

WHO compendium of innovative health technologies for low-resource settings

2021

COVID-19 and other health priorities



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Glossary of terms

Term	Definition
Affordability	<p>“Health facilities, goods [including medical devices], and services must be affordable for all. Payment for healthcare services, as well as services related to the underlying determinants of health, must be based on the principle of equity, ensuring that these services [and goods], whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households [settings and countries] should not be disproportionately burdened with health expenses as compared to richer households [settings or countries].” CESCR (Committee on Economic, Social and Cultural Rights) General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12).</p> <p>This refers to securing a standard of living (e.g., housing, education, or health) at a price that does not impose, in the eyes of a third party (usually government), an unreasonable burden on household incomes.</p> <p>In the context of this report, it is the extent to which the intended recipients of a service can pay for it, be it a public, governmental, or private service.</p>
Biocompatibility	<p>Biocompatibility is a general term describing the property of a material being compatible with living tissue. Biocompatible materials do not produce a toxic or immunological response when exposed to the body or bodily fluids. The internationally recognized standard for general medical device biocompatibility is ISO 10993. There are many other standards that cover various aspects of biocompatibility testing and/or biocompatibility issues specific to particular types of medical devices.</p>
510(k) Boundary Conditions	<p>The elements of an FDA cleared 510(k) that characterize the device and demonstrate substantial equivalence, such as descriptions, predicate comparisons, labeling, performance characteristic data, and evaluation criteria.</p>
510(k) Clearance	<p>A 510(k) is a notification submitted to the FDA to demonstrate that a medical device to be marketed in the USA is “substantially equivalent” to a legally marketed device. There are different types of 510(k) submissions (traditional, abbreviated, or special), depending on whether the device is new or already on the market and has been modified.</p> <p>Clearance is granted to devices that receive marketing permission from the FDA through the 510(k) process. The 510(k) process is not an approval process.</p>
Certificate to Foreign Government	<p>An FDA certificate that is required by some countries to prove that an exported medical device from the US is legally marketed in the US and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).</p>
Certificate of Free Sale (CFS)	<p>Many countries require a CFS, sometimes called a Certificate for Export. It is evidence that goods, such as medical devices, are legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in the country of origin.</p>
Clinical engineer	<p>A trained professional who supports and advances patient care outcomes by applying engineering, life sciences, and managerial skills to optimize healthcare technology life cycles.</p>

Term	Definition
Clinical engineering	An application of engineering, life sciences, and management attributes to optimally deploy and safely manage technological tools, risk management techniques, and system challenges associated with the provision of healthcare services, especially in the clinical environment.
Clinical Evaluation Report (CER)	This documents the conclusions of a clinical evaluation of a medical device. A CER consists of analyzed clinical data that was collected from a clinical investigation of a device or the results of other studies on substantially equivalent devices. A CER demonstrates that a device achieves its intended purpose without exposing users and patients to further risk. The EU's MEDical DEvices Documents (MEDDEV) 2.7.1 Rev. 3 guidelines and the Medical Device Regulation provide manufacturers with guidance regarding how to properly evaluate the clinical safety and performance of their devices.
Clinical outcomes	Measurable changes in health or quality of life as result of specific healthcare delivery interventions.
CE marking	European Conformity (Conformité Européenne) mark. A mandatory European mark for products (including medical devices) to indicate conformity with essential health and safety requirements set out in the EU directives and regulations.
Declaration of interest (DOI)	To ensure the highest integrity and public confidence in its activities, WHO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential or reasonably perceived conflict of interest related to the subject of the activity in which they will be involved. The term "conflict of interest" means any interest declared by an expert that may affect or reasonably be perceived to (1) affect the expert's objectivity and independence in providing advice to WHO and/or (2) create an unfair competitive advantage for the expert or persons or institutions with whom the expert has financial or business interests (such as adult children or siblings, close professional colleagues, administrative unit or department).
Design control	Design controls are an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of the design an integral part of development. As a result, deficiencies in design input requirements and discrepancies between proposed designs and requirements are made evident and corrected earlier in the development process. Design controls

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