Reference No. _____

**TERMS OF REFERENCE**

**Project Title: Procurement of Consulting Services for the Assessment of Health Technologies for selected priority topics under the 2024 Health Technology Assessment (HTA) Research Agenda**
**Funding Source:** GAA 2024 - DOST-Health Technology Assessment

## I. Background

Pursuant to the Universal Health Care (UHC) Act, all health technologies that the government will implement and cover shall undergo health technology assessment (HTA). This aims to ensure the rational utilization of various health technologies that will be funded by the government.

In this regard, a collaborative approach in HTA, through the commissioning of independent academic teams via the HTA research network as stipulated in Administrative Order 2020-0041, will streamline the work on evidence reviews, and accelerate the delivery of much-needed advice by decision-makers and health policy makers. In 2022 and 2023, the HTA Philippines commissioned assessments of priority health technologies through research partners to complement the current internal capacity for HTA.

This project is therefore being undertaken to facilitate the conduct of assessments that will generate clinical evidence for the 2024 prioritized health technology topics under the HTA general track (Cycle 2), to be appraised by the HTA Council in developing their financing recommendations to DOH and/or PhilHealth. Of the 160 nominations received from cycle 2 of HTA Topic Nomination, 64 priority topics were identified by the HTA Philippines to proceed to assessment. Twenty (28) topics for the following indications were then assigned for external commissioning: chronic obstructive pulmonary disease (COPD), breast cancer, lung cancer, ovarian cancer, Type 1 & 2 diabetes mellitus, stroke, patients with liver lesions/pathologies, meningococcal infection, diffuse large B Cell Lymphoma, end-stage renal disease, growth disturbance due to insufficient secretion of growth hormone among pediatric patients, and premature neonates, low birth weight neonates, procedural sedation, short-term treatment of acute pain and post-operative pain, protein supplementation, disease-related malnutrition, diaper dermatitis and incontinence-induced dermatitis.

This specific Terms of Reference (TOR) is for the contracting of external assessment of health technologies for selected HTA priority topics specifically on procedural sedation, short-term treatment of acute pain and post-operative pain, protein supplementation, disease-related malnutrition, diaper dermatitis and incontinence-induced dermatitis. The external assessment group (EAG) to be selected shall conduct the clinical assessment based on the guidelines stated in this TOR to ensure that evidence outputs are of high quality and can be used as evidentiary basis for the Health Technology Assessment Council (HTA Council) in

developing recommendations to DOH and PhilHealth policy-makers on coverage/financing decisions.

## II. Objectives

A. General Objective

To conduct the clinical assessment (using evidence synthesis methodologies) of selected priority topics that will be used by the HTAC in developing recommendations on coverage and financing decisions for DOH and PhilHealth, specifically:

a. Dexmedetomidine (as hydrochloride) for intensive care unit (ICU) sedation and procedural sedation
b. Glucose (544mL) + amino acids (315mL) + electrocytes + lipids (141mL), 1000mL for disease-related malnutrition in hospitalized patients
c. High protein (as Semi Modular Enteral Nutrition) for protein supplementation
d. Parecoxib for short-term treatment of acute pain and post-operative pain
e. Zinc oxide + calamine for incontinence-induced dermatitis and diaper dermatitis

B. Specific Objectives

1. To conduct literature review and stakeholder consultation in setting the Population, Intervention, Comparator, and Outcome (PICO) per topic
2. To conduct an initial scoping of evidence that will determine the clinical evidence synthesis methodology track* per topic
   *Possible *clinical evidence synthesis tracks depending on the existing evidence:*
   a. de novo systematic review with meta-analysis or network meta-analysis *(as applicable)*
   b. updating of an existing systematic review with meta-analysis or network meta-analysis *(as applicable)*
   c. adoption of an updated systematic review with meta-analysis or network meta-analysis *(as applicable)*
3. To perform clinical evidence synthesis including GRADE rating of evidence, based on the results of the initial scoping of evidence
4. To conduct a review of country guidelines relevant to the topics
5. To develop a technical report of clinical assessments per topic, including oral presentations to HTA Council Subcommittee and the Core Committee (*if needed*)
6. To conduct appraisal of new evidence (may or may not result into re-pooling of data) which may be possibly received during the stakeholder consultation phase of the preliminary recommendation of the HTA Council using the findings of the assessment outputs from this project *[**Note**: Applicable only for topics resulting in negative recommendations by the HTA Council based on the clinical assessment findings from this project]*

