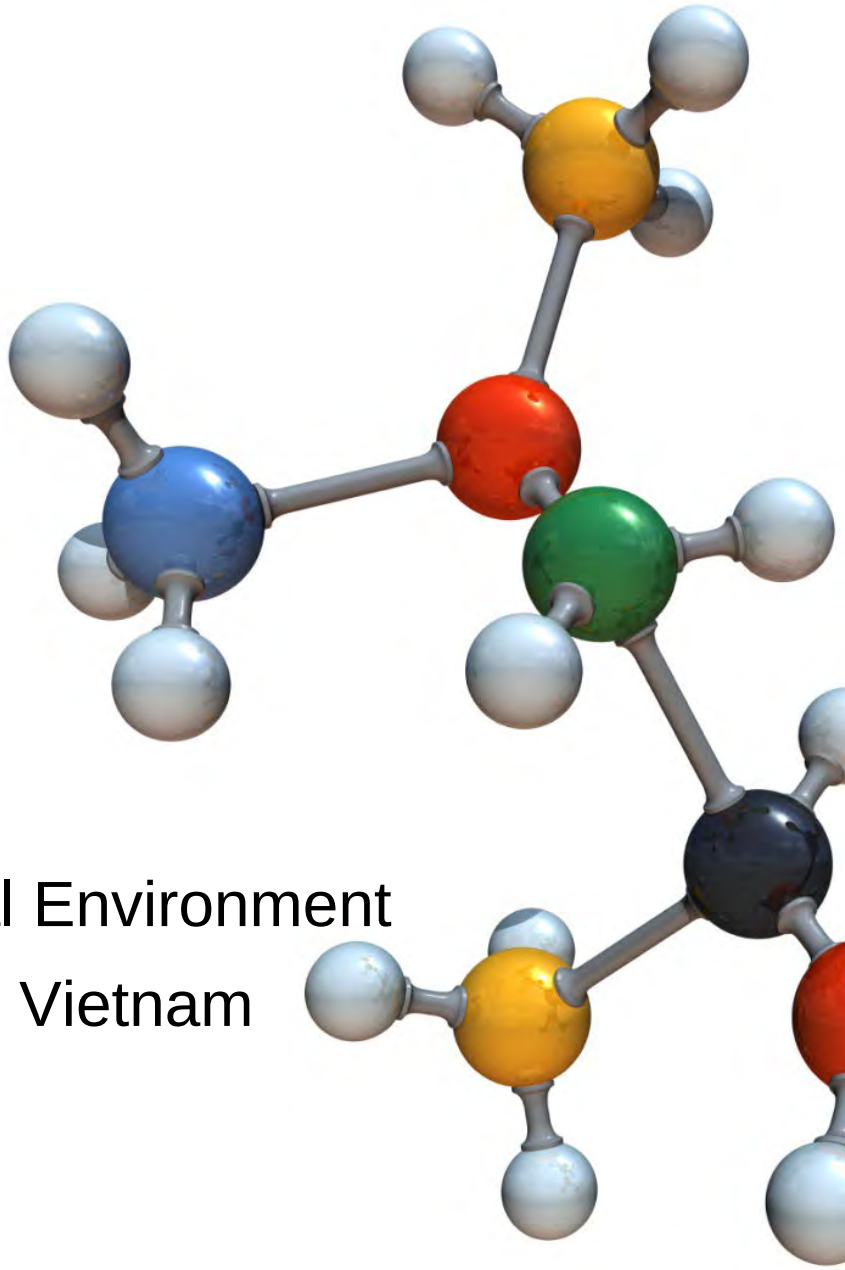
Point of Care Testing

Overview

- Definition
- Relevance
- Innovation
- POCT Questions
  - Quality
  - Cost
  - Outcome
- Implementing POCT in a Hospital Environment
- Some POCT devices available in Vietnam
- Future
- Summary



International Standard – ISO 22870

- International standard ISO 22870, *Point-of-care testing (POCT) - Requirements for quality and competence*, provides what may be considered as the current internationally accepted definition

- ISO 22870 is its own Standard; this interprets POCT in light of ISO 15189, the International Standard for Medical Laboratories

