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Clinical Effectiveness of POCT

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Learning Objectives

"Upon completion of this activity, you will be able to;

1. Define Clinical Effectiveness …..

2. Provide examples of how to measure clinical effectiveness …

3. Discuss the challenges of obtaining outcome data….

Pre – Assessment:
Multiple choice question #1

What statement best describes Clinical Effectiveness?

- Option#1 - How beneficial a test or treatment is under usual or everyday conditions, compared with doing nothing or opting for another type of care.

- Option#2 - A process for monitoring standards of clinical care to see if it is being carried out in the best way possible.

- Option#3 - An assessment or determination of the most efficient and least expensive approaches to providing health care and preventive medicine services.

Definitions:

Clinical effectiveness is defined (Department of Health, 1996) as "the application of the best knowledge, derived from research, **clinical** experience and patient preferences to achieve **optimum processes and outcomes** of care for patients. The process involves a framework of informing, changing and monitoring practice."

Effectiveness (NICE)
How beneficial a test or treatment is under usual or everyday conditions, compared with doing nothing or opting for another type of care.

Outcomes are the results people care about most when seeking treatment, including functional improvement and the ability to live normal, productive lives.

Value Based Healthcare is defined as the outcomes that patients experience relative to the cost of delivering those outcomes.

value = outcome (benefit)/cost

Clinical effectiveness

Clinical effectiveness has three distinct parts:

- Obtaining evidence – from research, either published in journals or available on databases; from national level studies based on research, for example, clinical guidelines, systematic reviews or national standards.

- Implementing the evidence – by changing practice to include the research evidence and, where possible, locally adapting national standards or guidelines.

- Evaluating the impact of the changed practice and readjusting practice as necessary, usually through clinical audit and patient feedback.
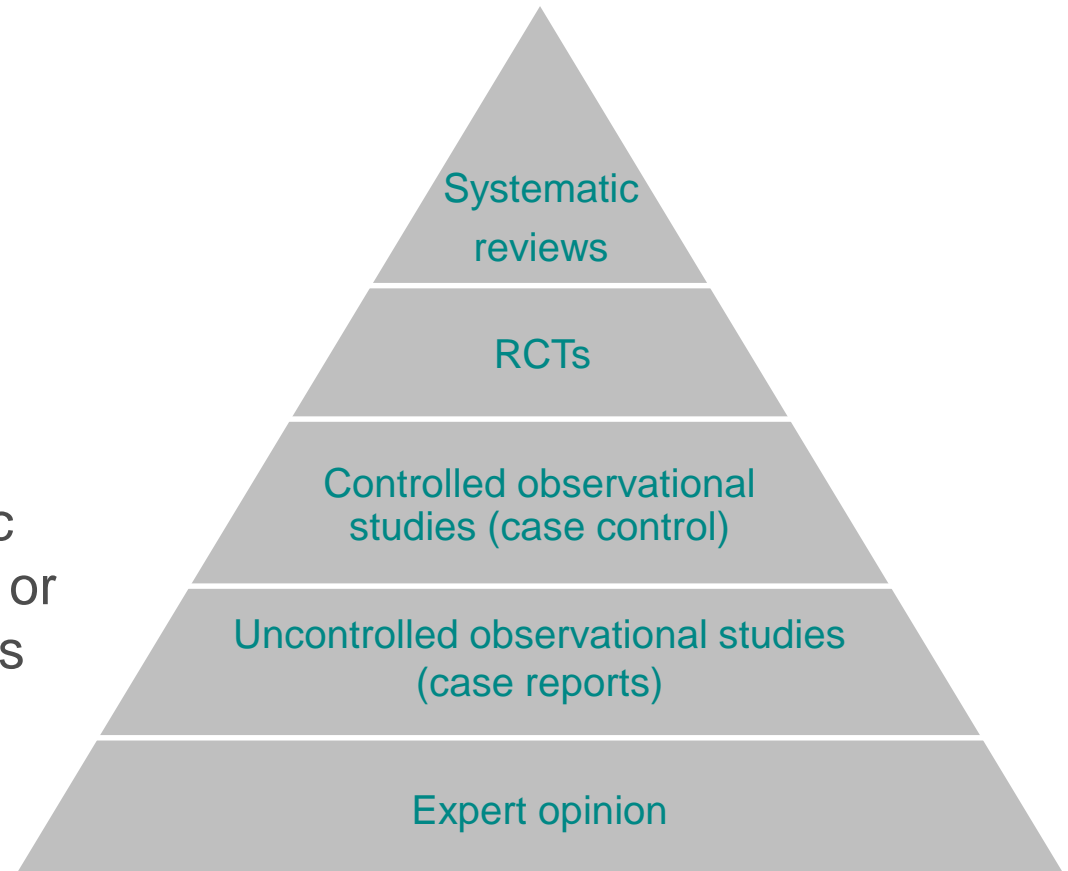
Assessment of Clinical effectiveness

from NICE

Evidence from studies:

- End to end studies if available

- Evidence on diagnostic accuracy from existing or new systematic reviews

Expert elicitation

Systematic reviews

RCTs

Controlled observational studies (case control)

Uncontrolled observational studies (case reports)