## III. Scope of Work

1. Implement the research project as per the developed and approved (with technical and ethical clearances, if applicable) research proposals;
2. Submit all research project deliverables according to the prescribed timelines below and following the forms or templates as prescribed in the Official Call Guide incorporating the HTA Process Guide and Methods Guide;

| Phase | Output(s) | Timeline |
|---|---|---|
| Pre-implementation | 1. Pre-implementation meeting before inception report submission<br><br>2. Inception report which will include the following:<br>- suggested scope of the PICO (Population, Intervention, Comparator, Outcomes) of the research questions for each of the four (4) priority topics that will be consulted among identified stakeholders;<br>- Methodological Plan<br>- Detailed budget proposal<br>- Detailed and Feasible Work Plan | **Month 1:**<br><br>*Within 5 working days after signing of the Memorandum of Agreement*<br><br>*Within 5 working days after the pre-implementation meeting* |
| Research Question Finalization | 1. Stakeholder-validated PICO for each topic, for HTA Council vetting and approval<br>2. HTA Council approval of | **Month 2**:<br><br>*Within 15 to 20 working days weeks after the approval of the inception report* |

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| | | stakeholder-validated PICO (*through meeting or ad ref*) | |
| | Clinical Assessment (initial phase) | 1. Clinical evidence synthesis methodology track before proceeding to assessment<br><br>2. Midterm Clinical Assessment Report per research question, including:<br>- Final included studies with extraction<br>- Results of evidence appraisal | **Month 3**:<br>*Within 5 working days after the approval of the PICO/Research Questions*<br><br>*Within 30 working days after the approval of the final evidence synthesis methodology track* |
| | Final Clinical Assessment Report per topic<br><br>(Finalization phase) | 1. Draft Final Report prior to the presentation meetings<br><br>2. Meetings to present findings:<br><br>- EAG presentation of findings to the HTA Council Subcommittee | **Month 4 to Month 5** :<br>*Within 2 to 2.5 months after the approval of the evidence synthesis methodology track*<br><br>*Within 10 working days after the HTA Philippines sent the comments on the initial Final Report*<br><br>*Note: There may be more than one EAG presentation to the HTA Council Subcommittee, depending on whether the comments are addressed by the EAG. There may be comments at the Subcommittee-level that will need revisions in the assessment report, in preparation for their presentation to the Core level* |

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| | | - <u>For topics resulting in negative recommendation:</u> HTA Council Subcommittee Presentation to the Core Committee where the EAG can be invited as resource persons (if necessary)<br><br>3. Final Clinical Assessment Report<br><br>Note: The clinical assessment report shall be finalized after the *Subcommittee approves the presentation of the assessment findings of the EAG (<u>For topics with positive clinical judgement</u>); OR after the stakeholder consultation period (<u>For topics with negative clinical judgement resulting in negative HTA Council recommendation)</u>* | **Month 6:**<br>*Within 10 working days after the HTA Council Subcommittee generates its recommendation based on the assessment*<br><br>**Month 7:**<br>*<u>For topics with positive clinical judgement:</u>*<br>*Within 5 working days after the Subcommittee approves the presentation of findings from the EAG*<br><br>*<u>For topics with negative clinical judgment resulting in negative HTAC recommendation:</u>*<br>*Within 5 working days after the HTA Council Core Committee finalizes its recommendation after the appeals period/ stakeholder consultation of the recommendation* |
| | Closing of the project | Final Financial Report | **Month 8:**<br>*Within 10 working days after the release of the last tranche* |

