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Value of Diagnostic Information in Value-Based Healthcare in MEA

White Paper by

mecomed

1. INTRODUCTION

In Vitro Diagnostics (IVD) provide vital information to aid clinical decisions from screening, diagnosis, treatment, prognosis, and monitoring. They are key to ensuring the right treatment is delivered to patients within critical timeframes.

Healthcare decision-making is accelerating and professionals are expected to do more with timely information. Rapid delivery of accurate lab tests, with consistent reliability and quality are vital to delivering improved patient outcomes. IVDs create value for clinicians, healthcare executives, and patients. To this end, the Value of Diagnostic Information (VODI) maximizes the utility of IVDs in efficient healthcare systems.

Most countries in the Middle East and Africa provide public healthcare programs, complemented by private healthcare insurance. Public funding is commonly strained by limited budgets, health emergencies such as SARS-CoV2-, and constantly increasing demand. Obtaining real value from IVDs are therefore vital for sustaining our healthcare systems. The Value of Diagnostic Information (VODI) includes four categories of value (Figure 1) and goes beyond conventional cost containment approaches:

Clinical Impact | **Non- Clinical Impact** | **Care Delivery Revenue & Cost-Impact** | **Public / population Impact**

Figure.1 – Value Driven Access Model.[1]

Middle Eastern healthcare procurement is vulnerable to oil price fluctuations and possible collapse, and healthcare emergencies such as SARS-CoV2-. This paper, explores how IVDs create value for patients, health systems, and society through the four categories of a value-driven access model. It also demonstrates how healthcare systems rely on VODI to make related policy recommendations. This paper highlights how medical diagnostics are used in a wide range of clinical applications, and how diagnostics has been undervalued by traditional Health Technology Assessment methods.
VODI- Value Drivers[1]
Diagnostic tests and technologies impact on both quality and cost of patient care processes.

Clinical Impact:

The extent of clinical utility and health outcomes associated with the test information

Diagnostics/imaging is the foundation of 70% of clinical decisions. It is central to screening, diagnosis, prognosis, and monitoring of treatment response.

Vital components that realize a favorable patient health outcome include:

- Screening: Predicts populations at higher risk of certain diseases, leading to early treatment and reduction in disease burden. Identifies patients who do not require intensive monitoring, and avoids unnecessary expense of inappropriate, frequent testing.
- Diagnosis: Early and accurate diagnosis guides healthcare professionals to select appropriate patient management and to avoid unnecessary procedures.
- Prognosis: Prognostic markers help healthcare decision-makers to understand disease progression and to select the best care-choice.
- Monitoring: - Measuring patients' response to treatment is critical for a favorable clinical outcome. Patients respond in different ways to the same medication. Determining the efficacy of treatment will help healthcare professionals intervene earlier to ensure the best outcome for the patient.
- Quality control to ensure that both precision & accuracy of sample results

Non-clinical Patient Impact:

The impact of non-clinical benefits for the patient (or caregiver), patient experience and patient economics (e.g. out-of-pocket costs).

- Location and ease of testing is important for patient experience and for adherence to treatment. [2]
- Any out-of-pocket (OOP) expenses should be minimal, the costs of tests should reflect their usefulness to both the clinician and the patient. [3]

Care Delivery Revenue and Cost Impact:

The impact of testing / solution on revenue and costs via bonuses or penalties associated with care quality metrics, impact on the care pathway, and other sources of operating efficiencies to payers, providers, or other risk bearing entities

- Early detection allows early treatment and reduces complications.
- Early diagnosis reduces Hospital Length of Stay (LOS).
- Monitoring limits wastage on ineffective medications [3], optimizes effective treatments and uncovers costly and detrimental treatment delivery failures. [4]

Public/Population Impact:

The impact of testing/solution to the health care system at-large, employers, or society as a whole

- Population Health: Delivering systematic and cost-effective services that improve society's health outcomes.
- Productivity: Proactive screening and timely diagnostics can increase employee and caregiver productivity. [5]

VODI IMPACT ON LOCAL HEALTHCARE SYSTEMS - CASE EXAMPLES

Heart Failure (HF):

Affects approximately 26 million people worldwide [6]. Middle Eastern HF patients are young and are more likely to be male, and poses a huge economic burden which, with a concurrently aging population will continue to rise [7]. **Cardiac biomarkers** can be a powerful weapon for combating HF. Example of cardiac biomarkers are NT-proBNP (N-terminal pro hormone BNP), BNP (brain natriuretic peptide) and to some extent, troponins are also used in heart failure.

