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RE-TEST THEM: A Human Factors Pilot Study to De-Risk the Adoption of Breath-Based Therapeutic Monitoring in Oesophagogastric Cancer

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ABSTRACT

Oesophagogastric (OG) cancer remains a cancer of unmet need, with poor survival driven by delayed diagnosis, aggressive tumour biology, and inherent treatment resistance. Analysis of exhaled breath volatile organic compounds (VOCs) offers a promising, non-invasive approach to characterising tumour biology and identifying potential therapeutic vulnerabilities. Within the RE-TEST THEM (bREath TESTing for THErapeutic Monitoring) project, a breath test has been developed to identify patients who may benefit from experimental therapies such as PARP inhibitors. However, its clinical value depends on its integration into clinical decision-making rather than analytical performance alone. This exploratory pilot study applied a human factors approach to examine the usability, acceptability, and decision-making implications of the breath test. Semi-structured interviews were conducted with eleven patients, alongside a vignette-based decision-making exercise with four consultant oncologists using four realistic scenarios covering curative and palliative pathways. Findings demonstrated a clear division in perceived utility between clinical settings. In the curative pathway, clinicians were highly cautious, requiring strong evidence and clear thresholds before allowing test results to influence potentially curative care. For palliative patients, the test was viewed as more acceptable for supporting nuanced decisions about treatment continuation or cessation. Importantly, from a practical perspective, breath testing was seen as easily feasible with limited patient burden, however, the key challenge of integrating results into complex clinical decision-making repeatedly highlighted. These findings demonstrate the value of early human factors evaluation in de-risking experimental diagnostics and guiding their responsible adoption in cancer care.

Keywords: Human factors engineering, Breath-Based diagnostics, Oesophagogastric cancer, Clinical decision-making

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INTRODUCTION

Oesophagogastric (OG) adenocarcinoma poses a significant global health burden; in the UK, OG cancer as the seventh leading cause of cancer-related death, accounting for around 5% of all cancer deaths and in England, it is associated with one-year survival rate of 42.3% and five-year survival rate at just 14.3% - substantially lower than for many other cancers (Cancer Research UK) (NHS England). These tumours frequently present at an advanced or metastatic stage, display aggressive biological behaviour, and respond poorly to conventional chemotherapy and radiotherapy, resulting in high recurrence rates and poor survival outcomes (Hsu, Chudasama et al., 2020, Zhan; Betge et al., 2025).

Poly(ADP-ribose) polymerase (PARP) inhibitors, such as olaparib, are targeted agents that disrupt DNA repair by inhibiting PARP enzymes, which normally repair single-strand DNA breaks and function as a critical "backup" repair pathway. In cancer cells with defects in homologous recombination repair (HRR), blocking PARP removes this backup mechanism, leaving the cell unable to repair accumulating DNA damage. This progressive DNA damage ultimately leads to cancer cell death, a process known as synthetic lethality (Wang, Zheng et al., 2021; Tai, Goes et al., 2025). In OG cancer, the use of PARP inhibitors remains experimental, with early-phase studies showing inconsistent benefit due to tumour heterogeneity in homologous recombination repair deficiency and the absence of robust predictive biomarkers (Tai, Goes et al., 2025). Consequently, only a small subset of patients is likely to benefit, and the lack of reliable patient selection tools remains a key unmet need.

Translating VOC-Based Breath Testing into Clinical Decision-Making for Oesophagogastric Cancer

Volatile organic compound (VOC) analysis of exhaled breath provides a non-invasive method to characterise tumour biology in OG cancer, with evidence showing that defined VOC panels can accurately detect disease and reflect underlying biological behaviour beyond diagnosis (Paschke, Mashir et al., 2010) (Markar, Wiggins et al., 2018). Building on this, the RE-TEST THEM (bREath TESTing for THErapeutic Monitoring) project has developed an innovative VOC-based breath test to support identification of patients who may benefit from experimental therapies such as PARP inhibitors. This approach is informed by the SOLAR study (Cartwright, Fong et al., 2020), in which patients with advanced OG cancer underwent serial breath testing before and during olaparib treatment. Preliminary findings suggest that breath-derived biomarkers may help identify patients more likely to respond to PARP inhibition. Because breath testing is safe, repeatable, cost-effective, and acceptable to patients, it has strong potential as a scalable tool for personalised cancer therapy (Woodfield, Belluomo et al., 2021). However, successful healthcare implementation requires moving beyond controlled research settings to account for real-world clinical contexts, stakeholders, and the sociotechnical factors that shape how new interventions are delivered, interpreted, and adopted in practice (Peters, Adam et al., 2013). Introducing