Expert opinion

Pre – Assessment:
Multiple choice question #2

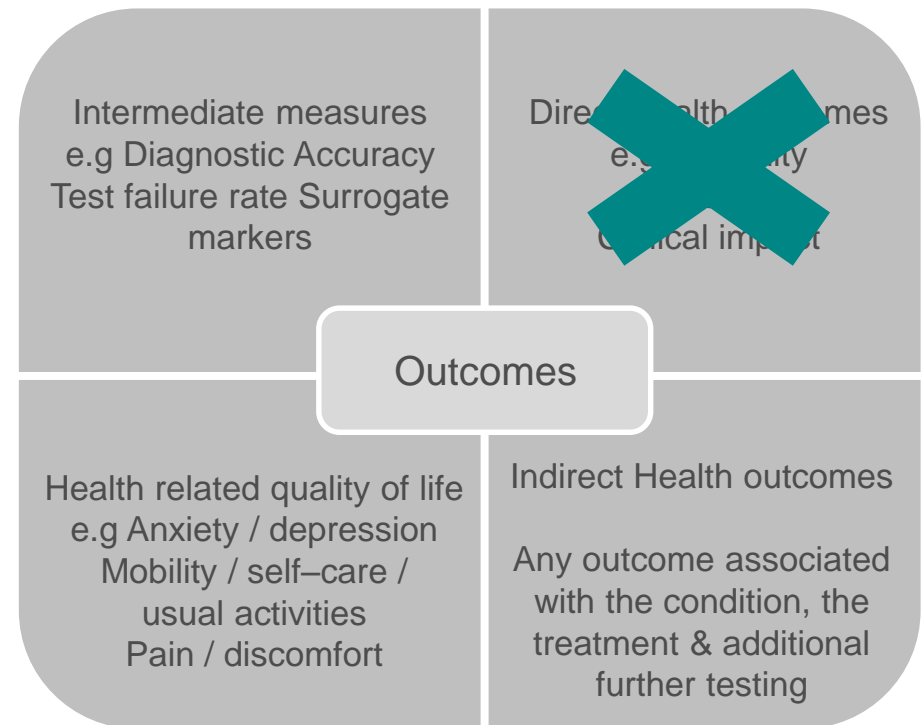Which of these statements best describes Diagnostic Accuracy of the intervention?

- Option#1 – How close a result comes to the true value.

- Option#2 – Relates to the ability of a test to discriminate between the target condition and health.

- Option#3 – Accuracy embraces both trueness and precision and be considered as describing the total error.

Evaluating the impact - Monitoring Outcomes

How has the introduction of POCT influenced the patient pathway?

What is the impact on health outcome?

How do we measure outcome?

Intermediate measures e.g Diagnostic Accuracy Test failure rate Surrogate markers	Direct health outcomes e.g mortality Clinical impact
Health related quality of life e.g Anxiety / depression Mobility / self–care / usual activities Pain / discomfort	Indirect Health outcomes Any outcome associated with the condition, the treatment & additional further testing

Outcomes

NICE

Pre – Assessment:
Multiple choice question #3

Which of these statements best describes how we should evaluate impact?

- Option#1 – Diagnostic Accuracy.

- Option#2 – Patient experience/ anxiety/ convenience.

- Option#3 – Both of these.

Intermediate measures - Diagnostic Accuracy

Diagnostic accuracy of any diagnostic procedure or a test gives us an answer to the following question:

"How well this test discriminates between certain two conditions of interest (health and disease; two stages of a disease etc)?"
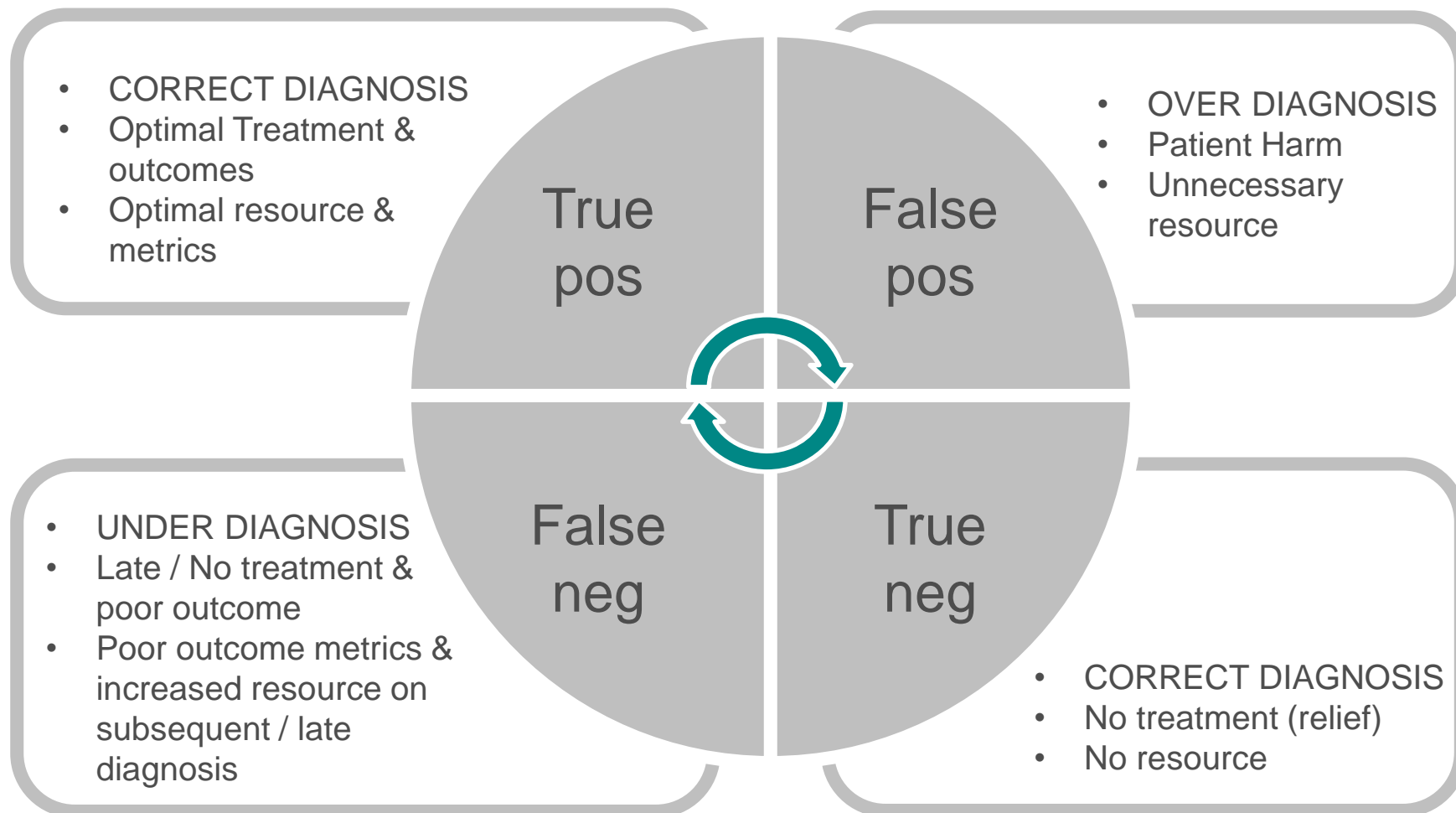
Measures of diagnostic accuracy:

