Comparative performance of four analysers used in the NHS Bowel Cancer Screening Programme FIT Pilot Study

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Background

For six months in 2014, the NHS Bowel Cancer Screening Programme (BCSP) in England ran a pilot study to assess the operational and financial implications of using a faecal immunochemical test for haemoglobin (FIT) rather than a guaiac faecal occult blood test (gFOBt).

The Pilot was run from two of the five BCSP Hubs (Southern (SH) and Midlands and North West (MNWH)); 1/28 (40,930) subjects were invited to complete a FIT instead of gFOBt. Staff with basic laboratory experience and scientific staff analysed routine pilot samples successfully.

Each Hub used two OC-SENSOR DIANA FIT analysers (Eiken Chemical Co. Ltd., Japan; supplied by Mast Group Ltd., Liverpool, UK). SH analysers are denoted S1 and S2; MNWH analysers MNW1 and MNW2). A clinical cut-off of 100 ng Hb/mL was used for the Pilot.

Figure 1: The OC-SENSOR DIANA analyser and sample collection bottle

Method

Acceptance testing of the performance of all four analysers was carried out prior to the Pilot by scientific staff:

- Imprecision and linearity was assessed using aqueous haemoglobin (Hb) solutions of known Hb concentration.
- Sample comparison: 40 faecal samples measured in another FIT research study were extracted from the collection bottles and frozen. Aliquots of the thawed samples were run on both analysers in one of the Hubs and the remainder of the samples sent frozen to the other Hub where they were thawed and measured in the same way.

Performance monitoring during the course of the Pilot five sets of 30 faecal samples (50-1000 ng Hb/mL buffer, 10-200 µg Hb/g faeces) were exchanged approximately every month between May and November 2014. They were analysed using the same procedure as in the acceptance testing.

Results

Acceptance testing

Table 1: 5-day imprecision (aqueous Hb samples, 3 replicates measured on each of 5 days)

Pilot analyser results	S1	S2	MNW1	MNW2	Eiken results	
Mean (ng Hb/mL) / Sr	134.4/1.88	145.5/7.54	150.5/3.46	146.5/3.46	**σ mean/Verification**	132.0/4.01
Mean (ng Hb/mL) / Sr	431.9/2.19	452.0/2.52	436.3/3.87	434.8/2.99	**σ mean/Verification**	450.0/10.59
If Sr values are less than verification then within acceptable imprecision quoted by manufacturer.						

Table 2: Within-batch imprecision (20 aqueous Hb samples)

Analyser	S1	S2	MNW1	MNW2	S1	S2	MNW1	MNW2
Mean	127.4	133.4	129.0	130.9	420.0	437.5	441.0	432.7
SD	2.25	7.29	3.58	2.59	4.22	2.84	3.99	4.75
CV	1.77	5.46	2.77	1.98	1.01	0.65	0.91	1.10

Linearity: The gradient of the lines varied 1.07-1.27 and R^2 0.9985-0.9996 (SH) and 1.05-1.16 and 0.9977-0.9997, respectively, (MNWH).

Sample comparison:

