INNOVATIVE TECHNOLOGIES THAT ADDRESS GLOBAL HEALTH CONCERNS

OUTCOME OF THE CALL
GLOBAL INITIATIVE ON HEALTH TECHNOLOGIES
2010

World Health Organization

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List of Abbreviations

WHO	World Health Organization
AGIT	Advisory Group for Innovative Technologies
PMD	Priority Medical Devices (project)
GBD	Global Burden of Disease (study)
MDGs	Millennium Development Goals
WHA	World Health Assembly
GDP	Gross Domestic Product

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1. Introduction

The World Health Assembly (WHA) Resolution 60.29 on Health Technologies recognizes that medical devices are indispensable tools in health care delivery for prevention, diagnosis, treatment and rehabilitation *(1).* It acknowledges that medical devices are essential to attain the internationally agreed health-related development goals, including those contained in the Millenium Declaration *(2).* It is widely accepted that the availability of, and access to appropriate and affordable health technologies in low- and middle-income countries are still insufficient.

In addition the WHA Resolution 61.21 on global strategy and plan of action on public health, innovation and intellectual property, acknowledges that (current) initiatives are not sufficient to surmount the challenges of ensuring access to, and innovation of, much needed health products and medical devices *(3)*.

As a result of these resolutions, the World Health Organization (WHO) launched the Global Initiative on Health Technologies. Funded by the Bill and Melinda Gates Foundation, the initiative's goal is to make available the benefits of core health technologies at an affordable price particularly to communities in resource limited settings in order to effectively control important health problems. This initiative includes the development of guidelines and tools for health technology management, a call for innovative technologies (the results of which are discussed in this report), and the organization of a Global Forum on Medical Devices in Bangkok in September 2010.

The call for innovative technologies that took place from September 2009 to June 2010 sought to identify and evaluate innovative medical devices (including assistive devices) either existing or under development, which address global health concerns. A total of 84 submissions from 28 countries were received by the deadline of 31 January 2010.

Following an initial screening by WHO, 68 applications were sent for evaluation by external experts. From these, 15 were selected and posted on the web site[1] of the WHO Department of Essential Health Technologies in June 2010. This report discusses the selection process of the call and presents the 15 innovative technologies deemed to hold promise in reducing the global burden of disease. It is hoped this report will foster the development and availability of these technologies, particularly for those in low- and middle-income countries. Additional information about the call, including its guidelines and scope, is available in Annex 1.

Selection of these technologies does not imply WHO endorses any particular product; WHO solely aims to draw stakeholders' attention to innovative technologies to further their development, availability, and access. Interested parties should consider this report a call for further research and evaluation of not just the technologies selected, but all others submitted that can potentially reduce the burden of disease and disability worldwide.

The challenges faced by the applicants to succeed in getting their technologies into resource-limited settings are numerous and have been detailed in the WHO report *Medical devices: managing the mismatch (4)* as well as being discussed here. Once these challenges are met with the resources from industry, academia, and other stakeholders, these and many other innovative technologies can begin to ameliorate the health and well-being of all people. To this end, WHO will continue to work in search of appropriate, affordable, and available health technologies (in particular medical devices) that can reduce the global burden of disease.

1 http://www.who.int/medical_devices/call_selected_innovative_tech/en/index.html.

2. Background

2.1 Programme Objectives

Successful health care delivery requires effective medical devices to act as tools for the prevention, diagnosis, and treatment of diseases, as well as for rehabilitation purposes. Despite the exponential growth in scientific and technological development, low- and middle-income countries are still largely excluded from access to appropriate and affordable health technologies. Attainment of the health-related Millennium Development Goals (MDGs),[1] effective control of many diseases, and empowerment of those living with disabilities will not be possible without certain basic technologies.

The WHA Resolution 60.29 on health technologies emphasizes the role of medical devices and health technologies in health care, as well as their current suboptimal contribution to health outcomes:

> "Understanding that health technologies, and in particular medical devices, represent an economic as well as a technical challenge to the health systems of many Member States, and concerned about the waste of resources resulting from inappropriate investments in health technologies that do not meet high-priority needs, are incompatible with existing infrastructures, are irrationally or incorrectly used, or do not function efficiently" *(1)*.

A strategic objective of WHO's plan for 2008–2013*(5)* is to ensure improved access, quality, and use of medical products including medical devices; this recognizes medical devices as tools with which to provide health care and enhance the health of people. In order to facilitate equitable access to the necessary core technologies, the WHO Department of Essential Health Technologies is tasked with identifying and promoting innovative technologies that address global health concerns and stimulating their further development.

2.2 Global investment in health technology

The Landscape analysis conducted by WHO *(6)* investigated the likelihood of any technology corporation developing or adapting technologies for global health purposes using their own funds. The following section summarizes some of the findings of that report relating to technology innovation.

Low- and middle-income countries bear a greater share of the global burden of disease than do high-income countries. In 2004, the regions of South-East Asia and Africa – comprising primarily low- and middle-income countries – bore 54% of the global disease burden, though they account for only about 40% of the world's population. Despite this inequity, low- and middle-income countries spent much less on health as a percentage of gross domestic product (GDP) than did high-income countries *(7)*.

Since 2002 an average of 200 new technologies per year have been added to the EuroScan database for innovative health technologies *(8)*. A review of EuroScan's public access database[2], however, showed an apparent lack of information on technologies suitable for low-income countries.

1 http://www.who.int/topics/millennium_development_goals/en/.

2 http://www.euroscan.org.uk/

One common indicator of innovation activities is the number of new patents being registered. In terms of the country of origin the largest number of patent applications in the field of medical technology between 2001 and 2005 came from the United States of America (35%) and Japan (20%) although it is worth noting that several emerging economies such as Brazil, China, and India ranked high on the list *(9)*.

As shown through patent activities and the EuroScan database, the focus of industry is not on innovative technologies for the developing world. In order to address this gap, new strategies are required to encourage investment in health technologies that deal with challenges specifically faced in low- and middle-income countries.

2.3 Global Initiative on Health Technologies

The Department of Essential Health Technologies initiated the Global Initiative on Health Technologies[1] in March 2008. The overall goal of the initiative is to help address important health problems associated with communities in resource-limited settings by making available the benefits of core health technologies, through equitable access and affordability. This requires technology innovation, either in the technologies themselves or in the processes designed to facilitate their dissemination, application, and utilization.

The two specific objectives of the initiative are to challenge the international community to establish a framework for the development of national health technology programmes that will lower the burden of disease and ensure effective use of resources; and challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on improving public health in developing countries.

2.3.1 Call for innovative technologies

The call for innovative technologies challenged manufacturers, institutions, universities, governments, individuals, and non-profit organizations which design, manufacture and/or supply any type of medical device to focus their activities towards addressing the global health concerns outlined below.

- Alcohol use disorders
- Birth asphyxia and birth trauma
- Cancer
- Cerebrovascular disease
- Chronic obstructive pulmonary disease
- Deficient maternal health
- Diarrhoeal diseases
- Disability
- HIV/AIDS
- Infant and child (under 5) mortality
- Ischaemic heart disease
- Lower respiratory infections
- Malaria
- Neonatal infections
- Prematurity and low birth weight
- Refractive errors
- Road traffic accidents
- Tuberculosis
- Unipolar depressive disorders

1 http://www.who.int/medical_devices/appropriate_use/en/.

The project aims to optimize public health outcomes by encouraging innovation through:

- increasing understanding among decision-makers about the critical role of health technologies and innovation in promoting public health;
- stimulating the development of new technologies;
- promoting the use of technologies that are safe and/or simpler to use than earlier solutions;
- promoting technologies that are more cost-effective than previous technologies;
- identifying new health-related uses of existing non-health technologies that can have a significant and immediate impact on improving public health; and
- facilitating the dissemination, application, and utilization of new technologies.

3. Call for innovative technologies

3.1 Key phases

The key phases of the call for innovative technologies consisted of the launch, outreach, deadline, and announcement of results; they are detailed below. Further information regarding the call can be found on the web site of the Department of Essential Health Technologies[1].

3.1.1 Launch

WHO launched the call for innovative technologies at the World Congress on Medical Physics and Biomedical Engineering in Munich on 11 September 2009. The health concerns to be addressed and the selection criteria to be used, which were developed with assistance of the Advisory Group on Innovative Technologies (AGIT) and WHO collaborating centres for health technologies, were also presented.

3.1.2 Outreach

To disseminate the call WHO engaged in outreach activities including participation in MEDICA (the world's largest medical device trade fair), mailing information out to health technology stakeholders such as professional societies, manufacturers' umbrella organizations, and posting on health technology web sites.

3.1.3 Deadline

The deadline for submissions was 31 January 2010. In total, 84 submissions were received from 28 countries.

3.1.4 Announcement of results

A list of selected technologies was posted on the WHO web site[2] on 30 June 2010.

3.2 Screening and Selection Process

3.2.1 Categories

The applicants had the opportunity to submit their technology into one of two categories, based on their level of maturity.

> **Category 1** comprises commercialized products or products which are ready to be commercialized. This includes new products; products which have been commercialized for less than five years in high-income countries and which are not (yet) widely used in low- and middle-income countries; recent adaptation of existing non-health products for a health purpose; and/or recent adaptation of an existing medical device for low- and middle-income settings.

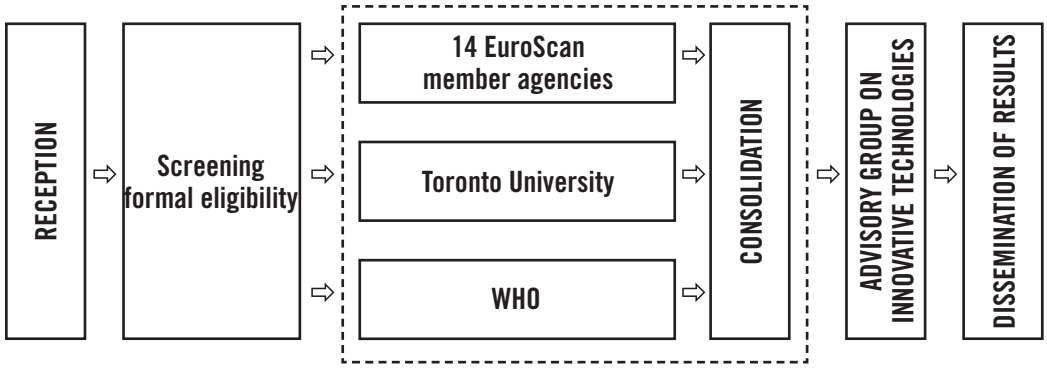
1 http://www.who.int/medical_devices/call_selected_innovative_tech/en/index.html.

2 http://www.who.int/medical_devices/call_selected_innovative_tech/en/index.html.

Category 2 comprises products in a non-commercialized stage or that are not ready to be commercialized; it includes products which are under development or otherwise in a conceptual stage.

The process for screening, evaluation and selection is shown in Figure 1.

Figure 1. Overview of the screening, evaluation and selection process



3.2.2 Reception and screening of submissions

WHO only considered applications which were complete, within the scope of the call, and which were received by 31 January 2010. An identifier code was assigned to each application and all information about the applicant was removed to maintain confidentiality during the evaluation process.

3.2.3 Evaluation

The 68 anonymous applications that passed the initial screening by WHO in February 2010 were then sent to selected WHO collaborating institutions to determine how well they conformed to the selection criteria of the call and to assess their level of innovation.

The evaluation and grading process was undertaken by WHO staff, two teams of experts at Toronto University (appointed by WHO), and 14 member agencies of EuroScan during a period of approximately six weeks. All external evaluators signed confidentiality agreements. The evaluators were of different professional backgrounds including physicians, biomedical engineers, usability experts and health technology assessment specialists. The applications were graded on a scale from 1 to 5 by the evaluators solely based on the submission forms received without annexes. The grading was returned to the WHO Secretariat, which compiled the data to prepare for the selection process.

