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# Cancer panel clinical applicability and affordability

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## Why was this study done?

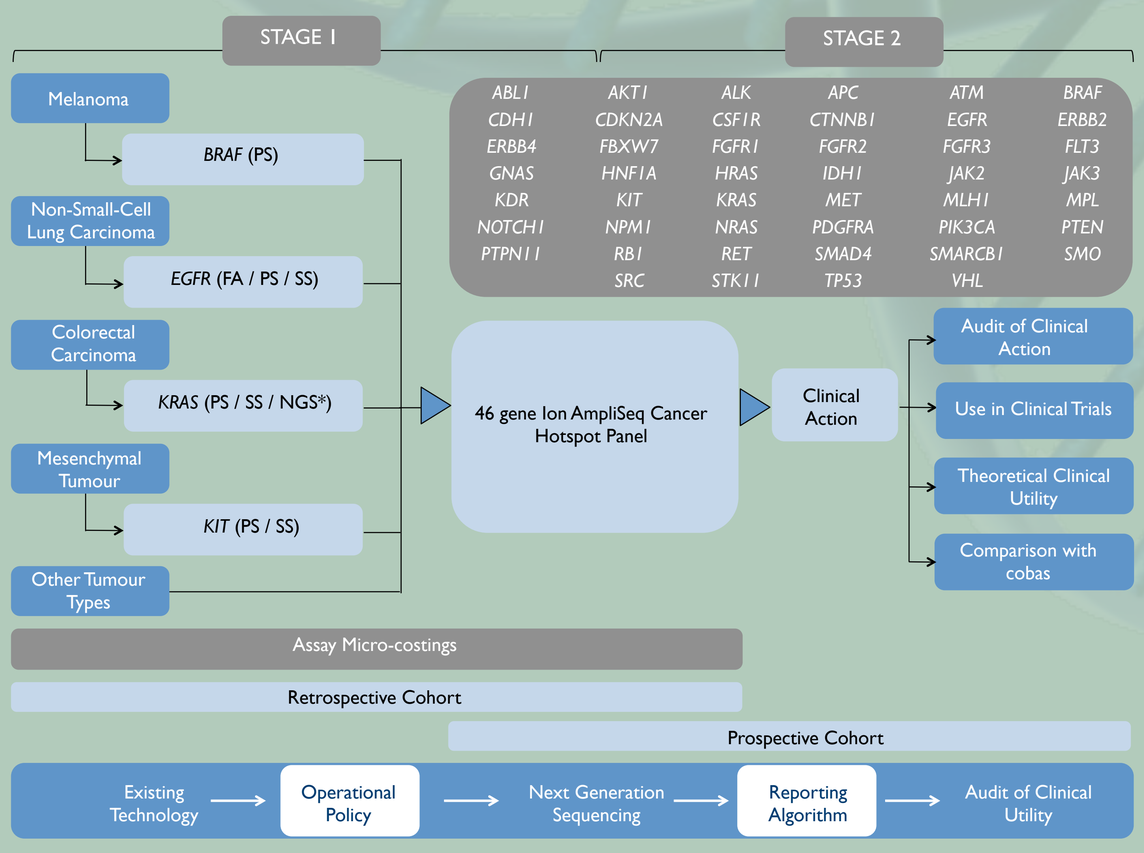
Healthcare planners and oncologists require real world evidence that next generation sequencing (NGS) technologies improve gene mutation detection and enable more appropriate use of targeted drug therapies.

With a range of genomic testing options available for cancer patients, we need to know whether healthcare systems can afford to implement cancer panels in routine clinical care, even if they are effective.

This study assessed a 46-gene hotspot cancer panel (CP) assay allowing multiple gene testing of small diagnostic cancer biopsies in the context of the UK National Health Service. Tumour samples from 351 patients who treating clinicians thought might benefit from more extensive genetic analysis underwent NGS using the panel. A clinical report was produced with a median turnaround time of seven working days that detailed all mutations detected, including those with potential diagnostic, prognostic, therapeutic, or clinical trial entry implications. Among the prospective cohort, 79% (278/351) of samples had tandem cobas (single gene) analysis performed, allowing comparison of the two alternative technologies.

