

# iProSE — A Scale for Assessing Progress on Institutional Use of Evidence to Inform Priority–Setting in Health

# "How-To" Guide for Implementing iProSE in a Country Context

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### **Abbreviations**

BMGF The Bill and Melinda Gates Foundation

CGD Center for Global Development
EIPS Evidence-informed priority-setting
HTA Health Technology Assessment

iProSE iDSI Progression Scale for Evidence-Informed Priority-Setting in

LMIC healthcare Low- and middle-income country

WHO World Health Organization

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### 1. Introduction

### 1.1 Background

The Center for Global Development (CGD) has developed *iProSE – iDSI Progression Scale for implementing EIPS*. iProSE is a **self-assessment scale** whose design is informed by the current literature on institutionalising priority-setting mechanisms in health, particularly in low- and middle-income countries (LMICs).

The principal aim of iProSE is to enable countries and associated development partners to understand and measure their progress on institutionalising EIPS, and thus strategically plan for its improvement. More specifically, it aims to:

- support countries, and LMICs in particular, in understanding where they are on the EIPS journey and how they can best continue their progress;
- allow fair, objective comparisons of countries' EIPS institutionalisation progress with a view to facilitating policy learning;
- provide technical assistance providers with a tool to track a country's progress in implementing EIPS and, thus, inform its planned support;
- inform development partners to strategically target support to countries to develop EIPS processes.

A <u>distinct paper</u> outlines the concept and design of iProSE. This document accompanies that paper and describes how to apply the scale when conducting a country assessment.

### 1.2 The concept of the self-assessment scale

This section summarises the key components of iProSE, with further details in the main paper.

The self-assessment scale comprises eight aspirational statements over two domains:

- 1. two statements about how evidence is used to **inform spending decisions**; and
- 2. six statements about **enabling factors** for the production and use of evidence.

The scale firstly attempts to capture the extent to which decisions with substantial influence over the health budget, i.e., "What health technologies to cover from public funds?" and "At what prices to procure health technologies from public funds?" are systematically informed by evidence. In the context of the self-assessment scale, "health technology/intervention" refers to six major categories: diagnostic tests, medical devices, pharmaceuticals/medicines, vaccines, medical procedures, and public health programs.

The "enabling factors" refer to elements that are needed to promote and set up the use of evidence to support policy decisions. We selected six from the literature as the most critical factors: capacity for producing evidence; capacity for using evidence; systematic interactions between producers and users of evidence; political commitment for the production and use of evidence; "soft infrastructure" to support the production and use of evidence, such as healthcare cost databases or cost-effectiveness thresholds; and inclusive stakeholder participation in the decision-making process.

The two statements on spending decisions are scored for each type of health technology/intervention based on two factors: what type of health economic evidence is used, and the extent to which evidence informs spending decisions. The statements on enabling factors are scored based on the extent of their implementation across the healthcare system (not by health technology/intervention). Each statement is assessed and scored against an implementation

spectrum ranging from "no documentary evidence about the statement" (minimum score) to "documentary evidence indicates that the statement is fully implemented" (maximum score) (**Table 1**). The scores are aggregated at the level of each domain and then into a single score reflecting the overall extent of EIPS implementation.

Table 1. Conceptual design of the self-assessment scale

| Domaina             | Ctatamanta   | Implementation spectrum |                  |             |             |                       |                      |  |  |
|---------------------|--------------|-------------------------|------------------|-------------|-------------|-----------------------|----------------------|--|--|
| Domains             | Statements   | None                    | Policy           | Legislative | Operational | Implemented partially | Implemented<br>fully |  |  |
| Decisions           | 2 statements |                         | Statement scores |             |             |                       |                      |  |  |
| Enabling<br>factors | 6 statements |                         |                  |             |             |                       |                      |  |  |

**By "Evidence", we focus intentionally on health economic evidence.** Evidence on the clinical effectiveness and safety of health technologies is commonly considered in all contexts, therefore it has little discriminatory power and it is not, by itself, sufficient for robust priority-setting, as it doesn't enable consideration of trade-offs and opportunity costs. Instead, iProSE focuses on comparative health economic evidence and broader system-level aspects, which are recognised as essential components of priority-setting processes and for which there is much more variability across countries.

Specifically, three tiers of "evidence use" on health technologies are identified:

- 1) costs and health-related outcomes of health technologies;
- 2) comparative economic evaluation evidence on health technologies:
- 3) comparative economic evaluation evidence *plus* evidence on at least one broader, system-level aspect pertaining to the ethical, organisational, legal, or socio-economic implications of implementing the health technology/intervention.