3.2.4 Recommendation for selection

The submission forms and the related grading were presented to the Advisory Group on Innovative Technologies (AGIT) by the WHO Secretariat. The AGIT was composed of experts in the field of health technologies representing a wide panel of competencies and geographical origins. Its members declared any conflicts of interest prior to participation; expert reviewers with any conflicts did not participate in the review.

In the advisory group meeting that took place 27-29 April 2010 in Copenhagen, the experts were divided into four groups, two for each category. The four expert groups reviewed the original selection as well as identified outliers. Outliers here refer to technologies that had been graded very differently by different evaluators. Each member of the group read the information provided on the application. Subsequently the groups discussed the submissions

with regard to the six selection criteria. All groups provided their recommendation for or against selection including reasoning and general comments. After reviewing all submissions, the two teams for each category presented their results to each other and engaged in further discussions. The final recommendation to the WHO Secretariat was provided in a plenary session.

Reviewers considered the following criteria when evaluating the submitted technologies:

- level of safety for the user, patient and the environment;
- effectiveness in addressing the health concern in question;
- level of adaptation to local infrastructures in resource-limited settings;
- ease of use and maintenance;
- total cost of ownership, cost-effectiveness and affordability; and
- level of cultural and social acceptability.

The major limitation identified by the experts was the difficulty to apply a single set of criteria in a consistent fashion to applications pertaining to a vast array of medical devices addressing numerous diseases and at very different levels of development.

The final selection of the 15 technologies discussed in this report was made by WHO based on the recommendations from the AGIT.

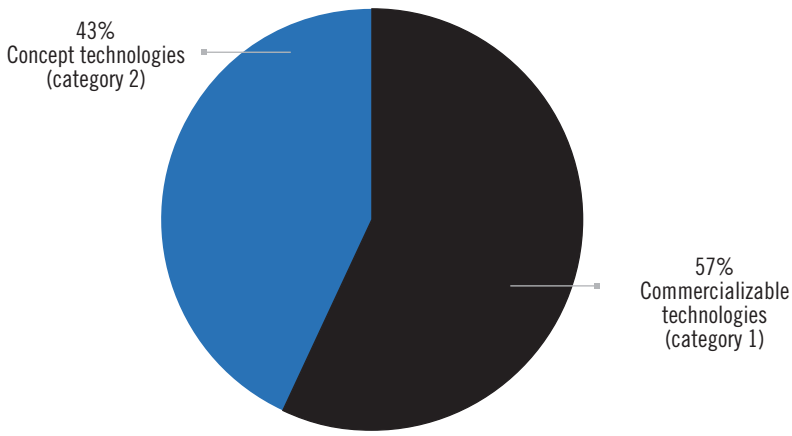
Evaluations were based solely on the information provided in the submitted documents. Therefore, further independent evaluation will be needed to ensure the successful implementation of the submitted technological innovations.

3.3 The Response

3.3.1 Submissions by category

Of the 68 submissions that passed initial screening more than 50% were commercialized or able to be commercialized (Figure 3).

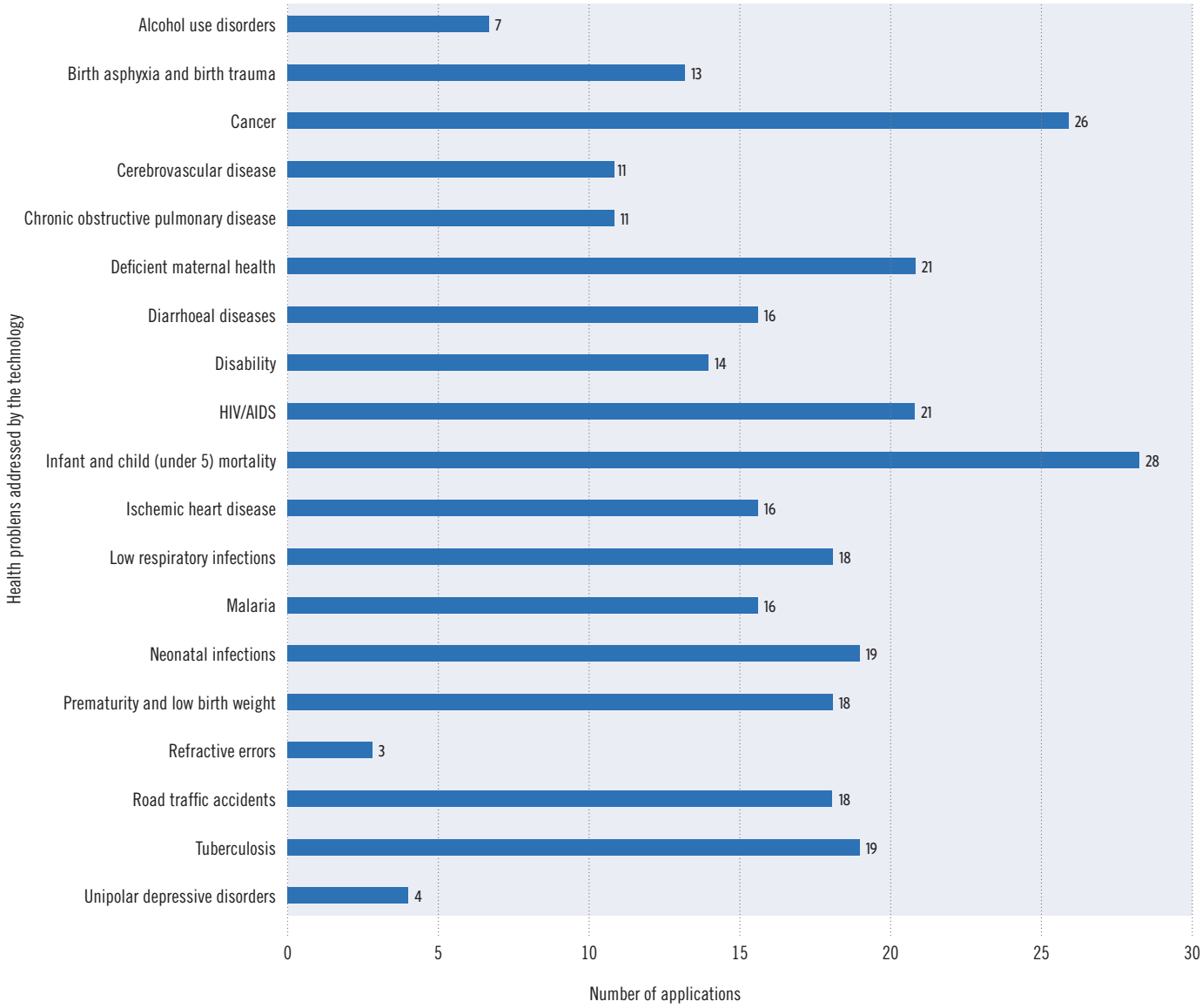
Figure 3. Submissions by category: commercializable and concept technologies



3.3.2 Global health concerns addressed

Each applicant claimed that the submitted technology addressed one or more of the 19 global health concerns indicated in the scope of the call. Each applicant could select more than one health concern and a number of the products do in fact serve multiple needs within the medical sector (Figure 4).

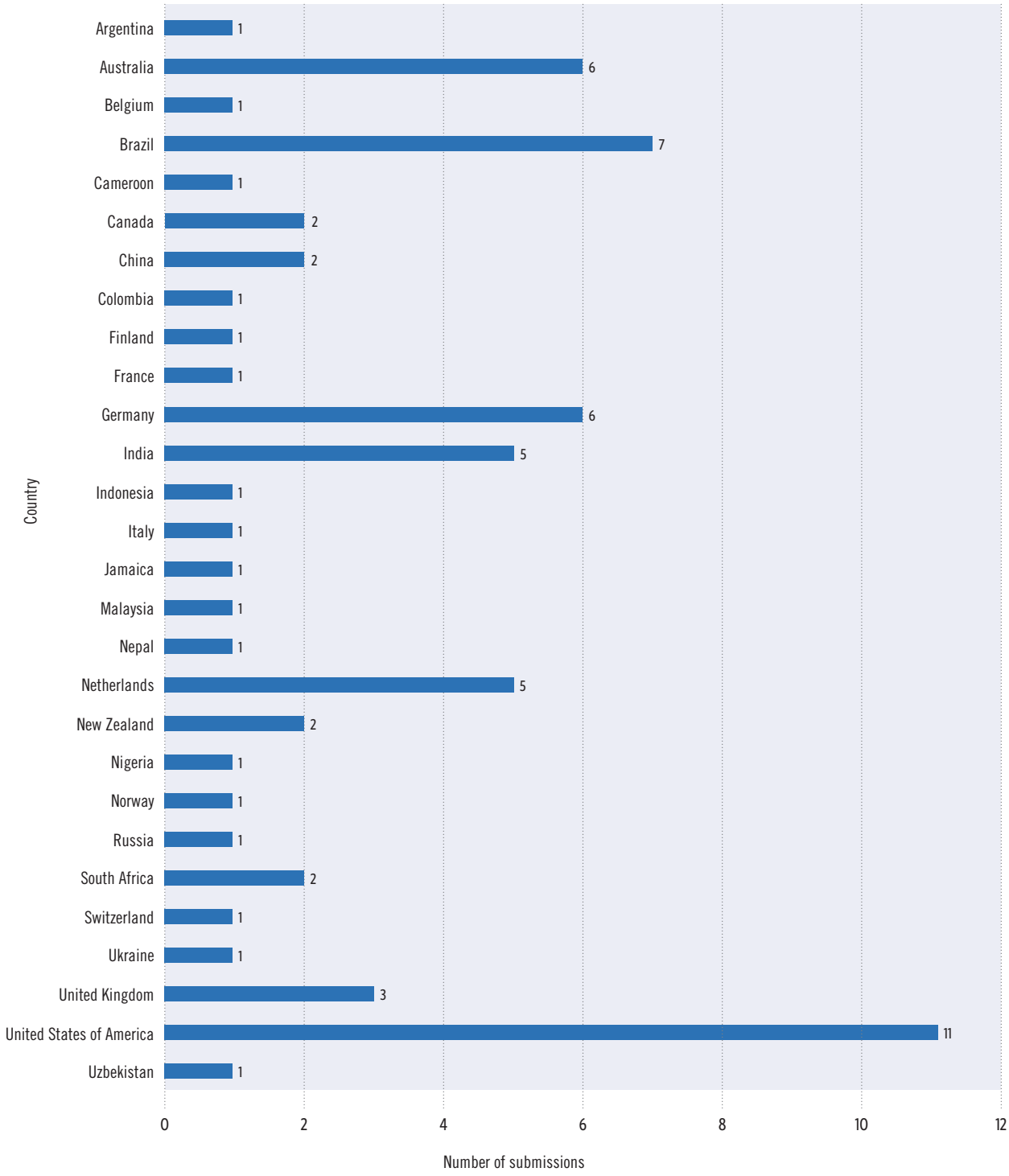
Figure 4. Global health concerns addressed by the technology (by number of applications)



3.3.3 Country submissions

Figure 5 shows the 28 countries from which technologies were submitted. Participation came from countries with diverse income levels.