♦ sensitivity and specificity

♦ positive and negative predicative values (PPV, NPV)

♦ likelihood ratio

♦ the area under the ROC curve (AUC)

♦ Youden's index

♦ diagnostic odds ratio (DOR)

Comparison to laboratory test

	POCT Test +	POCT Test -
Lab test +	%True pos	%False neg
Lab test -	%False pos	%True neg

Assumption is that lab test is 100% accurate – frequently not the case
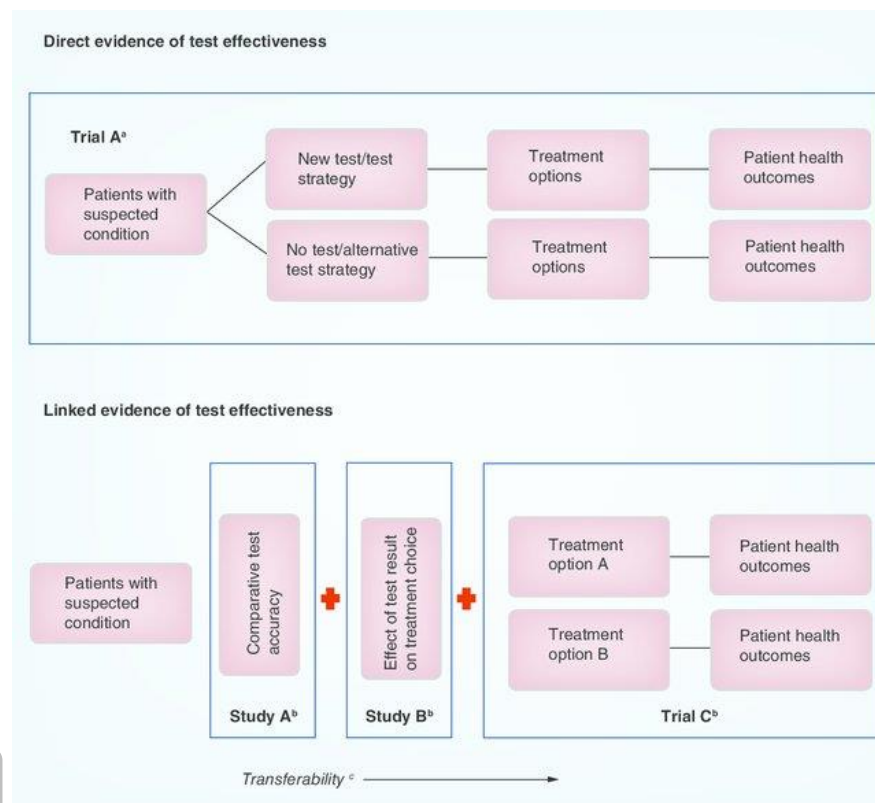
EJIFCC. 2009 Jan; 19(4): 203–211

Indirect Health outcome

- CORRECT DIAGNOSIS
- Optimal Treatment & outcomes
- Optimal resource & metrics

True pos

False pos

- OVER DIAGNOSIS
- Patient Harm
- Unnecessary resource

- UNDER DIAGNOSIS
- Late / No treatment & poor outcome
- Poor outcome metrics & increased resource on subsequent / late diagnosis

False neg

True neg

- CORRECT DIAGNOSIS
- No treatment (relief)
- No resource

NICE

Linked evidence of test effectiveness

- Test accuracy data, direct outcomes from the test, indirect health outcomes

- Combined through a linked evidence approach

| Diagnostic Accuracy | Impact on treatment decisions | Impact on outcomes |

Merlin T et al, The use of the 'linked evidence approach' to guide policy on the reimbursement of personalized medicines, June 2014, Personalized Medicine 11(4):435-448

Measuring HRQoL

HRQoL is frequently measured with 'tools' in the form of questionnaires, e.g the 36 Item Short-Form (SF-36®) Survey or the EuroQoL 5 Domain (EQ-5D) tool.

- EQ-5D asks patients to rate their health on 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety / depression

- Each dimension has 3 scores : 1 no problem, 2 some problems, 3 extreme problems.

- These can then be represented by a 5 digit code e.g. 12311 and can be converted to an utility value.

RAND (2016) 36-Item Short Form Survey from the RAND Medical Outcomes Study. *RAND Corporation.* Retrieved 11 Oct, 2018, from http://www.rand.org/health/surveys_tools/mos/mos_core_36item.html
EuroQoL (2016). 'About EQ-5D'. Retrieved 12 February, 2016, from http://www.euroqol.org/about-eq-5d.html

The International Consortium for Health Outcomes Measurement (ICHOM) is a non-profit organization with the purpose to transform health care systems worldwide by measuring and reporting patient outcomes in a standardized way.

Established Standard Set for 26 disease conditions. Each set is made up of the following components:

Outcomes: The patient-centered outcomes that represent true success in managing the specified medical condition.

Case-mix variables: Factors that will affect the outcomes above, but which we cannot control as part of management of the condition. We measure these to build risk-adjustment models that ensure fair comparison of outcomes across centres.

Measurement tools: Validated instruments that are used to measure the outcomes and case-mix variables.