**Each of the eight statements can receive a single score based on information available in official documents. The score reflects the nature of these documents.** The typology of documentary evidence draws on the WHO Global Benchmarking Tool, which distinguishes between legislative and operational documents as sources of evidence for making country assessments. The scale considers four types of documents (**Table 2**):

- **Policy documents** receive the lowest scores e.g., the country has a Health Technology Assessment (HTA) strategy. These are important to acknowledge because they signal political intent in the direction of institutionalising EIPS, but they are usually non-binding.
- **Legislative documents** receive somewhat higher scores than policy documents e.g., laws, decrees. These reflect a higher level of commitment to EIPS than policy statements, however they do not guarantee implementation.
- **Operational documents** receive even higher scores e.g., standard operating procedures, manuals, norms. These are documents internal to relevant institutions e.g., Ministry of Health, which operationalise policies and legislation on EIPS into actionable steps.

Implementation documents, which attest to decisions being implemented or to EIPS enabling factors being enacted, receive the highest scores. A distinction is made between **partial implementation** (e.g., pilots, the process is applied in some instances, but not in others without any apparent explanation) and **full implementation**, where the process is applied predictably in (nearly) all instances. What these documents are exactly is specific to each statement; indicatively, they can include expenditure statements, procurement orders, budget breakdowns, minutes of meetings, peer-reviewed publications.

Table 2. Operational framework of the self-assessment scale

|  | Implementation stage  |   |  |  |   |                      |
|--|---|---|--|--|---|----------------------|
| Statement  | None  | Policy  | Legislative  | Operational                                    | Implemented<br>partially  | Implemented<br>fully |
| Decisions  | l   |   |  |  |   |                      |
| When deciding which health technologies to reimburse using public funds, health economic evidence on the respective health technologies is considered in the decision.   | implemer<br>each of 6 t<br>procedure<br>public hea<br>Total poss  | nted fully) b<br>types of hea<br>es, medical<br>alth progra | ased on infor<br>alth technolo<br>devices, diag<br>mmes. | rmation in o<br>gies: medici<br>gnostic tests, | ige (from 0-noi<br>fficial documei<br>nes, vaccines, r<br>,<br>s of health tech | nts for<br>nedical   |
| When negotiating prices as part of a public procurement procedure for health technologies, health economic evidence on the respective health technologies is considered in price negotiations.   | 90. Statement scored against implementation stage (from 0-none to 15-implemented fully) based on information in official documents for each of 4 types of health technologies: medicines, vaccines, medical devices, diagnostic tests.  Total possible score when assessing all 4 types of health technologies: 60. |   |  |  |   |                      |
| Enabling factors   | •   |   |  |  |   |                      |
| Organizational structures are in place with the mandate to generate health economic evidence on health technologies.  Organizational structures are in place with the mandate to interpret health economic evidence on health technologies and make recommendations or resource allocation decisions.  | 5-implem  | ented fully   |  | formation in                                   | tion stage (froi<br>official docum<br>30.                                       |                      |
| Formal linkages are in place to bring together producers and users of health economic evidence on health technologies.  The Government funds organizational structures to produce and/or use health economic evidence on health technologies to inform resource allocation decisions.  Soft infrastructure is in place (e.g., cost databases, methods guide, rules-based thresholds, health-related quality of life tariffs) to support producers/users of health economic evidence for resource allocation decisions. |   |   |  |  |   |                      |

|   |      | Implementation stage |             |             |                       |                      |  |
|---|------|----------------------|-------------|-------------|-----------------------|----------------------|--|
| Statement   | None | Policy               | Legislative | Operational | Implemented partially | Implemented<br>fully |  |
| When deciding which health technologies to reimburse using public funds, relevant health system stakeholders have their perspectives heard. |      |                      |             |             |                       |                      |  |

### 1.3 About this guide

The purpose of this guide is to facilitate the application of the iProSE scale to a country context. The following sections give more information on how to operationalise the process of conducting the assessment, including how to make judgements on scoring the eight statements. An accompanying Excel file helps documenting the assessment, scoring statements, and synthesising findings.

### 2. Conducting the self-assessment

### 2.1 Preliminary considerations

The following considerations apply to all eight statements of the scale.

Which health technologies? All types of health technologies can be considered for the purpose of the self-assessment. Specifically, the scale allows for six distinct types: pharmaceuticals/medicines, medical procedures, vaccines, medical devices, diagnostic tests, and public health interventions. Ideally, when conducting a country assessment all six types of health technologies will be considered. In practice, the country assessment team can make a deliberate decision upfront to focus on specific types of health technologies e.g., medicines and vaccines; if such a decision to restrict or focus the scope of the assessment is made, a justification should also be provided - e.g. work in-country focuses on specific types of health technologies, or the government stakeholders may be interested in focusing on some but not all of them.

Which health benefit packages or benefit plans? In some countries public funds may flow through more than one channel, each with its population coverage, entitlements, spending rules and governance particularities. For example, there may be a health benefit package for the general population, one for public servants and another for members of the armed forces – each with its distinct payer organisation and possibly network of health service providers. As such, the same health technology/intervention may be available in different degrees to different people because of different resource allocation arrangements. The country assessment team should ideally focus the self-assessment on the benefit package and accompanying governance arrangements which serve the largest proportion of the general population in the country; and be specific about it when documenting the assessment.

