WHO compendium of innovative health technologies for low-resource settings

2021

COVID-19 and other health priorities

World Health Organization

WHO compendium of innovative health technologies for low-resource settings

2021

COVID-19 and other
health priorities

World Health Organization

WHO compendium of innovative health technologies for low-resource settings 2021. COVID-19 and other health priorities.

ISBN 978-92-4-003250-7 (electronic version)

ISBN 978-92-4-003251-4 (print version)

Graphic design and layout by Mrs Jillian Reichenbach Ott, Genève Design.

Contents

Acknowledgements iv
Glossary of terms v
Objectives xii
Methodology xiii
Terms, conditions and disclaimers for the call xxiii
Key for icons xxv

COMMERCIALLY AVAILABLE PRODUCTS 1

Bleach additive, colourized 2
Deployable facility, for emergencies, shipping container based . . . 4
e-voucher, vaccination management 6
Heart rate meter, for newborn 8
Infrared thermography camera 10
MP3 radio, solar, wind-up powered 12
Oxygen generation plant, deployable 14
Oxygen, portable rebreathing 16
Respiratory monitoring system, portable 18
Solar-powered oxygen concentrator 20
Tele-education, for COVID-19 22
Ventilator, for low oxygen inlet pressure 24
Ventilator, mechanical, pressure control 26
Ventilator, with extended battery time 28
X-ray detector, dual energy, portable 30

PROTOTYPE PRODUCTS 33

Face mask, reusable, polypropylene based 34
Microfluidic based, COVID-19 test 36
Optical screeing jaundice device, neonatal 38
Pediatric automated ultrasound 40
Personal protective equipment, biodegradable, jute cellulose based . 42
Personal protective equipment suit reusable, ventilated 44
Solar Powered Oxygen Concentrator & Compressor (SPOCC) . . . 46
Ventilator, resuscitator bag based 48
Ventilator, ICU with waveform display 50

Non-listed products 52
Discussion 53

Acknowledgements

The call, compilation, and evaluation of submissions for the Compendium of Innovative Technologies for Low-Resource Settings (hereinafter referred to as the Compendium) to address COVID-19 were managed by the World Health Organization (WHO) under the coordination of Adriana Velazquez Berumen, Team Lead Medical Devices and *In vitro* Diagnostics from the Health Product Policy and Standards Department under the Access to Medicines and Health Products Division.

WHO acknowledges and is most grateful to the consultants and reviewers who dedicated their time and expertise to help identify potential health technology solutions for global health priorities, as well as the German Federal Ministry of Education and Research for their financial support.

Special acknowledgement is given to the WHO consultants listed below who were specially dedicated to the different phases of the project: initiating the call, designing the survey, organizing the information required by external and internal reviewers, supporting the logistics of the selection process, and compiling the information for the publication. They are WHO independent consultants: Gabriela Jimenez Moyao, Mexico; Debjani B. Mueller, India/South Africa/Germany; Caroline Soyars, USA; Cesar Vieira, Portugal; Kim Walker, USA; from EuroScan: Hans-Peter Dauben, Germany; Iñaki Gutiérrez-Ibarluzea, Spain; Maximilian Otte, Germany; and from the Global Clinical Engineering Alliance: Yadin David and Tom Judd, USA.

WHO acknowledges the above-mentioned consultants and the following reviewers, all of whom provided declaration of interest (DOI) documents, which were assessed by the WHO secretariat, and no conflicts of interest were found.