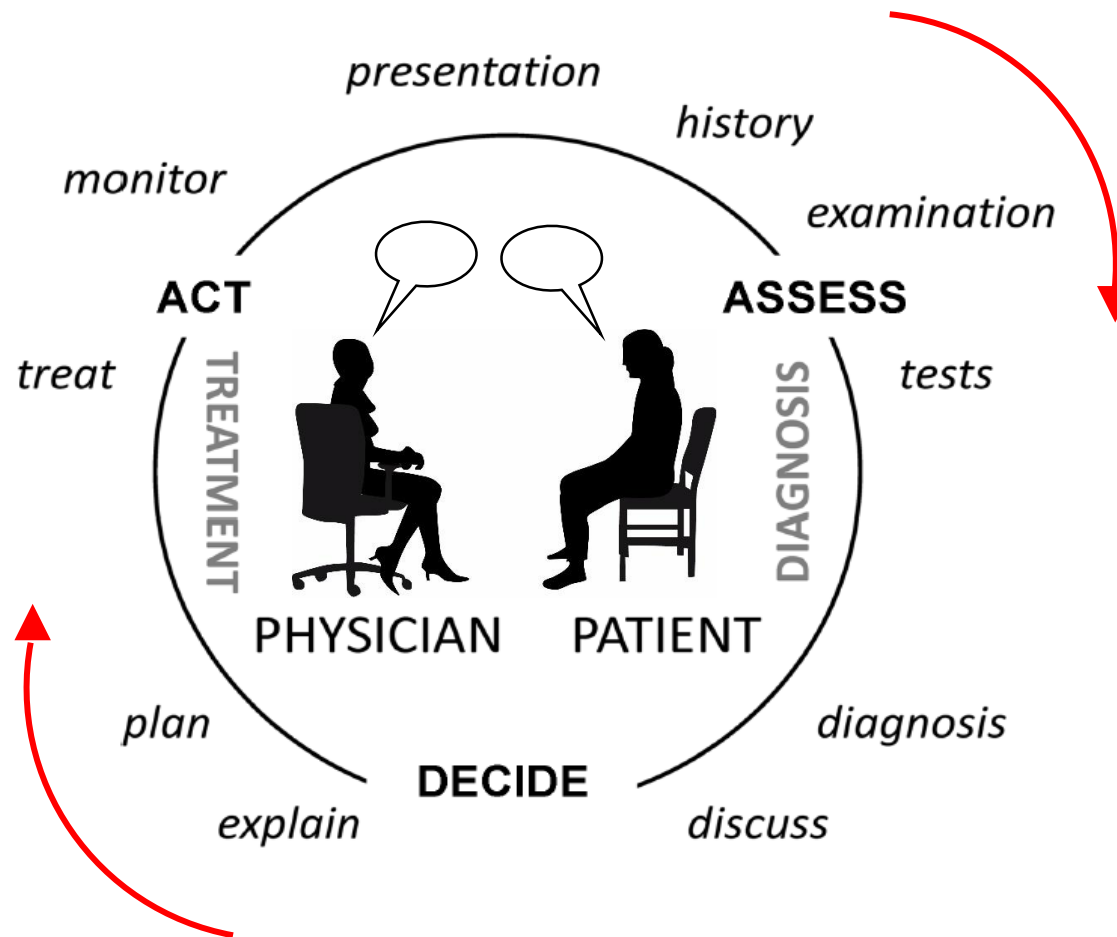**Data sources:** These can be administrative, clinician-reported or patient-reported.

Time points: Specified time points for data collection.

Outcome metrics - the "benefit" and impact is not always easy to measure.

Outcome	Metric
Has this intervention resulted in improved patient experience?	e.g. patient satisfaction surveys to identify whether more convenient, greater awareness or greater self motivation to manage condition.
Has this intervention resulted in improved disease outcome?	e.g. rate of secondary complications, improvement in symptoms, readmission, urgent acute admissions, survival rate, percentage of patients with improved diagnostic test .
Has this intervention resulted in improved treatment optimisation?	e.g. side effects, quality of life
Has this intervention resulted in a cost reduction?	e.g. reduction in staff resource, avoidance of transport cost, reduction of admission to secondary care, reduce length of stay.

WSAC 2017: POLICY ON THE MANAGEMENT OF POINT OF CARE TESTING , WHAT, WHEN AND HOW?

What is the Value Proposition for POCT?