Which government level to consider? The self-assessment will ideally consider decision processes applicable at the national level. If health is a sub-national/devolved/decentralized competency, consider national level policy and legislative documents and sub-national operational documents and evidence of implementation in at least one relevant sub-national unit (e.g., province, region, county), with justification for which sub-national unit was chosen.

Which documentary evidence to review? Table 3 illustrates generic types of evidence that can be considered for each category: policy, legislative, operational and implementation. This table is

intended as a starting point; it is not intended to be a definitive resource akin to a "catalogue". An essential preparatory step in conducting the assessment is to contextualise it to the country in focus.

Table 3. Examples of documentary evidence that can be considered in the assessment

| Level of implementation | Examples of documentary evidence                                   |
|-------------------------|--|
| Policy                  | Policy paper   |
|                         | Health (sub-) sector strategy                                      |
| Legislative             | Promulgated law, bill, ordinance, decree or other published in the |
|                         | Official Gazette or equivalent official legislative resource       |
| Operational             | For processes: standard operating procedure, manual, guide,        |
|                         | rulebook, mission statement, charter, constitution, terms of       |
|                         | reference, organogram, contract, memorandum of                     |
|                         | understanding or similar.  |
|                         | For action: executive decision or equivalent (e.g., ministerial    |
|                         | decision).   |
| Implementation          | Specific to each statement, see sections below                     |

For example, in some countries, legislation is operationalised through "application norms", which are also legislative documents but with the level of detail and specificity of standard operating procedures. In such instances, "application norms" can be considered operational documents for the purpose of the assessment. In some countries it may be common practice that operational procedures are issued before provisions are legislated; in this case, the country assessment team may argue that scoring for legislative and operational documents should be reversed because legislative documents show a deeper sense of commitment to EIPS than operational documents.

Furthermore, clarifications on available documents may be sought by way of formal communication with relevant institutions (e.g., letters, emails) or from country experts (e.g., key informant interviews, workshops, group discussions); however, communication alone cannot form the basis of the assessment, it can only nuance or clarify information in an official document.

What constitutes valid evidence? For documentary evidence to be considered in the assessment as the basis for scoring statements, it needs to be **complete** and **actual**. "Complete" means that it is a full document with no parts missing other than possibly redacted information for confidentiality purposes e.g., names, monetary amounts. "Actual" means that <u>both</u> the document <u>and</u> the provisions relevant to each statement in the scale are in force at the time of conducting the assessment; in other words, that its content is not outdated.

If an otherwise valid document has relevant provisions due to be in force at some point in the future relative to the time of conducting the assessment (e.g., developing an HTA strategy is mentioned as a milestone in the National Health Strategy, but it hasn't occurred yet; a promulgated law stipulates that HTA processes will become effective starting with 1st January 202X in the future), it cannot be considered.

Evidence of implementation can be considered if it is not older than 1 year from the time of starting the assessment.

### 2.2 The process of the self-assessment

This section outlines the steps to be taken when conducting the self-assessment.

1. **Establishing the purpose(s) of the assessment**. The purpose of iProSE is described in Section 1 above. However, the purpose of conducting the assessment (using the scale) could be much

more nuanced. For example, the purpose may be to map quickly, based on readily available information, a country's EIPS institutional capacity to identify areas for in-depth exploration and engagement; or it may be to develop a shared understanding together with domestic institutional partners of the key areas for building institutional capacity for EIPS; or it may be to compare across several countries the nature of EIPS processes relevant for a given type of health technology/intervention. Expected timelines, required resourcing and level of engagement with institutional partners would be different depending on the assessment's specific purpose. The expectation is that CGD or other technical partners would help clarify this purpose at the outset and adjust it, as needed, over the course of the assignment. Consultations with and buy-in from in-country counterparts (e.g., Ministry of Health) may be crucial at this stage, depending on the purpose(s).