- http://www.iso.org

ISO 22870 Definition

Point of Care Testing:

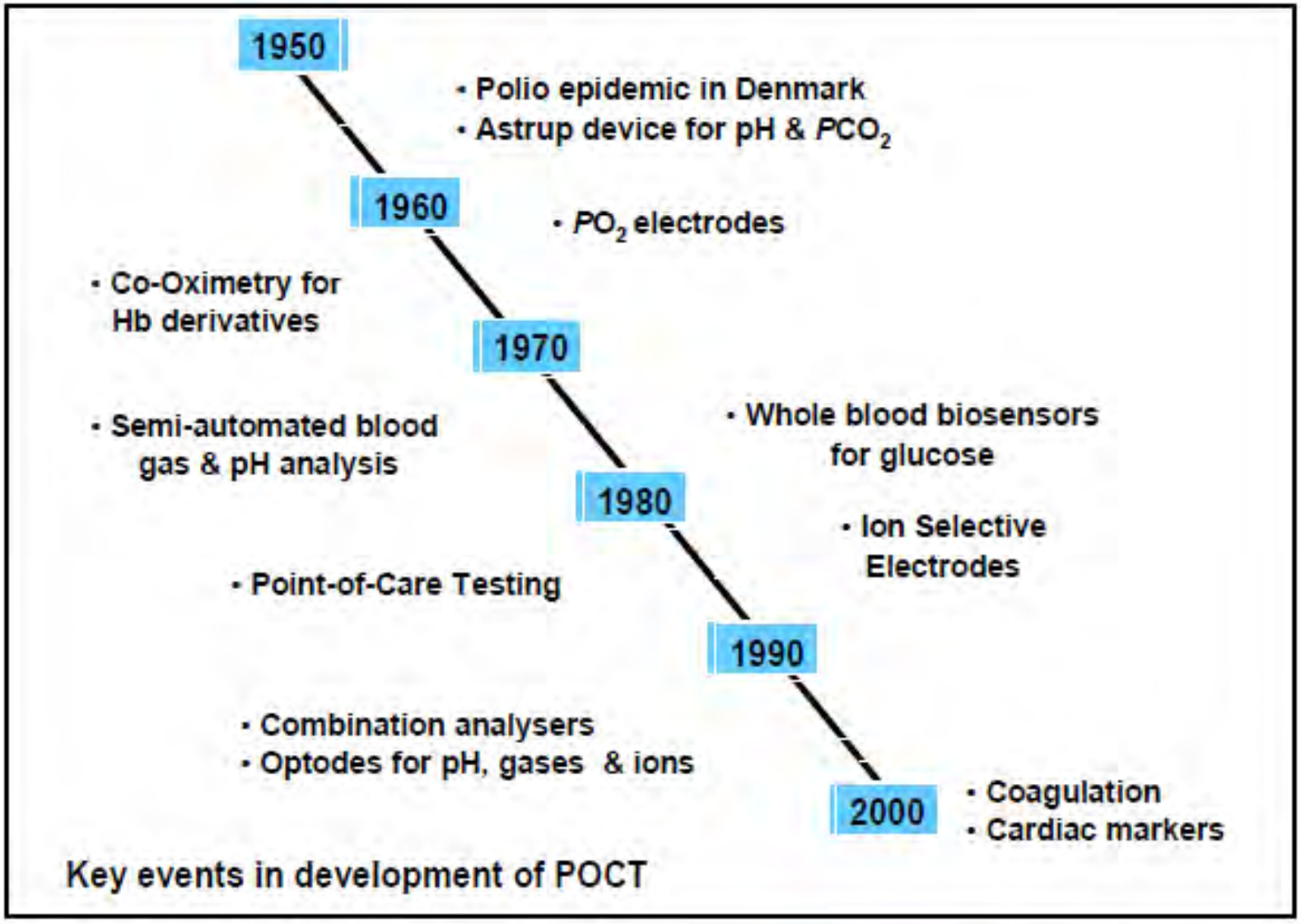
"testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient"

