## VALUE INITIATIVE

## **IVI MDD-Value Model**

## **Glossary of Terms**

Terms	Definition
Average cost- effectiveness ratio (ACER)	The ratio of the average cost divided by the average effectiveness of an intervention without reference to a comparator.
Cohort models	"Cohort models consider and characterize the 'average' patient experience from a population that shares the same characteristics. <sup>i</sup> Decision tree and Markov models are the two most common cohort models." <sup>ii</sup>
Cost-utility analysis (CUA)	"Cost-utility analysis (CUA) is a variant of cost effectiveness analysis where the health outcome measure of interest is usually expressed as a quality- adjusted life year, a single index that combines length of life and a quality adjustment for less than perfect health (i.e., the utility score)." <sup>iii</sup>
Comparative effectiveness research (CER)	"The generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, or monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels." <sup>iv</sup>
Comparator	The treatment or treatment pathway used as a reference in the analysis, often the current standard of care.
Cost-effectiveness analysis	A method to compare the costs and benefits of one or more interventions. It is usually expressed as incremental cost divided by incremental effectiveness, typically assessed relative to a comparator, such as the current standard of care.
Continuous-time models	Models in which events may occur at any point in time, as compared with discrete-time models (also called cycle-based models) in which events occur at discrete time points. Continuous-time models allow for more granularity and may be more accurate in some cases.
Decision analysis	A formal, quantitative approach to comparing options based on assessing the probabilities of various factors and calculating expected outcomes.

Sensitivity analysis	Sensitivity analysis is a technique used in economic evaluation or decision analysis to determine to what extent plausible changes in uncertain clinical or cost variables affect the main results of the analysis. Sensitivity analysis can be used to examine uncertainty in the cost-effectiveness of interventions through a series of one-way (where only one parameter is varied) or multiway (where multiple parameters are varied simultaneously) analyses.
Discounting	"Economic discounting is the process of converting costs or benefits to be incurred or received at different points in the future to a present value so that they can be compared in commensurate units as if they all occurred at the same point in time. Discounting is used in economic evaluations to adjust for social or individual preferences for the timing of costs and outcomes." <sup>v</sup>
Discount rate	A percentage reduction that is applied over time to costs and health outcomes that are predicted to occur in the future to account for people's preference to have benefits now rather than at some future time.
Economic impacts	<ul> <li>Estimated total costs incurred because of a disease or condition, including:</li> <li>Costs of direct medical expenses for the condition</li> <li>Non-clinical healthcare costs</li> <li>Societal impacts</li> <li>Caregiver costs</li> <li>Ability to work</li> <li>Education and job impacts</li> </ul> Underlying health equity factors, the patient's health journey, and demographic factors all influence the experience and extent of economic impacts. <sup>vi</sup>
Effectiveness	The beneficial effects that are produced by a given treatment or therapy in actual practice.
Efficacy	The ability of a given treatment or therapy to generate a desired, beneficial result in ideal circumstances (e.g., in a clinical trial).
Health economic modeling	"Analytic approaches used in health economic assessments to synthesize clinical, epidemiological, and economic evidence from different data sources into an evaluation framework that enable researchers or decision makers to generate estimates for specific outcomes of interest. Models are usually a simplified representation of the real world to inform decision-making by characterizing uncertainty in projecting outcomes." <sup>vii</sup>
Health technology assessment (HTA)	A multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. A health technology is the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of lives for individuals affected. <sup>viii</sup>