Figure 2: Faecal sample result compared with the mean result

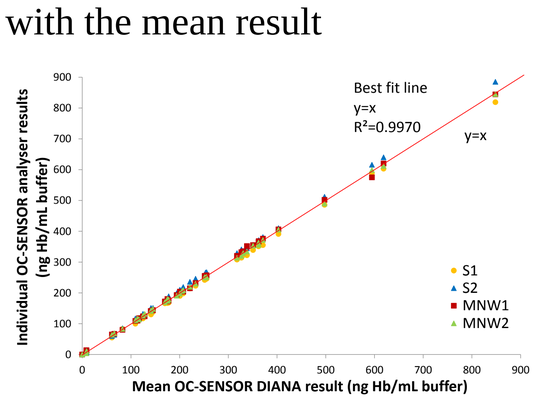
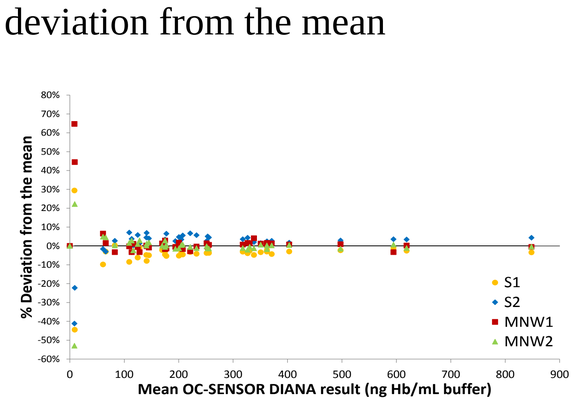


Figure 3: Faecal sample result deviation from the mean



Performance monitoring demonstrated consistently good agreement of results between the four analysers. The percentage deviation from the mean was < 10% for 94.5% of the results. The maximum and minimum deviations from the mean showed little monthly variation and almost all were < 10% of the mean.

Figure 4: Sample result compared with the mean result

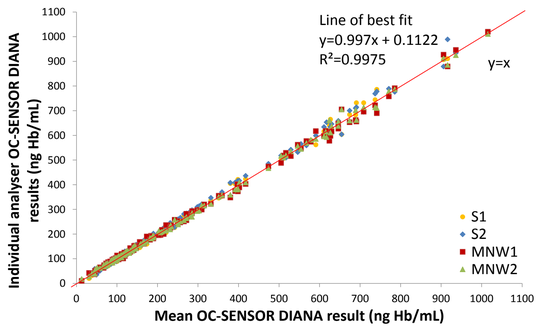


Figure 5: Sample result deviation from the mean

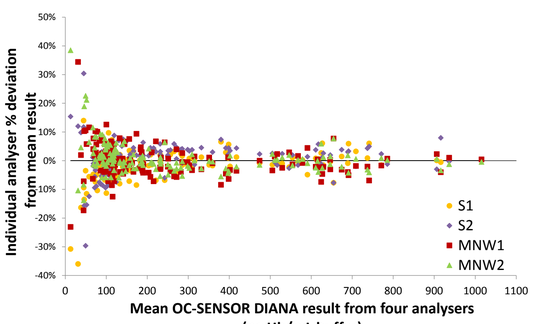


Figure 6: Maximum deviation as a percentage of the mean result

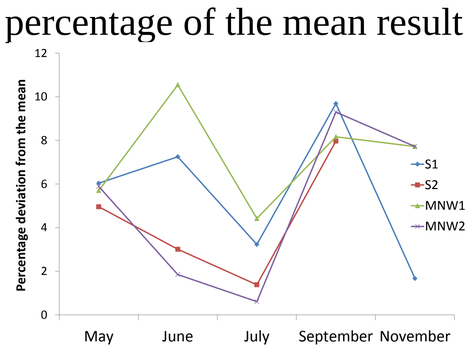
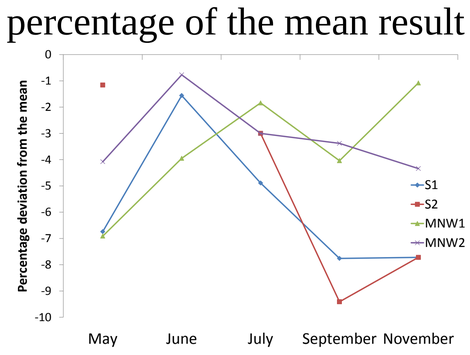


Figure 7: Minimum deviation as a percentage of the mean result



Conclusions

These results demonstrated very good comparable performance between the four OC-SENSOR DIANA analysers used in the FIT Pilot Study and sets a benchmark for such analysers in a screening programme.

Disclosure of potential conflicts of interest: none