Abbreviation

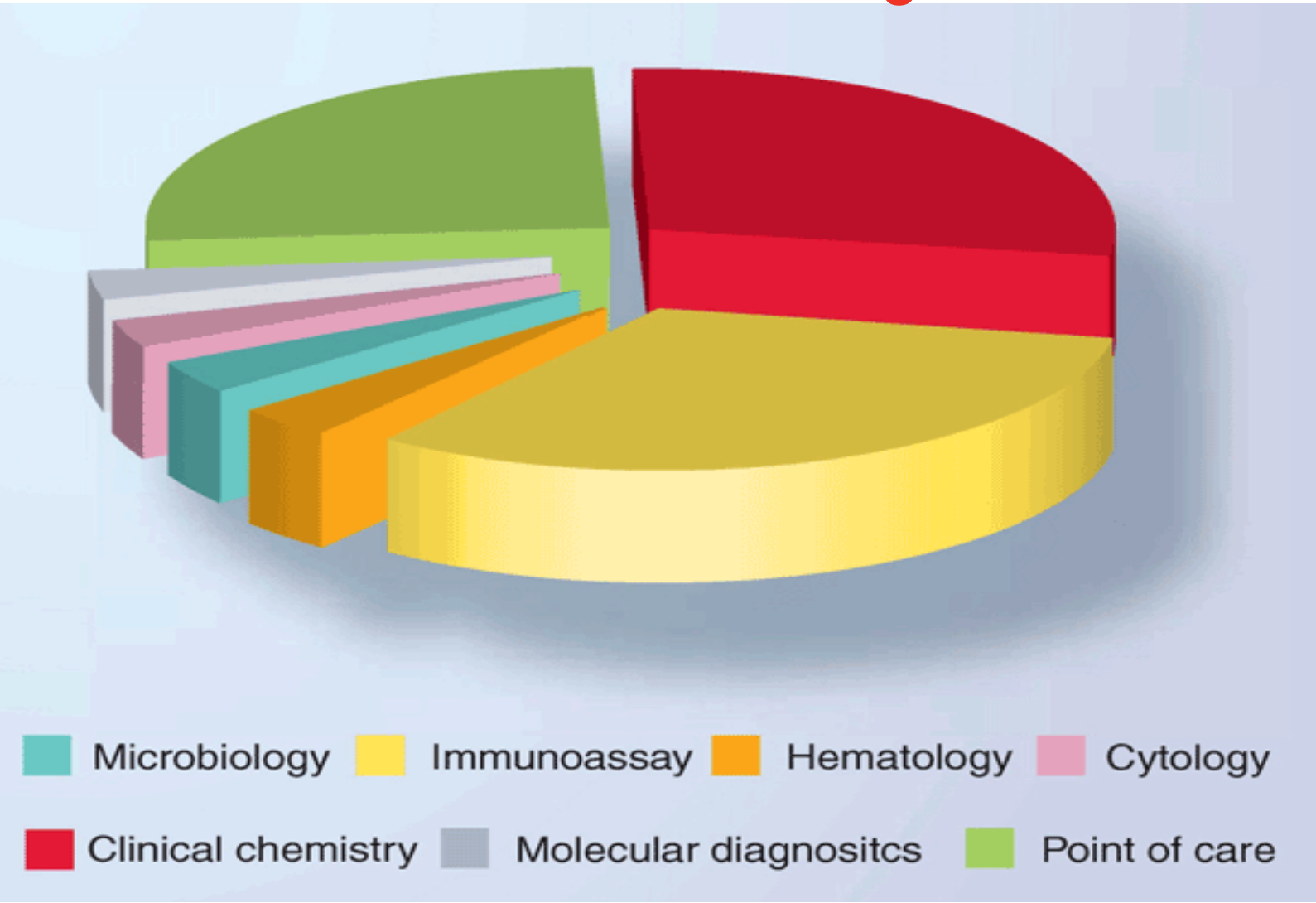
- The Australasian Association of Clinical Biochemists (AACB) point of care testing committee has developed the abbreviation **PoCT** instead of **POCT**

- **POCT** is used throughout this presentation as it is the abbreviation used in ISO 22870

Some History



Global IVD market segments



http://www.medscape.com/viewarticle/584399_5. The diagram represents the global IVD market of US$45 billion in 2007, including POCT at $11.5 billion.