decision-making tools into cancer care is inherently complex because it requires more than demonstrating analytical accuracy: it demands changes in clinical behaviour, workflow integration, and alignment with how clinicians and patients think, make decisions, and manage uncertainty (Jalil, Ahmed et al., 2013, Soukup, Gandamihardja et al., 2019). Clinical utility—how a device informs or changes decisions—must therefore be considered alongside effectiveness and usability to ensure meaningful impact in practice (Smart, 2006). Importantly, incorporating the patient perspective from the earliest stages of development is increasingly recognised as essential for successful adoption. Patients' experiences, preferences, and tolerance for burden influence acceptability, adherence, and trust in new technologies, particularly in chronic and high-burden conditions such as cancer (Shah, Robinson et al., 2009).

Guided by these principles, the aim of this paper is to explore clinical utility, acceptability, and decision-making implications of the new breath-based diagnostic test for OG cancer through an exploratory pilot study, drawing on both clinician and patient perspectives to de-risk its adoption and inform future development.

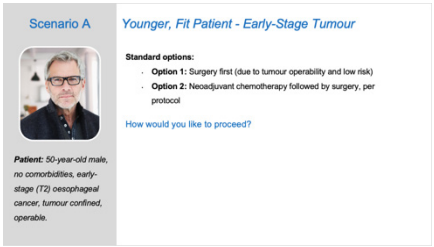
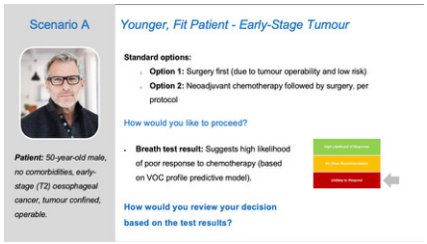
METHODS

This study adopted an exploratory qualitative methodology comprising three complementary activities:

- First, semi-structured interviews were conducted with consultant oncologists to explore clinical utility and decision-making. Interviews focused on identifying gaps and bottlenecks within the current OG cancer pathway and examining how the breath test could potentially mitigate these. Topics included limitations of existing monitoring approaches, decision-making around experimental therapies, requirements for clinician trust and adoption, and integration within multidisciplinary workflows.
- Second, a vignette-based decision-making exercise was embedded within clinician interviews to examine how the breath test might influence decisions at key points in the OG cancer pathway. Four realistic patient scenarios were developed with the clinical team (Table 1): two curative (Scenarios A and B) and two palliative (Scenarios C and D). For curative scenarios, clinicians first described standard-of-care management before reviewing hypothetical breath test results; *Scenario A* (younger, fit patient) presented a result suggesting low likelihood of chemotherapy response, while *Scenario B* (older, frail patient) indicated a high likelihood of response. These contrasting cases tested whether the test would reinforce or challenge standard curative decisions. Palliative scenarios were presented with breath test results already available, reflecting a monitoring context; *Scenario C* suggested likely response despite emerging symptoms, while *Scenario D* indicated low likeyhood of response in advanced disease. Across scenarios, breath test outputs were intentionally designed to confirm or challenge standard care, enabling exploration of trust, actionability, and integration into existing decision frameworks.

- Third, semi-structured interviews with patients with lived experience of OG cancer explored acceptability. Interviews covered patient experiences of the care pathway, followed by an explanation of the breath test and discussion of perceived benefits, feasibility, concerns, and implementation preferences. The final section examined communication needs, shared decision-making, and acceptability of introducing a new tool into routine cancer care.

Table 1: Illustrative patient scenario presented to consultant oncologists in vignette study.

Curative / Monitoring Setting	
Before	**After**
Scenario A	
	

Semi-structured interviews with clinicians and patients were conducted remotely via Microsoft Teams or Zoom, lasting approximately 30–45 minutes. With consent, interviews were video-recorded, transcribed verbatim, and analysed using process mapping and framework analysis to identify themes related to usability, integration, and decision-making. Participant confidentiality was maintained through the use of unique identifiers for clinicians (O01–O04) and patients (P01–P11).