Supporting the patient-carer relationship

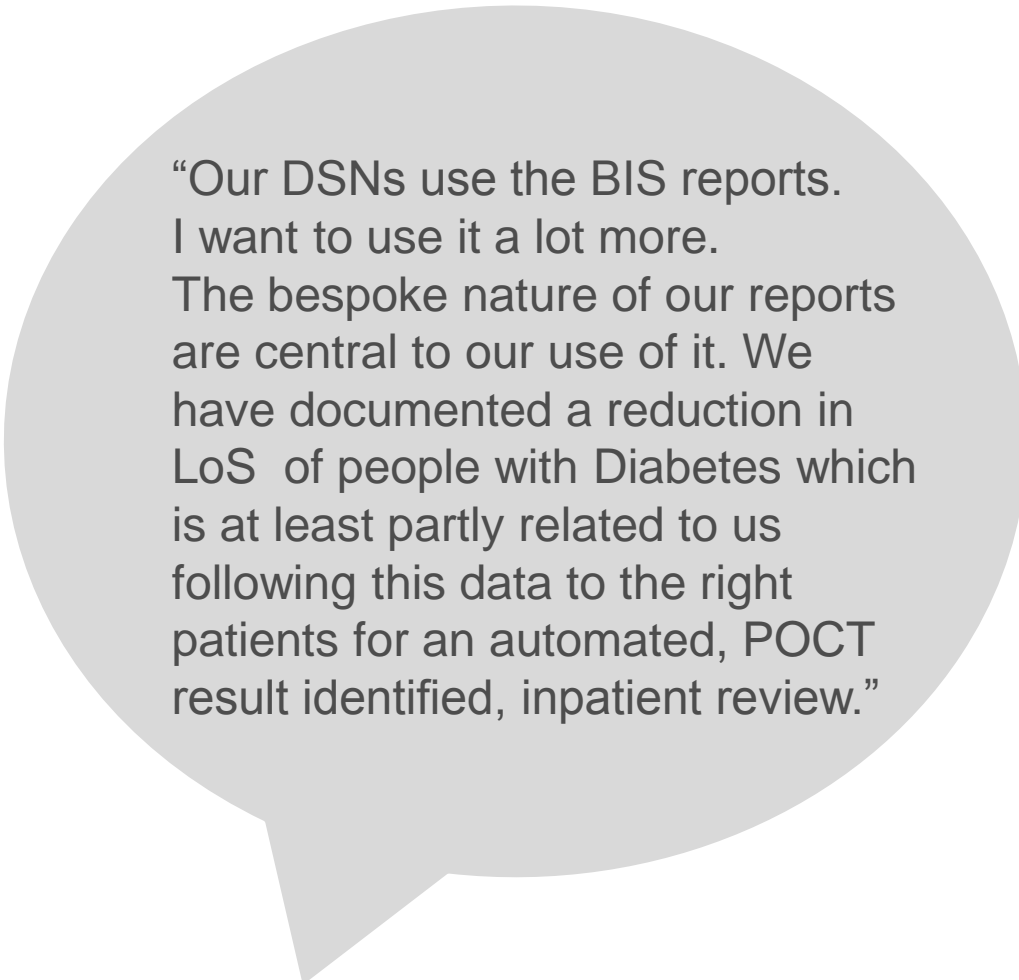Professor Christopher P Price

Benefits Assessment in implementing POCT

Setting	Clinical Application	Perceived Benefit
Home	Management of long term conditions - diabetes/ Heart Failure. Early detection of complications e.g. infection in patients on chemotherapy Home ventilation unit for measurement of patients on Oxygen therapy.	Better awareness / self motivation to manage condition – less complications Avoid need to attend hospital Avoid cost of transport Avoid time off work/ patient Patient convenience / acceptability
General Practice	Management of long term conditions. Antibiotic stewardship. Enhanced Service for Anticoagulation monitoring. Out-Of-Hours Service.	Patient convenience / acceptability Improved access to relevant population Reduction in acute admissions. Avoid cost of transport. Avoid time off work/ patient convenience. Improve relationship with GP – supporting shared decision making.
Community / Pharmacy	Management of long term conditions Anticoagulation monitoring Health Checks Antibiotic stewardship	Patient convenience / acceptability Improved access to relevant population Reduce need to visit GP
Ambulance	Pre-hospital testing Monitor patients during inter hospital transport. Treatment of sick neonates in transit	Faster triage through Emergency Department Earlier intervention Reduce risk of complications during transport
Urgent care centres	Urgent care for non-life threatening conditions Rule out testing	Avoid need to attend Emergency Department
Emergency Department	Rapid triage testing and treatment	Reduced length of stay in Emergency Department Treatment of patients with time-dependent conditions
Theatre	Monitoring operative procedures	Reduce post OP care requirement Convert to day case – reduce need for hospital bed
Intensive Treatment Unit / Critical Care Unit	Monitoring vital parameters	Improved mortality and morbidity Reduce length of stay

Outcome metrics - the "benefit" and impact is not always easy to measure. You know it's there but can't quite put a figure on it!

Intervention: POCT glucose in all clinical areas. Hypoglycaemic events captured in BI dashboard for Diabetes team.

Metric: Time to normoglycaemia, LoS

Outcome: Reduced time to management/ reduced LoS

"Our DSNs use the BIS reports. I want to use it a lot more. The bespoke nature of our reports are central to our use of it. We have documented a reduction in LoS of people with Diabetes which is at least partly related to us following this data to the right patients for an automated, POCT result identified, inpatient review."

Outcome metrics - the "benefit" and impact is not always easy to measure. You know it's there but can't quite put a figure on it!

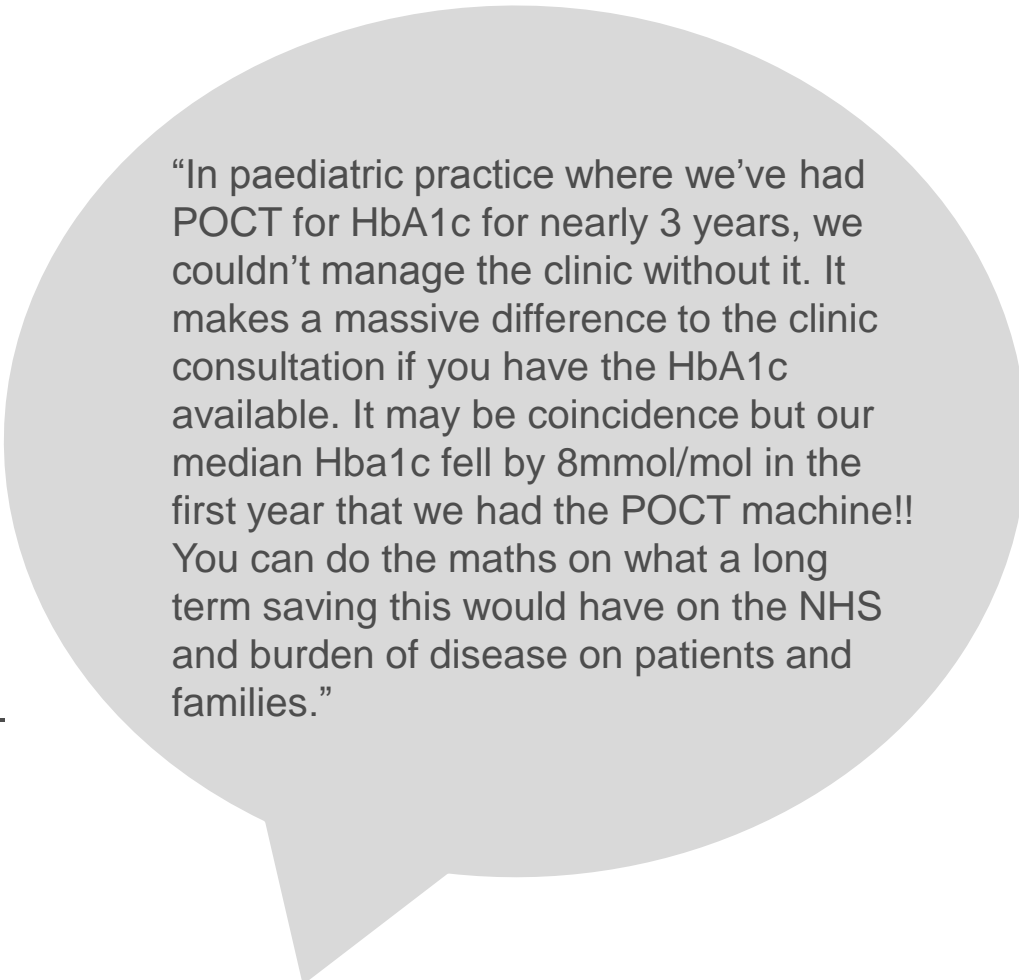Intervention: POCT HbA1c available in Paediatric Diabetes Clinics
Metric: HbA1c monthly trends / patient satisfaction survey.