- 2. **Assembling the country assessment team**. It is conceivable that a single person with sufficient expertise and experience in health sector EIPS as well as knowledge of and legitimacy in the country context could conduct the assessment by themselves. However, it is more likely that for most assessment purposes the required expertise, experience, legitimacy, and country knowledge are spread over more than one person or organization. Once the specific purpose(s) is/are clear, an appropriate team can be assembled. If CGD is involved in the assessment, CGD can support or lead in assembling a team comprising member(s) of CGD, in-country partners and potentially other stakeholders to conduct the assessment.
- 3. **Engaging with the iProSE scale and the "how-to" guide**. The members of the country assessment team are then expected to familiarise themselves with the concept of the iProSE scale, the "how-to" guide and the accompanying <a href="Excel tool">Excel tool</a>. Other than aligning everyone's understanding of what iProSE is and how it works, it is crucial to contextualise it and make team decisions on several aspects:
  - a. Clarifying the nature of documentary evidence to support scoring statements see Section 3 below, particularly Table 3 and the paragraph "Evidence to review" under each statement. This is the area where most country specificities are likely to occur, given the legislative and administrative setup in each country, the history of EIPS in the health sector and other contextual considerations. The country assessment team will need to define at the outset the types of documentary evidence needed to substantiate the statement scores, while anticipating the required effort to obtain and validate the information and weighing the strengths and weaknesses of potential documentary alternatives in relation to the assessment's purposes (see point 1 above) and the resources available for the assessment.
  - b. Clarifying how to approach the interpretation and application of scoring rules for every statement in the case of "borderline" situations, depending on the situation in the country.
  - c. Some of the documentary evidence will be ambiguous or even contradictory. There may be cases where translation (literal from one language to another or functional from one thematic area to another), clarifications and judgement calls will be required. The assessment team will need to agree upfront on how such situations will be managed when they arise e.g., formal information requests, group discussions, key informant interviews, third party moderation.
- **4. Gathering and using the documentary evidence to score the scale's statements.** Once documentary evidence is gathered, its validity will be examined (see section 2.1 above) and, if found valid, considered in the assessment. This guide provides definitions and criteria for how each of the scale's statements is to be scored against the available documentary evidence.
- 5. **Reporting the findings**. The Excel tool accompanying this guide is meant as a tool both to record the progress of the assessment and to synthesise the statement scores in visualisations that can inform producing a narrative interpretation of the EIPS situation in the country.

### 2.3 Scoring statements on resource allocation decisions

The scoring grid for these two statements is as follows:

| Type of health   | Type of documentary evidence |        |                 |             |                       |                      |  |
|--|------------------------------|--------|-----------------|-------------|-----------------------|----------------------|--|
| technology evidence  | No<br>document               | Policy | Legislati<br>ve | Operational | Implemented partially | Implemented<br>fully |  |
| Costs and outcomes,<br>not as an economic<br>evaluation    | 0                            | 1      | 2               | 3           | 5                     | 12                   |  |
| Economic evaluation  | 0                            | 3      | 4               | 5           | 7                     | 14                   |  |
| Economic<br>evaluation +<br>At least one broader<br>aspect | 0                            | 4      | 5               | 6           | 8                     | 15                   |  |

### 2.3.1 Statement 1 on which health technologies to cover using public funds

The first statement under "Resource allocation decisions" is "Decisions on which health technologies to reimburse using public funds are informed by evidence on the respective health technologies."

### Specific terminology

In the context of this statement:

- "reimbursing" and "reimbursement" refer here to committing public funds towards delivering health technologies to the population.
- "informed by evidence" refers here to presenting, critiquing, or discussing health economic evidence as part of the decision process.

#### Scope

Any type of health technology/intervention can be considered. Decisions may refer to both reimbursement and disinvestment i.e., no longer covering a health technology/intervention from public funds. The statement focuses on the decision "whether" to reimburse, irrespective of the level of reimbursement ("how much" to reimburse). It is not necessary for reimbursement to cover the total cost of the technology/intervention for it to be considered in the assessment i.e., without contributions from other payment plans (public or private), co-payments, or user fees. In other words, partial reimbursement is acceptable for scoring purposes.

#### **Evidence to review**

Policy, legislative and operational evidence per Table 3. Evidence of implementation should aim to demonstrate that health technologies are being delivered at service provision level (or not being delivered in for decisions to disinvest); the exact nature of documentary evidence is to be discussed and agreed upon by the country assessment team.

### 2.3.2 Statement 2 on procurement prices for health technologies

The second statement under "Resource allocation decisions" is "Price negotiations in public procurement procedures for health technologies are informed by evidence on the respective health technologies."

### Specific terminology

In the context of this statement:

- "prices" refers to the price at which a public entity procures specific health technologies from other entities (usually private entities e.g., medicine wholesalers).
- "price negotiation" refers to the process of establishing the procurement price as part of the procurement procedure.
- "procurement procedure" refers to the bureaucratic process through which a public entity buys specific health technologies from other entities.

### Scope

This decision will apply to health technology goods that can be procured i.e., drugs, vaccines, diagnostic tests, and medical equipment.

### Evidence to review

Policy, legislative and operational evidence per Table 3. Evidence of implementation should aim to establish that price negotiations in practice are likely to be informed by health economic evidence on the respective health technologies. Such negotiation processes are usually sensitive, therefore available documentation may be scarce or non-existent – perhaps more so than any other statement in the iProSE scale. Expert testimony may be necessary to make an assessment. The exact nature of documentary evidence to be discussed by the country assessment team.