Participants

Patient participants were recruited through a mailing list distributed by the OPA Cancer Charity (Oesophageal and Gastric Support). Clinicians were recruited through the NIHR HRC IVD and Imperial College London networks. Interested members received a Participant Information Sheet and contacted one of the researchers (MM) via email to express interest. Following written consent, a suitable interview date was arranged. Participants and clinicians were compensated for their time. A total of 15 participants took part in the study, comprising four consultant medical oncologists and eleven patients with lived experience of OG cancer. The oncologists had direct experience with multidisciplinary team (MDT) decision-making and treatment pathways. All clinician participants contributed to the semi-structured interviews; two clinicians did not complete the vignette study due to either lack of direct OG cancer experience (O03) or a focus on therapeutic evidence rather than case-based decision-making (O01). The cohort of patients consisted of a total of 11 individuals. Of these, 10 were patients who had undergone different stages of the OG cancer pathway,

including diagnosis, systemic treatment, surgery, and follow-up care; one (P08) was a family member who also had professional experience as a general practitioner (GP). Ethical approval for this study was obtained prior to data collection from the Research Governace and Integrity Team (RGIT) at Imperial College (Application ID 7350467).

FINDINGS

Clinical Utility – Semi Structured Interviews

Qualitative analysis revealed several interrelated gaps and bottlenecks in the management and monitoring of OG cancer, particularly at points of high clinical uncertainty and limited decision-making support. Within the constraints of the current clinical pathway, participants discussed opportunities for the new breath test in relation to its potential clinical utility and its ability to address existing gaps. Table 2 summarises the key gaps identified, alongside a qualitative assessment of the breath test's potential to mitigate each gap.

Table 2: Summary of key clinical gaps and qualitative assessment of breath test clinical utility.

Gaps in the Current Pathway	Description	Breath Test Utility
Absence of evidence to support the use of PARP inhibitors in this disease area	A lack of robust clinical trial evidence supporting PARP inhibitor use in OG cancer, resulting in their exclusion from UK treatment pathways.	It could support future evidence generation by identifying biologically relevant subgroups earlier in the pathway, but on its own cannot replace the need for robust clinical trial data.
Limitations in patient selection for immunotherapy	Use of existing cancer markers (HER2 and PD-L1) offers modest survival benefit, underscoring the need for better predictive stratification tools.	It could help refining patient selection and inform decisions on continuation or discontinuation of immunotherapy.
Lack of robust biomarkers to guide treatment decisions	Existing tumour markers (e.g. CEA, CA19-9) were widely regarded as insufficient to guide treatment changes, reinforcing reliance on radiological assessment as the gold standard.	It could offer earlier, non-invasive signals of response or non-response, helping to reduce the information gap during the first treatment cycles.
Lack of early interim monitoring between treatment initiation and first response scan	The absence of interim monitoring between treatment initiation and the first response scan leaves clinicians without objective insight during early treatment, particularly given delayed immunotherapy effects and tumour heterogeneity.	It could complement imaging and existing markers by adding a dynamic, functional signal to support clinical judgement.

(Continued)

Table 2: Continued.

Gaps in the Current Pathway	Description	Breath Test Utility
Unreliable patient reported symptoms	Symptom-based assessment was viewed as unreliable for detecting progression in asymptomatic or low-burden cases.	It could provide an objective counterbalance to subjective symptom reporting, particularly in patients with low-burden or asymptomatic disease.
Challenges in translating early signals into treatment decisions	Earlier detection does not resolve uncertainty about optimal treatment sequencing, given limited systemic options.	It could help flag subtle or silent progression earlier, but its impact would depend on clear evidence about how early signals should change treatment strategy.

The greatest perceived clinical utility of the new test lay early in the treatment pathway: deploying the test at diagnosis or prior to treatment initiation could help identify patients unlikely to benefit from standard therapies, at a point when patients are fitter and tumours less treatment-resistant (O01). The test was also seen as potentially addressing the lack of early interim monitoring, particularly for immunotherapy where responses may be delayed or difficult to interpret. In older or frailer patients, clinicians felt it could support decisions favouring less toxic treatment strategies, prioritising tolerability and quality of life over maximal intensity. At a system level, the test was additionally perceived as having potential to reduce reliance on imaging and associated pressures on radiology services (O02). Overall, clinicians valued additional information that could improve prediction of treatment response or intolerance, given the limited number of effective therapies and the high stakes of treatment selection in OG cancer (O01-O04).