Clinical Impact	Non-Clinical Impact	Care Delivery Revenue & Cost Impact	Public/Population Impact
• Reduces the risk of missed HF diagnosis. [8] • Strongest predictor of cardiovascular events in patients with Type-2-Diabetes. [9] • Can reduce need for echocardiogram by up to 45% [10] • Can predict emergencies such as cardiac decompensation and allows simple tracking of disease. [11]	• Predicts LOS, aids planning for efficient discharge and reduces admission time. [12] • Robust solution to exclude HF in individuals presenting to the Emergency Department (ED) [8] and can be deployed as rapid Point Of Care Testing (POCT) aiding timely decision making.	• Can reduce cost/need of specialist care (monitoring and expensive, operator-needed techniques). [13] • Can reduce LOS costs and readmission, staffing time, clinical examination and imaging. [14] • Allows long-term care move to primary care, with cost and quality of life advantages. [12] • Enhances triage in complex cases. [10]	• Predicts short-and long-term mortality and readmission rates. [15] • Help patients adapt their lifestyle and retain control. • Allows for resource planning to meet HF societal challenges. [6]

Infectious Diseases and Sepsis:

Require rapid diagnosis and intervention. Sepsis affects all age groups and ethnicities. Sepsis accounts for 5.3 million deaths annually worldwide [16]. **Antimicrobial Resistance (AMR)** causes 670,000 infections and 33,000 deaths per annum in Europe alone. [17] Approximately 700,000 people worldwide die from infections that no drugs can treat. [18]

Clinical Impact [19-29]	Non-clinical Impact [19-29]	Care Delivery Impact & Revenue [19-29]	Public/Population Impact [19-29]
• Reduced laboratory turnaround time & time to diagnosis and appropriate therapy. • Comprehensive diagnostic yield. • Shortened triage and LOS. • Better utilization of isolation resources. • Procalcitonin (PCT) gives vital early diagnosis of sepsis with a 6% reduction in mortality. • 85% reduction in Antibiotic related adverse effects.	• Improved workflow and optimal lab staff assignment. • Full information availability. • Reduced inappropriate antibiotics usage, meeting AMR reduction targets. [17]	• Reduction in ancillary testing. • Time spent by physicians / nurses. • 42% reduction in ICU LOS, 28% reduction in overall LOS. • 9% reduction in overall treatment cost. • 72% reduction in Antibiotic use in primary care.	• Sick leave/ productivity losses. • Epidemiological mapping of pathogens, pandemic prediction. • PCT-guided therapy gave: - 21% reduced Antibiotic use. - 43% reduced Antibiotics cost. - Use of second-line Antibiotics reduced.

Personalized Healthcare and Companion (PHC) Diagnostics:

Medical decisions are tailored to the individual patient based on their susceptibility to disease or response to a particular treatment. It includes assessment of genetic information to identify targeted treatment options. There is no 'one-size-fits-all' treatment for many diseases, including cancer. Diagnostic tests help tailor disease prevention, diagnosis, and treatment based on the genetic makeup of individual patients. [30]

Clinical Impact [19-29]	Non-clinical Impact [19-29]	Care Delivery Impact & Revenue	Public/Population Impact
• Improves risk-benefit ratio in guided treatment [31] • Predictive assays enhance oncologists' ability to create targeted and personalized therapies for patients.	• Up to 80% of patients respond to targeted, personalized therapies. [32]	• A c.49% decrease in overall treatment cost aligning treatments with immune checkpoints inhibitor testing. [33]	• Reduced costs & improved outcomes. [32] • Saving of €38.9m for a national healthcare budget from aligning treatment with PD-L1 cancer biomarker testing. [34]

Coronary Artery Disease (CAD):

Is the most common cause of death in developed countries, for which platelet inhibition remains the focus of medical therapy. The evaluation of the effectiveness of antiplatelet medication and forecast of future cardiovascular complications are essential for many patients. Immature platelets are more reactive compared to mature platelets and have a higher prothrombotic potential. [35-38] Studies show that they play an important role in the risk assessment and therapy monitoring of coronary artery diseases. The IPF# (immature platelet count) parameter delivers insight to address these issues.

