THE EMERGENCY USE AUTHORIZATION, COMPASSIONATE USE AND RESEARCH ETHICS DURING HEALTH EMERGENCIES

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INTRODUCTION

The Declaration of Helsinki, a cornerstone document in research ethics, provides valuable principles and guidelines for the conduct of medical research involving human subjects.

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When considering emergency use authorization (EUA) and compassionate use during health emergencies in the context of the Declaration of Helsinki, several ethical considerations come to the forefront.

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The Declaration of Helsinki emphasizes the protection of research participants and the importance of balance between the welfare of individuals and the advancement of knowledge for the common good.

EMERGENCY USE AUTHORIZATION (EUA) AND COMPASSIONATE USE

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EMERGENCY USE AUTHORIZATION (EUA) AND COMPASSIONATE USE

Specifically, the following principles are relevant to EUA and compassionate use:

1. INFORMED CONSENT:

1. Informed Consent: The Declaration stresses the need for voluntary informed consent from participants. In the context of EUA and compassionate use, where urgency may be heightened due to health emergencies, mechanisms for rapidly conveying essential information to patients and families are crucial to allow for informed decision-making.

1. INFORMED CONSENT:

However, such processes must maintain ethical rigor and provide patients with the necessary information about risks, benefits, and available alternatives.

2. RISKS AND BENEFITS:

2. Risks and Benefits: An essential ethical consideration is the careful assessment of risks and benefits associated with investigational interventions.

2. RISKS AND BENEFITS:

This includes the need for continuous monitoring and evaluation of the outcomes and potential harms of the interventions authorized for use.

2. RISKS AND BENEFITS:

Transparency in communicating the available evidence and any emerging concerns is vital to uphold ethical standards and maintain public trust.

3. EQUITABLE ACCESS:

3. Equitable Access: The ethical frameworks outlined in the Declaration of Helsinki stress the importance of fair and equitable access to investigational therapies.

3. EQUITABLE ACCESS:

This principle emphasizes that vulnerable populations should not be further marginalized and should have the opportunity to benefit from potentially life-saving treatments during health emergencies.

RESEARCH ETHICS IN THE DECLARATION OF HELSINKI

The Declaration of Helsinki offers comprehensive ethical principles for the conduct of research, particularly in the context of health emergencies. These principles are relevant to emergency use authorization and compassionate use.

1. WELFARE OF PARTICIPANTS:

The primary focus on protecting the welfare of research participants is particularly crucial in the context of expedited pathways such as EUA and compassionate use.

1. WELFARE OF PARTICIPANTS:

Prioritizing participant safety and well-being while balancing the need for timely access to interventions is in line with the Declaration's emphasis on the welfare of individuals involved in research.

2. INDEPENDENT OVERSIGHT:

The Declaration highlights the importance of independent ethical review throughout the research process.

2. INDEPENDENT OVERSIGHT:

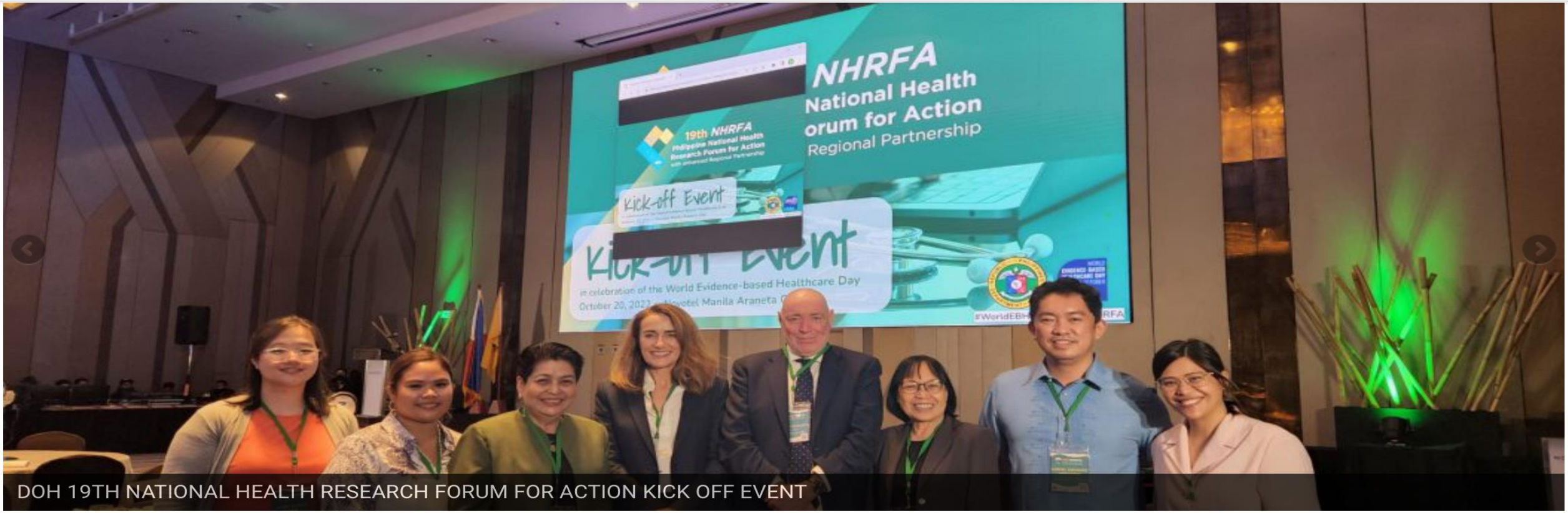
This oversight becomes particularly critical during health emergencies when the urgency to provide access to potentially beneficial treatments must be balanced with ethical rigor to protect vulnerable populations.