### 2.4 Scoring statements on enabling factors

The scoring grid for these statements is as follows:

|  | Type of documentary evidence |        |                 |             |                       |                      |  |  |  |
|--|------------------------------|--------|-----------------|-------------|-----------------------|----------------------|--|--|--|
|  | No<br>document               | Policy | Legislati<br>ve | Operational | Implemented partially | Implemented<br>fully |  |  |  |
|  |                              |        |                 |             |                       |                      |  |  |  |
| All six statements on enabling factors | 0                            | 1      | 2               | 3           | 4                     | 5                    |  |  |  |

# 2.4.1 Statement 3 on structures for generating health economic evidence on health technologies

The first statement under "Enabling factors" (the fourth statement in the complete scale) is "Organizational structures are in place with the mandate to produce evidence on health technologies."

### Specific terminology

In the context of this statement:

- "organizational structures" refers to organizations or units within organizations (e.g., directorates, departments, units, teams) or across organizations (e.g., committees, task forces). Organizations could be public (e.g., ministries, government agencies) or private (e.g., universities, NGOs).
- "mandate" refers to a statutory obligation. This could be reflected in the organization's statutory documents (e.g., charter, constitution, mission statement), in legislation or in a formal agreement with a public authority (e.g., contract, memorandum of understanding).
- "producing evidence" refers to applying research methodology (e.g., evidence synthesis, statistical analysis of existing datasets, decision modelling) in order to generate health economic evidence on a/several question(s) pertaining to the value of a specific health technology.

### Scope

The organizational structure needs to be based or formally registered in the country of assessment, irrespective of the staff's nationality; for example, an agreement with an overseas university does not amount to the enabling factor being present.

### Evidence to review

Policy, legislative and operational evidence per Table 3. Examples of implementation evidence may include documents, published or unpublished, reporting the production of health economic evidence of the three types considered in the assessment (costs and outcomes; economic evaluation; economic evaluation and at least one other broader aspect) which are authored by employees of the organizational structure.

### Scoring

| Situation at the time of the assessment  | Score |
|--|-------|
| Multiple documents indicate that health economic evidence on health technologies   | 5     |
| is widely produced.  |       |
| At least one document is available where health economic evidence on a specified   | 4     |
| health technology/intervention has been produced.                                  |       |
| An operational document specifies how the named organizational structure exerts    | 3     |
| the mandate to produce health economic evidence on health technologies.            |       |
| A legislative document identifies an organizational structure with the mandate to  | 2     |
| produce health economic evidence on health technologies.                           |       |
| A policy document identifies an organizational structure with the mandate to       | 1     |
| produce health economic evidence on health technologies.                           |       |
| There is no documentary evidence to indicate that any organizational structure has | 0     |
| the mandate to produce health technology evidence.                                 |       |

# 2.4.2 Statement 4 on structures for using health economic evidence on health technologies

The second statement under "Enabling factors" (the fifth statement in the complete scale) is "Organizational structures are in place with the mandate to use evidence on health technologies for making (recommendations on) resource allocation decisions."

### **Specific terminology**

In the context of this statement:

- "organizational structures" refers to organizations or units within organizations (e.g., directorates, departments, units, teams) or across organizations (e.g., committees, task forces). Organizations could be public (e.g., ministries, government agencies) or private (e.g., universities, NGOs).
- "use" refers to health economic evidence being presented, critiqued, and discussed as part of the decision process.

#### Scope

Any type of health technology/intervention can be considered. The resource allocation decisions do not necessarily have to be those captured by statements 1 and 2 in the scale; other resource allocation decisions can be considered if they are made explicit (e.g., for deciding how to distribute the budget for public health programs across sub-national units).

### **Evidence to review**

Policy, legislative and operational evidence per Table 3. Evidence of implementation should aim to demonstrate that organizational structures function as intended from an EIPS perspective i.e., with the consideration of health economic evidence on health technologies. Examples of such

documentary evidence are minutes of meetings or activity reports; the exact nature of acceptable documentary evidence to be established by the country assessment team.

### Scoring

| Situation at the time of the assessment  | Score |
|--|-------|
| Multiple documents indicate that health economic evidence on health technologies   | 5     |
| has been widely used in making (recommendations on) (a) specific resource          |       |
| allocation decision(s).  |       |
| At least one document reports that health economic evidence on a specified health  | 4     |
| technology/intervention has been used in making (recommendations on) a specific    |       |
| resource allocation decision.  |       |
| An operational document specifies how a named organizational structure exerts the  | 3     |
| mandate to use health economic evidence on health technologies for making          |       |
| (recommendations on) a specific resource allocation decision.                      |       |
| A legislative document identifies an organizational structure with the mandate to  | 2     |
| use evidence on health technologies for making (recommendations on) a specific     |       |
| resource allocation decision.  |       |
| A policy document identifies an organizational structure with the mandate to use   | 1     |
| evidence on health technologies for making (recommendations on) a specific         |       |
| resource allocation decision.  |       |
| There is no documentary evidence to indicate that any organizational structure has | 0     |
| the mandate to use evidence on health technologies for making (recommendations     |       |
| on) a specific resource allocation decision.                                       |       |

# 2.4.3 Statement 5 on linkages between structures for generating and using health economic evidence on health technologies

The third statement under "Enabling factors" (the sixth statement in the complete scale) is "Formal linkages are in place to bring together producers and users of health economic evidence on health technologies."