Clinical Impact [19-29]	Non-clinical Impact [19-29]	Care Delivery Impact & Revenue	Public/Population Impact
• IPF# is a biomarker of residual platelet reactivity and predictor of the efficacy of antiplatelet therapy. • An increased level of immature platelets indicates insufficient platelet inhibition in response to aspirin, clopidogrel and prasugrel treatment, but not to ticagrelor. [38-44]	• Rational selection and dosage of antiplatelet drug leading to reduced patient burden and decreased overall cost. • A readily available diagnostic parameter from routine laboratory test, which can be processed during the complete blood count.	• Reduced cost in terms of overall healthcare budget for the payer.	• Cost Effective treatment. • Lower sick leave and productivity losses. • Better general health and reduced financial burden with CAD treatment.

CONCLUSIONS AND RECOMMENDATIONS FOR VARIOUS STAKEHOLDER GROUPS

IVDs play a critical role in driving clinical decision-making. Their appropriate use is integral to high quality healthcare including informing earlier, more targeted healthcare interventions and averting healthcare outcomes and unnecessary costs. The Value of Diagnostic Information (VODI) influences up to 70% of healthcare decisions by clinicians in all settings of the healthcare system. This paper emphasized that VODI impacts different aspects of clinical and economic outcomes of healthcare; and thus measuring the value of those decisions made by healthcare professionals needs to be cited and analyzed accordingly [45].

In contemporary economic terms, value aims to maximize patient outcomes through strategic investments in healthcare by spending wisely on interventions with measurable economic benefits for patients and society. New ways of thinking about financing and investment models are therefore essential to achieve value and protecting sustainable universal health coverage.

How Can Patients Benefit From VODI & VBHC?

- Rapid, appropriate clinical response
- Elimination of unnecessary and ineffective testing
- Empowered patients who understand their medical situation/status
- Routine inclusion of the patient's perspective and feedback on healthcare interventions would lead to improved service delivery.

How Can Each Stakeholder Contribute to Making Value-based Healthcare a Reality?

Policy Makers – Enabling Value Based Models:

- Look to, and shape, the future of healthcare delivery and how it functions in tomorrow's society.
- Break down barriers between purchasing departments and put in place processes that work beyond simple order fulfillment, considering providers' future planning interest.
- Foster data sharing to create regional value-based healthcare models.
- Value-Based Procurement that include the full investment lifecycles of products and services.
- Ensure that any investment in healthcare technology is futureproofed.
- Seek out evidence for value-based healthcare decisions.

Providers – Executing Policy:

- Collaborate with different stakeholders to serve patient needs better.
- Create innovative Win-Win Value-Based agreements with the MedTech Industry.
- Measure/ benchmark/ communicate and optimize outcomes to benefit, educate and better inform other relevant stakeholders.
- Remove barriers to change within organizations through education and dissemination of value-based presentations and proposals based on referenced evidence.

Payers and Procurers – Rewarding Value:

- Engage with value-based models and review current approaches to favour longer-term investment cycles and true societal value.
- Pay for performance as opposed to pay for services.
- Reward providers, who actively engage by measuring and communicating clinical outcome KPIs.
- View DRGs, where applicable, not as "simple cases" but as an opening to deliver the most cost-effective solutions.

MedTech Industry – Innovation and Performance-driven Risk Sharing:

- Provide value-based innovative solutions rather than "selling products".
- Engage in innovative partnerships with providers to bring valuable products to the market quicker, and to share change-risk.
- Sharing expertise and knowledge on value-based healthcare models in other regions and their relevance for MEA.
- Actively support education of all stakeholder groups on Value of Diagnostics Information
- Participate in the evaluation of outcome measurement via clinical trials and localized real-world evidence to create cost-benefit analyses relevant to specific markets.
- Collaborate with providers to offer solutions that complement the organization's operations and culture.

Mecomed and its members actively support progressive health systems that seek to set models and standards for patient outcomes measurement and establish partnerships in value-based healthcare programs. Mecomed commits to continue being a supportive and valued partner in implementing value-based healthcare to enable stakeholders and healthcare providers in building strong foundation for sustainable, innovative and cost-effective care to patients in the Middle East and Africa region.

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