UEG Week 2014

WEO World Endoscopy Organization

EWG FIT for Screening, Vienna, October 17, 2014

Who should perform the FIT analysis? Pros and cons of FIT as a POCT v analysis in Hospital Laboratories.

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Meaning of POCT

- Point of Care Testing (POCT), in simple terms, is "medical laboratory testing" performed in a non-laboratory setting.
- Huge literature. and much regulation and/or recommendations in many countries, and ISO standards.
- POCT done in many settings including wards, units and clinics in secondary and tertiary care, and in primary care.
- Primary care (in the community):
  community clinics, community pharmacies, GP surgeries, health centres, independent sector, industrial medical centres, mobile units, diagnostic centres, residences.

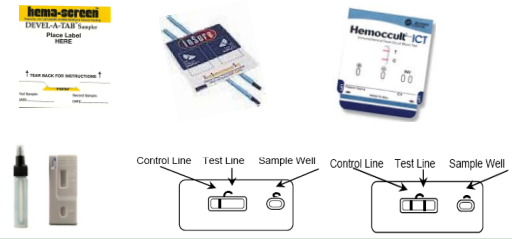
The spectrum of POCT

Analysers and kits for HbA1c, bilirubinometers, blood gas analysers, blood glucose meters, cardiac testing: BNP, troponin, D dimer, cholesterol tests, coagulometers, electrolyte analysers, MRSA screening tests, pregnancy tests, rapid test kits for infectious disease markers, urinalysis test strips. Manual tests and small and large analytical systems used.

NOTE: usually no mention of "tests for occult blood in faeces" – probably because gFOBT not recommended in guidelines in assessment of the symptomatic and screening is different - but FIT are not gFOBT! AND now ever-growing evidence-base exists that FIT is a really good test for exclusion of significant disease in patients with lower abdominal symptoms as a "rule-out" test – low faecal haemoglobin means disease unlikely and endoscopy unnecessary. FIT will become ubiquitous!

Qualitative FIT

Positive/negative – usually sample collected onto a card or on a probe or stick – then analysis done with immunochromatographic test cassettes or strips.



Qualitative FIT

Some advantages include:

- Simple to do (as pregnancy tests).
- Inexpensive, even in small numbers.
- No need for instrumentation.
- Can be done by others in health care than professionals in laboratory medicine (and by the public?).
- Easy to store – no refrigeration.
- No calibration needed.
- Integral quality monitor.
- Result available within minutes.
- Easy to interpret results.
- Cards can be posted easily – stable – although tube devices less so – although improving.

Qualitative FIT

Some disadvantages include:

- Not simple to interpret faint lines.
- Colour development dynamic – negatives become positive!
- No real quality control with appropriate matrix unless use further tests – not really IQC.
- Difficult and time consuming to do large numbers.
- No automation - although small readers available.
- Impossible to download data directly – transcription mistakes.
- Faecal haemoglobin cut-off concentration NOT the same for different FIT – set by manufacturer (although some will prepare what is specified).
- Lot-to-lot variation (acceptance quality checks needed).

Qualitative FIT

FIT	Positivity (%)	Sensitivity (%)	Specificity (%)
A	6.4	29.8	96.7
B	11.0	30.5	92.9
C	22.3	53.2	81.8
D	24.1	56.0	82.0
E	35.0	59.6	70.2
F	46.8	73.4	58.8

1330 patients prior to colonoscopy
Brenner H, et al. Int J Cancer 2010;127:1643–9

Qualitative FIT

- Levy BT, et al. Test characteristics of faecal immunochemical tests (FIT) compared with optical colonoscopy. J Med Screen. 2014;21:133-43.
- Individuals scheduled for a colonoscopy were invited to complete a FIT prior to their colonoscopy preparation. Because of product issues, four different FIT manufacturers were used.
- Daly JM, et al. Evaluation of fecal immunochemical tests for colorectal cancer screening. J Prim Care Community Health 2013;4:245-50.
- About two thirds of the commonly used FIT products performed acceptably on spiked samples of human hemoglobin. However, some had low sensitivity and specificity and probably should not be used for population-based or other screening.

Quantitative FIT

A number of analytical systems available – and spectrum growing all the time with new releases.

Calibrators and reagents (FOB Gold) are available that can be used in many analytical systems.

Quantitative FIT

Some disadvantages include:

- Expensive if few FIT analyses done.
- Need for instrumentation, installation, training, etc.
- Need to evaluate/validate for accreditation systems and then document.
- Difficult to choose which FIT system since most rather comparable in general terms.
- Cannot be done by others than professionals in laboratory medicine.
- Refrigeration required for latex reagent and quality controls and calibrators.
- Cards not used – specimen collection devices.
- Stability of haemoglobin issues – although improving as products evolve.

Quantitative FIT

Some advantages include:

- High quality analyses with good reproducibility.
- Easy to monitor quality using TQM techniques - "guaranteed" quality through ISO15198 accreditation.
- High throughput of samples – as needed for programmatic screening.
- No visual interpretation of results.
- Download data into LIS via middleware eliminating transcription errors and facilitating record keeping.
- Linkage with other data – for example, age and gender - important for the future for risk scoring or monitoring.
- Provide many data which enhance understanding of colorectal disease.
- Cut-off f-Hb concentration(s) for referral for colonoscopy can be set by programme organisers.

The question – POCT v Labs

The real answer – BOTH!

Hospital laboratories ideal for large sophisticated programmatic screening efforts, especially when health services are well-organised nationally or regionally and financed properly.

POCT when smaller screening initiatives only are possible (for whatever reason) including where large set-up costs are prohibitive. But care is needed and the following guidance, *inter alia*, is highly recommended.

Management and use of IVD point of care test devices December 2013

MHRA

www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON071082