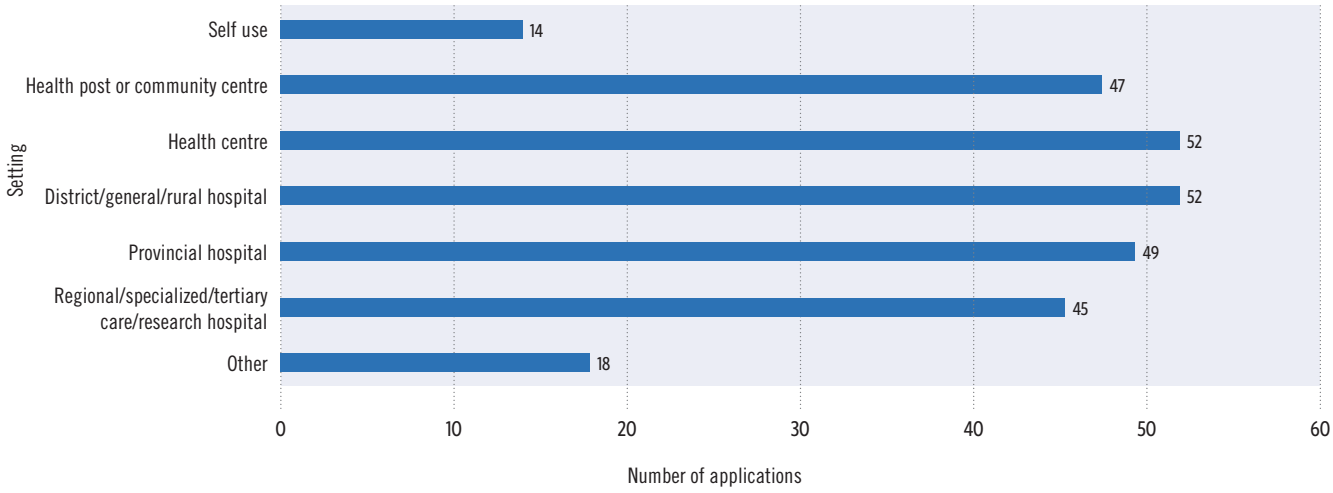
Figure 5. The number of technology submissions received, by country



3.3.4 Intended users of submitted technologies

Most submissions are intended for use by health-care professionals but 14 are intended for self-use. Each applicant could select more than one intended user and it seems that most innovations can be used in multiple health care settings (Figure 6).

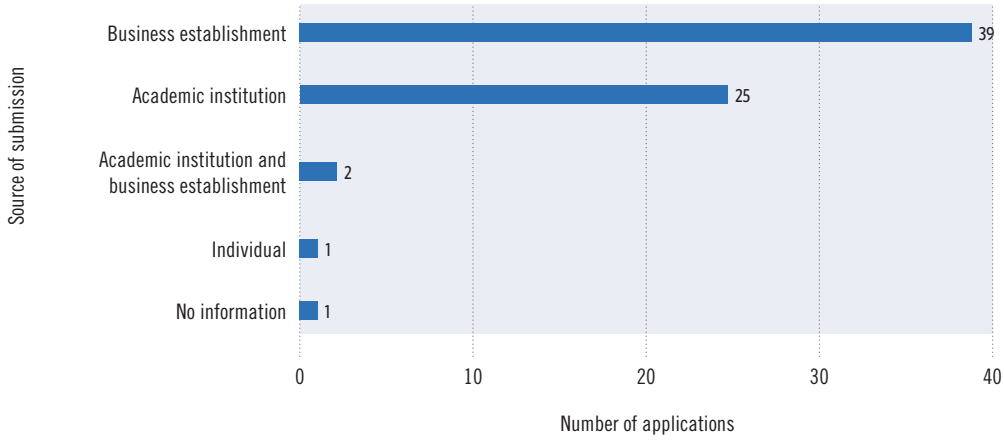
Figure 6. Settings for intended use of proposed technologies



3.3.5 Source of submissions

The vast majority of proposals were submitted by academia and industry; a few were also contributed by individuals and organizations specialized in innovative technologies for resource-scarce settings (see Figure 7).

Figure 7. Submissions received, by type of institution



3.4 Submissions

3.4.1 Submitted technologies

Tables 1 and 2 show the 84 submitted technologies, and reflect the variety of technologies and diversity of intended use.

Table 1. Submitted commercialized technologies or those ready to be commercialized (category 1)

Cervical cancer screening based on detection of cell membrane cancer markers in cervical smears
Clinical decision support software
Clinical patient data software
Congenital disease screening system
Diabetic foot detection system based on temperature measurement
Diagnostic/Screening test for bladder cancer
Digital X-ray system
Electric stimulation neurotherapy
Electronic health record patient interface
Exercise kit
External fixator
Face masks
Fluorescence visualization of abnormalities in oral cavity
Fuel efficient wood stove
Gravity-based blood separation system
Isothermal nucleic acid amplification system for tuberculosis diagnosis
Laryngoscope
LED phototherapy unit
Magnetic coils for destruction of pathogens
Mobile laboratory for diagnosis (cardiac, cancer, respiratory)
Mobile phone system for sending microscope images
Multi parametric patient monitor
Nano filters for water treatment
Newborn simulator
Patient data information system
Patient management system software
Portable haemoglobin meter
Portable telemedicine system
Portable ultrasound imaging system
Portable ventilator for chronic obstructive pulmonary disease
Radiation treatment system for health care waste
Reusable neonatal suction system

Rotational field quantum nuclear magnetic resonance
Single use male circumcision device
Short message service (SMS) for smoking cessation
Stool sample collection and preparation kit
System for on-site production of wound irrigation solution
Telehealth system
Transcutaneous bilirubin measurement system
Ultrasound transducer disinfection system
Vapour sterilization system
Water dispenser for hand wash
Web-based ECG cardiac diagnosis system
Wheelchair based on standard components
X-ray imaging system

Table 2. Submitted technologies in a non-commercialized stage of development (category 2)[1]

Accuracy tester for electronic fetal heart rate monitor
Ambient gas plasma system for antisepsis
Anti thrombotic coronary artery bypass graft
Bio potential and impedance measurement-based monitoring for cardiovascular diseases
Birthing simulator
Decision support system for paediatric HIV
Drug authentication system
Drug packaging with extended shelf life
External fixator
Isolator system for minimally invasive surgery
Laboratory in a backpack
Micro-endoscope for cancer screening
Mobile phone-based pregnancy risk assessment system
Mobile phone-based pulse oximeter
Mosquito repellent skin lotion
Multi fever diagnosis system
Paediatric stretcher
Patient data information system
Portable infant warmer
Portable infusion system
Portable on-site cell sorter and counter for HIV and malaria diagnosis

1 Two submitted applications were incomplete and one was a repeat application and are therefore not presented in the list.

Portable telemedicine system
Remote fetal heart rate and activity monitoring
Remote palliative radiotherapy system for terminal cancer
Safety seat for children (road transport)
Semi-automated system for mycobacteria detection
Simplified anaesthesia unit
Single use assistive vaginal delivery system
Single use male circumcision device
Solar reading light
Solar-powered autoclave
Sub-dermal implant for drug delivery
System for biological screening to be used in current hygiene products
Telemedicine resource for emergency care
Transcutaneous anaemia monitoring system
Wireless system for transmission of vital signs in neonatal intensive care units

3.5 The selected technologies

Fifteen innovative medical devices were selected from the submissions: eight from category 1 and seven from category 2. In this section, each selected medical device is briefly introduced. Each applicant provided a poster that describes the submitted technology. Applicants' contact information is also provided to facilitate communication between the innovator and any interested parties.

The innovative technologies that were selected by the AGIT, external evaluators, and the WHO Secretariat, show potential to help reduce the global burden of disease.

Bearing in mind that the evaluation by the team of experts is solely based on the assessment of data and information submitted in the applicants' dossiers, inclusion in the Lists of Selected Innovative Technologies does not constitute a warranty of the fitness of any selected technology for a particular purpose. Besides, the responsibility for the quality, safety and efficacy of each selected technology remains with the manufacturer. The decision to list a particular technology is subject to change on the basis of new information that may become available to WHO. If there is evidence of serious safety and/or quality issues in relation to a listed technology, WHO may withdraw the technology concerned from the list until results of further investigations become available and are assessed by WHO.

WHO will not be held to endorse nor to recommend any listed technology. The Lists of Selected Innovative Technologies solely aim at drawing stakeholders' attention to innovative medical devices, either existing or under development, with a view to fostering the development and availability of, and/or access to, innovative health technologies which are likely to be accessible, appropriate and affordable for use in low- and middle-income countries.

Inclusion in the Lists of Selected Innovative Technologies does not furthermore warrant or represent that:

1. the list is complete or error free; and/or that
2. the technologies which have been found to meet the selection criteria will continue to do so; and/or that
3. the use of the selected technologies listed is, or will be, in accordance with the national laws and regulations of any country, including but not limited to patent laws; and/or that
4. any medical device or product that may be developed from selected applications will be successfully commercialized in target countries or that WHO will finance or otherwise support the development or commercialization of any such medical device or product.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and/or use of any listed technology or resulting medical device or product and any future development thereof.

COMMERCIALIZABLE TECHNOLOGIES (CATEGORY 1)

3.5.1 Stool sample collection and preparation kit

The purpose of the kit is to simplify faecal examination by reducing the number of consumables and steps required for the procedure. The kit could therefore facilitate the diagnosis of parasitological diseases. Additionally, the kit does not appear to require water or electricity and is claimed to prevent contamination of the environment.

Name: José Carlos Lapenna
Email: jczl@globo.com
Country: Brazil

3.5.2 LED phototherapy unit

The purpose of the unit is to treat hyperbilirubinaemia in newborn infants by phototherapy. The unit could increase the safety of the procedure by using a radiation source that produces blue light and minimizes exposure to harmful ultraviolet radiation. Further potential advantages are that the unit measures the actual output of light at useful wavelengths and is claimed to have lower energy consumption than previous designs.

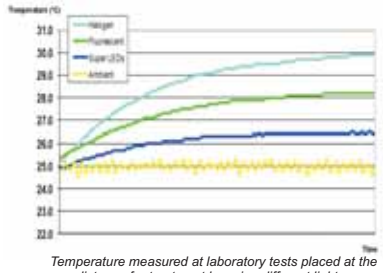
Jaundice: Innovative LED phototherapy

Need of Phototherapy

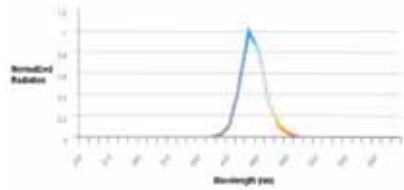
Phototherapy is used for treatment for jaundice, a common condition in newborn infants caused by high levels of seric bilirubin, which may cause chronic bilirubin encephalopathy (kernicterus). Jaundice newborns have yellowing of the skin and the whites of the eyes. This condition is common in more than 70% of the newborns. Phototherapy treatments decrease the bilirubin levels in the blood by changing the trans-bilirubin into cis-bilirubin isomer, which is water-soluble.

Technology by Super LEDs

Phototherapy is the most effective treatment when the light used is around 450nm of the light spectrum wavelength, which corresponds to the blue color. Super LEDs provide light precisely at this wavelength and have an abrupt attenuation of the irradiance from the infra-red and ultra-violet wavelength ranges, reducing undesired effects to the infant's skin. The radiance levels are higher, which decreases treatment time considerably. Also, the power consumption and the heating caused by the Super LEDs are very low when compared with other sources of light.