What is Innovation?

Innovation is an invention that is successfully applied in practice

What drives innovation in health?

- Improvements in:
  - Patient outcomes
  - Quality of care
  - Process of care
- Development of:
  - New biomarkers
  - New treatments
- Reduction in:
  - Resource management
  - Damage to the environment

Innovation in Laboratory Medicine

….the rise of automation

Is it sustaining or disruptive?

Automation = centralized laboratory service?

Slide from 2010 AACC presentation by Christopher Price and Andrew St John, “Disruptive Innovation: Opportunities and Implications for Laboratory Medicine”

Advantages of Automation

- ECONOMIC
  - Cost of automation vs. cost of labour
  - Allows redeployment of staff to worthwhile tasks
- STRATEGIC
  - Improvement in TAT
  - Allows for future expansion without extra costs
- QUALITY
  - Reduction of error (human)
  - Objective monitoring of error
- SAFETY
  - Less exposure of laboratory staff to sample

Disadvantages of Automation

- ECONOMIC
  - Capital Outlay
  - Potential increase in consumable costs
- STRATEGIC
  - Dependency on automation without expensive backup
  - Increased dependency on LIS as driver of laboratory
- QUALITY
  - Decreased human surveillance
  - Potential for massive errors

Automation vs POCT

FORCES to AUTOMATE

- Decreased Reimbursement
- Increased consumable costs
- Labour cost is highest
  - Therefore reduce labour cost
- Decreased availability of Staff
- Create Economy of Scale
- Centralisation of Laboratories
  - Increased volume of testing
  - Need automation to cope
- Litigation
  - Improve Quality, remove 'Human Error'
    - Most errors at the front end
- Increase Lab Safety
  - AIDS, Hep C

POCT

Most debated issue currently in laboratory medicine

Essential technology

or

Expensive toy ?

Types of Innovation

- Advances in laboratory automation are **sustaining** innovations
  - Innovations that only lead to marginal improvements

- POCT is a **disruptive** innovation
  - "more radical change that achieves substantially greater benefits, primarily by reaching the needs of an unmet market"

Point-of-care testing: Needs, Opportunity, and Innovation 3rd Ed 2010
Edited by Price, St John & Kricka. AACC press

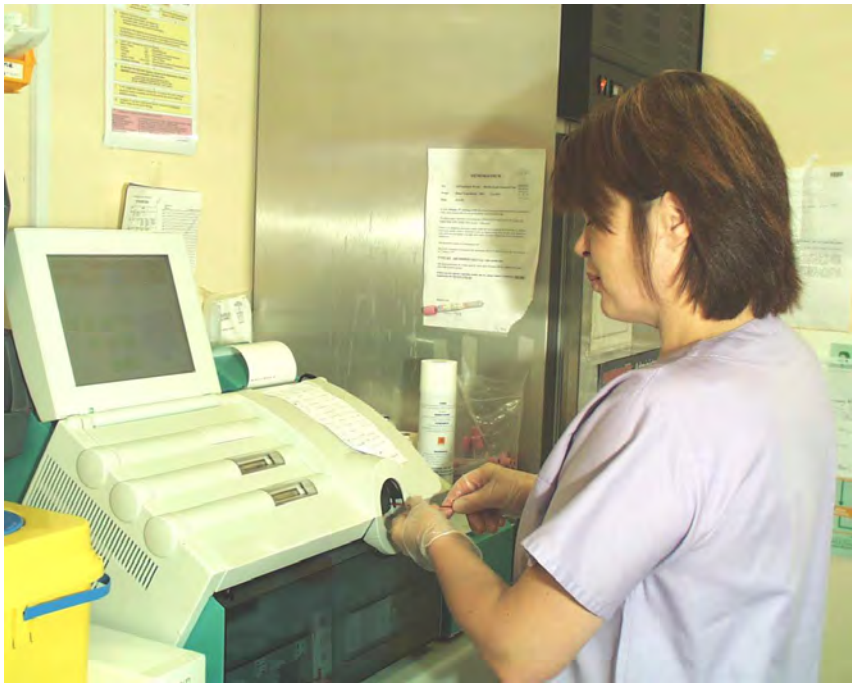
Examples of Disruptive Innovation

Communication plus

Slide from 2010 AACC presentation by Christopher Price and Andrew St John, “Disruptive Innovation: Opportunities and Implications for Laboratory Medicine”

Why is POCT a disruptive innovation?