Effectiveness – Vignette Study

Across all four scenarios presented to clinicians in the Vignette Study, clinicians emphasised that decision-making in OG is highly contextual and shaped by uncertainty, patient fitness, and treatment intent, with the breath test viewed as a potential adjunct rather than a replacement for existing assessments:

Scenario A (Early-Stage, Potentially Curative)

Effectiveness: *Enhances decision-making effectiveness in borderline cases by complementing existing clinical assessments without altering established judgment frameworks*

Across Scenarios A and B, clinicians described decision-making as centred on standard staging, MDT discussion, and careful assessment of patient fitness, with neoadjuvant chemotherapy generally favoured in potentially curative cases due to concerns about under-staging. In both scenarios, the breath test was viewed by one clinician (O02) as potentially helpful in grey or borderline cases, where it could add nuance to decisions such as avoiding overtreatment, selecting modified chemotherapy regimens, or tipping management toward direct surgery in frail patients. However, the other

clinician (O04) consistently emphasised that pilot-level evidence would be insufficient to change practice, and that patient presentation, performance status, comorbidities, and surgical suitability would remain the decisive factors regardless of additional biomarker-like information.

Scenario C (Second-Line Treatment, Uncertain Response)

Effectiveness: *Improves real-world treatment decision-making by helping clinicians interpret symptoms alongside imaging and determine whether to continue therapy when quality-of-life trade-offs are finely balanced.*
Clinicians agreed that the breath test would not replace imaging. O02 viewed CT scans as indispensable for identifying both disease progression and treatment-related complications, while O04 highlighted the potential value of the test in supporting nuanced decisions—such as whether to allow more time for treatment to work—when balanced against quality-of-life considerations.

Scenario D (Advanced Disease, Limited Options)

Effectiveness: *Demonstrates effectiveness by supporting patient-centred decisions that reduce unnecessary treatment burden in late-stage care.*

Clinicians recognised its potential role in prompting earlier reassessment or supporting shared decisions to avoid non-beneficial therapy, particularly within a trial or protocol-driven context, while reiterating the need for robust validation.

Acceptability – Patients' Perspective

From the patient perspective, the care pathway is experienced in a more subjective and relational way, shaped by interactions with multidisciplinary teams (MDTs), communication around treatment decisions, and the impact of care on quality of life. Several patients described positive experiences with multidisciplinary teams (MDTs), reporting regular consultations with oncologists, specialist nurses, and surgeons and feeling supported through collaborative decision-making (P03, P05, P06, P07, P09, P10). Others reported more limited or unsatisfactory MDT engagement; one patient expressed significant dissatisfaction with surgical care and self-referred to another Trust to seek better support (P01). While most patients trusted clinicians to make appropriate treatment decisions, some stressed the importance of being actively consulted, particularly when plans changed due to side effects or complications (P06, P11). Others preferred to be kept informed even if not directly involved in decisions (P01, P03, P07, P10). Across the pathway, patients reported substantial physical and psychological burden. Severe treatment-related side effects—including fatigue, nausea, neuropathy, and hospitalisation—were common, with some requiring dose reductions or early discontinuation of chemotherapy due to toxicity (P01, P03, P04, P05, P06, P07, P09, P10, P11). Post-surgical complications such as dumping syndrome, aspiration, dietary restrictions, and prolonged recovery were also reported (P04, P05, P06, P09, P10, P11), alongside significant psychological distress, including anxiety, fear of recurrence, and distress during waiting periods (P01, P03, P06, P07, P09, P10, P11).

Within the reported patient experiences, feedback clearly delineated what was considered acceptable and unacceptable regarding the introduction of the new breath test. Patients were comfortable with the breath test when it was integrated into existing hospital visits, such as chemotherapy sessions or routine blood tests, thereby avoiding additional travel (P01, P04, P05, P07, P09, P11). However, this resulted impractical during periods of treatment-related fatigue (P01, P04, P05, P07, P09, P11). Several patients suggested that community- or home-based testing could further improve accessibility for those with mobility issues or severe fatigue (P05, P09, P11) but one participant (P08, a GP by background) highlighted that primary care delivery was impractical due to limited space, time, and resources. Concerns were also raised about logistical reliability, specifically potential delays in transporting breath samples to laboratories if collected outside hospital environments, which could undermine confidence in the test (P08, P09, P11). They also expressed strong trust in their oncologists to interpret test results and adjust treatment appropriately (P01, P03, P04, P06, P07, P08, P09, P10, P11). Most preferred to be informed of test outcomes, even if they did not wish to be directly involved in decision-making (P01, P03, P06, P07, P09, P10, P11). Clear communication was seen as essential, with several patients emphasising the need for plain-language explanations, ideally delivered verbally and supported by written materials (P01, P03, P06, P07, P08, P09, P11). Managing expectations upfront—particularly around whether and how results would be shared—was highlighted as critical (P01).