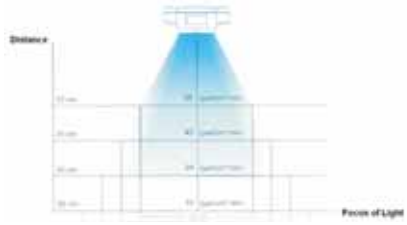


Temperature measured at laboratory tests placed at the same distance for treatment by using different light sources

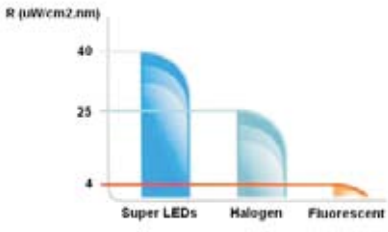


Super LEDs Radiation Spectral Curve Range

Data and Testing Methodology



Estimated Radiance at different Distances



Radiance Measured by different light sources

Product Features

- Reduced Size (23.5cm x 11.5cm)
- Great radiation in both the middle and the borders of the irradiation area
- Low energy consumption
- Advanced blue spectrum irradiation technology
- Infra-red and ultra-violet rays attenuator
- Soft touch buttons and microprocessor of various functions
- Wide adjustment of radiation intensity according to basic necessities
- Watch/Calendar
- Lamp time counter
- Treatment time counter
- Memory of radiation, manual or automatic measurements, to print in report.
- RS-232 output for printers or computers
- Easy Access to the supply module, for cleaning and maintenance
- Radiometer with Optical Probe can be integrated

Super LEDs Phototherapy with Integrated Radiometer

Versatility

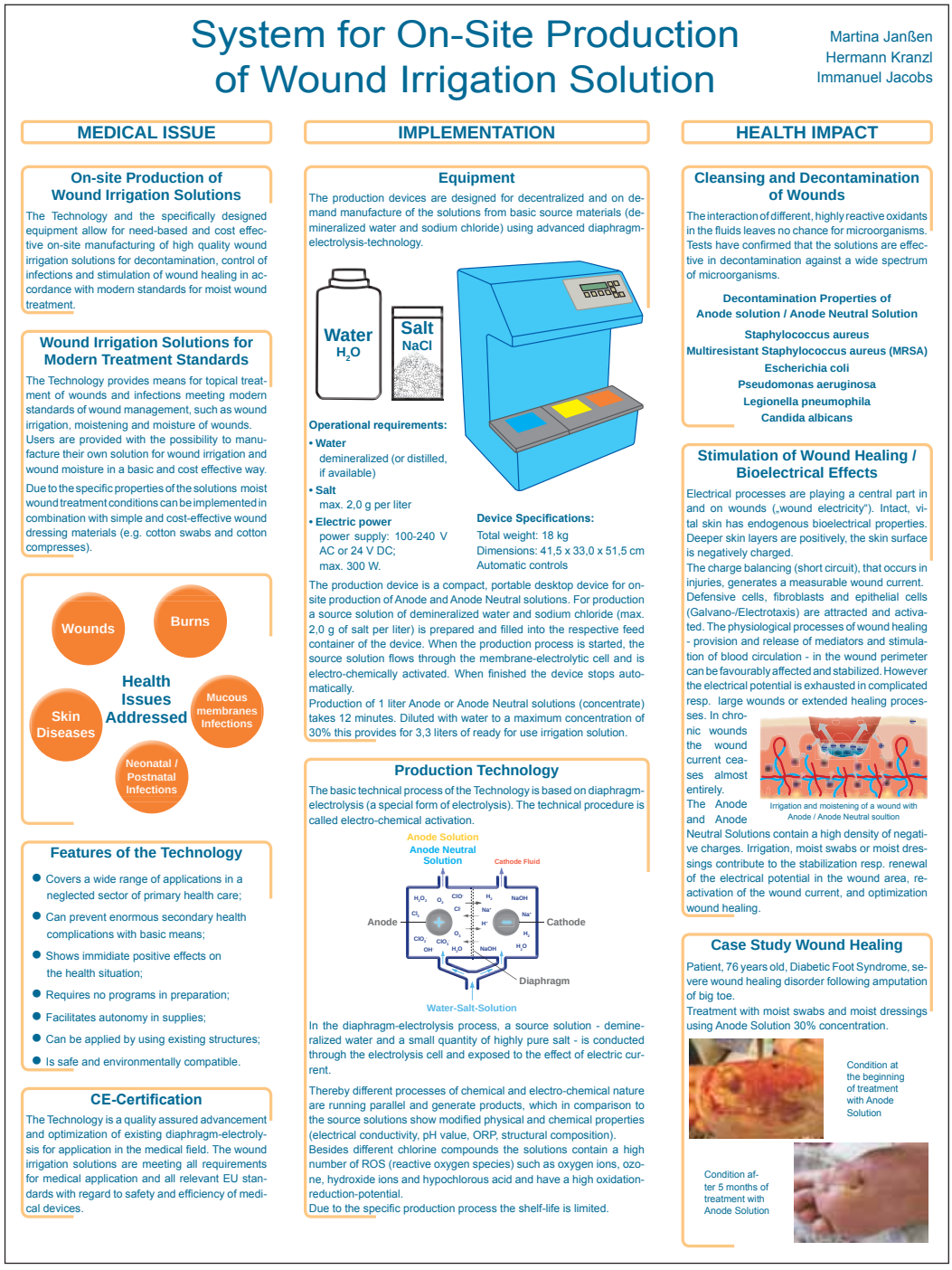
Infant can be treated in cradles, incubators and infant warmers

References:
1.Martins BM, de Carvalho M, Moreira ME, Lopes JM. Efficacy of new microprocessed phototherapy system with five high intensity light emitting diodes (Super LED). J Pediatr (Rio J). 2007;83(3):253-258.
2.Leone CR, Sadeck LSR, Barros JCR, Toma E, Vaz FAC. Blue Super-LED Phototherapy use in newborns and Hyperbilirubinemia Evolution.

Name: Nancy Gambaroni
E-mail: nancy.gambaroni@terra.com.br
Country: Brazil

3.5.3 System for on-site production of wound irrigation solution

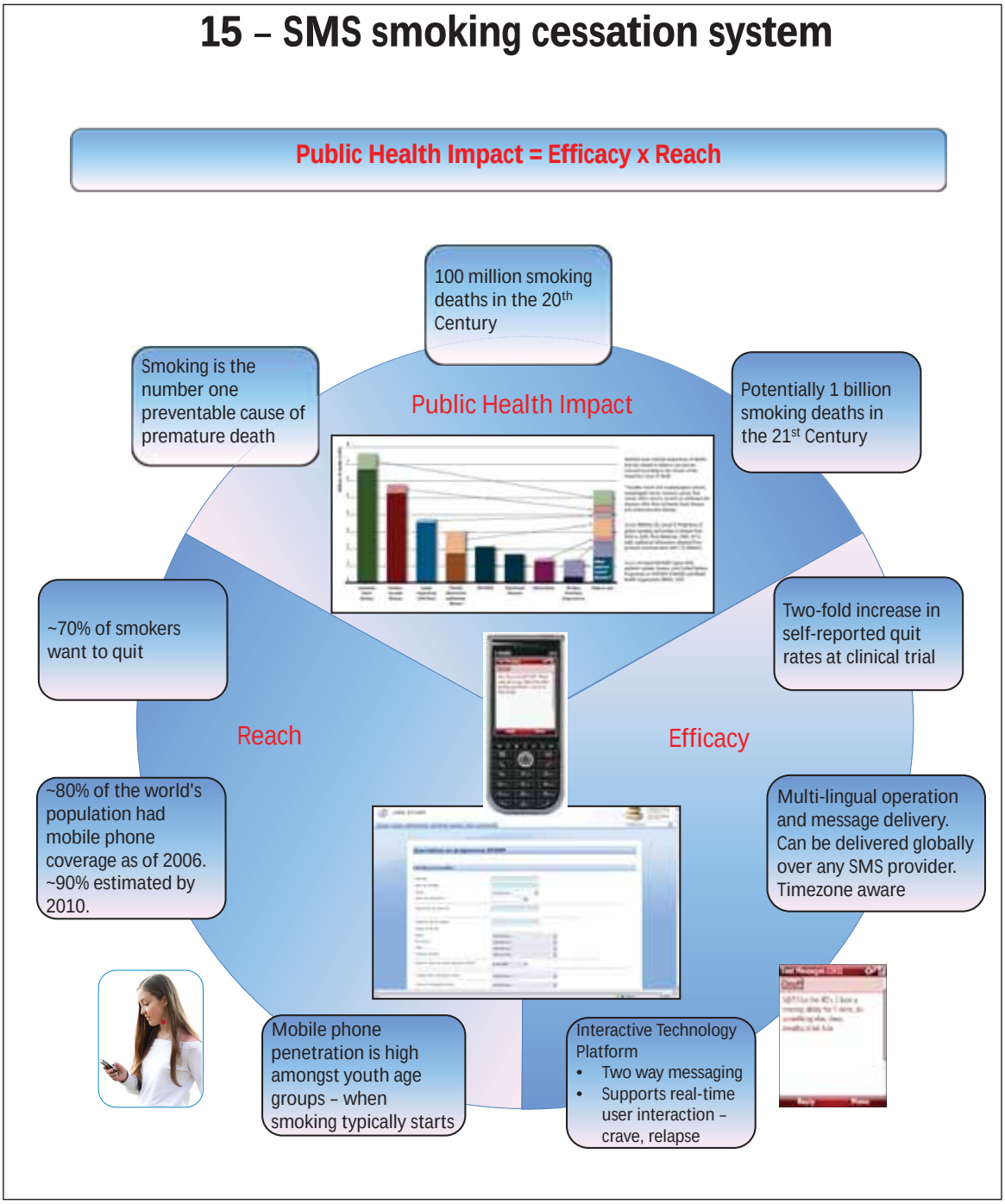
The purpose of the system is to produce aqueous solutions for the topical treatment of wounds and infections using a power source, dematerialized water, and salt. Solutions produced by the system could be used to treat a host of conditions including traumatic injuries, post-natal infections, and neglected tropical diseases that cause ulcerations and infections.



Name: Hermann Kranzl
Email: hkranzl@gmail.com
Country: Germany

3.5.4 Short messaging service (SMS) smoking cessation system

The purpose of the system is to provide tailored SMS-based smoking cessation support to its users. According to preliminary research the system facilitates self-management of smoking cessation and increases the likelihood of user adherence to smoking cessation programmes. The interactive system is claimed to be capable of answering messages about cravings to support the user.



Name: Matt Hector-Taylor
Email: matt.hector.taylor@gmail.com
Country: New Zealand

3.5.5 Reusable neonatal suction system

The purpose of this system is to remove obstructive mucus from the air passages of newborn infants, to reduce the risk of asphyxia, and support neonatal resuscitation. The device is claimed to be made of silicone and therefore reusable (capable of being boiled between uses). The device also requires no electricity.

Reusable neonatal suction system

BACKGROUND

Actual need

WHO estimates that nearly 1 million newborns in low and middle income countries die from birth asphyxia each year. A similar number are disabled due to inadequate breathing at birth.[1] To stimulate spontaneous breathing, or perform bag-mask ventilation effectively, an open airway is mandatory. Often this requires clearing the mouth and nose of mucous and meconium using vacuum.[2,3]

Current situation

Whereas available neonatal suction devices available cannot be cleaned for reuse, budgets generally prevent single patient use.[4]

Meeting a challenge

UN's Millennium Development Goal No 4 (MDG 4) aims at reducing the mortality of children, including newborns, by 2/3 by 2015. To help reach the MDG 4 we have developed a new neonatal suction device which is clinically effective, easy and safe to use, available at a low price and can be reused for multiple patients over a very long period of time. This device is also suitable for large scale training of birth attendants.

References:

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4. Stephen N. Wall , Anne CC Lee, Susan Niermeyer, Mike English , William J. Keenan , Wally Carlo, Zulfiqar A. Bhutta , Abhay Bang , Indira Narayanan, Iwan Ariawan, Joy E. Lawn. (2009). Neonatal resuscitation in low-resource settings: What, who, and how to overcome challenges to scale up? IJGO 2009; 107: s47-64
5. Biomatech. Final Report; Cleaning and disinfection procedure validation according to the AAMI TIR technical report and NF EN ISO 17664 standard on the Silicone Suction Unit, reference part number 986000, batch 5/2010. July 01, 2010. France.

PRODUCT QUALITIES

Design

- Ergonomic shape allows convenient one hand operation
- Inviting non-clinical look as represented by a friendly penguin
- Easy opening and closure in connection with emptying and cleaning
- One-part design requires no disassembly/reassembly

Material

- Transparent silicone rubber permits immediate visual inspection of any suctioned matter
- Can be cleaned in high temperatures by methods including boiling and autoclaving
- Soft beak shaped nozzle will not hurt baby's mouth and nostrils
- Withstands aging and discoloring during storage over extended periods of time

Cleaning

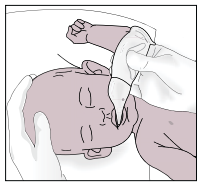
- Penguin head can easily be flipped to the side to allow easy emptying of suctioned matter during use, and can as easily and quickly be flipped back for continued suction
- After mechanical removal of debris boiling in water for 10 min. has been documented to provide effective decontamination to be safely ready for reuse[5]

Effectiveness

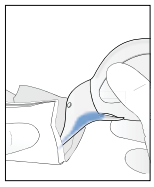
- Meets recommendations of providing vacuum of up to 100 mm HG (136 cm H_2O)

Affordability

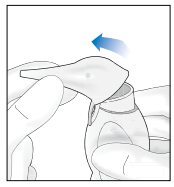
- Low purchase price and use for large numbers of patients over years make this suction device most suitable for general use in low income countries.
- Also ideal for large scale sponsor facilitated distribution on a not-for-profit basis.



