Appendix 1: Approaches to evaluating value propositions in provider organizations

Hospital-Based HTA

AdhopHTA has developed a toolkit[1] and handbook[2] to guide HB-HTA professionals in establishing HB-HTA programs and producing technology evaluation reports that meet the information needs of hospital decision makers. The domains of information typically included in a hospital-based technology assessment are: (1) the health problem and current use of the technology, (2) clinical effectiveness, (3) safety, (4) cost and economic evaluation, (5) organizational aspects, (6) political aspects, and (7) strategic aspects, all assessed from a hospital-specific perspective.[3] Consistent with the adaptation from formal HTA processes, guiding principles for good practices in HB-HTA[4] emphasize the need for use of systematic, unbiased, transparent methods and high-quality evidence in producing assessment reports. Other principles include the need to involve all relevant stakeholders in the process, clearly communicate results to hospital decision makers, and measure the impact of recommendations, given that the assessment process is often separated from the final decision process. But, increasingly, HB-HTA professionals are moving toward involvement in the full process, offering decision support programs that can be used to guide the evaluation of individual technologies, prioritize competing technologies, or identify currently used technologies for disinvestment.[5-7] While currently limited in the US, HB-HTA programs offer hospital administrators tools to maximize the value of investments and improve evidence-informed decision making, with the potential for economic benefits.[8]

Value Analysis

Many hospitals in the US use value analysis methods to inform technology adoption decisions, improving on traditional procurement processes. With procurement, evaluation criteria are typically limited to the technical characteristics or clinical specifications of new technologies, the capabilities of vendors, and costs (with varying and incomplete definitions of included costs). Use of such narrowly defined evaluation criteria can hinder decision makers' ability to identify potential clinical and economic benefits, especially when innovative technologies are being considered. This is compounded by reliance on manufacturer-provided evidence which can introduce bias into the adoption decision. In decisions to introduce new technologies, value analysis methods instead seek to achieve improvements in patient outcomes along with cost reductions, informed by context-relevant data and clinical evidence. Importantly, value analysis methodologies are evolving toward use of systematic processes and high-quality evidence[9] to inform a range of decisions: introduction of new technologies or services, practice changes, utilization management, and standardization of products to reduce variability and improve the quality of care.[10] Value analysis is a 5-step process that starts with identifying opportunities to achieve value within the organization, followed by gathering of relevant information, analyzing the information to make a decision recommendation, implementing the decision, and monitoring outcomes and impact on the organization.[11] A key element of value analysis is use of multidisciplinary committees to capture the perspectives of all who will be affected by value-based decisions. Value analysis committees (VACs) also enable assessment of system-wide impacts and facilitate communication and transparency in processes, minimizing bias and conflicts of interest. Engaging physicians and nurses in VAC functions has the potential to greatly improve the value analysis process given their professional commitment to improving

patient outcomes.[12] Clinicians can encourage a long-term assessment of value across the full care pathway and play critical roles in obtaining and interpreting key evidence to support the value of new technologies.

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Appendix 2: Tools and resources to assist test developers with creating value propositions

A recent framework[1] defines the value of laboratory diagnostics across three dimensions: (1) optimization of operational efficiencies, (2) optimization of patient management, and (3) influence on patient behavior and other effects. AdvaMedDx suggests identification of value drivers within four categories (clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and public and population impact) to define the full spectrum of value of a diagnostic test relative to its specific context of use.[2]

For groups making recommendations about appropriate use of healthcare-related tests and diagnostic test strategies within defined care pathways, the DU-diagnosis expert group recommends consideration of several essential factors to expand beyond sole reliance on test accuracy, which is often insufficient for making inferences about impact on patient outcomes, a critical element of defining value.[3] These additional factors relate to clinical decision making, overall benefits and harms, values and preferences of various stakeholders, resource implications, quality of evidence, ethical and legal considerations, as well as feasibility, applicability, and organizational considerations.

Resources exist to guide developers on generating the evidence required to show value for policy-level assessments, such as the NICE Medtech Early Technical Assessment (META) Tool[83] and the EXCITE International program[84] While these resources currently support developers only in specific countries, they can serve as examples of the types of guidance that can help with the creation of value propositions. This type of assistance is especially important in the field of POC testing, given the typical focus of manufacturers on test accuracy and clinical

performance as required evidence, with other stakeholders seeking evidence of the link between test use and outcomes and looking to industry to provide it.

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Appendix 3. Tools to assist with implementation planning

The Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework can help organizations predict and evaluate the success of technology implementations by assessing and reducing complexity across seven domains.[1] While the NASSS framework is not specific to POC testing, the developers studied its applicability to telehealth and remote patient monitoring programs, which share similar characteristics to POC testing programs. A supporting tool is available to assist users in applying the framework.[2]

The AMA Digital Health Implementation Playbook[3] offers best practices for implementing a remote patient monitoring program. This type of guide could provide much-needed assistance to resource-constrained organizations considering implementing POC testing programs.

A recent review offers a framework that primary care practices can use to identify and overcome issues related to implementing complex interventions or programs (such as a new technology evaluation decision process).[4] The framework provides recommendations to help practices understand four types of contextual factors: (1) characteristics of the intervention, (2) characteristics of the professionals involved, (3) organizational features, and (4) details of the external context, with the fit between the intervention and the context playing a likely role in successful implementation.

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