## Methods and findings

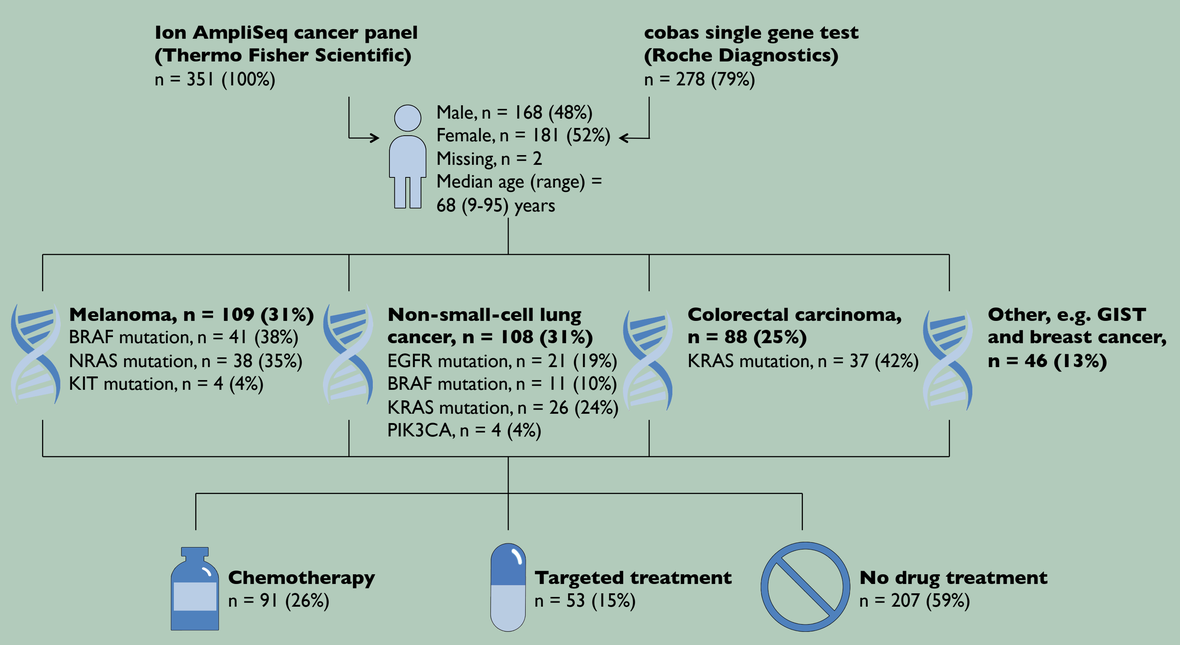
### Study design




Outline of the study design demonstrating the existing genetic testing repertoire of the laboratory and the proposed NGS assay (cancer panel). Stage 1 involved the technical validation of the panel using a retrospective cohort of samples and performance of micro-costings. Stage 2 involved the panel's introduction into diagnostic pathways using a prospective patient cohort. FA, fragment analysis; NGS*, alternative next generation sequencing; PS, pyrosequencing; SS, Sanger sequencing.

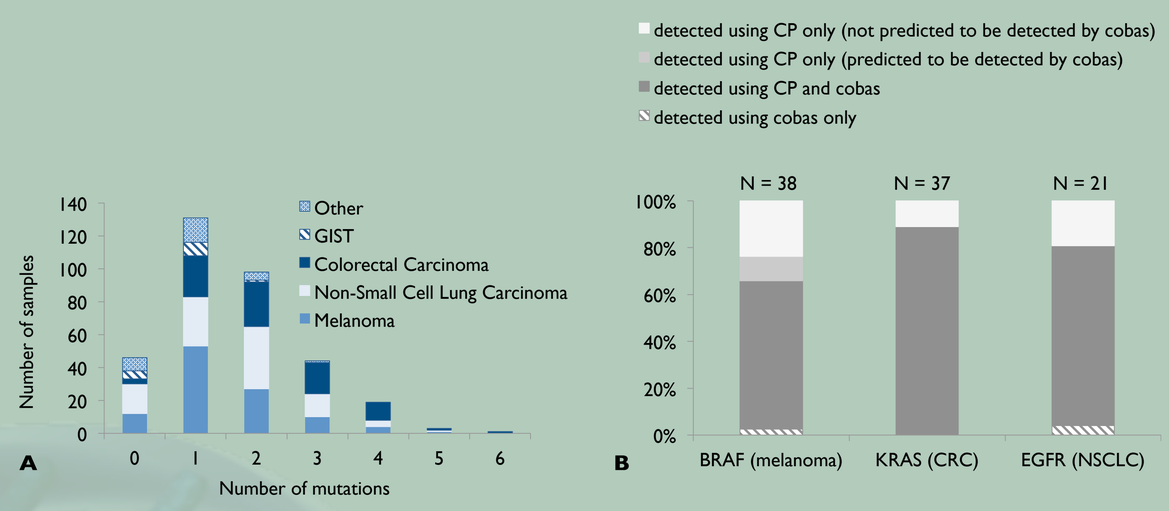
### Patient characteristics

Clinical data were collected for patients whose tumour samples underwent sequencing in order to assess changes to clinical management resulting from this test.