Outcome:
Reduction in median HbA1c (surrogate marker of secondary complications).

Improved patient experience – shared ownership of management.

"In paediatric practice where we've had POCT for HbA1c for nearly 3 years, we couldn't manage the clinic without it. It makes a massive difference to the clinic consultation if you have the HbA1c available. It may be coincidence but our median Hba1c fell by 8mmol/mol in the first year that we had the POCT machine!! You can do the maths on what a long term saving this would have on the NHS and burden of disease on patients and families."

Intervention: POCT CRP testing to support clinical decisions in primary care for management of common infections.

Metric: Antimicrobial prescribing rate.

Outcome: patients presenting with acute RTI demonstrated a reduction in prescribing of antibiotics during the study period compared to the same period in the previous year (Hughes et al. 2016). No adverse effects.

Reduction in prescribing – Benefit as part of long term strategy to reduce AMR

Intervention: POCT INR in AF & heart valve disease: self monitoring

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Intermediate outcomes:
- time and values in therapeutic range (TTR)
- international normalised ratio (INR) values
- test failure rate
- time to test result.

Patient adherence to testing and treatment:
- frequency of testing
- frequency of visits to primary or secondary care clinics.
- Health-related quality of life.

Clinical outcomes:
- frequency of bleeds or blood clots
- morbidity (for example, thromboembolic and cerebrovascular events) and mortality from INR testing and vitamin K antagonist therapy
- adverse events from INR testing, false test results, vitamin K antagonist therapy and sequelae.

Patient-reported outcomes:
- anxiety associated with waiting time for results and not knowing current coagulation status and risk
- acceptability of the tests

NICE Diagnostics guidance [DG14]

Intervention: Biomarker tests to help diagnose preterm labour in women with intact membranes
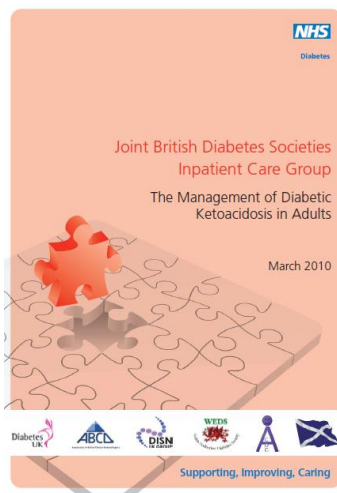
Most publications report **Intermediate outcomes:**

- Diagnostic Accuracy

- Metric: Delivery within 7 days
  Delivery within 48 hours

Recommendation: Further research is needed on the accuracy of the tests and their effect on clinical outcomes

- Effect of gestational age on the accuracy of the tests

- how the tests affect clinical decision-making

- the effect of the tests on outcomes for mother and baby.

NICE Diagnostics guidance [DG33] published July 2018

Intervention: POCT ketone in new DKA pathway

NHS
Diabetes

Joint British Diabetes Societies
Inpatient Care Group

The Management of Diabetic
Ketoacidosis in Adults

March 2010

Supporting, Improving, Caring

Adult Diabetes ketoacidosis guidelines implemented in Nov 2010.
POCT Ketone testing implemented in selected wards (capacity planned with requester restrictions).

Implementation followed education programme on care pathway, introduction of testing protocol (frequency) and training on POCT devices.

Only approved and trained operators allowed access.

Diabetologists and DSNs provided access to POCT data manager to track patients results (outcome), activity (no of tests), and operator usage (order patterns).
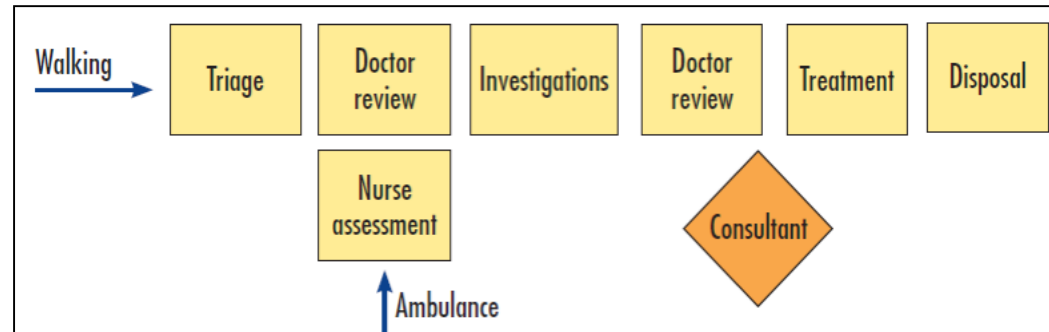
Diabetic Ketoacidosis	
Processes	
Protocol	Availability of diabetes management guidelines based on national examples of good practice
Implementation	Availability of hospital wide pathway agreed with diabetes speciality team and regular audit of key components. Evidence of rolling education program for all medical and nursing staff
Specialist review	People with diabetes who are admitted to hospital with diabetic ketoacidosis are reviewed by a specialist diabetes physician or nurse prior to discharge
Environment	HDU access or monitored bed for DKA
Outcome measures	
Incidence	Benchmark incidence of DKA against equivalent national and regional data for admissions using widely available local and national datasets
Income	Length of stay. Time of conversion to subcutaneous regimen
Ketosis	Time to blood ketonaemia or acidosis resolution
Morbidity & mortality	Complication rate of DKA treatment (e.g.cerebral oedema). In hospital death rates. In hospital complications cerebral oedema, pulmonary oedema, ARF, septicaemia. Readmission rate for DKA over 12-month period

Challenge: How do we quantify the direct impact of POCT in the pathway redesign?

