



World Health
Organization

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ISBN 978-92-4-004174-5 (electronic version)

ISBN 978-92-4-004175-2 (print version)

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Suggested citation. Emergency use of unproven clinical interventions outside clinical trials: ethical considerations. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

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Acknowledgements

This guidance is the result of collaboration between the WHO Working Group on MEURI and members of the WHO Clinical Management Working Group.

The document has been developed under the leadership of the Health Ethics & Governance Unit of the Department of Research for Health, in close collaboration with the Department of Country Readiness Strengthening and the Department of Regulation and Prequalification.

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Acronyms and abbreviations

BCG bacilli Calmette-Guérin

EUL emergency use listing

EVD Ebola virus disease

MEURI monitored emergency use of unregistered and experimental interventions

PAHO Pan American Health Organization

PHEIC public health emergency of international concern

RCT randomized controlled trial

REC research ethics committee

Glossary

Below is a glossary of terms ordered according to the order of a conceptual analysis of the designation “emergency use of unproven clinical interventions outside clinical trials contexts”.

Emergency use (use during a public health emergency): In this document, “emergency use” is shorthand for “use during public health emergencies”. It is important not to confuse a *public health emergency* with *emergency care*¹, which may be provided during or outside a public health emergency, nor with a *state of emergency* declared and lifted by a competent authority, such as a public health emergency of public health concern (PHEIC) by WHO or a national or local public health emergency by a competent local authority.

Intervention (general definition): The terms “intervention” and “use of an intervention” refer to a specific action in a biomedical setting, including clinical care, research and public health. It is better defined as “intervention ensemble”.

Intervention ensemble (technical definition): Although we define interventions as specific actions in a biomedical setting, they are usually identified with their most noticeable material, such as drugs, biologicals (e.g. antibodies, vaccines), devices, procedures and behaviour. What truly identifies an intervention, however, is how a material is used. Hence, an aspirin taken for a headache and an aspirin taken to prevent a heart attack involve the same material but are used in two different interventions. Consequently, an intervention could be defined as a coordinated set of *materials*, *operative dimensions* (e.g. dose, schedule, route of administration, risk mitigation, end-point, duration, co-interventions) and *constraints* (e.g. target populations, contraindications, likely side-effects) (2). The term “intervention ensemble” – a set of coordinated materials, operative dimensions and constraints – is a reminder that an intervention has many dimensions other than its materials (2). This definition is also useful from a regulatory point of view (3, 4).

Clinical intervention (use and regulation): In this document, “clinical intervention” refers to the use or regulation by health-care workers and/or relevant national health authorities of an intervention intended to provide a clinical benefit. The term “clinical benefit” is typically used as a synonym for the well-being or best interests of the recipients of an intervention (5). Nevertheless, use of clinical interventions has other consequences for public health and society and can benefit or harm populations. Hence, an adequate ethical evaluation of and justification for the use and regulation of clinical interventions must be broader than clinical benefit (4, 6). This document is based on a broader public health ethics evaluation of clinical interventions.

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