### Distribution of mutations

The panel demonstrated at least one mutation in 87% (296/342) of successfully sequenced tumours.



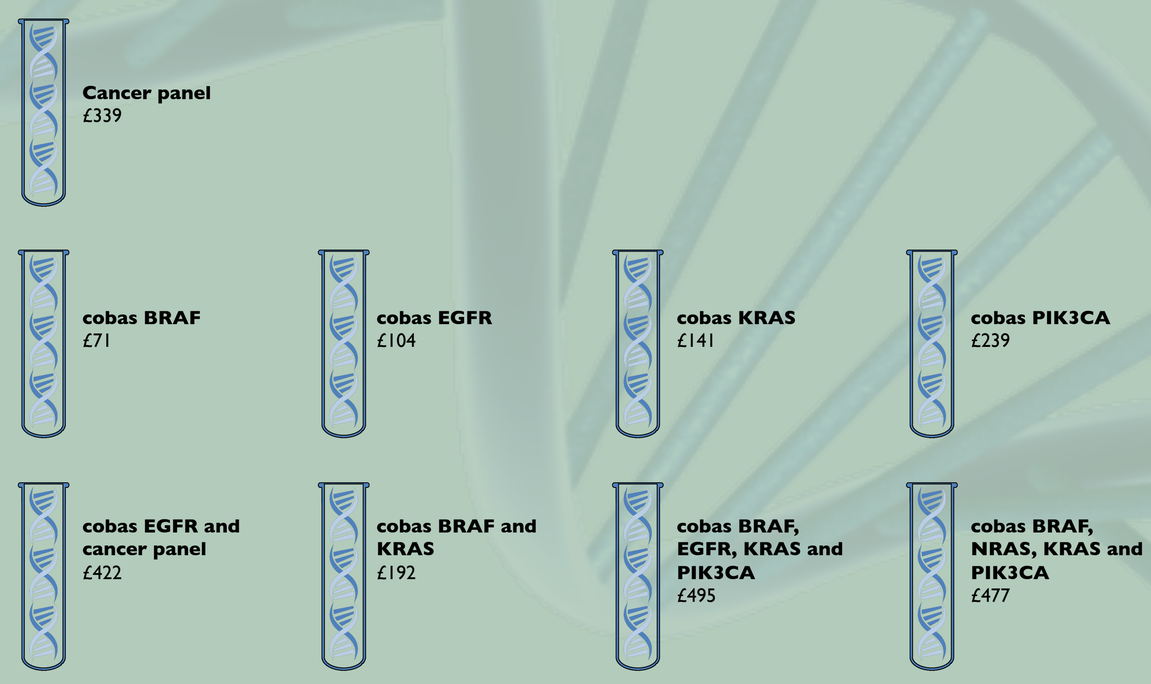

(A) Number of mutations per histological sample by tumour type. (B) Percentage of mutations in key clinically actionable genes detected by standard diagnostic methods and the panel in the prospective cohort. CRC, colorectal carcinoma; GIST, gastrointestinal stromal tumour; NSCLC, non-small-cell lung carcinoma.

### Changes in patient management

Forty patients in this cohort received targeted treatments on the basis of genetic data obtained using the panel. For 22 of these patients, there was no alternative genetic test available locally to produce this data.

### Potential testing pathways

An accompanying detailed cost analysis was performed to determine the affordability of the panel compared to existing single gene testing options. Mutation detection with the panel costs £339 per patient, compared with single gene testing ranging from £71 to £141 per test, depending on the mutation type. If more than two or three genes are examined (depending on the cancer type), using the panel is less expensive than single gene testing.




## What do these findings mean?

The panel assay is a useful method to identify genetic mutations in tumours that can extend the range of therapeutic options available to patients.

In terms of costs and affordability, the panel may be a justifiable option if 2–3 or more genes need to be examined.

Further data need to be collected on the clinical outcomes of patients accessing drugs as a result of more extensive sequencing data outside the scope of single gene/mutation tests.

In addition to supporting routine clinical care, the panel can be used to support research studies where treatment choices are genetically determined.

## Reference

Hamblin A☯, Wordsworth S☯, Fermont JM☯, Page S, Kaur K, Camps C, et al. (2017) Clinical applicability and cost of a 46-gene panel for genomic analysis of solid tumours: Retrospective validation and prospective audit in the UK National Health Service. PLoS Med 14(2): e1002230. doi:10.1371/journal.pmed.1002230

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