To suction



To empty during suction



To prepare for cleaning after use

Technical specifications	
Nozzle dimensions at tip:	*Inner diameter (ID): 3.0 mm* *Outer diameter (OD): 4.5 mm*
Suction strength (typical):	*100 mm Hg (136 cm H_2O)*
Operating temperature:	*0 °C (32 °F) to 50 °C (122 °F)*
Storage temperature:	*-20 °C (-4 °F) to 60 °C (160 °F)*
Material:	*Transparent silicone rubber*

Name: Jens Petter Ianke
Email: suctiondevice@gmail.com
Country: Norway

3.5.6 Fluorescence visualization of abnormalities in oral cavity

The purpose of the system is to use the natural fluorescence of mucosal tissues when excited by a violet/blue light to inform clinicians about the presence of abnormalities in the mucosa in the oral cavity. This system could aid in the early detection of oral/oropharyngeal cancers and thereby reduce morbidity and mortality associated with these diseases.

Name: David Morgan
Email: d.c.morgan@hotmail.com
Country: Canada

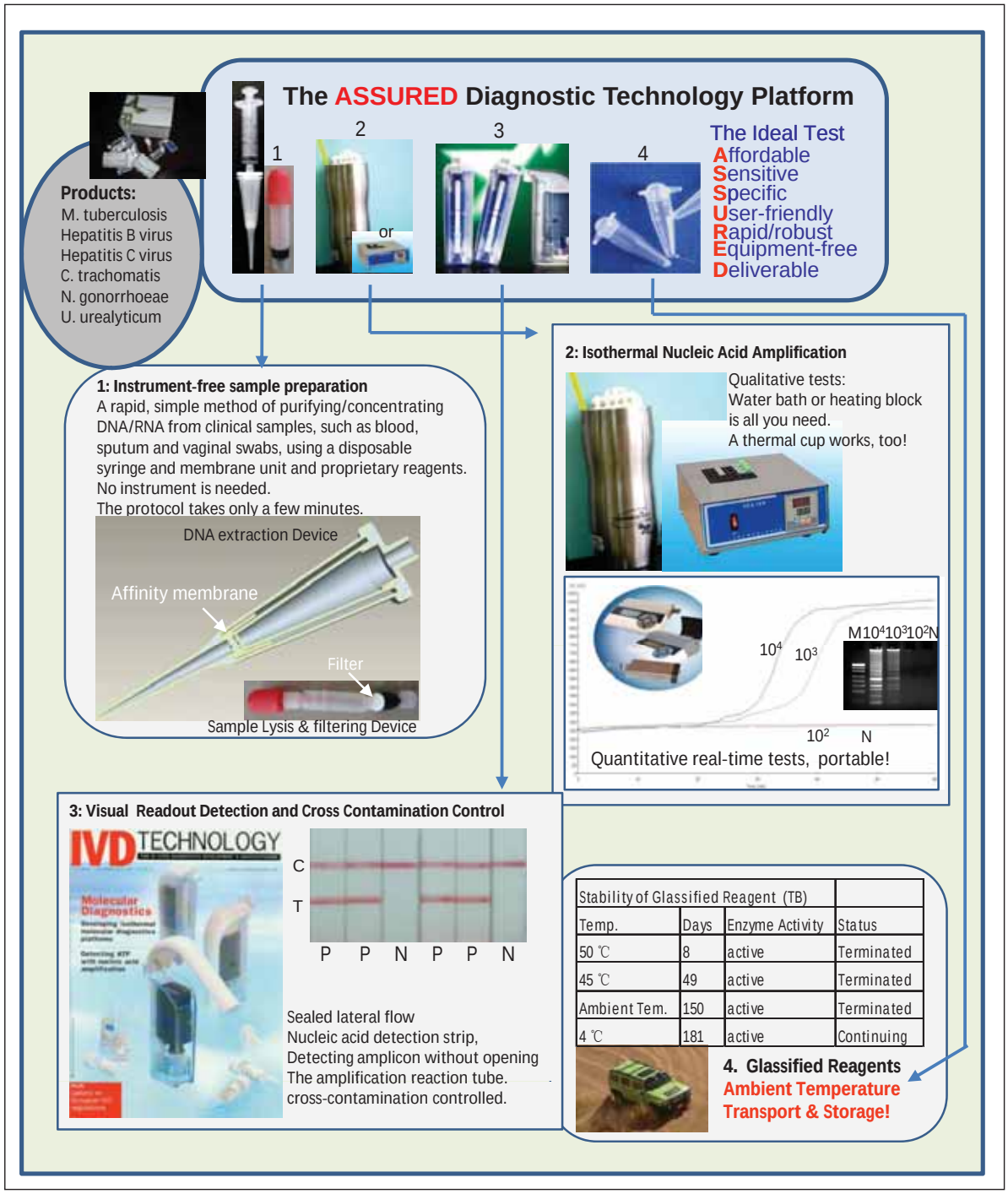
3.5.7 Transcutaneous bilirubin measurement system

The purpose of the system is to provide an alternative to blood sample analysis for the diagnosis of hyperbilirubinaemia in newborn infants. The system uses spectral analysis of light reflected from the patient's vascular bed to determine levels of blood bilirubin. The device is claimed to be non-invasive and to provide a rapid read-out.

Name: Sue Jones
Email: susan.jones115@virginmedia.com
Country: France

3.5.8 Isothermal nucleic acid amplification system for tuberculosis diagnosis

The purpose of the system is to offer a point-of-care alternative to sputum smear microscopy. The technology is claimed to require no additional equipment and to yield a rapid visual read-out of the diagnostic result..



Name: Qimin You
Email: qiminyou2000@163.com
Country: China

CONCEPT TECHNOLOGIES (CATEGORY 2)

3.5.9 Simplified anaesthesia unit

The purpose of the unit is to function as an anaesthesia machine for surgical use in low-resource settings. The device features an innovative valve system with reduced technical complexity compared to traditional devices. The device is claimed to function with oxygen from different sources, including ambient air, and therefore would not require compressed oxygen.

Name: Mark Zimmerman
Email: aygallego@gmail.com
Country: Nepal

3.5.10 Single use assistive vaginal delivery system

The purpose of the system is to assist fetal extraction, in cases of prolonged second stages labour, without having to use forceps, a vacuum extractor, or to resort to caesarean sectioning. The lack of rigid instruments in the system is claimed to reduce the risk of injury to both mother and child.

SINGLE USE ASSISTIVE VAGINAL DELIVERY SYSTEM

Background

World-wide, 10- 20% of deliveries require some form of intervention, and this intervention is frequently a caesarean section.(1) Instrumental vaginal deliveries (forceps and vacuum extraction) account for 2–23% of deliveries.(2-3) Obstetric history of assisted vaginal delivery started with the invention of instruments designed 400 years ago. However, it is only in the last 20 years of different intervening methods that scientific evaluation of risks and benefits have been discussed (4). Operative vaginal delivery rates in Latin American countries are low compared with those in most developed countries. Data from hospital deliveries in 18 countries show that rates do not exceed 6% and are below 2% for half of them (Latin American Center for Perinatology, 1985 - 1995). It is a region with low operative vaginal delivery rates and high caesarean section rates (5). The forceps is the standard instrument used in our countries.
This profile makes particularly relevant the introduction of a new device which would prioritize maternal fetal safety, would be easy to use, disposable and would not require a highly skilled attendant. In this sense, people from all over the world could have access to it and the most vulnerable populations would benefit to a higher extent.
The new device provides an extractive mechanism as well as a mechanism to facilitate the physiological expulsion of the cephalic pole, and neither instruments nor devices for the extraction of the fetal head have been developed over the last 160 years. It also provides a physical mechanism of action different from the forceps or the vacuum extractor, or Thierry spatulas.

Device physical mechanism of action

This instrument has been designed on the basis of a double physical phenomenon consisting of a conveyor belt and an air clamp. The device consists of a polyethylene sleeve with a cuff-like fold on the fetal insertion edge, which fits the fetal head diameter. This sleeve is introduced using two flexible plastic spatulas 3-mm thick. One of them is straight and is used to crown the fetal head, and the other one follows the fetal cephalic curvature and allows placing the device in the adequate final position.
After applying the device, a small amount of air may, or not, be insufflated at zero pressure. The atmospheric air entering during the device application with the spatulas is generally enough to produce the air clamp around the fetal head. However, the air clamp effect may be enhanced by insufflating a small amount of air at zero pressure through an insufflation cannula, which runs along the device until reaching a chamber in the distal edge of the fold. Thus, an air clamp is obtained, which holds the fetal head at 360º. This adds to the conveyor belt or sliding effect occurring between the inner parts of the fold upon force exertion. Such force may be either external, i.e., through traction from outside the device, or internal, i.e., arising from the natural forces that bring about uterine contractions and maternal pushing. The optional traction handle would allow maintaining the polyethylene sleeve diameter, thus facilitating maternal soft tissues distension during the extraction of the cephalic pole.
In order to test the physical phenomenon, a real size pregnant uterus was designed. This was a 1-inch glass uterus at full cervical dilation (10 cm). Through its transparent walls can be seen both physical phenomena: the air clump (figure 1) and the belt conveyor phenomenon (figure 2).

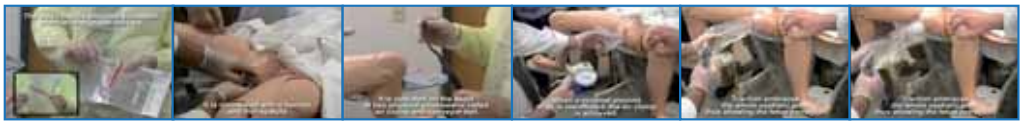
Figure 1: The air clump is achieved when a minimal amount of air is insufflated. This results in a sealing effect between the cephalic pole and the maternal uterus.

Figure 2: The belt conveyor phenomenon is observed by the displacement of the lines printed in the device.

Simulation Laboratory

To perform a preclinical study, an obstetric simulator was considered. Superior primates (chimpanzee, gorilla, and orangutan) would be the best choice for testing the device. However, this option is not feasible, since any experimental maneuver would require general anesthesia and would interfere in the physiological mechanisms of labor. Previous studies have demonstrated the effectiveness of childbirth simulator for the teaching of forceps placement, and the extraction manipulation.(6-8).
According to the above mentioned, the research was performed in a childbirth simulator (simulator S 575 – "Noelle") at the Obstetric Simulation Laboratory in Des Moines University (DMU), Iowa, USA, October 21–23, 2008. Multiple trials were successful. Action physical mechanisms (A- the air clamp and B- conveyor belt) generated upon device placement were objectively proved in the simulator obtaining the expulsion of the cephalic pole.

We believe that the use of the device in humans will be technically easier because of the elasticity of tissues and the biological fluids lubrication compared with the rigidity and lack of lubrication of the simulators. On the other hand, uterine contractions and the strength of maternal pushes represent another advantage compared with the simulators.