Heterogeneity	Heterogeneity usually refers to differences in participants' characteristics in a study (e.g., clinical trial or economic evaluation.). <sup>ix</sup> In the IVI-MDD Value Model, we use this to refer to differences in specific characteristics within the modeled population.
Incremental cost- effectiveness ratio (ICER)	"An incremental cost-effectiveness ratio is a statistic used to summarize the cost-effectiveness of an intervention compared with an alternative (comparator). An ICER is calculated by dividing the difference in total costs between the intervention and comparator (incremental cost) by the difference in the chosen measure of health outcome or effect (incremental effect)."x
Individual-patient simulation model	"A patient-level simulation is a type of model in which outcomes are estimated for modelled patients one at a time. In this model, the determination of outcomes is usually based on random (stochastic) selection of patients: a large number of patients are required to be simulated in order to estimate the mean outcomes (and their distribution) for the population considered in the analysis. Benefit of this type of model over cohort models is that it allows individual patient histories to be recorded, and the model can capture (first order) heterogeneity in the patient population." <sup>xi</sup>
Input	A piece of information or data that is used within an economic model or framework.
Major Depressive Disorder (MDD)	Major depressive disorder (MDD) is a mood disorder that is characterized by a person experiencing persistently low or depressed mood or decreased interest in pleasurable activities, feelings of guilt or worthlessness, lack of energy, poor concentration, appetite changes, psychomotor retardation or agitation, sleep disturbances, or suicidal thoughts. <sup>xii</sup>
Markov model	"A model in which patients with a specific clinical problem can exist in a finite set of health states (e.g., with no symptoms, with symptoms leading to reduction in health-related quality of life, or dead) between which they can move over time. Movement between these health states occurs over a discrete time interval, for example yearly (known as a Markov cycle) based on pre-set transition probabilities. By attaching resource costs and health outcome consequences to each Markov state (which may vary based on use of an intervention), it is possible to test how such an intervention might influence outcomes and resource use (on average) for a group of patients with a clinical problem." <sup>xiii</sup>
Microsimulation	"Microsimulation models usually consider the individual patient characteristics and variability between patients as individuals are moved through the model one at a time. The accumulated patient history can then be used to determine transitions, costs, and health related quality of life."xiv

Net monetary benefit (NMB)	"A summary statistic that represents the value of a treatment in monetary terms, with a dollar value applied to all costs and benefits. To calculate, the net benefit from an intervention is multiplied by the willingness to pay for that benefit (e.g., \$150,000 per QALY) and total costs are subtracted to calculate net monetary benefit, with the value of benefits exceeding costs when positive, and vice versa."
Multi-criteria distributional analysis (MCDA)	A structured deliberative approach used to evaluate different treatment options based on multiple, and sometimes conflicting, criteria and priorities to identify the preferred option in decision-making (e.g., selecting the best treatment by weighing time to relief, duration of relief, and out-of-pocket cost).
Open-source model	Model software for which the original source code is made freely available and may be redistributed and modified.
Opportunity cost	Opportunity cost, a concept central to economics and health economics, rests on two principles, scarcity of resources and choice. Due to the scarcity of resources, society must make choices about what health programs to fund and which ones to forgo. The benefits of the next best alternative health program(s) that is/are forgone because the funds are not spent on that program constitute the opportunity cost. <sup>xv</sup>
Patient-centered	Health technology assessment that reflects the diversity of patient
value assessment	preferences and circumstances, includes patients as equal partners throughout the development process, incorporates methods to address health equity, and reflects real-world patient and caregiver experiences.
Patient-centered outcomes	"Any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."xvi
Patient inputs	A wide range of information and perspectives from patients including but not limited to informal comments; patient opinions expressed publicly, including through social media; patient responses to qualitative surveys; and quantitative measurements of patient-reported outcomes.
Patient perspectives	A specific type of patient input describing patients' lived experiences with a disease or condition and its management.
Patient preferences	"Qualitative or quantitative assessment of the relative desirability or acceptability to patients of specified alternatives or choices among outcomes or other attributes that differ among alternative health interventions."xvii
Perspective	"Perspective is a key point to consider in planning an economic evaluation. It is the viewpoint (patient, health system or society) from which the study should be conducted, that is, which costs and effects should be included in the analysis. From the perspective of the health service/health care provider,