### **Specific terminology**

In the context of this statement:

- "formal linkages" refers to any type of mechanism or arrangement through which producers and users of health economic evidence on health technologies can systematically meet and exchange information with a view to informing policy debates and decisions on resource allocation. Examples may include regular meetings of task forces, committees etc.

#### Scope

One-off or spontaneous linkages such as meetings as part of national conferences and symposia are not considered.

#### Evidence to review

Policy, legislative and operational evidence per Table 3. Evidence of implementation should aim to demonstrate that such linkages are active as intended. Examples of such documentary evidence are minutes of meetings or activity reports; the exact nature of acceptable documentary evidence to be established by the country assessment team.

### Scoring

| Situation at the time of the assessment  | Score |
|--|-------|
| Document(s) report(s) that a formal linkage between producers and users of health  | 5     |
| economic evidence on health technology/interventions takes place regularly.        |       |
| At least one document reports that a formal linkage between producers and users of | 4     |
| health economic evidence on health technology/interventions has been active.       |       |
| An operational document specifies the nature of a formal linkage between           | 3     |
| producers and users of health economic evidence on health                          |       |
| technology/interventions.  |       |
| A legislative document stipulates a formal linkage between producers and users of  | 2     |
| health economic evidence on health technology/interventions.                       |       |
| A policy document indicates a formal linkage between producers and users of health | 1     |
| economic evidence on health technology/interventions.                              |       |
| There is no documentary evidence to indicate formal linkages between producers     | 0     |
| and users of health economic evidence on health technology/interventions.          |       |

# 2.4.4 Statement 6 on public funding for generating and/or using health economic evidence on health technologies

The fourth statement under "Enabling factors" (the seventh statement in the complete scale) is "Public funds support organizational structures that produce and/or use evidence on health technologies to inform resource allocation decisions."

### **Specific terminology**

"organizational structures", "producing evidence", "using evidence" and "inform" retain the meanings from previous statements.

### Scope

This statement focuses only on "whether" any public funding is going towards producers and/or users of evidence on health technologies. Sufficiency of funding is outside of scope.

### **Evidence to review**

Policy, legislative and operational evidence per Table 3. Evidence of implementation should focus on financial proof that the structure(s) is/are publicly funded; the exact nature of documentary evidence to be established by the country assessment team.

### Scoring

| Situation at the time of the assessment  | Score |
|--|-------|
| Document(s) report(s) that government funding is the main source which supports    | 5     |
| structures that produce and/or use health economic evidence on health              |       |
| technologies.  |       |
| Document(s) report(s) that government funding supports (not as a main source)      | 4     |
| structures that produce and/or use health economic evidence on health              |       |
| technologies.  |       |
| An operational document specifies how government funding supports structures       | 3     |
| that produce and/or use health economic evidence on health technologies.           |       |
| A legislative document stipulates that government funding supports structures that | 2     |
| produce and/or use health economic evidence on health technologies.                |       |
| A policy document indicates that government funding supports structures that       | 1     |
| produce and/or use health economic evidence on health technologies.                |       |

| There is no documentary evidence to indicate that any government funding       | 0 |
|--|---|
| supports structures that produce and/or use health economic evidence on health |   |
| technologies.  |   |

# 2.4.5 Statement 7 on research infrastructure for using health economic evidence on health technologies

The fifth statement under "Enabling factors" (the eighth statement in the complete scale) is "Soft infrastructure is in place to support producers/users of health economic evidence for resource allocation decisions."

### Scope

Any of the following applies: healthcare delivery cost database; economic evaluation or HTA methods guide; a rules-based decision threshold.

#### Evidence to review

Policy, legislative and operational evidence per Table 3. Evidence of implementation should focus on the element of soft infrastructure being accessible e.g., a document, an electronic resource.

### Scoring

| Situation at the time of the assessment   | Score |  |  |
|---|-------|--|--|
| Document(s) indicate(s) multiple instances of using soft infrastructure when            |       |  |  |
| generating or using health economic evidence for resource allocation decisions.         |       |  |  |
| At least one document reports that soft infrastructure has been used to support         | 4     |  |  |
| producers/users of health economic evidence for resource allocation decisions.          |       |  |  |
| An operational document specifies how to use soft infrastructure to support             | 3     |  |  |
| producers/users of health economic evidence for resource allocation decisions.          |       |  |  |
| A legislative document stipulates that any soft infrastructure is in place to support   | 2     |  |  |
| producers/users of health economic evidence for resource allocation decisions.          |       |  |  |
| A policy document indicates that any soft infrastructure is/will be in place to support | 1     |  |  |
| producers/users of health economic evidence for resource allocation decisions.          |       |  |  |
| There is no documentary evidence to indicate that any soft infrastructure is in place   | 0     |  |  |
| to support producers/users of health economic evidence for resource allocation          |       |  |  |
| decisions.  |       |  |  |

### 2.4.6 Statement 8 on participatory decision-making

The sixth statement under "Enabling factors" (the ninth statement in the complete scale) is "When deciding which health technologies to reimburse using public funds, relevant health system stakeholders have their perspectives heard."