Potential comparative advantages over other devices: forceps or vacuum

Medical advantages:
- It could decrease the risk of fetal-maternal injury
- It could help to the physiologic development of the second stage of labor
- It could help to contraction forces and maternal pushing efforts
- It could reduce prolonged second stage
- It could reduce postpartum hemorrhage (uterine atony) through a reduction in the second stage of labor
- It would decrease operative delivery
- It would reduce perineal damage (low incidence of episiotomy)
- It would result in less malpractice claims
- It would decrease perinatal infections acquired through the birth canal (HIV and Streptococcus B haemoliticus)

Technical advantages:
- It does not require expertise and individual training
- Easy-to-learn technique
- Easy, rapid and smooth insertion
- Very low production cost
- Disposable

FEASIBILITY AND SAFETY STUDY OF THE VAGINAL DELIVERY DEVICE FOR ASSISTED

Main Objective: The main objective is to evaluate the safety and feasibility, in terms of ease of application and successful delivery, of the new device in assisting vaginal delivery in singleton term pregnancies during the second stage of labor.
Safety will be assessed by examining potential short and long-term maternal and infant outcomes. Feasibility will be evaluated by observing successful expulsion of the fetal head after one-time application of the device under standardized conditions (full cervical dilation, anterior presentation, +2 station, normal fetal heart rate) in singleton non-complicated pregnancies.
Study design and Population: A prospective study enrolling 100 pregnant women at the Centro de Educación Médica e Investigaciones Clínicas "Norberto Quirno" (CEMIC) University Hospital in Buenos Aires, Argentina over a period of 12 months. Only women with singleton uncomplicated pregnancies will be enrolled in the study.
Ethical Considerations: This project has been approved by CEMIC and the World Health Organization Ethics Committees.

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8. Dupuis O, Moreau R, Pham MT, Redarce T. Assessment of forceps blade orientations during their placement using an instrumented childbirth simulator. BJOG. 2009 Jan;116(2):327-32

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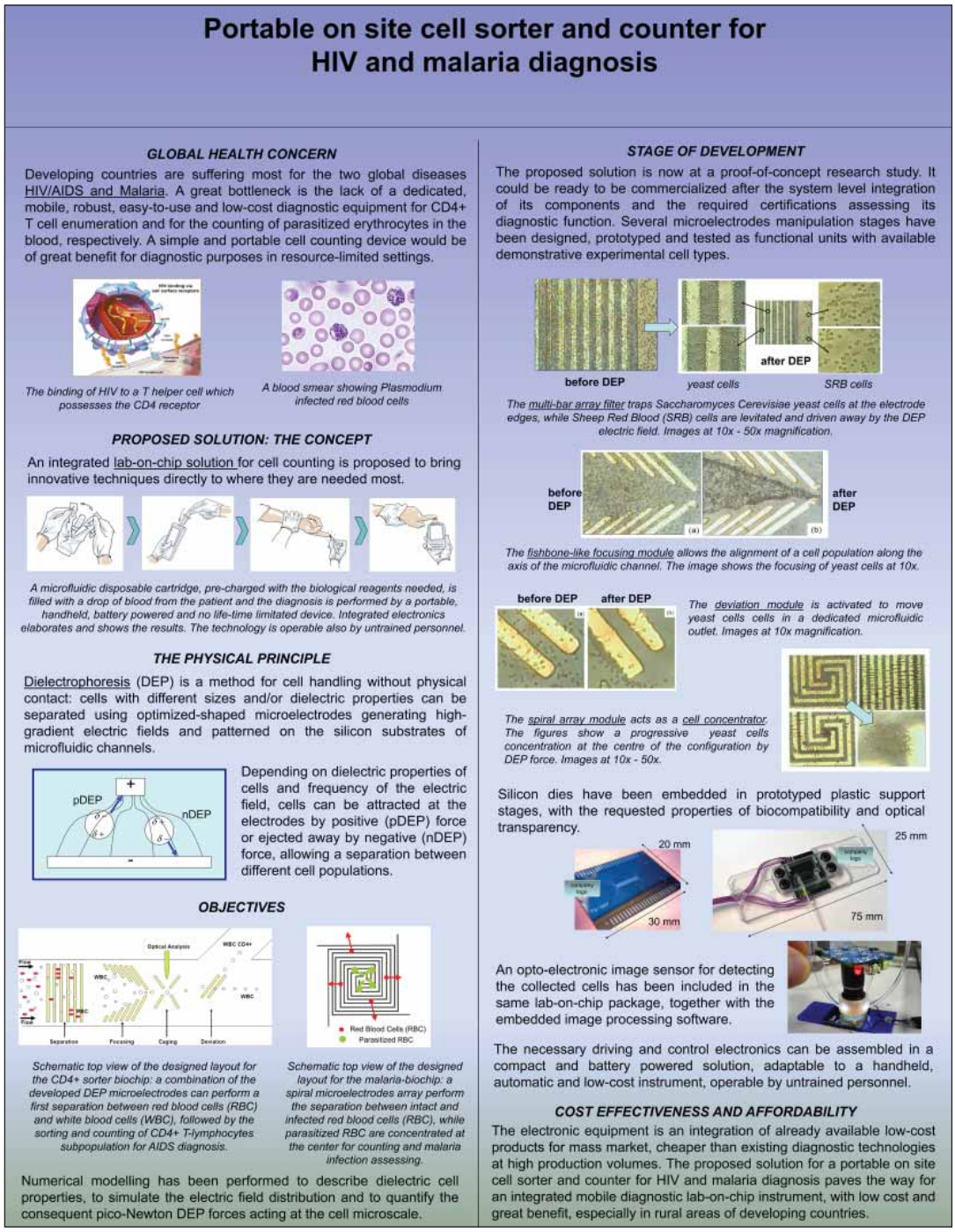
Country: Argentina

3.5.11 Portable on-site cell sorter and counter for HIV and malaria diagnosis

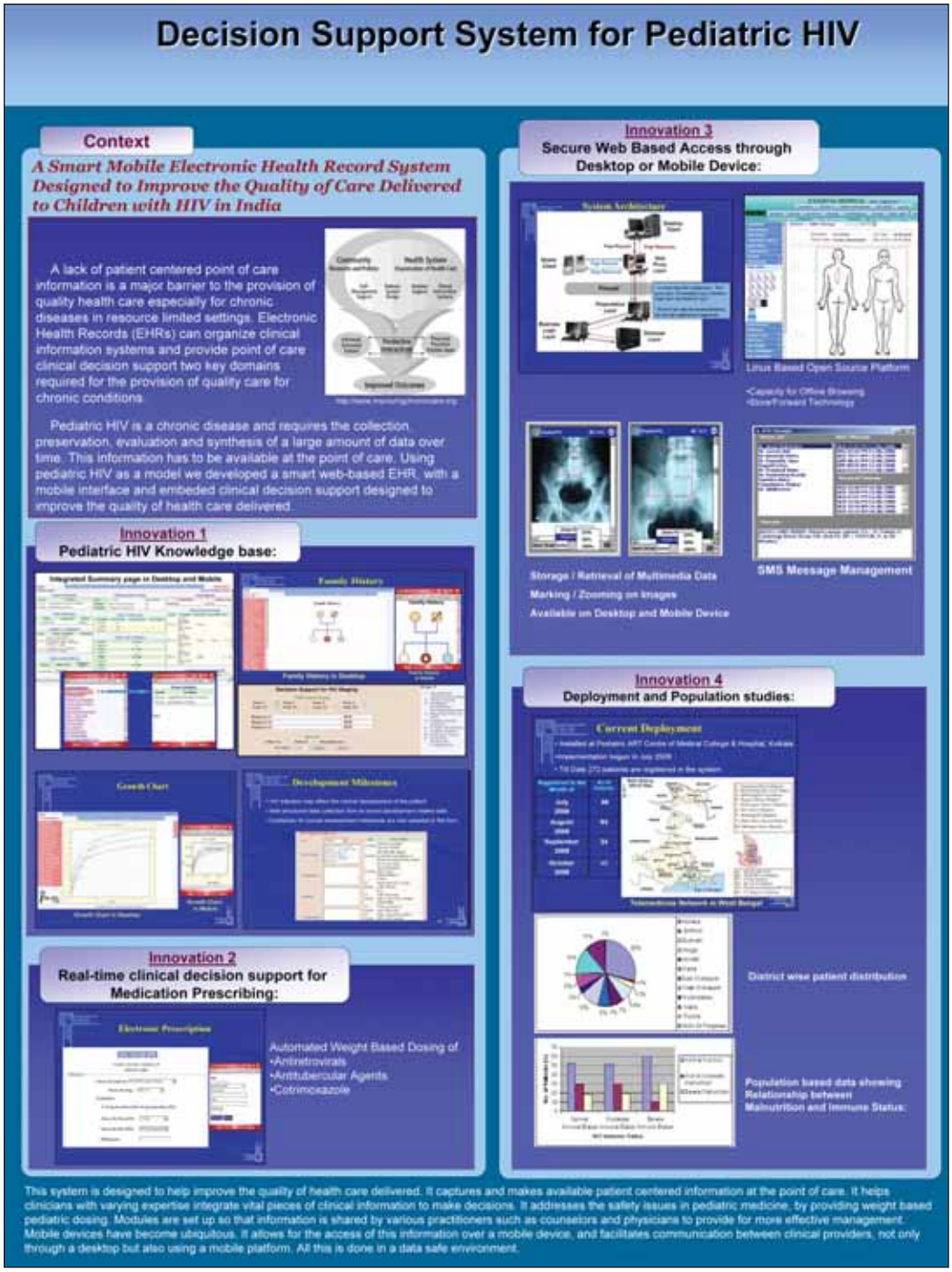
This is a lab-on-a-chip device to monitor AIDS in HIV-infected people as well as blood cell alterations indicating malaria. The device appears to be small and portable and it is claimed to allow for rapid automated screening of a blood sample for indicators of AIDS and/or malaria.



Name: Sarah Burgarella
Email: sarah.burgarella@gmail.com
Country: Italy

3.5.12 Decision support system for paediatric HIV

The purpose of this system is to move away from paper-based medical records while ensuring easy and reliable access to patient-centred information. This electronic health records system is targeted at paediatric HIV cases and is intended to aid clinical decision-making processes such as weight-based dosing support for antiretroviral drugs.



Name: Sangeeta Das Bhattacharya
Email: sangeeta.das.bhattacharya@gmail.com
Country: India