	patient-related costs such as time off work due to illness are not included, but from the societal perspective, all costs and benefits are considered regardless of whom they fall on. The societal perspective is thus broader as all important costs are included."xviii
Real-world data	<ul> <li>Real-world <i>data</i> are data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can include:</li> <li>Electronic health records (EHRs)</li> <li>Claims and billing activities</li> <li>Product and disease registries</li> <li>Patient-generated data including in home-use settings</li> <li>Data gathered from other sources that can inform on health status, such as mobile devices<sup>xix</sup></li> </ul>
Real-world evidence	"Real-world <i>evidence</i> is clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD. RWE can be generated by different study designs or analyses, including but not limited to randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective)."xx
Socioeconomic status (SES)	"Socioeconomic status is the position of an individual or group on the socioeconomic scale, which is determined by a combination of social and economic factors such as income, amount and kind of education, type and prestige of occupation, place of residence, and—in some societies or parts of society—ethnic origin or religious background."xxi
Subgroup analysis	"Subgroup analyses are additional analyses that are ideally pre-planned that are conducted in addition to the main analysis of a primary or model-based study to investigate whether the effect of the intervention differs by particular groups of patients. For example, whether treatment is more or less effective in women or treatment effectiveness is better or worse among older people." <sup>xxii</sup>
Time toxicity	"Time spent in coordinating care, visits to a health care facility (including travel and wait times), seeking urgent/emergent care for side effects, hospitalization, and follow-up tests."xxiii
Value element	Refers to specific aspects or components that stakeholders may consider to be part of an overall assessment of value (e.g., different mode of administration, reduced risk, lower cost).
Value assessment (VA)	Comparison of the relative benefits and costs of a given technology or service for a specific person or population (see health technology assessment).
Willingness to pay	Amount that a decision maker is willing to pay for an additional benefit (e.g., hospitalization avoided, QALY gained).

<sup>v</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf <sup>vi</sup> Malik E, Bright J, Ridley E, Cope E, Edmunds M (2023). A Research Framework to Understand the Full Range of Economic Impacts on Patients and Caregivers. Alexandria, VA. Innovation and Value Initiative and AcademyHealth. <sup>vii</sup> Glossary – Health Economics [online]. (2016). York; York Health Economics Consortium; 2016. https://yhec.co.uk/glossary/

<sup>viii</sup> O'Rourke, Brian, Wija Oortwijn, and Tara Schuller. "Announcing the New Definition of Health Technology Assessment." Value in Health 23.6 (2020): 824-825.

<sup>ix</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf <sup>x</sup> https://yhec.co.uk/glossary/incremental-cost-effectiveness-ratio-icer/

<sup>xi</sup> Patient-Level Simulation Model [online]. (2016). York; York Health Economics Consortium; 2016. <u>https://yhec.co.uk/glossary/patient-level-simulation-model/</u>

<sup>xii</sup> Bains N, Abdijadid S. Major Depressive Disorder. [Updated 2023 Apr 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559078/

xiii Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf x<sup>iv</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf <sup>xv</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal

<sup>&</sup>lt;sup>i</sup> Briggs, A., Sculpher, M. & Claxton, K. 2006. Decision modelling for health economic evaluation, OUP Oxford. <sup>ii</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf <sup>iii</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf <sup>iv</sup> Sox HC. Defining comparative effectiveness research: the importance of getting it right. Med Care. 2010 Jun;48(6 Suppl):S7-8. doi: 10.1097/MLR.0b013e3181da3709. PMID: 20473202.

Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf <sup>xvi</sup> National Quality Forum

<sup>xvii</sup> ISPOR-FDA Summit 2020: Using Patient-Preference Information in Medical Device Regulatory Decisions: Benefit-Risk and Beyond [Internet]. Available from: https://www.ispor.org/conferences-education/conferences/pastconferences/ispor-fda-summit-2020

<sup>xviii</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf xix https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

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<sup>xxi</sup> American Psychological Association. <u>https://www.apa.org/topics/socioeconomic-status</u>

<sup>xxii</sup> Adapted from Chapter 12 of the book Evidence Based Health Economics: From Effectiveness to Efficiency in Systematic Review (Evidence-Based Medicine) (Currie, 2002) and Chapter 16 of Abdelhamid, A. & Shemilt, I. 2010. Glossary of terms. Evidence-Based Decisions and Economics Health Care, Social Welfare, Education and Criminal Justice. 2nd ed. Oxford: Wiley-Blackwell, 186-197. Available:

https://methods.cochrane.org/sites/methods.cochrane.org.economics/files/uploads/ccemg\_website\_glossary.pdf xxiii Gupta, A., Eisenhauer, E., and C. Booth. <u>The Time Toxicity of Cancer Treatment</u>

Journal of Clinical Oncology 2022 40:15, 1611-1615.