*Note: Timelines may vary as all the outputs are subject to review of the HTA Philippines which may require revisions in order to comply with the HTA Methods Guides.*

3. Provide regular updates following the prescribed timelines to HTA Division on the status of the assessment through electronic mails and/or checkpoint meetings;
4. Closely coordinate with the HTA Division for any issues or advice/ guidance needed in the activities within the project;

5. Submit the final HTA Council-approved technical report one month before end of project and final financial report one month after end of the project;
6. Ensure submission of all deliverables according to the specifications indicated in Section VI.B. by the end of the contract

## IV. Expected Outputs or Deliverables

- Inception report per priority topic, *to include:*
  - *suggested scope of the PICO (Population, Intervention, Comparator, Outcomes) of the research question, after content experts consultation*
  - *Budget and work plan*
- *SH-consulted PICO per priority topic*
- Checkpoint meetings, as necessary
- Midterm Assessment Report *per priority topic*
  - Scoping review: final included studies with extraction
  - Results of evidence appraisal
- Initial Clinical Assessment Report *per priority topic*
  - Refer to the HTA MG Annex 10 for the outline of reports for the following clinical evidence synthesis tracks depending on the existing evidence*:*
    - de novo systematic review with meta-analysis or network meta-analysis *(as applicable)*
    - updating of an existing systematic review with meta-analysis or network meta-analysis *(as applicable)*
    - adoption of an updated systematic review with meta-analysis or network meta-analysis *(as applicable)*
- Final Clinical Assessment Report *per priority topic*, including oral presentation to the HTA Council Subcommittee assigned to review the topics
  - Refer to the HTA MG Annex 10 for the outline of reports for the following clinical evidence synthesis tracks depending on the existing evidence*:*
    - de novo systematic review with meta-analysis or network meta-analysis *(as applicable)*
    - updating of an existing systematic review with meta-analysis or network meta-analysis *(as applicable)*
    - adoption of an updated systematic review with meta-analysis or network meta-analysis *(as applicable)*

  - Note: For topics which result in **positive** HTA Council Recommendation, the final report is the version after the Subcommittee approves the presentation of findings by the EAG.
    For topics which result in **negative** HTA Council Recommendation, the Final Clinical Assessment Report must have already included the appraisal of new evidence that may be received from appellants during the stakeholder consultation phase.

## V. Project Duration

These Terms of Reference shall take effect upon signing by both Parties hereto and shall remain effective for ***seven (7) months*** upon signing of the Memorandum of Agreement/Contract. All deliverables shall be submitted within ***seven (7) months*** from the date of the notarized Memorandum of Agreement/Contract.

## VI. Implementation Agreement

A. Contact persons:
All communications and reports must be addressed to:

**ANNE JULIENNE GENUINO-MARFORI, RPh, MSc**
Division Chief
Health Technology Assessment Division
Department of Science and Technology

B. Reporting Obligations, notices and approval process including minimum or essential reports' contents

| **Deliverables** | **Technical and formatting requirement** |
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| Inception Report per priority topic | 1. Title<br>2. Protocol information<br>3. Background<br>4. Research question<br>5. Methodological Plan for Clinical Assessment: Evidence Synthesis from clinical studies<br>6. Methodological Plan for Clinical Assessment: Review of Guidelines<br>7. References<br>8. Annexes<br>9. Declarations<br>10. Timelines |
| Stakeholder-consulted PICO (1 report covering consultation for the four (4) priority topics | PICO Consultation Report which includes the proposed PICO for HTAC approval and finalization |
| Midterm Clinical Assessment Report | 1. Background<br>- Health problem and clinical management options<br>- Description, technical characteristics, and use of the health technologies |