Intervention: Changing the Process in the ED use of the Emergency Department Intervention Team
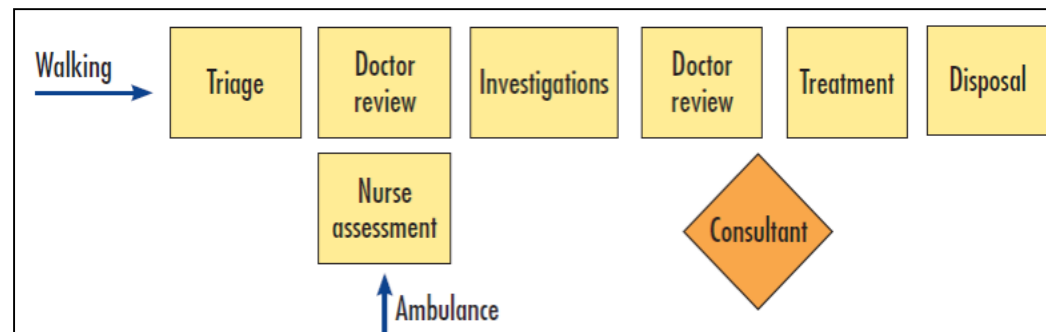
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Traditional Model

The Problem

- System designed to make patients wait (Triage is a step to decide how long you should wait)

- Two access points to the service

- Investigations requested late

- Potential for inexperienced staff to order unnecessary investigations
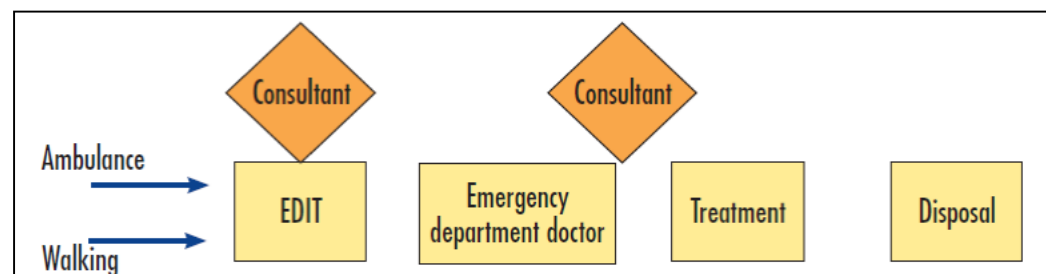
Jarvis et al 2014

Realising the benefit - Changing the Process in the ED use of the Emergency Department Intervention Team

Traditional Model

New Model

Jarvis et al 2014

3 Phased approach

Phase 1 – Evaluate the performance of the traditional ED model - 1st April to 24th May 2013 (3835 patients)

Phase 2 – Evaluate introducing POCT into traditional ED model - 28th May to 29th September 2013 (7033 patients)

Phase 3 – Evaluate POCT and EDIT model together – 30th September to 18th October 2013 (1200 patients)

POCT impact on TAT

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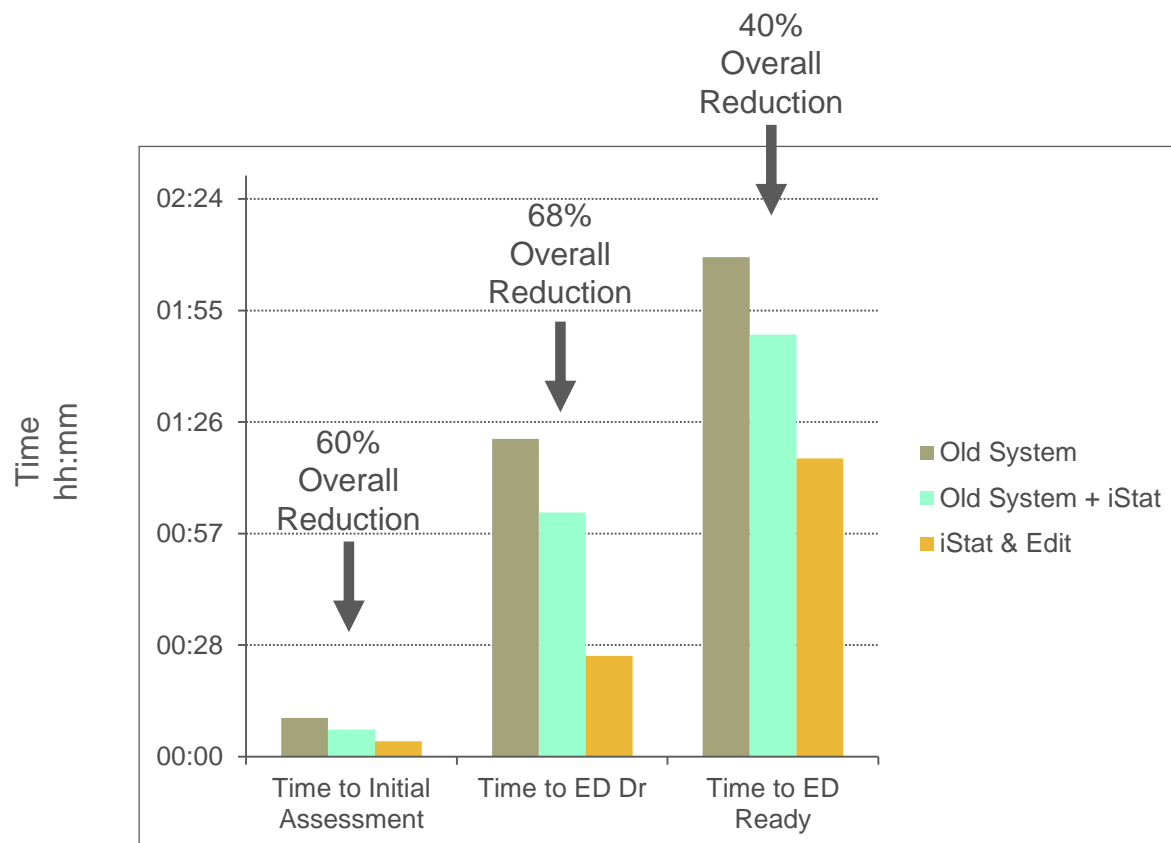**Before Trial**