### **Specific terminology**

In the context of this statement:

- "relevant health system stakeholders" may include representatives of one or more of the following – patients, health service providers, health workers, pharmaceutical and medical device industry, civil society organisations. In essence, constituencies other than the regulator (usually Ministry of Health) and payer(s).

### Scope

This statement focuses on the participatory nature of the priority-setting process. At least one category of stakeholder (other than the regulator and payer(s)) is sufficient for scoring purposes. The

resource allocation decisions do not necessarily have to be those captured by statements 1-2 in the scale; other resource allocation decisions can be considered if they are specified (e.g., for deciding how to distribute the budget for public health programs across sub-national units).

### Evidence to review

Policy, legislative and operational evidence per Table 3. Evidence of implementation should aim to demonstrate that such stakeholders participate in the decision process. Examples of such documentary evidence are minutes of meetings or activity reports; the exact nature of acceptable documentary evidence to be established by the country assessment team.

### Scoring

| Situation at the time of the assessment   | Score |
|---|-------|
| Document(s) indicate that relevant health system stakeholders routinely have had  | 5     |
| their perspectives heard when making resource allocation decisions.               |       |
| At least one document reports that relevant health system stakeholders have had   | 4     |
| their perspectives heard when making resource allocation decisions.               |       |
| An operational document specifies how relevant health system stakeholders can     | 3     |
| make their perspectives heard when making resource allocation decisions.          |       |
| A legislative document stipulates that relevant health system stakeholders should | 2     |
| have their perspectives heard when making resource allocation decisions.          |       |
| A policy document indicates that relevant health system stakeholders should have  | 1     |
| their perspectives heard when making resource allocation decisions.               |       |
| There is no documentary evidence to indicate that relevant health system          | 0     |
| stakeholders have their perspectives heard when making resource allocation        |       |
| decisions.  |       |

### 3. Documenting the self-assessment

This section outlines how to use the accompanying <u>Excel tool</u> to document the assessment and generate the results. It follows the worksheet structure of the Excel file.

### Before using the Excel file

The file is in format .xlsm, which is Excel's macro-enabled format. Macros need to be enabled by the user for the interactive functions of the file to work properly.

The user is advised to change the contents of dark blue cells ONLY. The content of light blue cells is automatically calculated based on the content of other cells. Grey cells contain essential content of the statements in the iProSE scale.

### The "Scale" sheets

There are two "Scale" sheets: "Scale\_time1" is for capturing the present EIPS situation in the country and "Scale\_time0" is for capturing the EIPS situation at a chosen moment in the past. This is to allow presenting progress in institutionalising EIPS. The contents of the two sheets are identical.

Each "Scale" sheet shows the eight statements of the scale which were discussed in the previous section. Statements 1 and 2, the resource allocation statements, are disaggregated by type of health technology/intervention.

For each row, the user should aim to select from drop-down menus in columns B and C¹ the values that make a complete and correct statement across column B, column C, and pre-filled column D. The scoring levels for each statement can be selected from drop-down menus (columns B and C), and the corresponding scoring values are loaded automatically – see snapshot below.

There is also space next to each statement for giving details about the supporting documents (column F) and other considerations (column G), for example on how the scoring level was chosen etc.

If a type of health technology/intervention is not included in the assessment, select "Not assessed" in either column B or C. The score in column E will appear as "#N/A". This is normal.

Resetting the scores of both "Scale" sheets can be done by pressing the "Reset scale scores" button at the top.

<u>Action required</u>: to complete the scale, fill in the dark blue cells in columns B (drop-down), C (drop-down), F (free text) and G (free text).