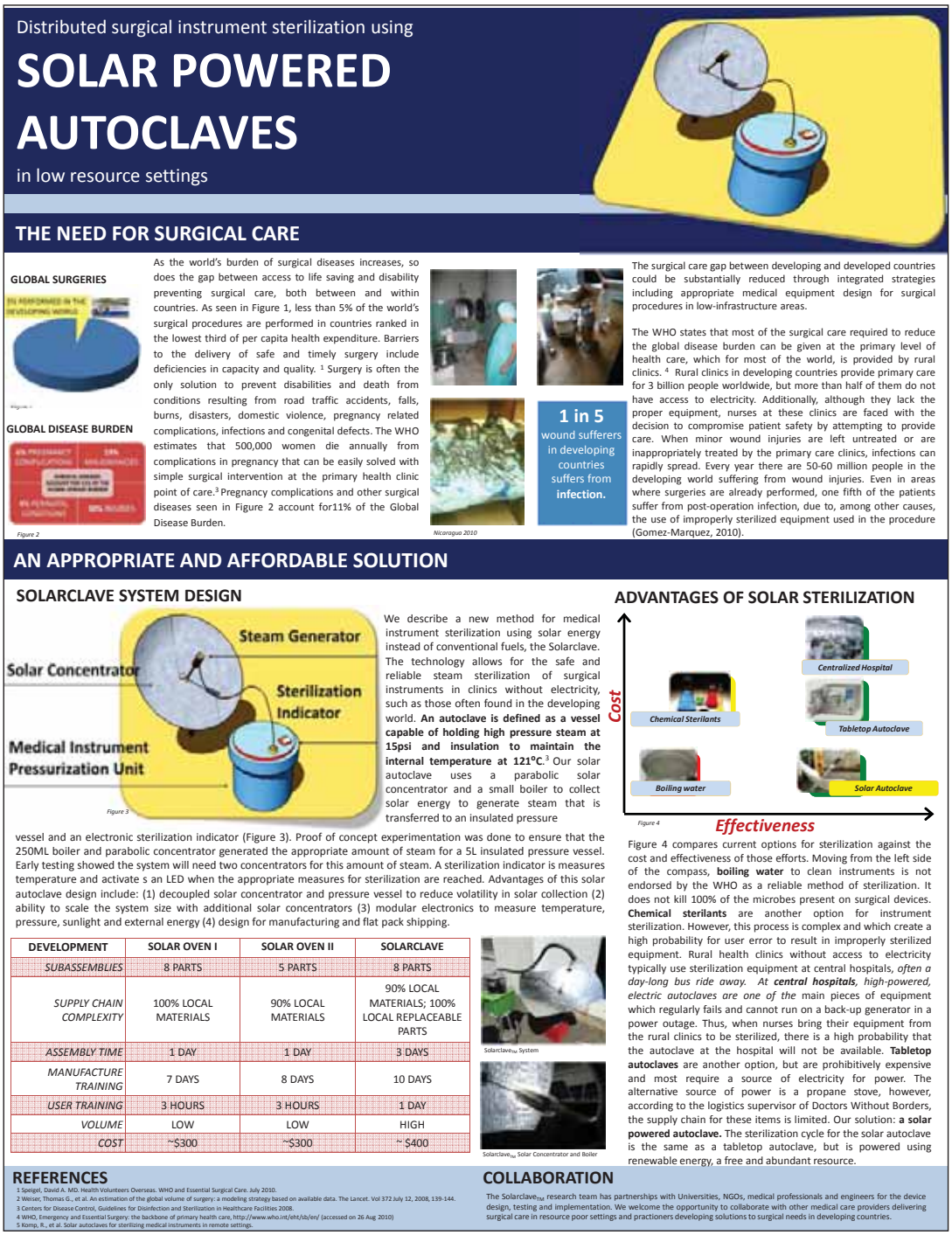
3.5.13 Transcutaneous anaemia monitoring system

The purpose of this system is to screen populations for insufficient levels of haemoglobin in the blood and to carry out diagnosis of severe anaemia. The system is claimed to be based on spectrophotometric analysis. The device appears to be portable, non-invasive and is claimed to provide a read-out in less than a minute.

Name: Aman Midha
Email: screen.anaemia@gmail.com
Country: India

3.5.14 Solar-powered autoclave

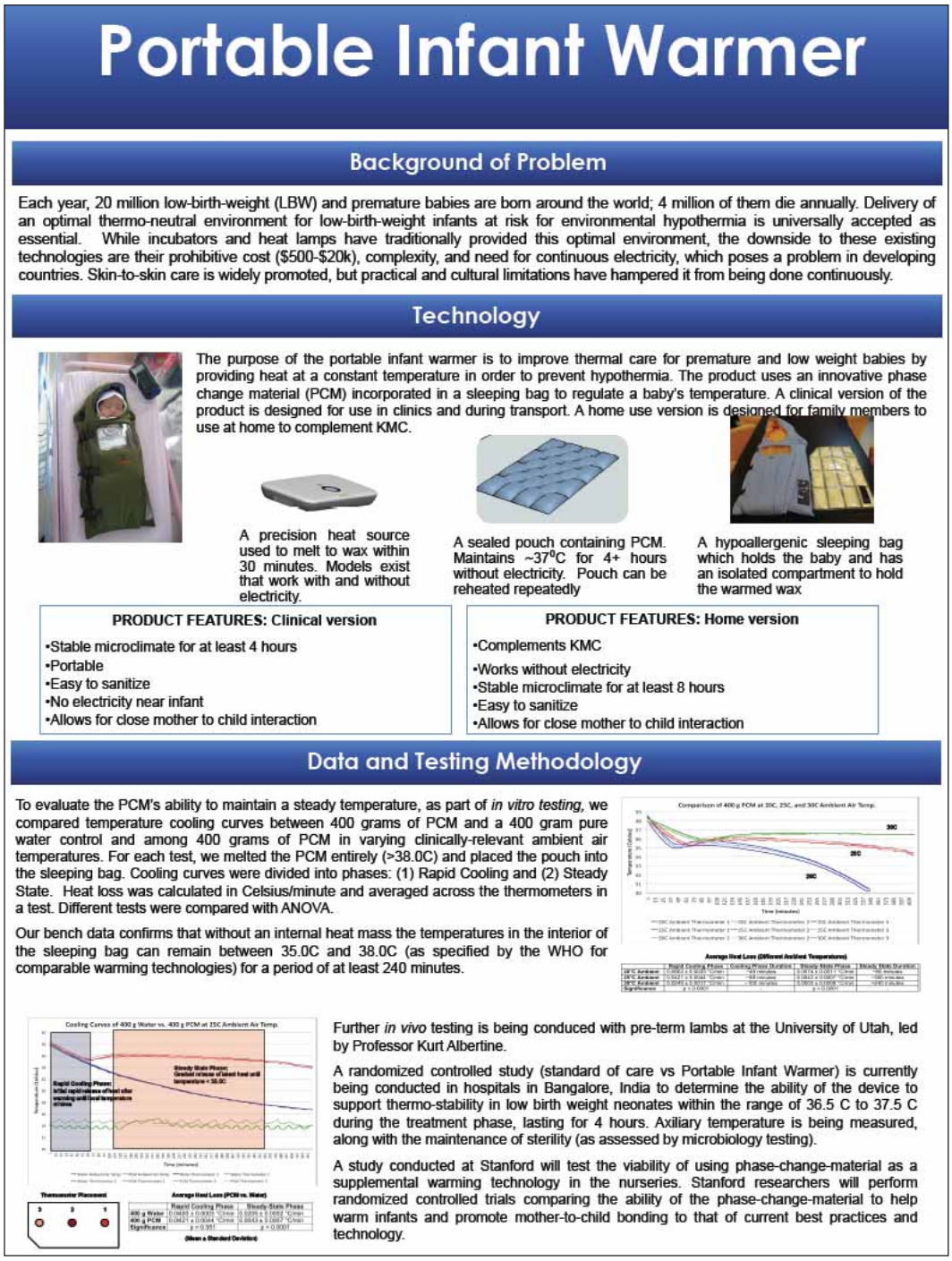
This device is intended to sterilize medical instruments and is claimed to run solely on solar power. This technology could allow sterilization of medical instruments in remote areas with no access to electricity and hence reduce the risk of infections associated with performing medical interventions with unhygienic equipment.



Name: Matt Pittinger
Email: solarautoclave@gmail.com
Country: United States of America

3.5.15 Portable infant warmer

The purpose of this device is to improve the care of premature and low-birth-weight babies by providing a constant temperature in order to prevent hypothermia. This portable device is claimed to require no electricity and would allow for close mother-to-baby contact. The product is targeted for use in urban and rural health care settings, as well as home settings.



Portable Infant Warmer

Background of Problem

Each year, 20 million low-birth-weight (LBW) and premature babies are born around the world; 4 million of them die annually. Delivery of an optimal thermo-neutral environment for low-birth-weight infants at risk for environmental hypothermia is universally accepted as essential. While incubators and heat lamps have traditionally provided this optimal environment, the downside to these existing technologies are their prohibitive cost ($500-$20k), complexity, and need for continuous electricity, which poses a problem in developing countries. Skin-to-skin care is widely promoted, but practical and cultural limitations have hampered it from being done continuously.

Technology

The purpose of the portable infant warmer is to improve thermal care for premature and low weight babies by providing heat at a constant temperature in order to prevent hypothermia. The product uses an innovative phase change material (PCM) incorporated in a sleeping bag to regulate a baby's temperature. A clinical version of the product is designed for use in clinics and during transport. A home use version is designed for family members to use at home to complement KMC.

A precision heat source used to melt to wax within 30 minutes. Models exist that work with and without electricity.

A sealed pouch containing PCM. Maintains ~37°C for 4+ hours without electricity. Pouch can be reheated repeatedly

A hypoallergenic sleeping bag which holds the baby and has an isolated compartment to hold the warmed wax

PRODUCT FEATURES: Clinical version

- Stable microclimate for at least 4 hours
- Portable
- Easy to sanitize
- No electricity near infant
- Allows for close mother to child interaction

PRODUCT FEATURES: Home version

- Complements KMC
- Works without electricity
- Stable microclimate for at least 8 hours
- Easy to sanitize
- Allows for close mother to child interaction

Data and Testing Methodology

To evaluate the PCM's ability to maintain a steady temperature, as part of *in vitro testing,* we compared temperature cooling curves between 400 grams of PCM and a 400 gram pure water control and among 400 grams of PCM in varying clinically-relevant ambient air temperatures. For each test, we melted the PCM entirely (>38.0C) and placed the pouch into the sleeping bag. Cooling curves were divided into phases: (1) Rapid Cooling and (2) Steady State. Heat loss was calculated in Celsius/minute and averaged across the thermometers in a test. Different tests were compared with ANOVA.

Our bench data confirms that without an internal heat mass the temperatures in the interior of the sleeping bag can remain between 35.0C and 38.0C (as specified by the WHO for comparable warming technologies) for a period of at least 240 minutes.

Further *in vivo* testing is being conduced with pre-term lambs at the University of Utah, led by Professor Kurt Albertine.

A randomized controlled study (standard of care vs Portable Infant Warmer) is currently being conducted in hospitals in Bangalore, India to determine the ability of the device to support thermo-stability in low birth weight neonates within the range of 36.5 C to 37.5 C during the treatment phase, lasting for 4 hours. Axiliary temperature is being measured, along with the maintenance of sterility (as assessed by microbiology testing).

A study conducted at Stanford will test the viability of using phase-change-material as a supplemental warming technology in the nurseries. Stanford researchers will perform randomized controlled trials comparing the ability of the phase-change-material to help warm infants and promote mother-to-child bonding to that of current best practices and technology.

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Email: christinalaurenchao@gmail.com
Country: United States of America

4. Challenges to making innovative technologies available

Each applicant was asked to identify any challenges they could foresee with regard to the successful implementation of their technology. Figures 8 and 9 show the challenges cited by applicants of commercialized and non-commercialised technologies respectively. A great challenge foreseen by all applicants was a lack of funding: 39% of category 1 and 83% of category 2 applicants cited this.

Distribution was also identified as a major challenge for innovations in category 1 and 2 (43% and 61% of applicants respectively; Figure 8 and 9). This is the largest concern identified by category 1 technologies, which may be due to the fact that products in this category are either on the market (or soon will be) and therefore require effective distribution channels to ensure their success. Alternatively, applicants of technologies in category 2 noted a greater need for manufacturing partners (50% compared to 14% of category 1 applicants; Figure 9 and 8 respectively), as their products are in the earlier stages of development.