- POCT Changes:
  - How we provide pathology tests
  - When we can do testing
  - Where testing is performed
  - Who performs testing
- POCT does not change:
  - Why we test



POCT at NHP

POCT

- **Hospital Testing**
  - critical care facility in major hospital (ED, ICU, CCU, etc)
  - hospital ward or hospital clinic
  - rural (remote) hospital or health clinic
- **Decentralised testing**
  - GP offices – e.g. cholesterol and glucose
  - Work Places – e.g. drug testing
  - Remote locations – e.g. diabetes management, infectious diseases
  - Road Side testing – e.g. police drug and alcohol testing
- **Home Testing**
  - home use, self testing
  - pharmacy

A useful website is:

www.acutecaretesting.org

POCT devices

- POCT is a term that encompasses a variety of testing situations that are distinct within themselves but all have the one common feature – testing is done outside of the central laboratory

- Non-instrumental disposable systems
  - e.g. drug screens, urine dip sticks, pregnancy tests
- Hand held devices
  - e.g. blood glucose meters
- Bench top analysers
  - e.g. blood gas analysers

Characteristics of an ideal POCT device

1. Physical
   - Small
   - Light in weight
   - Transportable
2. QC
   - Lockout
   - Allows 3rd part QC
   - External QA available
3. Standardisation
   - Traceable
   - Comparable to central lab
4. ID
   - Operator lockout
   - Patient lockout
5. Samples
   - Small
   - Capillary if blood sample
6. Operation
   - Simple
   - Robust
   - Minimal Maintenance
   - Long reagent lot life
   - Company support

Clinical Aspects of POCT

Question: Is the quality of POCT comparable to testing carried out in the central laboratory?

Answer: POCT technologies can provide comparable answers provided:

- Users are trained
- QC procedures are followed
- Results are integrated into the patient record

External quality assurance programs

- The Royal College of Pathologists of Australasia (RCPA) provides Quality Assurance Programs (QAP) both for laboratories and also POCT
- Some examples of POCT programs are :
  - Blood Gas and co-oximetry
  - Near patient Testing (general chemistry tests)
  - On-site urine toxicology screening
  - PoCT (cardiac and diabetes markers)
  - Urine Pregnancy
  - INR
- The regulatory requirement mandating participation in a relevant EQA varies based on where POCT is conducted and whether it falls under NPAAC requirements.

Clinical Aspects of POCT

Question: What is the true cost of POCT?

Answer:

- Early studies gave misleading answers
- More recent studies are better designed but still equivocal
- Need to prevent POCT duplicating centralised testing

Cost Assessment worksheet:
Adapted from CLSI* - Table D1

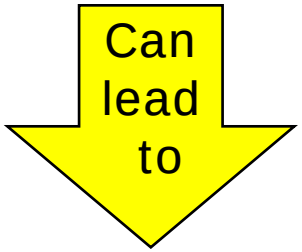
Calculation Steps	Cost Per Test	Instructions
Direct Costs		
1. Consumables (reagent supplies) cost		Enter results from formula 1, Table D2
2. Labour Costs		Enter results from formula 2, Table D2
3 Subtotal Direct costs		Add lines 1 and 2
Indirect Costs		
4 Depreciation costs		Enter results from formula 3, Table D2
5. Maintenance costs		Enter results from formula 4, Table D2
6. Site preparation costs		Enter results from formula 5, Table D2
7. Sub total indiect costs		Add lines 4, 5 and 6
Total Indirect and Direct costs		
8. Subtotal Direct and Indirect Costs		Add lines 3 and 7
9. Multiply by sites % indirect costs (typically ranges from 60% to 148%)		Multiply line 8 by result from formula 6, Table D2 (example line 8 subtotal multiplied by 60%)
10. Total cost per test		**Add lines 8 and 9**

*CLSI Selection Criteria for Point of Care Testing Devices, Approved Guidelines

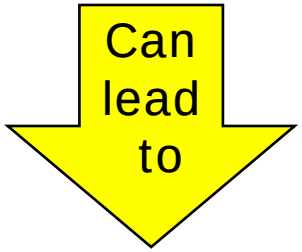
Clinical Aspects of POCT

Question: Does POCT lead to better patient outcomes?