Acceptability of the new test is closely linked to patients' trust in their clinicians, the transparency and clarity of communication around test use and results, and sensitivity to the physical and emotional demands of cancer treatment.

DISCUSSION

The results of this pilot study underscore that decision-making in OG cancer is a complex process, heavily reliant on the MDT approach to synthesize varied diagnostic inputs (Soukup, Lamb et al., 2019). The integration of a new therapy prediction tool adds a layer of complexity; clinical evidence suggests that without careful implementation, the addition of novel data can exacerbate "decision fatigue," potentially impairing team performance rather than enhancing it. Consequently, the successful adoption of the breath test depends not only on its analytical performance but on how well it integrates into existing MDT workflows (Soukup, Gandamihardja et al., 2019), which vary across healthcare systems and may influence its impact, particularly in settings where decision-making is led by individual clinicians rather than MDT-based consensus. Only in the advanced palliative scenario (Scenario D) of the vignette study did clinicians express greater confidence in using the breath test to identify patients unlikely to benefit from further treatment, thereby supporting decisions to avoid non-beneficial therapy. This finding highlights a critical need to understand how novel diagnostic evidence can be methodologically integrated with established clinical standards, rather than used in isolation, to inform complex treatment decisions in advanced cancer care.

A major barrier to adoption identified in this pilot relates to clinicians' trust in new technologies and evidence to support their integration. Credibility in a technology's evidence and perceived legitimacy is a primary determinant of clinicians' willingness to adopt new medical devices, particularly in complex, multidisciplinary care settings (Greenhalgh, Robert et al., 2004). Clinicians often exhibit reluctance to alter treatment pathways if the new test result contradicts their clinical gestalt or the patient's physical presentation (Berner and Graber, 2008). This tension is most acute in "grey areas" where the test system indicates a specific biological status (e.g., potentially responsive tumour) that conflicts with the clinical evidence (e.g., a patient appearing physically frail or palliative). Such discrepancies can create decisional confusion, increasing cognitive load and potentially reducing the perceived integrity of the decision-making process. However, rather than viewing these conflicts as failures, these are precisely the scenarios where the test can offer an extra level of information to support decision-making. From the acceptability perspective, patients' accounts highlighted that any new decision-support tool must be understood within the complex and demanding context of OG cancer care, where individuals experience ongoing side effects, frequent clinical appointments, and, at times, changes to treatment plans. Future implementation strategies should prioritise the development of clear, comprehensive guidelines that account for a broad range of patient scenarios and ensure that interpretation of breath test results is consistently aligned with established MDT standards of care. By optimizing the "intrinsic load" of the new information—making it relevant and easy to process—we can ensure that the new guidelines do not overwhelm the clinician's working memory during complex case reviews (Baxter, Sachdeva et al., 2025).

In line with human factors research on human–automation interaction (Parasuraman and Riley, 1997), positioning this new test as a complementary source of objective biological information—rather than a replacement for clinical judgment—may support decision-making in marginal cases, helping clinicians balance risk–benefit considerations and mitigate errors associated with inappropriate reliance on automated outputs.

CONCLUSION

This pilot study demonstrates the value of a qualitative, exploratory human factors approach for understanding the complexity of introducing a novel prediction therapy test in cancer care, extending beyond assessments of clinical utility alone. It demonstrates the importance of distinguishing between two interrelated but conceptually different levels of analysis when evaluating novel decision-support tools in cancer care: technical feasibility and integration, and clinical actionability. By combining oncologists' perspectives on decision-making and actionability with patients' views on real-world acceptability and burden, the study highlights how usability, context, and lived experience shape and de-risk adoption. Together, these insights underscore that innovation in cancer care is driven not only by technical performance, but by alignment with clinical judgement and patient realities.

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