Figure 8. Expected challenges to the success of innovation as described by applicants to category 1

Commercializable technologies (category 1)

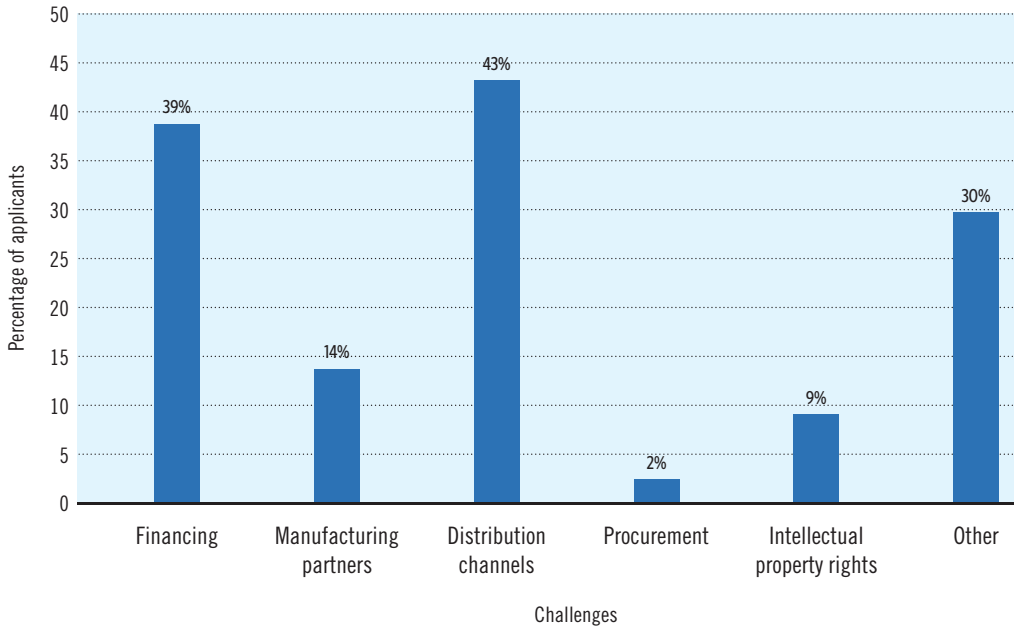
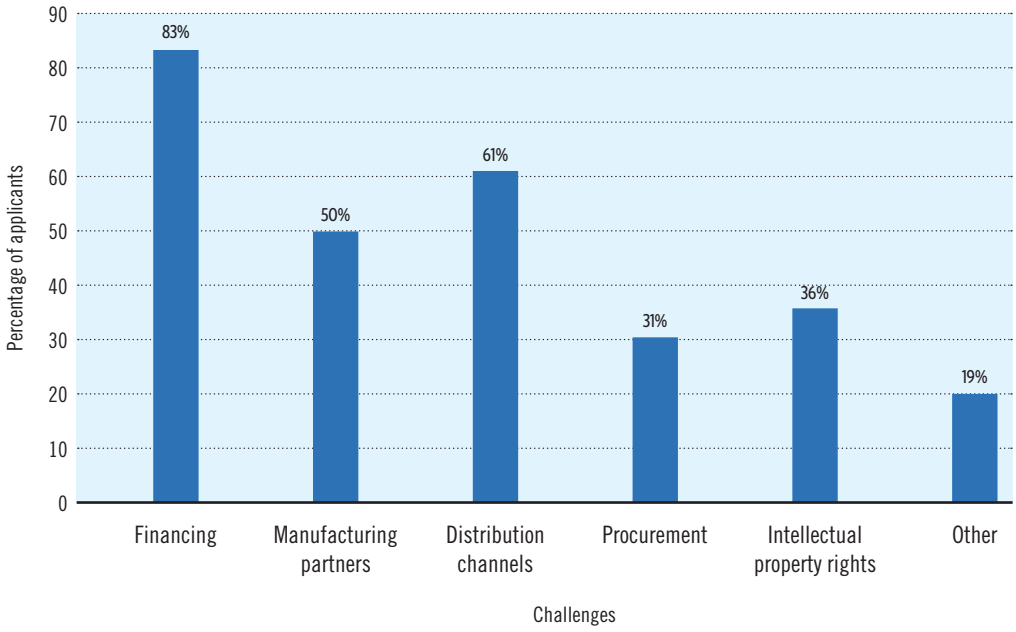


Figure 9. Expected challenges to the success of innovations as described by applicants to category 2

Concept technologies (category 2)



5. Conclusion

This report presents a selection of innovative technologies from those submitted in response to the WHO call for innovative technologies. The call is one of the ways that WHO is working to achieve its strategic objective to ensure improved access, quality and use of medical products and technologies *(3)*. Further work is required to ensure that these innovations are accessible to those in need of them in low- and middle-income countries. In particular, further evaluation of the clinical safety and effectiveness of the technologies and assessment of their robustness and affordability is required.

Innovative technologies are necessary to increase the cost-effectiveness of health care and ease the burden of chronic diseases worldwide. However, much work remains to be done to achieve results in this domain. Specifically, stakeholders need to explore novel ways of approaching distribution and financing which are appropriate to local infrastructure.

WHO will continue to interact with industry, funding agencies, academia and international organizations to raise awareness of the need to design, produce and commercialize innovative, accessible and robust technologies which address the needs of health systems particularly in low-resource settings.

Through this first call for innovative technologies, WHO is working towards making innovative and appropriate technologies affordable and accessible in all settings to increase the quality of health care, and most importantly improve the quality of life of all people.

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Annex 1: Rules of the call for innovative technologies

1. Background and Aim of the Call

Medical devices are indispensable in health care delivery as tools for prevention, diagnosis, treatment and rehabilitation. However, despite the exponential growth of scientific and technological development, availability of and access to appropriate and affordable health technologies in low- and middle-income countries are still insufficient.

One of the WHO Department of Essential Health Technologies' goals is to help make available the benefits of core health technologies with a view to addressing global health concerns by developing a framework for health technology programmes and by challenging the scientific and business community to identify and develop innovative technologies.

This call for innovative technologies aims at identifying and evaluating innovative medical devices, including assistive devices, either existing or under development, which address global health concerns and which are likely to be available, appropriate and affordable for use in low- and middle-income countries.

Selected innovative technologies will be highlighted on the WHO Essential Health Technologies website. They will be shared with governments, donors and other stakeholders, with a view to generally fostering the development, availability of and access to innovative health technologies, particularly in low- and middle-income countries.

2. Key Dates

11 September 2009	Launch of the call for innovative technologies at the World Congress on Medical Physics and Biomedical Engineering, Munich[1].
31 January 2010	Deadline for submission of applications.
27–29 April 2010	Selection of applications by the Advisory Group on Innovative Technologies, Copenhagen.
30 June 2010	Posting of the list of selected innovative technologies on the WHO website[2].

1 http://www.wc2009.org/World-Congress-2009/Pages/Home.aspx
2 http://www.who.int/medical_devices/en/

3. Eligibility

3.1 Who can apply

The call for innovative technologies targets manufacturers, institutions, universities, governments, individuals and non-profit organizations which design, manufacture and/or supply any type of medical device that address the global health concerns mentioned in section 5. One submission per applicant will be accepted.

4. The Scope of Innovative Technologies

4.1 Medical Devices

Eligible health technologies are limited to medical devices as defined by the Global Harmonization Task Force (GHTF)[3]. They include instruments, medical equipment, implants, disposables, assistive devices and software used mainly for the purpose of prevention, diagnosis, monitoring or treatment of disease, rehabilitation, control of conception and/or measuring, restoring correcting physiological functions.

The call for innovative technologies does not cover clinical procedures, medicinal products, vaccines, biological therapeutic products or tissue engineered medical products.

4.2 Innovative Technologies

To qualify for consideration, a technology must be deemed "innovative" by providing the evidence that the solution:

- Has not previously existed;
- Has not previously been made available in low- and middle-income countries;
- Is safer and/or simpler to use than earlier solutions; and/or
- Is more cost effective than previous technologies.

4.3 Two Categories

Category 1 Commercialized/-sable products

- New products
- Products which have been commercialized for less than five years in high-income countries and which are not (yet) widely used in low- and middle-income countries
- Recent adaptation of existing non-health products for a health purpose
- Recent adaptation of an existing medical device for low- and middle-income country settings

Category 2 Products in a non-commercialized/-sable stage

- Products which are under development or otherwise in a conceptual stage

3 http://www.ghtf.org/documents/sg1/sg1n29r162005.pdf

5. The Health Problems to be Addressed

The health problems addressed by the innovative technologies should be related to the following key global health concerns:

- Lower respiratory infections
- Diarrhoeal diseases
- HIV/AIDS
- Malaria
- Prematurity and low birth weight
- Neonatal infections
- Birth asphyxia and birth trauma
- Unipolar depressive disorders
- Ischemic heart disease
- Cerebrovascular disease
- Tuberculosis
- Road traffic accidents
- Chronic obstructive pulmonary disease
- Alcohol use disorders
- Refractive errors
- Deficient maternal health
- Infant and child (under 5) mortality
- Cancer
- Disability.

6. Submission of Applications and Deadline

Interested applicants can download the submission form from: www.who.int/medical_devices. The applications should be completed in English, signed, scanned and e-mailed as a PDF document to medicaldevices@who.int.

Deadline for applications is 31 January 2010. Receipt of applications will be confirmed by e-mail.

7. Screening and Selection

Step 1 — WHO will screen all applications. The ones which are incomplete will, in principle, not be processed further. An identifier code will be assigned to the application and all information about the applicant will be removed to maintain confidentiality.

Step 2 — Applications without identification data will be sent to selected WHO collaborating institutions for a second screening with respect to conformity to the scope of the call for innovative technologies. Those applications which do not fall within the scope of the call will not be sent to the selection committee, the so-called Advisory Group on Innovative Technologies.

Step 3 — Proposals are evaluated and selected by the Advisory Group on Innovative Technologies, which is composed of experts in the field of health technologies. A confidentiality agreement will be signed by the members of such Advisory Group. Any expert reviewer with a declared conflict of interest will not be authorized to participate in the review.

8. Selection Criteria

The following considerations will be taken into account in the selection of the applications:

- Level of safety for user, patient and the environment;
- How effectively the technology addresses the related health concern;
- How well the technology is adapted to local infrastructures in resource-limited settings;
- Ease of use and maintenance;
- Total cost of ownership, cost-effectiveness and affordability; and
- Cultural and social acceptability of the technology.

9. Notification

Each applicant will be notified in writing (by e-mail) in June 2010 whether or not the submission has been selected. A list of the selected innovative technologies will then be posted on the WHO web site.

10. Terms, Conditions and Disclaimers

WHO reserves the right not to select any application or to annul the solicitation process at any time, without thereby incurring any liability or any obligation to inform the applicants of the grounds for the WHO's action. WHO reserves the right, at any time during the solicitation process, to modify the scope of the call. At any step in the evaluation process, WHO reserves the right to issue an amendment to the call detailing the change to only those applicants who have not been officially eliminated at that point in time. Applications will be evaluated by WHO, in collaboration with partner experts and institutions, in its sole discretion, taking into account the criteria outlined above. There is no obligation by WHO to reveal, or discuss with any applicant, how a submission was assessed, or to provide any other information relative to the selection process.

Incomplete applications and applications submitted after the deadline will, in principle, be disregarded, unless WHO in its sole discretion, decides otherwise in respect of such incomplete or late application. WHO may request applicants to submit complementary or additional information as a condition for consideration. Any possible requests to submit complementary information and/or to submit a more detailed application, as well as any discussions ensuing there from, will be exploratory only, and do not mean that the applicant concerned will be selected.

WHO will not be held to offer applicants any explanation or justification as to why their proposal has been rejected and/or why they have not been selected. The list of selected applications will not necessarily be made public as such. The submission of applications, the subsequent selection process and outcome of the selection process will not be subject to any claim of any kind whatsoever, or appeal. Each applicant will be notified in writing by WHO (by e-mail) whether or not the submission has been selected.

Any and all costs and expenses incurred in relation to, or ensuing from, the submission of an application (including the possible complementary information and/or a more detailed proposal, if so requested by WHO) will not be subject to claims for financial compensation of any kind whatsoever.

WHO does not warrant that any medical devices, innovations, concepts or products that may be used, identified or otherwise developed from selected proposals will be successfully commercialized in target countries, or that WHO will finance or otherwise support the development or commercialization of any product. By selecting applications, WHO will not be held to endorse any product but will solely aim at drawing stakeholders' attention to innovative technologies, either existing or under development, with a view to furthering development and availability of, and access to, such innovative health technologies.

The mention of specific companies or of certain manufacturers' products at any stage of the selection process or subsequently will not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned, nor that they have been found to be safe and efficacious.

Without WHO's prior written approval, selected applicants shall not, in any statement of an advertising or promotional nature, refer to their selection under this call for innovative technologies. In no case shall selected applicants use the name or the emblem of the World Health Organization, or any abbreviation thereof, in relation to their business or otherwise. The same applies to all applicants during the selection process and thereafter.

www.who.int/medical_devices

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