

1 IMPROVING ACCESS TO INNOVATION FROM INTERNATIONAL HEALTH
2 TECHNOLOGY ASSESSMENT

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11 The field of healthcare has evolved from an emphasis on evidence-based medicine,
12 with a focus on efficacy, safety and tolerability, to the pursuit of evidence-based
13 efficiency and sustainable innovation in many respects (healthcare budgets, carbon
14 print....). This evolution can be attributed, in part, to the contributions of Health
15 Technology Assessment (HTA) bodies, which have facilitated the incorporation of
16 various factors into the decision-making process¹. These factors include
17 comparative effectiveness, quality of life, efficiency, budgetary impact and
18 organizational impact, among others. Within the domain of healthcare, irrespective
19 of the perspective of each entity (e.g. Food and Drug Administration, European
20 Medicines Agency, etc.), there is an imperative for the presence of evidence and its
21 assessment in the most transparent manner possible, with the objective of ensuring
22 the incorporation of healthcare technologies.

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23 This has led to the conclusion that in order to promote innovation in health, as a tool
24 to improve health systems and population's well-being, it is necessary to encourage
25 early dialogue between the different stakeholders in the sector in the effort to
26 optimize, accelerate and maximize the benefit of health technologies. Ensuring
27 access to the most effective health technologies for the appropriate patients in the
28 most efficient manner for the health system, while taking into consideration the
29 technical and operational capacity of the health system, is also fundamental.

30 The HTA Group² has highlighted the need to establish a common framework
31 defining what early HTA is, as a first step to provide a common anchor for
32 researchers and developers to optimize their resources and being of benefit to
33 society at large. Unlike other assessments, this is a process rather than a final
34 milestone. We have to take into account that there are several phases of pre-
35 concept, prototyping, clinical development and pharmaco-economic evidence
36 before the technology is on the market, leading to the first version with minimum
37 value (minimum viable technology), which can be improved by incremental
38 innovation once it is on the market. For this reason, whether for the need to improve
39 development, evidence or to obtain funding (angel investors, venture capital,
40 investment funds, etc.), early HTA is a process that should help researchers shape
41 their value proposition for society. It is not about generating value in a spurious way,
42 as we are seeing in some cases with AI and other technologies³, which are
43 sometimes based more on magnifying the benefit from an advertising arguments
44 than on duly justified necessity, but to ensure that, in the development of health
45 technologies, clinical and non-clinical aspects have been evaluated with the highest
46 possible degree of evidence, to avoid surprises in HTA evaluations or, in the case
47 of Europe, in the Joint Clinical Assessment (JCA)⁴.

48 Value assessment from an HTA point of view is under constant review. Long after
49 the first definitions of HTA assessment and the publication of Drummon's book on
50 Economic Evaluation of Health Care Programmes^{5,6}, different definitions of value
51 have appeared at the macro level, such as the one proposed by Michale Potter⁷, to
52 the present day, where International Society For Pharmacoeconomics And Outcome
53 Research (ISPOR) has proposed a flower of value⁸ with petals that are even linked
54 to value of hope, and other variants that try to emphasize the social perspective^{9,10}.
55 They are all aimed at the provision of health services and the uptake of health
56 technologies, but they do not have such a clear focus on development through risk
57 mitigation and optimizing market access as early HTA. To bridge this gap between
58 the development process and final evaluation, many organizations have promoted
59 initiatives or programs to assist researchers. In this regard, the FDA has the
60 Breakthrough Therapy Designation and Breakthrough Device Program, a program
61 that helps identify unmet needs by guiding development pathways, National Institute
62 for Health and Care Excellence (NICE) has the Early Dialogue within its Scientific
63 Advice Program, which includes the generation of evidence aligned with the
64 requirements of HTA. Others have addressed the importance of improving
65 integration and cooperation between three key processes in healthcare: regulation,
66 HTA and the development of clinical guidelines¹¹. Although these processes are
67 independent, they share a common evidence base, and their alignment can be of
68 great help to developers.

69 One of the keys to early HTA, and this is emphasized in the manuscript², is that this
70 process attempts to identify the essential elements where the evidence needs to be
71 improved and to identify the key parameters that will be amenable to final decision
72 making. Although the economic evaluation at this stage is not based on evidence

73 but on potential scenarios, it is a very useful exercise for the developer that allows
74 him/her to focus on the development of his/her product. In the end, all aspects of
75 early HTA, whether clinical, economic or other aspects linked to unmet needs
76 among others, will help developers to understand the value of their product not only
77 for themselves, but also for society and potential investors; key to providing value
78 for money and rapid access to patients.

79 Within early HTA, health technology must be evaluated in each of the MIRE
80 (Magnitude, budget Impact, Relevance and Efficiency) attributes to successfully
81 demonstrate value.

82 **Magnitude:** The target therapeutic market is a critical consideration in the
83 early stages of health technology development. It involves assessing the
84 current and potential market, in line with potential competitors and unmet
85 needs.

86 **Budget Impact:** Financial modeling is a valuable instrument in the initial
87 stages of health therapy development, as it enables companies to simulate
88 the potential market and the impact of the health technology on the market.
89 Additionally, it facilitates the identification of the return on investment.

90 **Relevance:** Understanding the burden of disease is essential as it allows
91 developers not only to assess the impact of the disease on patients and
92 society, but also the clinical impact that the new technology may have.

93 **Efficiency:** The cost-effectiveness of a new technology is a critical
94 consideration in its development, as it facilitates the identification of the
95 potential market price and key parameters.

96 Although terminology has been subject to debate as exemplified by the difficulty of
97 reaching consensus on a shared definition, its use is very useful. Employment may
98 serve to heighten awareness among developers and to further cultivate
99 collaboration between institutions, as well as public-private collaboration. Moreover,
100 the term's usage in publications will facilitate the identification of use cases that may
101 align with developers' needs.

102 There is a need to bring together the efforts of all those involved because, in
103 addition to improving the health of society, investment in health technologies can
104 generate improvements in economic growth, can even generate long-term savings
105 and can be a focus for improving the equity of our healthcare systems. Given the
106 different incentives available to investors, we must all be able to promote
107 investment in health technologies because of their great added value. It is essential
108 to acknowledge that investment in health technologies is not merely a financial
109 expenditure; rather, it constitutes a strategic allocation of resources with the
110 potential to generate substantial returns across diverse societal sectors and to
111 make the system more robust/resilient to unforeseen events because it streamlines
112 according to relevance and generates a clear and traceable path. A healthier society
113 is a more equitable and wealthier society.

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