Reduced Turnaround Time



Quicker Treatment



Improved Patient Outcome

POCT Australian GP trial

DESIGN:

- Randomised control trial
- 5234 patients participated
- In 58 general practices
- Mixture of urban, rural and remote locations in NSW, Victoria and SA
- Analytes = HbA1c, INR, cholesterol, triglycerides, HDL, LDL, urine albumin/creatinine
- Trial funded by the Australian Government

RESULTS:

- Analytical Performance
  - ü results not inferior for most analytes except HDL
- Clinical Effectiveness
  - ü improvements with more patients in target range for HbA1c, urine albumin creatinine ratio, and lipids = better compliance
  - ü More GP visits, more process of care, little impact on prescribing patterns
  - ü Same or better adherence to medication

Implementation of POCT in a Hospital Environment

STEP 1

Form POCT committee

- Entrance through single door POCT Committee
  - Laboratory specialists
  - Clinicians
  - Nurses
  - Hospital management

STEP 2

All POCT Requests

- Committee Determines need for a new test
- Conducts clinical needs assessment

STEP 3

Specification Considerations

- Compare POC Testing Systems
- Operator Evaluation

STEP 4

Cost Assessment

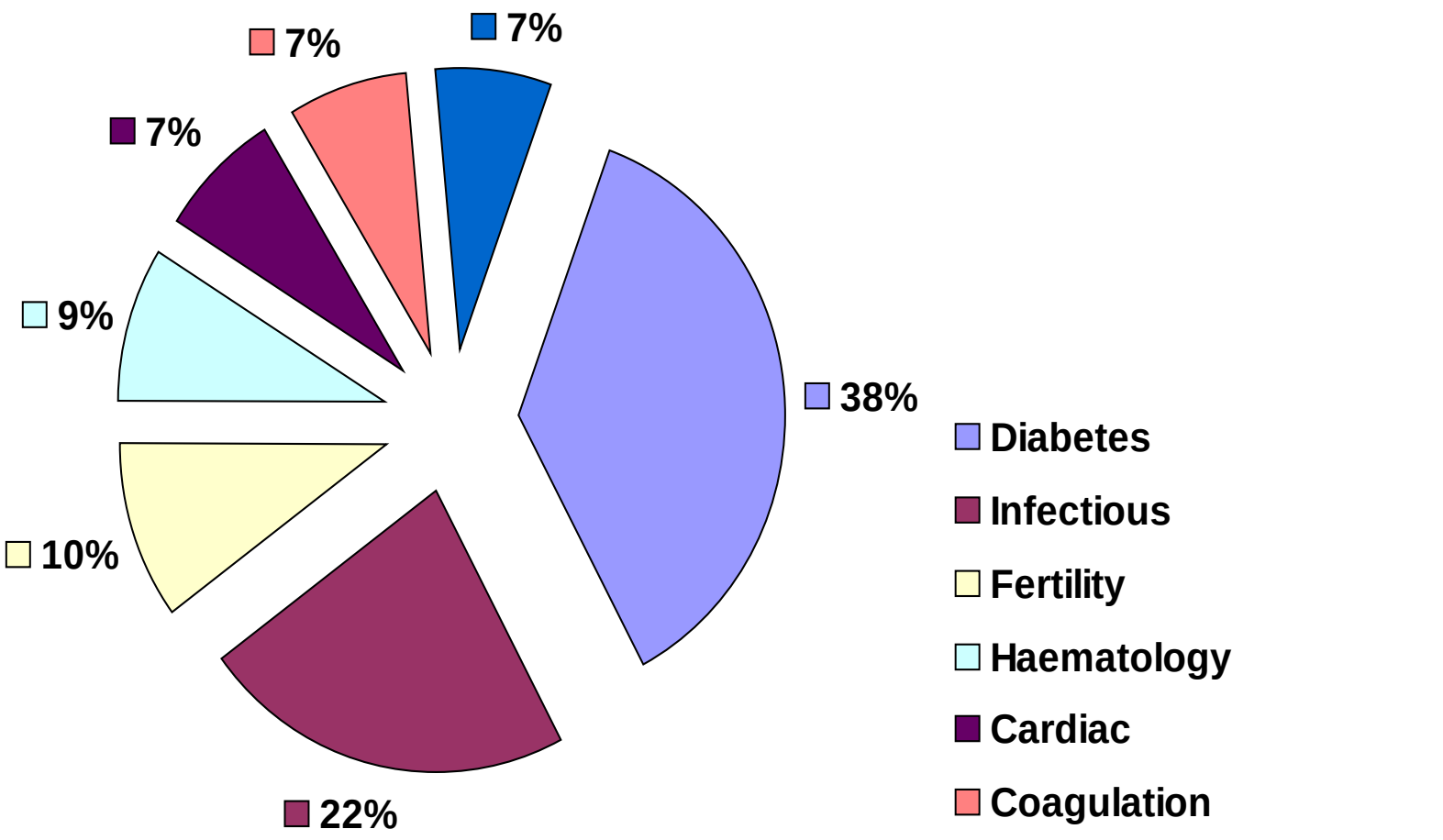
- Conduct Financial Feasibility
  - Cost of instruments and tests
  - Cost of laboratory support, training & maintenance
- Complete Cost Assessment worksheet