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| | 2. Brief Methodology<br>3. Initial findings of the Evidence Synthesis from clinical studies<br>*- If de novo evidence synthesis or updating of an existing SR with additional primary studies*<br>a. Description of included studies<br>i. PRISMA flow diagram<br>ii. Study characteristics of included studies<br>b. Critical appraisal (i.e. risk of bias assessment)<br>*- If appraisal and adoption of an existing SR*<br>a. Characteristics of the SR for adoption<br>b. Critical appraisal (i.e. risk of bias assessment)<br>4. Annexes (if applicable)<br>5. References |
| Initial Clinical Assessment Report per priority topic<br><br>*Note: The Initial and Final Assessment Report follows the same template content. The key difference is that the Initial Assessment Report is the first version of the report, prior to the presentation meetings to the HTA Council. Meanwhile, the Final Assessment Report already incorporates the comments of the HTA Council, as well as possible comments from stakeholders (found by the HTA Council to be meritorious) during the public consultation of the HTA Council recommendation on the health technology which presents the EAG report as evidence*. | 1. Background<br>- Health problem and clinical management options<br>- Description, technical characteristics, and use of the health technologies<br>2. Methodologies<br>3. Results:<br>a. Evidence Synthesis from clinical studies<br>*- If de novo evidence synthesis or updating of an existing SR with additional primary studies*<br>i. Study characteristics<br>ii. Critical appraisal (i.e. risk of bias assessment)<br>iii. Results of synthesis (including GRADE rating of evidence)<br><br>*- If appraisal and adoption of an existing SR*<br>i. Study characteristics<br>ii. Critical appraisal (i.e. risk of bias assessment)<br>iii. Results of the adopted SR (including GRADE rating of evidence)<br>b. Review of Guidelines<br>4. Discussion and Conclusion |

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| | 5. Annexes<br>6. References |
| Final Clinical Assessment Report *(Assessment report for each of the priority topics)* | 1. Background<br>- Health problem and clinical management options<br>- Description, technical characteristics, and use of the health technologies<br>2. Methodologies<br>3. Results:<br>a. Evidence Synthesis from clinical studies<br>- *If de novo evidence synthesis or updating of an existing SR with additional primary studies*<br>i. Study characteristics<br>ii. Critical appraisal (i,e., risk of bias assessment)<br>iii. Results of synthesis (including GRADE rating of evidence)<br>- *If appraisal and adoption of an existing SR*<br>i. Study characteristics<br>ii. Critical appraisal (i.e., risk of bias assessment)<br>iii. Results of the adopted SR (including GRADE rating of evidence)<br>b. Review of Guidelines<br>4. Discussion and Conclusion<br>5. Annexes<br>6. References |
| Final Financial Report | Pro Forma Financial Report by the Servicing Agency |
| Checkpoint meetings | As necessary |

**VII. Budget Proposal:**

For the estimation of budget proposal, below are our recommended rates depending on the specific clinical assessment methodologies which should be guided by an initial scoping of available evidence:

| **Clinical Assessment Method** | **All-in New Rates** *(inclusive of tax)* | **Duration** |
|---|---|---|
| Pairwise | ₱ 400,000.00 | **7 months**<br>6 months (clinical assessment)<br>+ 1 month (payment processing) |
| Network Meta-Analysis (NMA) | ₱ 800,000.00 | |

***Note: Cost to be determined based on the approved proposed methodology of evidence synthesis. The Full Proposal must provide rationale for the proposed methodology.***

**IX. Terms of Payment**

| **Release** | **% of Fund** | **Requirement** |
|---|---|---|
| 1st | 15% | ● Signed and notarized MOA/Contract |
| 2nd | 40% | ● Approved Full proposal<br>● Approved Inception report |
| 3rd | 35% | ● Approved Midterm Report |
| 4th | 10% | ● Approved Final Clinical Assessment Report |