|                                | Level of implementation                     | Health economic evidence used   |   | Score |
|--------------------------------|---|---|---|-------|
| Health technology/intervention | 1. What to reimburse?                       |   |   |       |
|                                | Documentary evidence confirms that          | evidence on both costs and outcomes, but not  |   |       |
| Medicines                      | operational procedures are in place so that | presented as an economic evaluation   | informs decisions on which medicines to reimburse using public funds.             |       |
| wedicines                      | operational procedures are in place so that | presented as an economic evaluation   | illionis decisions on which medicines to remibulse using public lands.            |       |
|                                | Documentary evidence confirms policy        | economic evaluation and at least one other  |   |       |
| Medical procedures             | intention that                              | aspect (societal, legal, ethical, organizational)   | informs decisions on which medical procedures to reimburse using public funds.    |       |
| Vaccines                       | Not assessed                                | Not assessed  | informs decisions on which vaccines to reimburse using public funds.              | #N/A  |
|                                |   |   |   |       |
|                                | Documentary evidence confirms policy        | economic evaluation and at least one other  |   |       |
| Medical devices                | intention that                              | aspect (societal, legal, ethical, organizational)   | informs decisions on which medical devices to reimburse using public funds.       |       |
|                                |   |   |   |       |
|                                | Documentary evidence confirms policy        | economic evaluation and at least one other  |   |       |
| Diagnostic tests               | intention that                              | aspect (societal, legal, ethical, organizational)   | informs decisions on which diagnostic tests to reimburse using public funds.      |       |
|                                |   |   |   |       |
|                                | Documentary evidence confirms that in some  | economic evaluation and at least one other  | informs decisions on which public health interventions to reimburse using public  |       |
| Public health interventions    | cases (e.g., ad hoc, pilot)                 | aspect (societal, legal, ethical, organizational)   | funds.  |       |
| 1lab 4bl                       | 2 44  |   |   |       |
| Health technology/intervention | 2. At what price(s) to procure?             | and the second bath and an arranged by the second bath and a second bath a second bath a second bath and a second bath a second bath a second bath a second bath and a second bath a second |   |       |
| Medicines                      | that  | evidence on both costs and outcomes, but not<br>presented as an economic evaluation   | informs price negotiations in the public procurement of medicines.                |       |
| wiedicines                     | triat                                       | evidence on both costs and outcomes, but not  | informs price negotiations in the public procurement of medicines.                | r     |
| Vaccines                       | Not assessed                                | presented as an economic evaluation   | informs price negotiations in the public procurement of vaccines.                 | #N/A  |
| vaccines                       | There is no documentary evidence to suggest |   | million is price negotiations in the public procurement of vaccines.              | mis/A |
| Medical devices                | that  | presented as an economic evaluation   | informs price negotiations in the public procurement of medical devices.          |       |
| Diagnostic tests               |   | evidence on both costs and outcomes, but not  | morns price negotiations in the passic procurement of medical devices.            |       |
|                                | that  | presented as an economic evaluation   | informs price negotiations in the public procurement of diagnostic tests.         |       |
| olugilostic tests              |   | presented as an economic evaluation   | morns price negotiations in the passic procurement of angrisoite tests            |       |
|                                | Enabling factors                            |   |   |       |
|                                | Documentary evidence confirms policy        |   | organizational structures mandated by the government are expected to produce      |       |
| Producers of evidence          | intention that                              |   | any type of evidence on health technologies.                                      |       |
|                                |   |   | organizational structures mandated by the government are expected to use any      |       |
|                                | Documentary evidence confirms policy        |   | type of evidence on health technologies for making (recommendations on)           |       |
| Users of evidence              | intention that                              |   | resource allocation decisions.  |       |
|                                | Documentary evidence confirms policy        |   | formal linkages should be in place to bring together producers and users of       |       |
| Formal linkages                | intention that                              |   | evidence on health technologies.  |       |
|                                | Documentary evidence confirms policy        |   | public sources should provide majority funding to producers and users of evidence |       |
| Public funding                 | intention that                              |   | on health technologies that informs resource allocation decisions.                |       |
|                                | Documentary evidence confirms policy        |   | elements of soft infrastructure should be in place to support producers and/or    |       |
| Soft infrastructure            | intention that                              |   | users of evidence on health technologies.   |       |
|                                | Documentary evidence confirms policy        |   | when deciding which health technologies to reimburse using public funds, relevant |       |
| Stakeholder engagement         | intention that                              |   | health system stakeholders should have their perspectives heard.                  |       |

### The "Results" sheet

This sheet translates the scores in the two "Scale" sheets in summary tables. Action required: no action from the user is required on this sheet.

### The "Visuals" sheet

This sheet translates the scores in the two "Scale" sheets in visualisations. Action required: no action from the user is required on this sheet.

<sup>&</sup>lt;sup>1</sup> Column C only for decision statements, not for enabling factors.

### The "Glossary" sheet

This sheet explains the meanings of key terms for applying iProSE and for completing the <u>Excel tool</u>. The definitions are consistent with those used in the main paper and in this guide. <u>Action required</u>: no action from the user is required on this sheet.

### The "Process" sheet

This worksheet is meant to act as a "diary" where the country assessment team can keep track of the meetings and analytical decisions they make over the course of the assessment.

<u>Action required</u>: optional – complete the dark blue cells with free text details on the country team assessment composition and meetings.

### The "List" sheet

This worksheet imports the pre-filled statements and the values used to calculate scores in the two "Score" sheets (columns D and E, respectively.

Action required: None – the user must not change this sheet.