

method can be a sustainable solution is missing. Leveraging the concepts of necessary and sufficient conditions from organizational research, this study provides guidance on resolving challenges and defines stakeholders' roles for successfully implementing this reimbursement approach.

## OD29 From Listening To Lift Off: Developing A Three-Year Public Involvement And Engagement Strategy For NICE

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**Introduction:** Involving patients in the health technology assessment (HTA) lifecycle is a core principle at the National Institute for Health and Care Excellence (NICE). To achieve this, NICE has adopted a mixed approach to patient and public involvement and engagement (PPIE) spanning the entire appraisal process. To ensure the PPIE approach enables meaningful involvement, NICE engaged with stakeholders to review its effectiveness and identify areas for improvement.

**Methods:** In 2023, an independent consultant reviewed NICE's PPIE approach and engaged with NICE staff and external stakeholders from patient organizations, individual patient contributors, and engagement leads at national health and social care organizations. The engagement included interviews with NICE staff (n=19) and external stakeholders (n=13), and an online survey that received 83 responses from patient organizations and patient contributors. Using this feedback, NICE's patient and public involvement program conducted four focus groups to develop a framework of improved methods and processes for PPIE with NICE staff, patient organizations, and patient contributors.

**Results:** The engagement identified many positives in NICE's approach to PPIE, including:

- lay members sitting on each HTA committee as equal members
- patient organizations providing written evidence to HTA committees
- patient experts providing written and verbal testimony to HTA committees
- support provided by NICE.

The engagement also identified areas where PPIE could have a greater impact, including:

- improved methods for collecting patient evidence and insight
- strengthening the role of lay members
- collating and reusing previously collected patient evidence
- taking a proportionate approach to involving small organizations

- allocating staff resources to focus on impactful PPIE practices.

**Conclusions:** NICE has developed a draft framework for an improved approach to increase the impact of PPIE in HTA decision-making. In 2024, NICE will publicly consult with NICE staff and external stakeholders to review the framework, agree the strategic aims, and develop metrics for measuring success. Following this consultation, the findings and NICE's updated approach to PPIE will be presented.

## OD30 Clinician-Driven Health Technology Assessment: National Cancer Medicines Review For Off-Label Uses And On-Label Off-Patent Uses In NHSScotland

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**Introduction:** Publicly funded cancer services face significant financial and capacity challenges. It is estimated that 40 percent of medicines used to treat cancer are outside their marketing authorization or "off-label." These uses are usually outside the remit of health technology assessment (HTA) groups. Accessing emerging off-label uses is mostly through individual patient requests, which are resource intensive, delay patient treatment, and produce inequity.

**Methods:** A program providing national HTA review of off-label and off-patent cancer medicine uses has been established by Healthcare Improvement Scotland. Processes include horizon scanning, support for proposing clinicians, and engaging patient groups. Relevant published and unpublished clinical and cost-effectiveness information—identified through systematic literature searches, engagement with pharmaceutical companies, academic and health service data groups—supports independent appraisal and decision-making. Where cost-effectiveness information is unavailable, a value-judgment framework, including magnitude of clinical benefit, uncaptured benefits, and budget and service impact, is utilized to standardize review. The decision-making Council includes public partners, and advice is shared across NHSScotland.

**Results:** From July 2022 to October 2023, the program has published advice on nine proposals—eight off-label uses and one on-label off-patent use. Health economic models from a pharmaceutical company and an academic group supported decision-making on two proposals, value-judgment frameworks for two proposals, and real-world evidence for one proposal. Eight proposals were supported, and one was not supported. Each supported proposal slowed cancer, prolonged life, or reduced toxicity compared to standard treatment options. Four were cost-saving and three had a low medicines budget

impact. Three were service-saving and three had no significant impact on services.

**Conclusions:** Novel HTA programs can address gaps in medicines governance to improve patient outcomes and support sustainability. Clinical connections, patient group engagement, health economic collaborations and linkage to national cancer data teams and academics have facilitated bespoke approaches to evidence-gathering despite limited resources. Our agile and adaptive approach has enabled robust review and decision-making on varied and impactful proposals.

## OD31 Value-Based Healthcare And Health Technology Assessment: Opportunities For Implementing A Colorectal Cancer Patient-Centered Care System

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**Introduction:** The value-based healthcare (VBHC) concept links dollars spent to outcomes that matter to patients, rather than to the volume of services. A health technology assessment (HTA) was carried out to determine if the VBHC model could be effective to improve care delivery in colorectal cancer at the CHU de Québec-Université Laval.

**Methods:** A systematic review on VBHC models implemented in oncology was conducted in indexed databases and grey literature between January 2000 and January 2022. Semistructured interviews were conducted from various key informants in our hospital (n=19), including three patients, to characterize the colorectal cancer care organization. HTA was conducted with an interdisciplinary group including surgeons, nurses, hospital managers, and patients.

**Results:** Key factors to consider in the implementation of VBHC include organizing care around the same medical condition, measuring outcomes and costs for every patient, and tracking data through information technology platforms. Results from case studies suggest that VBHC may have promising effects on clinical, patient-reported, and process outcomes measures. Several issues regarding the degree of agreement with the VBHC principles have been identified in our facility, including a non-uniform care trajectory, a lack of an integrated interdisciplinary team, and the absence of efficient information technologies.

**Conclusions:** It was recommended that the CHU de Québec-Université Laval initiates an organizational transformation in

colorectal cancer care to implement a VBHC model. An effective care transformation will require a significant culture change with impacts on organization and practices but also with positive spin-offs by creating value and patient-centered care.

## OD32 Single Nucleotide Polymorphism Marker Analysis In Donor-Derived Cell-Free DNA For Solid Organ Transplantation (Next-Generation Sequencing): Systematic Review

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**Introduction:** Single nucleotide polymorphism marker analysis in donor-derived cell-free (dd-cf) DNA for solid organ transplantation is a technique for post-transplantation monitoring, including early detection of injury to the transplanted organ, signs of infection, and treatment decision-making, by measuring dd-cf-DNAs as a percentage of the total cf-DNAs in the patient's body in donors and recipients of kidney, heart, lung, or liver transplants.

**Methods:** The assessments were performed via a systematic review. Searching five databases (KoreaMed, Ovid MEDLINE, Ovid Embase, and Cochrane) yielded 1,619 related studies. Two reviewers independently assessed the quality of these studies using a Scottish Intercollegiate Guidelines Network checklist, and the assessment results were described based on the results of the quality appraisal and level of evidence.

**Results:** The population of the included studies was patients who underwent kidney, heart, lung, or liver transplantation. Medical outcomes in kidney transplantation patients were reported in 15 studies. The index test was reported to have an area under curve (AUC) of 0.68 to 0.99 and a sensitivity of 0.24 to 1.00. Four studies reported effectiveness data for the index test for lung transplantation patients. The diagnostic accuracy of the index test for acute cell-mediated rejection was reported have an AUC of 0.72. Sensitivity was reported as 0.44 and specificity as 0.80 for heart transplant patients, and sensitivity as 0.73 to 1.00 and specificity as 0.60 to 0.95 for liver transplant patients.

**Conclusions:** This is a safe and effective technique for post-transplantation monitoring, including the early detection of injury to the transplanted organ and signs of infection, and for treatment decision-making, by measuring dd-cf-DNA as a percentage of total cf-DNA in the patient's body in recipients and donors of kidney, heart, lung, or liver transplantation (level of evidence: C).