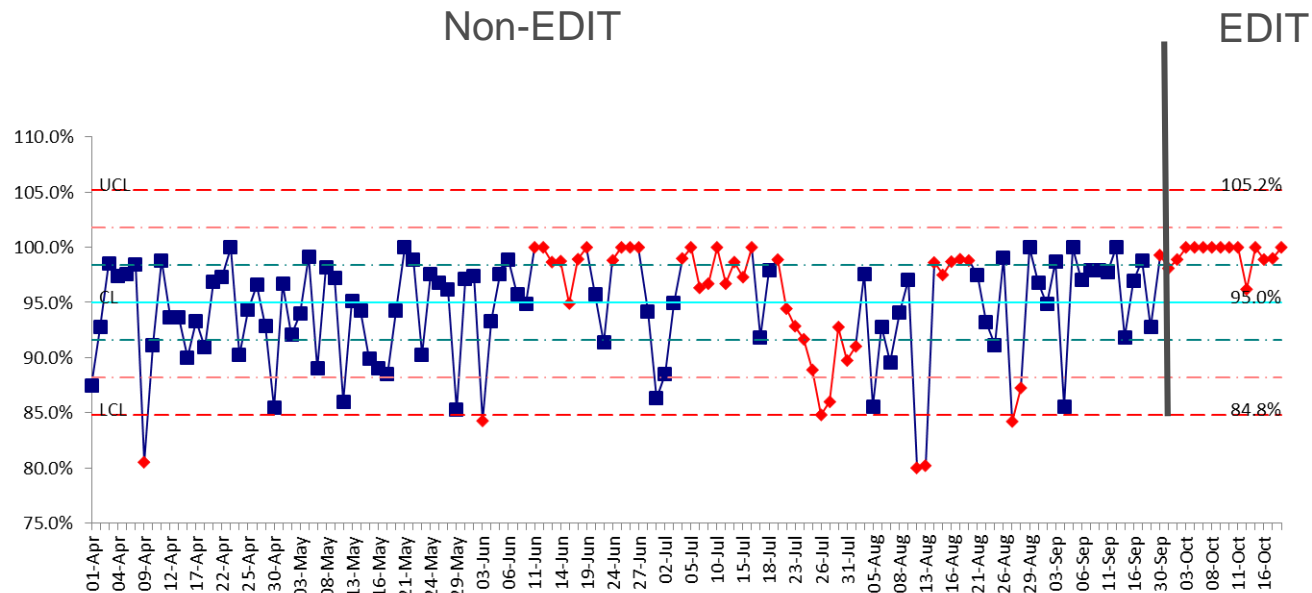Median Blood Results available: 63 minutes

Trial Results

Median: 3 minutes

Able to do 60% of ED bloods using POCT

Results After Changing the Process - use of the Emergency Department Intervention Team

Jarvis et al 2014

Breach Performance

Consistently meeting 4 hour target

Much less variation with EDIT based model

Conclusion

Introduction of a consultant-led assessment process (EDIT) and POCT provides:

40% reduction in the median time from patient arrival to being declared 'ED Ready'
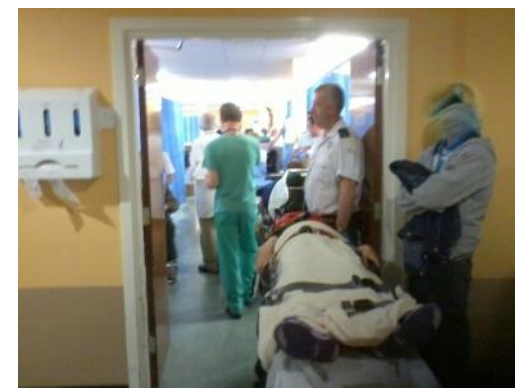
2.5% reduction in the median number of patients admitted

Conclusion

Traditional	EDIT & POCT
9 patients are undergoing ED Care in the ED central area at any one time (Monday to Friday 9-5).	**5** patients are undergoing ED Care in the ED central area due to quicker processing of patients.
3% of patients seen in ED Central Area Monday to Friday 9-5 are discharged with 30 minutes of arriving.	**10**% discharged with 30 minutes of arriving with the additional benefit of being seen by a consultant.
21.5% rate of admission.	**19.0%** rate of admission 2.5% reduction = 9 fewer admissions per day.
11.4% of patients seen in ED Central Area Monday to Friday 9-5 return within 7 days of their initial presentation.	**9.1%** of patients seen in ED Central Area Monday to Friday 9-5 return within 7 days of their initial presentation.

Reduces Overcrowding

Frees up time to Care

Jarvis et al 2014

Post – Assessment:
Multiple choice question #1

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Multiple choice question #2

Which of these statements best describes Diagnostic Accuracy of the intervention?

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- Option#2 – Relates to the ability of a test to discriminate between the target condition and health.

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Post – Assessment:
Multiple choice question #3

Which of these statements best describes how we should evaluate impact?

- Option#1 – Diagnostic Accuracy.

- Option#2 – Patient experience/ anxiety/ convenience.

- Option#3 – Both of these.

Take away message – Challenges and Enablers

Challenges

How do we identify the effectiveness (benefit)?

How do we measure the benefit?

How do we collect the data?

How do we link POCT data to outcomes?

Enablers

POCT device connectivity to a POCT database and hospital BI.

POCT data needs to be part of a much larger Data warehouse providing BI where TAT, time to treatment, LoS, Infection rates, complication rates, staff rosters, HRQoL are available.