3. CONTINUOUS EVALUATION:

The Declaration's principles emphasize the need for continuous evaluation of ongoing studies and interventions.

3. CONTINUOUS EVALUATION:

This is especially relevant when considering the dynamic nature of health emergencies and the rapid dissemination of new information about investigational interventions.



DOH 19TH NATIONAL HEALTH RESEARCH FORUM FOR ACTION KICK OFF EVENT

COVID-19 Guidance

Learn how HTA Philippines is supporting the DOH COVID-19 response.

COVID-19 Guidance

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HTAC Evaluation Framework for COVID-19 Vaccine Assessments

What are the factors the Health Technology Assessment Council considers in assessing COVID-19 Vaccines?

HTA Philippines publishes HTAC Evaluation Framework for COVID-19 Vaccines

THE HEALTH TECHNOLOGY ASSESSMENT

Health technology assessment (**HTA**) is a multidisciplinary process that uses systematic and explicit methods to evaluate the properties and effects of a health technology.

THE HEALTH TECHNOLOGY ASSESSMENT

A health technology is conceived as any intervention (test, device, medicine, vaccine, procedure, program) at any point in its lifecycle (premarket, regulatory approval, post-market, disinvestment).

THE HEALTH TECHNOLOGY ASSESSMENT

The HTA aim is to inform "decision-making in order to promote an equitable, efficient, and high-quality health system ."

THE HEALTH TECHNOLOGY ASSESSMENT

HTA plays a crucial role in informing decision-making, resource allocation, and policy development during health emergencies when expedited pathways for drug approval are utilized.

THE HEALTH TECHNOLOGY ASSESSMENT

Several key considerations arise in conducting HTA for drugs under EUA and Compassionate Use:

1. EFFICACY AND SAFETY EVALUATION:

HTA aims to assess the clinical efficacy and safety profile of drugs authorized for emergency use.

1. EFFICACY AND SAFETY EVALUATION:

This includes understanding the strength of evidence supporting the interventions, potential risks and benefits, and the comparability of these interventions with standard treatments or alternatives.

2. RAPID ASSESSMENT:

Given the urgent nature of health emergencies and the need to provide timely access to potentially life-saving treatments, HTA processes for drugs under EUA and Compassionate Use must be expedited.

2. RAPID ASSESSMENT:

This requires the adaptation of HTA methods to enable rapid yet evidence-based assessments that can inform critical healthcare decisions in a timely manner.

3. REAL-WORLD DATA AND POST-AUTHORIZATION MONITORING:

HTA involves the collection of real-world data to complement clinical trial results for drugs under EUA and Compassionate Use.

3. REAL-WORLD DATA AND POST-AUTHORIZATION MONITORING:

Ongoing monitoring and evaluation of patient outcomes post-authorization are essential to ensure the continued safety and effectiveness of these interventions.

4. COST-EFFECTIVENESS CONSIDERATIONS:

The economic impact of drugs under EUA and Compassionate Use is a vital aspect of HTA.

4. COST-EFFECTIVENESS CONSIDERATIONS:

Assessing the cost-effectiveness of these interventions within the context of health emergencies, as well as their potential long-term economic implications, is crucial for informed decision-making and resource allocation.

5. STAKEHOLDER ENGAGEMENT:

In the HTA process for drugs under EUA and Compassionate Use, involving a wide range of stakeholders, including patients, healthcare providers, policymakers, and experts, is essential to ensure that diverse perspectives and needs are considered.

6. ETHICAL AND EQUITY CONSIDERATIONS:

HTA should also address ethical and equity considerations, ensuring that vulnerable populations have access to these interventions while the societal implications, such as potential disparities in access and outcomes, are carefully examined.

PROPOSAL FOR INCLUSION IN THE DECLARATION OF HELSINKI

By integrating these considerations into the HTA process, decision-makers can make informed and ethical decisions about the authorization, use, and allocation of drugs during health emergencies.

PROPOSAL FOR INCLUSION IN THE DECLARATION OF HELSINKI

This proactive approach can help maximize the clinical benefits of these interventions, minimize potential risks, and ensure equitable access, all in alignment with ethical principles, patient safety, and public health objectives.

DEVELOPMENT OF THE DECLARATION OF HELSINKI

18th WMA General Assembly, Helsinki, Finland, June 1964.

29th WMA – Tokya, Japan, Oct-1975.

35th WMA – Venice, Italy, Oct-1983.

41st WMA – Hong Kong, Sep-1989

48th WMA – Somerset West, RSA, Oct-1996.

DEVELOPMENT OF THE DECLARATION OF HELSINKI

52nd WMA - Edinburgh, Scotland, Oct-2000.

- Clarifications of Articles 29 & 30 in 2002 & 2004,

53rd & 55th WMA General Assembly.

59th WMA - Seoul, Oct-2008.