John Adabie, Ghana; Neill Adhikari, Canada; Maliki Seidou Adjaratou, Benin; Degel Sharon Agoreyo, Ethiopia; Maizatul Akmal Abdul Muttlib, Malaysia; Syaqirah Akmal, Malaysia; Maria-Elena Algorri Mexico/Germany; Alfredo Aguilera, Mexico; Faisal Alshehri, Saudi Arabia; Mohammad Ameel, India; Md Ashrafuzzaman, Bangladesh; Manuel Antonio Muñoz Avilés, El Salvador; Diptesh Aryal, Nepal; Bayar Avirmed, Mongolia; Roberto Ayala, Mexico; Almir Badnjevic, Bosnia and Herzegovina; Elena Baños, Spain; Gaizka Benguria-Arrate, Spain; Paula Andrea Berrio, Colombia; Juan Antonio Blasco, Spain; Themis Bowcock, United Kingdom of Great Britain and Northern Ireland; Sandra Milena Perez Buitrago, Peru; Ricardo Silva Bustillos, USA; Tazeen Bukhari, Pakistan; Saide Calil, Brazil; Patricia Ching, China; May C. Chu, USA; Dan Clark, United Kingdom; Tobey Clark, USA; Thomas Devlin, USA; Riad Farah, Lebanon; Jim Fink, USA; Lorea Galnares, Spain; Pedro Galvan, Paraguay; Hui-Qing Ge, China; Jingyang Guanxin Gao, China; Nagwa Hasanin, Denmark; Madiha Hashmi, Pakistan; Emilio Hornsey, United Kingdom; Anwar Hossain, Bangladesh; Thierry Houngbo, Benin; Grace Li Ying Huang, Taiwan, China; Ashenafi Hussein, Ethiopia; Nora Ibargoyen, Spain; Einstein Albert Kesi, India; Baset Khalaf, Canada/South Africa/occupied Palestinian territory, including East Jerusalem; Niranjan Khambete, India; Mohidus Samad Khan, Bangladesh; Ayse Ayzit Kilinc, Turkey; Fatma Selcen Kilinc-Balci, USA; Richard Kojan, Democratic Republic of the Congo; Zheng Kun, China; Joanne Mei-Chi Lai, Taiwan, China; Hans-Joerg Lang, Germany; Ingrid Lara, El Salvador; Benoît-Pierre Ligot, France; Michael Lipnick, USA; Hui-Ling Lin, Taiwan, China; Eunice Lourenço, Portugal; Margarita Loyola, Mexico/Canada; Isabel Watanabe Ortega, Mexico; Michael Paddock, USA; Maurice Page, France; Nicolas Pallikarakis, Greece; Tashi Penjore, Bhutan; Silvia Perez-Protto, USA; Ledina Picari, Albania; Damas Magesa, United Republic of Tanzania; Zawiah Mansor, Malaysia; Duncan McPherson, United Kingdom; Claudio Meirovich, Spain; Mulugeta Mideska, Ethiopia; Martha Mulerwa, Uganda; Linda Mundy, Australia; Salome Mwaura, Kenya; Umberto Nocco, Italy; Ricardo Ortega Romero, México; Barun Kumar Rauniyar, Nepal; Adrian Richards, Australia; Erni Zurina Romli, Malaysia; Ana Maria Rule, USA; Ghina Safi, Lebanon; Neven Saleh, Egypt; Judit Rius Sanjuan, USA; Roza Sarimin, Malaysia; Mario Forjaz Secca, Mozambique; Jitendra Sharma, India; Letizia Songia, Italy; Robert Tamale Ssekitoleko, Uganda; Kallirroi Stavrianou, Greece; Alison Syrett, United Kingdom/Luxembourg; Orna Tal, Israel; Joshua Tim, Botswana; Bharath Kumar Tirupakuzhi Vijayaraghavan, India; Anna Worm, the Netherlands.

WHO also acknowledges the following WHO staff for their contribution: Louise Agersnap, April Baller; Janet Díaz; Tifenn Humbert; Ying Ling Lin; Garreth Mehl; Madison Moon; Peter Singer.

Glossary of terms

Term	Definition
Affordability	"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). 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. 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.
Biocompatibility	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.
510(k) Boundary Conditions	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.
510(k) Clearance	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. 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.
Certificate to Foreign Government	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).
Certificate of Free Sale (CFS)	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.
Clinical engineer	A trained professional who supports and advances patient care outcomes by applying engineering, life sciences, and managerial skills to optimize healthcare technology life cycles.

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