STEP 5

Review

- Develop Risk assessment
- Final Decision

European POCT market segments, 2009



Redrawn from: http://www.european-hospital.com/en/article/7895-POCT_brings_values.html

Blood Gases

- All blood gas analysers measure:
  - pH
  - pCO_2
  - pO_2
  - HCO_3-
- Other analytes :
  - Sodium
  - Potassium
  - Ionised calcium
  - Glucose
  - Lactate
  - Cooximetry
  - Haemoglobin

The original blood gas analyser developed in Denmark in association with Radiometer Radiometer is still the main bench top blood gas analyser in use in Australia to date

Abbott Istat analyser
Example of a hand held analyser

Diabetes

- The majority of glucose monitoring is conducted outside of the central laboratory
- Regular home glucose monitoring is essential for patients to proactively adjust their insulin levels and therefore achieve good glucose control
- The diabetes control and complications trial (DCCT) clearly established the link between achieving good control of glucose (as estimated by the measurement of HbA_1c) and the delay in onset of complications
- HbA_1c levels are often measured as POCT in tertiary diabetes clinics as well as remote communities including Aboriginal communities in Australia

Home glucose monitoring device

BioRad D10 HbA1c analyser – an example of a portable (with trolley) bench top analyser for the measurement of HbA1c

Coagulation

- It is important to monitor haemostasis for blood management to:
  - Identify and define imbalance
  - Monitor therapy
  - Avoid overcorrection
- Warfarin is a common oral anticoagulant which acts on the extrinsic coagulation pathway
- To determine the effect warfarin has on coagulation prothrombin time (PT) is assessed.
- To ensure uniformity between assays PT is recalculated and reported as INR

•Roche CoaguChek XS INR analyser
•Hand held analyser with test strips
•Used for near patient testing and self monitoring

POCT: Pre and Post analytical

PRE

- All the pre-analytical factors still apply for POCT including:
  - Positive patient ID
  - Correct collection tube
  - Correct time of collection
- Because of proximity to the patient, often time / temperature or delayed analysis problems mitigated

POST

- Variable accuracy with manual data entry
- Possible errors include:
  - Transcription errors
  - Test result errors
  - Missed testing ID
  - Incorrect units
  - Incorrect time
- Mitigation of Potential Errors:
  - Random frequent audits of worksheets
  - Well designed and easy to use worksheets
  - Automatic data capture

Summary

Requirements for POCT Technology

- Comparable results to central laboratory
- Low-maintenance
- User-friendly
- Compact/Portable
- Integration of patient results into the patient record
- On going operator training

Opinion: Laboratories should play a role in supporting such testing and work with physicians to provide a total testing service.

QUESTIONS

Email: ronda.greaves@rmit.edu.au